IN UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY, Plaintiffs, v. DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, *in his official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA. Defendants.	**No. 2:17-cv-04540-WB**

MOTION FOR A PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiffs Commonwealth of Pennsylvania and State of New Jersey, by and through their undersigned counsel, hereby file this Motion for a Preliminary Injunction, requesting that this Court enter an Order enjoining Defendants Donald J. Trump, President of the United States; Alex M. Azar II, Secretary of the United States Department of Health and Human Services; the United States Department of Health and Human Services; Steven T. Mnuchin, Secretary of the United States Department of the Treasury; the United States Department of the Treasury; Rene Alexander Acosta, Secretary of the United States Department of Labor; the United States Department of Labor; and the United States of America; and their agents, designees, and subordinates, as well as any person

acting in concert or participation with them, from enforcing the following Final Rules (the "Rules"):

a) Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (issued in interim form Oct. 6, 2017, and in final form Nov. 7, 2018); and

b) Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (issued in interim form Oct. 6, 2017, and in final form Nov. 7, 2018)

As set forth in the contemporaneously filed Memorandum of Law in Support of Plaintiffs' Motion for a Preliminary Injunction, Plaintiffs satisfy the necessary requirements to establish that injunctive relief is warranted. Plaintiffs will show that:

1. They are likely to succeed on the merits of their claim that the Rules are unlawful. The Rules purport to authorize employers and other providers of group health coverage to exempt themselves from the legal requirement that they provide coverage for contraceptive services without cost-sharing requirements. They are both procedurally and substantively defective, having been issued in violation of the Administrative Procedure Act, the Affordable Care Act, Title VII of the Civil Rights Act and the Pregnancy Discrimination Act, the equal protection guarantee of the Fifth Amendment, and the Establishment Clause of the First Amendment.

2. The Rules will cause irreparable harm to the Commonwealth of Pennsylvania, the State of New Jersey, and their citizens. They will impose costs on Plaintiffs, which are unrecoverable in any subsequent action. These will include costs associated with providing necessary contraceptive care to women who are denied it, and costs associated with treating

health conditions experienced by women who are unable to obtain contraceptive care. The Rules will jeopardize the health of Plaintiffs' female citizens and will impose additional costs on these women and their families, thus causing harm to Plaintiffs' interest in protecting the health, safety, and well-being of their citizens. All of these injuries are the result of Defendants' actions.

3. The balance of equities weighs in favor of an injunction. Plaintiffs will suffer serious and irreparable harm in the absence of an injunction. Defendants, by contrast, will not suffer any meaningful harm as a result of an injunction.

4. The public interest strongly favors an injunction. Women will face serious medical and financial injury if an injunction is not issued, and Plaintiffs will suffer direct financial harm, including harm to several vital health programs they fund.

This Motion is supported by the contemporaneously filed Memorandum of Law, the accompanying declarations and exhibits, Plaintiffs' Amended Complaint, and any additional submissions that may be considered by the Court.

December 17, 2018

Respectfully submitted,

GURBIR S. GREWAL
Attorney General of New Jersey
GLENN J. MORAMARCO
Assistant Attorney General
ELSEPTH FAIMAN HANS
Deputy Attorney General
KIMBERLY A. CAHALL
Deputy Attorney General
New Jersey Attorney General's Office
Richard J. Hughes Justice Complex
25 Market Street
Trenton, NJ 08625
(609) 376-3235
Glenn.Moramarco@law.njoag.gov

JOSH SHAPIRO
Attorney General
Commonwealth of Pennsylvania

/s/ Michael J. Fischer
MICHAEL J. FISCHER
Chief Deputy Attorney General
AIMEE D. THOMSON
Deputy Attorney General
Office of Attorney General
1600 Arch Street
Suite 300
Philadelphia, PA 19103
(215) 560-2171
mfischer@attorneygeneral.gov

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY, **Plaintiffs,** **v.** **DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, *in his official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA.** **Defendants.**	**No. 2:17-cv-04540-WB**

O R D E R

AND NOW, this day of , 2019, upon consideration of the Motion for a Preliminary Injunction filed by Plaintiffs Commonwealth of Pennsylvania and State of New Jersey, any response thereto, and for good cause shown, it is hereby **ORDERED** that the Motion is **GRANTED**.

It is further **ORDERED** that Defendants Donald J. Trump, President of the United States; Alex M. Azar II, Secretary of the United States Department of Health and Human Services; the United States Department of Health and Human Services; Steven T. Mnuchin, Secretary of the United States Department of the Treasury; the United States Department of the Treasury; Rene Alexander Acosta, Secretary of the United States Department of Labor; the United States Department of Labor; and the United States of America; and their agents,

designees, and subordinates, as well as any person acting in concert or participation with them, are hereby enjoined from enforcing the following Final Rules:

1. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (issued in interim form Oct. 6, 2017, and in final form Nov. 7, 2018); and
2. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (issued in interim form Oct. 6, 2017, and in final form Nov. 7, 2018).

Plaintiffs have demonstrated that they are likely to succeed on the merits of their claims, that they will suffer irreparable injury absent preliminary relief, that the balance of equities favors issuance of an injunction, and that a preliminary injunction would serve the public interest.

BY THE COURT:

_____

WENDY BEETLESTONE, J.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY,

Plaintiffs,

v.

DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, *in his official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA.

Defendants.

No. 2:17-cv-04540-WB

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B	*Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,592 (Nov. 15, 2018)
C	*Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792 (Oct. 13, 2017)
D	*Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838 (Oct. 13, 2017)
E	Memorandum of Law in Support of Plaintiff's Motion for a Preliminary Injunction, ECF No. 8-2 (Nov. 2, 2017)
F	Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps* (2011)
G	Health Resources & Services Administration, *Women's Preventive Services Guidelines* (2011)
H	Health Resources & Services Administration, *Women's Preventive Services Guidelines* (2016)
I	Executive Order No. 13798, *Promoting Free Speech and Religious Liberty* (May 4, 2017)
J	Transcript of Preliminary Injunction Hearing (Dec. 14, 2017)

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N	Snyder, *et al.*, *The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women*, Women's Health Issues 28-3 (2018)
O	Declaration of Samantha Butts, M.D., MSCE
P	Declaration of Seth Mendelsohn
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W	Spreadsheet from Administrative Record (Bates No. 670107)
X	Comments on Interim Final Rules (Dec. 5, 2017)

EXHIBIT A

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9840]

RIN 1545–BN92

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9940–F2]

RIN 0938–AT54

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, interim final rules concerning religious exemptions and accommodations regarding coverage of certain preventive services issued in the **Federal Register** on October 13, 2017. These rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an ''accommodation'' process as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Jeff Wu, at (301) 492–4305 or *marketreform@cms.hhs.gov* for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; William Fischer, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline, 1–866–444–EBSA (3272) or visit the Department of Labor's website (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this rule is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47792), ''Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (the Religious IFC). The rules are necessary to expand the protections for the sincerely held religious objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, a requirement that was created by HHS through guidance promulgated by the Health Resources and Services Administration (HRSA) (hereinafter ''Guidelines''), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules maintain a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's Guidelines. The changes being finalized to these rules will ensure that proper respect is afforded to sincerely held religious objections in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Expanded Religious Exemptions to the Contraceptive Coverage Requirement

These rules finalize exemptions provided in the Religious IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held religious beliefs opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's Guidelines. The rules finalize exemptions to the same types of organizatons and individuals for which exemptions were provided in the Religious IFC: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals. The rules also finalize the regulatory restatement in the Religious IFC of language from section 2713(a) and (a)(4) of the Public Health Service Act.

In response to public comments, various changes are made to clarify the intended scope of the language in the Religious IFC. The prefatory language to the exemptions is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to clarify that, where an exemption encompasses a plan or coverage established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, the exemption applies to each employer, organization, or plan sponsor that adopts the plan. Language is also added to clarify that the exemptions apply to non-governmental entities, including as the exemptions apply to institutions of higher education. The Departments revise the exemption applicable to health insurance issuers to make clear that the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement. The Departments also restructure the provision describing the religious objection for entities. That provision specifies that the entity objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for either: coverage or payments for some or all contraceptive services; or, a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The final rule specifies that the individual exemption ensures that the HRSA Guidelines do not prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. Optional Accommodation

These rules also finalize provisions from the Religious IFC that maintain the accommodation process as an optional process for entities that qualify for the exemption. Under that process, entities can choose to use the accommodation process so that contraceptive coverage to which they object is omitted from their plan, but their issuer or third party administrator, as applicable, will arrange for the persons covered by their plan to receive contraceptive coverage or payments.

In response to public comments, these final rules make technical changes to the accommodation regulations maintained in parallel by HHS, the Department of Labor, and the Department of the Treasury. The Departments modify the regulations governing when an entity, that was using or will use the accommodation, can revoke the accommodation and operate under the exemption. The modifications set forth a transitional

rule as to when entities currently using the accommodation may revoke it and use the exemption by giving 60-days notice pursuant to Public Health Service Act section 2715(d)(4) and 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), and 29 CFR 2590.715–2715(b). The modifications also express a general rule that, in plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an organization eligible for the accommodation may revoke its use of the accommodation process effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

The Departments also modify the Religious IFC by adding a provision that existed in rules prior to the Religious IFC, namely, that if an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable contraceptive coverage requirement from HRSA's Guidelines if the issuer complies with the obligations under this section applicable to such issuer. Likewise, the rule adds pre-existing ''reliance'' language deeming an issuer serving an accommodated organization compliant with the contraceptive coverage requirement if the issuer relies reasonably and in good faith on a representation by an organization as to its eligibility for the accommodation and the issuer otherwise complies with the accommodation regulation, and likewise deeming a group health plan compliant with the contraceptive coverage requirement if it complies with the accommodation regulation.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	The purpose of this provision is to ensure that the regulatory language that restates section 2713(a) and (a)(4) of the Public Health Service Act mirrors the language of the statute. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.
Expanded religious exemptions.	Expanding religious exemptions to the contraceptive coverage requirement will relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their religious beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage or using the accommodation in violation of their sincerely held religious beliefs.	We estimate there will be transfer costs where women previously receiving contraceptive coverage from employers will no longer receive that coverage where the employers use the expanded exemptions. Even after the public comment period, we have very limited data on what the scale of those transfer costs will be. We estimate that in no event will they be more than $68.9 million. We estimate that, where entities using the accommodation revoke it to use the exemption, the cost to industry of sending notices of revocation to their policy holders will be $112,163.
Optional accommodation regulations.	Maintaining the accommodation as an optional process will ensure that contraceptive coverage is made available to many women covered by plans of employers that object to contraceptive coverage but not to their issuers or third party administrators arranging for such coverage to be provided to their plan participants.	We estimate that, by expanding the types of organizations that may use the accommodation, some entities not currently using it will opt into it. When doing so they will incur costs of $677 to send a self-certification or notice to their issuer or third party administrator, or to HHS, to commence operation of the accommodation. We estimate that entities that newly make use of the accommodation as the result of these rules, or their issuers or third party administrators, will incur costs of $311,304 in providing their policy holders with notices indicating that contraceptive coverage or payments are available to them under the accommodation process.

B. Background

Over many decades, Congress has protected conscientious objections, including those based on religious beliefs, in the context of health care and human services including health coverage, even as it has sought to promote and expand access to health services.[1] In 2010, Congress enacted the

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their ''religious beliefs or moral convictions''); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any ''health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion for any reason); *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions''); *id.* at Div. E, Sec. 808 (regarding any requirement for ''the provision of contraceptive coverage by health insurance plans'' in the District of Columbia, ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.''); *id.* at Div. I, (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their ''religious or conscientious commitment to offer only natural family planning''); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide-related treatment services for youth where the parents or legal guardians object based on ''religious beliefs or moral objections''); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations

Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended the PPACA. As amended by HCERA, the PPACA is known as the Affordable Care Act (ACA).

The ACA reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter ''section 2713(a)(4)''), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women's preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, ''with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by'' HRSA's Guidelines.

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.[2] In the same time period, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, ''the Departments'') [3] have promulgated regulations to guide HRSA in exercising its discretion to allow exemptions to those requirements, including issuing and finalizing three interim final regulations prior to 2017.[4] In those regulations, the Departments defined the scope of permissible exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Many individuals and entities brought legal challenges to the contraceptive coverage requirement and regulations (hereinafter, the ''contraceptive Mandate,'' or the ''Mandate'') as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1 (''RFRA''). Several of those cases went to the Supreme Court. *See, for example, Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751 (2014); *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016).

The Departments most recently solicited public comments on these issues again in two interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017: the regulations (82 FR 47792) that are being finalized with changes here, and regulations (82 FR 47838) concerning moral objections (the Moral IFC), which are being finalized with changes in companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Religious IFC, the Departments explained several reasons why it was appropriate to reevaluate the religious exemptions and accommodations for the contraceptive Mandate and to take into account the religious beliefs of certain employers concerning that Mandate. The Departments also sought public comment on those modifications. The Departments considered, among other things, Congress's history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; protection of the free exercise of religion in the First Amendment and, by Congress, in RFRA; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); previously submitted public comments;

and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice (now Medicare Advantage) managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on ''conscience'' as protected in state law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on ''religious beliefs or moral convictions''); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); see also 8 U.S.C. 1182(g) (protecting vaccination objections by ''aliens'' due to ''religious beliefs or moral convictions''); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on ''moral or religious convictions''); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their ''religious or moral objection'').

[2] The references in this document to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women's Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to ''Contraceptive Methods and Counseling'' as ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' *https://www.hrsa.gov/womens-guidelines/index.html.* The Guidelines as amended in December 2016 refer, under the header ''Contraception,'' to: ''the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures,'' ''contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),'' and ''instruction in fertility awareness-based methods, including the lactation amenorrhea method.'' *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[3] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

[4] Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

and the extensive litigation over the contraceptive Mandate.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Religious IFC, with changes based on comments as indicated herein.[5]

II. Overview, Analysis, and Response to Public Comments

We provided a 60-day public comment period for the Religious IFC, which closed on December 5, 2017. The Departments received over 56,000 public comment submissions, which are posted at *www.regulations.gov*.[6] Below, the Departments provide an overview of the general comments on the final regulations, and address the issues raised by commenters.

These rules expand exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules finalize the accommodation process, which was previously established in response to objections of religious organizations that were not protected by the original exemption, as an optional process for any exempt entities. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.[7]

A. The Departments' Authority To Mandate Coverage and Provide Religious Exemptions

The Departments received conflicting comments on their legal authority to provide the expanded exemptions and accommodation for religious beliefs. Some commenters agreed that the Departments are legally authorized to provide the expanded exemptions and accommodation, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing religious exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the exemptions that existed prior to the Religious IFC, but not to expand them.

Some commenters who argued that section 2713(a)(4) does not allow for exemptions said that the previous exemptions for houses of worship and integrated auxiliaries, and the previous accommodation process, were set forth in the ACA itself, and therefore were acceptable while the expanded exemptions in the Religious IFC were not. This is incorrect. The ACA does not prescribe (or prohibit) the previous exemptions for house of worship and the accommodation processes that the Departments issued through regulations.[8] The Departments, therefore, find it appropriate to use the regulatory process to issue these expanded exemptions and accommodation, to better address concerns about religious exercise.

The Departments conclude that legal authority exists to provide the expanded exemptions and accommodation for religious beliefs set forth in these final rules. These rules concern section 2713 of the PHS Act, as also incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes.[9]

Where it applies, section 2713(a)(4) requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' Guidelines developed by HHS through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS, as the administering agency of HRSA, and to all three agencies, as the administering agencies of the statutes by which the Guidelines are enforced, to shape that development. *See* 26 U.S.C. 9834; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38,409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable Guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must ''provide for'' and ''support'' the application of Guidelines that it chooses to adopt. HRSA's authority to support ''comprehensive guidelines'' involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only ''as provided for in comprehensive guidelines supported by [HRSA].'' That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word ''as'' in the phrase ''as provided for,'' it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase ''as you like it.'' [10] When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See, e.g.*, 42 U.S.C. 1395x (''The Secretary shall establish procedures to make beneficiaries and providers aware

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[5] The Department of the Treasury and the Internal Revenue Service (IRS) published proposed and temporary regulations as part of the joint rulemaking of the Religious IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules. The Department of the Treasury and IRS are finalizing their proposed regulations.

[6] *See Regulations.gov* at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dktid=CMS-2014-0115* and *https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=7525&dct=PS&D=IRS-2017-0016.* Some of those submissions included form letters or attachments that, while not separately tabulated at *regulations.gov*, together included comments from, or were signed by, hundreds of thousands of separate persons. The Departments reviewed all of the public comments and attachments.

[7] *See, for example,* Family Planning grants in 42 U.S.C. 300 *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), and 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), and (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[8] The ACA also does not require that contraceptives be covered under the preventive services provisions.

[9] 26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92.

[10] See As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) (''[u]sed to indicate by comparison the way something happens or is done'').

of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.'') (emphasis added). Thus, the inclusion of ''as'' in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has been granted discretion in supporting how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word ''as'' is missing from the other three provisions in PHS Act section 2713(a). Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require ''evidence-based'' or ''evidence-informed'' coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The religious objections at issue here, and in regulations providing exemptions from the inception of the Mandate in 2011, are considerations that, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines ''exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,'' and ''it is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.'' *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a specific statutory mandate that contraceptives must be covered or that they be covered without any exemptions or exceptions, supports the conclusion that the Departments are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The conclusions on which these final rules are based are consistent with the Departments' interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4)'s grant of authority to include broad discretion regarding the extent to which HRSA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments defined the scope of the exemption to the contraceptive Mandate when HRSA issued its Guidelines for contraceptive coverage in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrators of self-insured church plans. *See* 80 FR 41323. Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. During prior rulemakings, the Departments also disagreed with commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or as incorporated into ERISA and the Code, and who contended instead that we must enforce the Guidelines on the broadest spectrum of group health plans as possible. *See, e.g.,* 2012 final regulations at 77 FR 8726.

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require coverage of preventive services for every type of plan that is subject to the ACA. *See, e.g.,* 76 FR 46623. On the contrary, Congress carved out an exemption from PHS Act section 2713 (and from several other provisions) for grandfathered plans. In contrast, grandfathered plans do have to comply with many of the other provisions in Title I of the ACA—provisions referred to by the previous Administration as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime and annual dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group health insurance markets, and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.[11] Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, ''there is no legal requirement that grandfathered plans ever be phased out.'' *Hobby Lobby,* 134 S. Ct. at 2764 n.10.

Some commenters argue that Executive Order 13535's reference to

[11] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' Henry J Kaiser Family Foundation (Sept. 2017), *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions to the Mandate in the Guidelines. The Departments, however, believe these final regulations are consistent with Executive Order 13535. Issued upon the signing of the ACA, Executive Order 13535 specified that ''longstanding Federal laws to protect conscience . . . remain intact,'' including laws that protect holders of religious beliefs from certain requirements in health care contexts. While the Executive Order 13535 does not require the expanded exemptions in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws that protect religious beliefs, and are consistent with the Executive Order's intent that the ACA would be implemented in accordance with the conscience protections set forth in those laws.

The extent to which RFRA provides authority for these final rules is discussed below in section II.C., The First Amendment and the Religious Freedom Restoration Act.

B. Availability and Scope of Religious Exemptions

Some commenters supported the expanded exemptions and accommodation in the Religious IFC, and the entities and individuals to which they applied. They asserted the expanded exemptions and accommodation are appropriate exercises of discretion and are consistent with religious exemptions Congress has provided in many similar contexts. Some further commented that the expanded exemptions are necessary under the First Amendment or RFRA. Similarly, commenters stated that the accommodation was an inadequate means to resolve religious objections, and that the expanded exemptions are needed. They objected to the accommodation process because it was another method to require compliance with the Mandate. They contended its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and that such coverage flowed in connection with the objecting organizations' health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to the religious objections that organizations would not have with an expanded exemption.

Several other commenters asserted that the exemptions in the Religious IFC are too narrow and called for there to be no mandate of contraceptive coverage. Some of them contended that HRSA should not include contraceptives in their women's preventive services Guidelines because fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of preventive health services. They also contended that contraceptives can pose medical risks for women and that studies do not show that contraceptive programs reduce abortion rates or rates of unintended pregnancies. Some commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacients and, therefore, violate federal conscience protections such as the Weldon Amendment, *see* section 507(d) of Public Law 115–141.

Other commenters contended that the expanded exemptions are too broad. In general, these commenters supported the inclusion of contraceptives in the Guidelines, contending they are a necessary preventive service for women. Some said that the Departments should not exempt various kinds of entities such as businesses, health insurance issuers, or other plan sponsors that are not nonprofit entities. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318). Some commenters said the Departments should not expand the exemptions, but simply expand or adjust the accommodation process to resolve religious objections to the Mandate and accommodation. Some commenters contended that even the previous regulations allowing an exemption and accommodation were too broad, and said that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible.

After consideration of the comments, the Departments are finalizing the provisions of the Religious IFC without contracting the scope of the exemptions and accommodation set forth in the Religious IFC. Since HRSA issued its Guidelines in 2011, the Departments have recognized that religious exemptions from the contraceptive Mandate are appropriate. The details of the scope of such exemptions are discussed in further detail below. In general, the Departments conclude it is appropriate to maintain the exemptions created by the Religious IFC to avoid instances where the Mandate is applied in a way that violates the religious beliefs of certain plan sponsors, issuers, or individuals. The Departments do not believe the previous exemptions are adequate, because some religious objections by plan sponsors and individuals were favored with exemptions, some were not subjected to contraceptive coverage if they fell under the indirect exemption for certain self-insured church plans, and others had to choose between the Mandate and the accommodation even though they objected to both. The Departments wish to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage. The lack of a congressional mandate that contraceptives be covered, much less that they be covered without religious exemptions, has also informed the Departments' decision to expand the exemptions. And Congress's decision not to apply PHS Act section 2713 to grandfathered plans has likewise informed the Departments' decision whether exemptions to the contraceptive Mandate are appropriate.

Congress has also established a background rule against substantially burdening sincere religious beliefs except where consistent with the stringent requirements of the Religious Freedom Restoration Act. And Congress has consistently provided additional, specific exemptions for religious beliefs in statutes addressing federal requirements in the context of health care and specifically concerning issues such as abortion, sterilization, and contraception. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive coverage Mandate by the exercise of agency discretion, that we also include exemptions for the protection of religious beliefs in certain cases. The expanded exemptions finalized in these rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. They are also consistent with the intent of Executive Order 13535 (March 24, 2010), which was issued upon the signing of the ACA and declared that, ''[u]nder the Act, longstanding federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Public Law 111–8) remain intact'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.''

Some commenters argued that Congress's failure to explicitly include

religious exemptions in PHS Act section 2713 itself is indicative of an intent that such exemptions not be included, but the Departments disagree. As noted above, Congress also failed to require contraceptive coverage in PHS Act section 2713. And the commenters' argument would negate not just these expanded exemptions, but the previous exemptions for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting religious beliefs in the context of certain federal health care requirements.

If there is to be a federal contraceptive mandate that fails to include some—or, in the views of some commenters, any—religious exemptions, the Departments do not believe it is appropriate for us to impose such a regime through discretionary administrative measures. Instead, such a serious imposition on religious liberty should be created, if at all, by Congress, in response to citizens exercising their rights of political participation. Congress did not prohibit religious exemptions under this Mandate. It did not even require contraceptive coverage under the ACA. It left the ACA subject to RFRA, and it specified that additional women's preventive services will only be required coverage as provided for in Guidelines supported by HRSA. Moreover, Congress legislated in the context of the political consensus on conscientious exemptions for health care that has long been in place. Since *Roe* v. *Wade* in 1973, Congress and the states have consistently offered religious exemptions for health care providers and others concerning issues such as sterilization and abortion, which implicate deep disagreements on scientific, ethical, and religious (and moral) concerns. Indeed over the last 44 years, Congress has repeatedly expanded religious exemptions in similar cases, including to contraceptive coverage. Congress did not purport to deviate from that approach in the ACA. Thus, we conclude it is appropriate to specify in these final rules, that, if the Guidelines continue to maintain a contraceptive coverage requirement, the expanded exemptions will apply to those Guidelines and their enforcement.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for religious beliefs in the context of certain Federal health care requirements. Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held religious beliefs to the extent the Guidelines otherwise include contraceptive coverage.[12] These exemptions do not prohibit any services, nor do they authorize employers to prohibit employees from obtaining any services. The Religious IFC and these final rules simply refrain from imposing the federal Mandate that employers and health insurance issuers cover contraceptives in their health plans where compliance with the Mandate would violate their sincerely held religious beliefs. And though not necessary to the Departments' decision here, the Departments note that the Church Amendments explicitly protect entities and that several subsequent federal conscience statutes have protected against federal mandates in health coverage.

The Departments note that their decision is also consistent with state practice. A significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[13] Although the practice of states is not a limit on the discretion delegated to HRSA by the ACA, nor is it a statement about what the federal government may do consistent with RFRA or other limitations or protections embodied in federal law, such state practices can inform the Departments' view that it is appropriate to protect religious liberty as an exercise of agency discretion.

The Departments decline to adopt the suggestion of some commenters to use these final rules to revoke the contraceptive Mandate altogether, such as by declaring that HHS through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). Although previous regulations were used to authorize religious exemptions and accommodations to the imposition of the Guidelines' coverage of contraception, the issuance of the Guidelines themselves in 2011 describing what items constitute recommended women's preventive services, and the update to those recommendations in December 2016, did not occur through the regulations that preceded the 2017 Religious IFC and these final rules. The Guidelines' specification of which women's preventive services were recommended were issued, not by regulation, but directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The Departments decline to accept the invitation of some commenters to use these rules to specify whether HRSA includes contraceptives in the Guidelines at all. Instead the Departments conclude it is appropriate for these rules to continue to focus on restating the statutory language of PHS Act section 2713 in regulatory form, and delineating what exemptions and accommodations apply if HRSA lists contraceptives in its Guidelines. Some commenters said that if contraceptives are not removed from the Guidelines entirely, some entities or individuals with religious objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in the Religious IFC and these final rules cover a broad range of entities and individuals. The Departments are not aware of specific groups or individuals whose religious beliefs would still be substantially burdened by the Mandate after the issuance of these final rules.

Some commenters asserted that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions.

[12] The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

[13] *See* Guttmacher Institute, ''Insurance Coverage of Contraceptives'', The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These rules focus on what religious exemptions and accommodations shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacients.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content of, and the process for developing and updating, the Guidelines, are welcome to communicate their views to HRSA, at *wellwomancare@hrsa.gov.*

The Departments conclude that it would be inadequate to merely attempt to amend or expand the accommodation process instead of expanding the exemption. In the past, the Departments had stated in our regulations and court briefs that the previous accommodation process required contraceptive coverage or payments in a way that is ''seamless'' with the coverage provided by the objecting employer. As a result, in significant respects, that previous accommodation process did not actually accommodate the objections of many entities, as many entities with religious objections have argued. The Departments have attempted to identify an accommodation process that would eliminate the religious objections of all plaintiffs, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but we stated in January 2017 that we were unable to develop such an approach at that time.[14] The Departments continue to believe that, because of the nature of the accommodation process, merely amending that accommodation process without expanding the exemptions would not adequately address religious objections to compliance with the Mandate. Instead, we conclude that the most appropriate approach to resolve these concerns is to expand the exemptions as set forth in the Religious IFC and these final rules, while maintaining the accommodation as an option for providing contraceptive coverage, without forcing entities to choose between compliance with either the Mandate or the accommodation and their religious beliefs.

Comments considering the appropriateness of exempting certain specific kinds of entities or individuals are discussed in more detail below.

C. The First Amendment and the Religious Freedom Restoration Act

Some commenters said that the Supreme Court ruled that the exemptions to the contraceptive Mandate, which the Departments previously provided to houses of worship and integrated auxiliaries, were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but exemptions beyond those are not. But in *Hobby Lobby* and *Zubik,* the Supreme Court did not decide whether the exemptions previously provided to houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate to other organizations unless RFRA prohibits the Departments from doing so. Moreover, the previous church exemption, which applied automatically to all churches whether or not they had even asserted a religious objection to contraception, 45 CFR 147.141(a), is not tailored to any plausible free-exercise concerns. The Departments decline to adopt the view that RFRA does not apply to other religious organizations, and there is no logical explanation for how RFRA could require the church exemption but not this expanded religious exemption, given that the accommodation is no less an available alternative for the former than the latter.

Commenters disagreed about the scope of RFRA's protection in this context. Some commenters said that the expanded exemptions and accommodation are consistent with RFRA. Some also said that they are required by RFRA, as the Mandate imposes substantial burdens on religious exercise and fails to satisfy the compelling-interest and least-restrictive-means tests imposed by RFRA. Other commenters, however, contended that the expanded exemptions and accommodation are neither required by, nor consistent with, RFRA. In this vein, some argued that the Departments have a compelling interest to deny religious exemptions, that there is no less restrictive means to achieve its goals, or that the Mandate or its accommodation process do not impose a substantial burden on religious exercise.

For the reasons discussed below, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement, or to merely attempt to create an accommodation that would mitigate the burden. Here, after further consideration of these issues and review of the public comments, the Departments have determined that a broader exemption, rather than a mere accommodation, is the appropriate response.

In addition, with respect to religious employers, the Departments conclude that, without finalizing the expanded exemptions, and therefore requiring certain religiously objecting entities to choose between the Mandate, the accommodation, or penalties for noncompliance—or requiring objecting individuals to choose between purchasing insurance with coverage to which they object or going without insurance—the Departments would violate their rights under RFRA.

1. Discretion To Provide Religious Exemptions

In the Religious IFC, we explained that even if RFRA does not compel the Departments to provide the religious exemptions set forth in the IFC, the Departments believe the exemptions are the most appropriate administrative response to the religious objections that have been raised.

The Departments received conflicting comments on this issue. Some commenters agreed that the Departments have administrative discretion to address the religious objections even if the Mandate and accommodation did not violate RFRA. Other commenters expressed the view that RFRA does not provide such discretion, but only allows exemptions when RFRA requires exemptions. They contended that RFRA does not require exemptions for entities covered by the expanded exemptions of the Religious IFC, but that subjecting those entities to the accommodation satisfies RFRA, and therefore RFRA provides the Departments with no additional authority to exempt those entities. Those commenters further contended that because, in their view, section 2713(a)(4) does not authorize the

[14] *See* Departments of Labor, Health and Human Services, and the Treasury, ''FAQs About Affordable Care Act Implementation Part 36,'' (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

expanded exemptions, no statutory authority exists for the Departments to finalize the expanded exemptions.

As discussed above, the Departments disagree with the suggestions of commenters that section 2713(a)(4) does not authorize the Departments to adopt the expanded exemptions. Nevertheless, the Departments note that the expanded exemptions for religious objectors also rest on an additional, independent ground: The Departments have determined that, in light of RFRA, an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified by the Supreme Court in *Hobby Lobby*. Indeed, with respect to at least some objecting entities, an expanded exemption, as opposed to the existing accommodation, is required by RFRA. The Departments disagree with commenters who contend RFRA does not give the Departments discretion to offer these expanded exemptions.

The Departments' determination about their authority under RFRA rests in part on the Departments' reassessment of the interests served by the application of the Mandate in this specific context. Although the Departments previously took the position that the application of the Mandate to objecting employers was narrowly tailored to serve a compelling governmental interest, as discussed below the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Particularly under those circumstances, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement or instead to attempt to create an accommodation that would mitigate the burden. And here, the Departments have determined that a broader exemption rather than the existing accommodation is the appropriate response. That determination is informed by the Departments' reassessment of the relevant interests, as well as by their desire to bring to a close the more than five years of litigation over RFRA challenges to the Mandate.

Although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive Mandate, pursuant to *Hobby Lobby*—neither RFRA nor the ACA *prescribes* the remedy by which the government must eliminate that burden, where any means of doing so will require departing from the ACA to some extent (on the view of some commenters, with which the Departments disagree, that section 2713(a)(4) does not itself authorize the Departments to recognize exceptions). The prior administration *chose* to do so through the complex accommodation it created, but nothing in RFRA or the ACA compelled that novel choice or prohibits the current administration from employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. After all, on the theory that section 2713(a)(4) allows for no exemptions, the accommodation also departed from section 2713(a)(4) in the sense that employers were not themselves offering contraceptive coverage, and the ACA did not require the Departments to choose that departure rather than the expanded exemptions as the exclusive method to satisfy their obligations under RFRA to eliminate the substantial burden imposed by the Mandate. The agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given the existing legal uncertainty as to whether the accommodation itself violates RFRA. *See* 82 FR at 47798; *see also Ricci* v. *DeStefano,* 557 U.S. 586, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban). Indeed, if the Departments had simply adopted an expanded exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because they should have invented the accommodation instead. Neither RFRA nor the ACA compels a different result now based merely on path dependence.

Although the foregoing analysis is independently sufficient, additional support for this view is provided by the Departments' conclusion, as explained more fully below, that an expanded exemption is required by RFRA for at least some objectors. In the Religious IFC, the Departments reaffirmed their conclusion that there is not a way to satisfy all religious objections by amending the accommodation, (82 FR at 47800), a conclusion that was confirmed by some commenters (and the continued litigation over the accommodation).[15] Some commenters agreed the religious objections could not be satisfied by amending the accommodation without expanding the exemptions, because if the accommodation requires an objecting entity's issuer or third party administrator to provide or arrange contraceptive coverage for persons covered by the plan because they are covered by the plan, this implicates the objection of entities to the coverage being provided through their own plan, issuer, or third party administrator. Other commenters contended the accommodation could be modified to satisfy RFRA concerns without extending exemptions to objecting entities, but they did not propose a method of modifying the accommodation that would, in the view of the Departments, actually address the religious objections to the accommodation.

In the Departments' view, after considering all the comments and the preceding years of contention over this issue, it is appropriate to finalize the expanded exemptions rather than merely attempt to change the accommodation to satisfy religious objections. This is because if the accommodation still delivers contraceptive coverage through use of the objecting employer's plan, issuer, or third party administrator, it does not address the religious objections. If the accommodation could deliver contraceptive coverage independent and separate from the objecting employer's plan, issuer, and third party administrator, it could possibly address the religious objections, but there are two problems with such an approach. First, it would effectively be an exemption, not the accommodation as it has existed, so it would not be a reason not to offer the expanded exemptions finalized in these rules. Second, although (as explained above) the Departments have authority to provide exemptions to the Mandate, the Departments are not aware of the authority, or of a practical mechanism, for using section 2713(a)(4) to require contraceptive coverage be provided

[15] *See* RFI, 81 FR 47741 (July 26, 2016); Departments of Labor, Health and Human Services, and the Treasury, ''FAQs, About Affordable Care Act Implementation Part 36,'' (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

specifically to persons covered by an objecting employer, other than by using the employer's plan, issuer, or third party administrator, which would likely violate some entities' religious objections. The Departments are aware of ways in which certain persons covered by an objecting employer might obtain contraceptive coverage through other governmental programs or requirements, instead of through objecting employers' plans, issuers, or third party administrators, and we mention those elsewhere in this rule. But those approaches do not involve the accommodation, they involve the expanded exemptions, plus the access to contraceptives through separate means.

2. Requiring Entities To Choose Between Compliance With the Contraceptive Mandate or the Accommodation Violated RFRA in Many Instances

Before the Religious IFC, the Departments had previously contended that the Mandate did not impose a substantial burden on entities and individuals under RFRA; that it was supported by a compelling government interest; and that it was, in combination with the accommodation, the least restrictive means of advancing that interest. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with sincerely held religious objections, that argument was rejected in *Hobby Lobby,* which held that the Mandate imposes a substantial burden and was not the least restrictive means of achieving any compelling governmental interest. *See* 134 S. Ct. at 2775–79. In the Religious IFC, the Departments revisited its earlier conclusions and reached a different view, concluding that requiring compliance through the Mandate or accommodation constituted a substantial burden on the religious exercise of many entities or individuals with religious objections, did not serve a compelling interest, and was not the least restrictive means of serving a compelling interest, so that requiring such compliance led to the violation of RFRA in many instances. (82 FR at 47806).

In general, commenters disagreed about this issue. Some commenters agreed with the Departments, and with some courts, that requiring entities to choose between the contraceptive Mandate and its accommodation violated their rights under RFRA, because it imposed a substantial burden on their religious exercise, did not advance a compelling government interest, and was not the least restrictive means of achieving such an interest. Other commenters contended that requiring compliance either with the Mandate or the accommodation did not violate RFRA, agreeing with some courts that have concluded the accommodation does not substantially burden the religious exercise of organizations since, in their view, it does not require organizations to facilitate contraceptive coverage except by submitting a self-certification form or notice, and requiring compliance was the least restrictive means of advancing the compelling interest of providing contraceptive access to women covered by objecting entities' plans.

The Departments have examined further, including in light of public comments, the issue of whether requiring compliance with the combination of the contraceptive Mandate and the accommodation process imposes a substantial burden on entities that object to both, and is the least restrictive means of advancing a compelling government interest. The Departments now reaffirm the conclusion set forth in the Religious IFC, that requiring certain religiously objecting entities or individuals to choose between the Mandate, the accommodation, or incurring penalties for noncompliance imposes a substantial burden on religious exercise under RFRA.

a. Substantial Burden

The Departments concur with the description of substantial burdens expressed recently by the Department of Justice:

> A governmental action substantially burdens an exercise of religion under RFRA if it bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice.
>
> Because the government cannot second-guess the reasonableness of a religious belief or the adherent's assessment of the connection between the government mandate and the underlying religious belief, the substantial burden test focuses on the extent of governmental compulsion involved. In general, a government action that bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice, will qualify as a substantial burden on the exercise of religion.[16]

The Mandate and accommodation under the previous regulation forced certain non-exempt religious entities to choose between complying with the Mandate, complying with the accommodation, or facing significant penalties. Various entities sincerely contended, in litigation or in public comments, that complying with either the Mandate or the accommodation was inconsistent with their religious observance or practice. The Departments have concluded that withholding an exemption from those entities has imposed a substantial burden on their exercise of religion, either by compelling an act inconsistent with that observance or practice, or by substantially pressuring the adherents to modify such observance or practice. To this extent, the Departments believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing substantial burden, to the burdens that an entity faces when it opposes, on the basis of its religious beliefs, complying with the Mandate or participating in the accommodation process, and is subject to penalties or disadvantages that would have applied in this context if it chose neither. *See also Sharpe Holdings,* 801 F.3d at 942. Likewise, reconsideration of these issues has also led the Departments to conclude that the Mandate imposes a substantial burden on the religious beliefs of an individual employee who opposes coverage of some (or all) contraceptives in his or her plan on the basis of his or her religious beliefs, and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because the Mandate requires that employer or issuer to provide a plan that covers all FDA-approved contraceptives. The Departments disagree with commenters that contend the accommodation did not impose a substantial burden on religiously objecting entities, and agree with other commenters and some courts and judges that concluded the accommodation can be seen as imposing a substantial burden on religious exercise in many instances.

b. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have concluded, after reassessing the relevant interests and, in light of the public comments received, that it does not. This is based on several independent reasons.

First, as discussed above, the structure of section 2713(a)(4) and the ACA evince a desire by Congress to

[16] *See* Federal Law Protections for Religious Liberty, 82 FR 49668, 49669 (Oct. 26, 2017).

grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans pursuant to section 2713(a)(4). This informs the Departments' assessment of whether the interest in mandating the coverage constitutes a compelling interest, as doing so imposes a substantial burden on religious exercise. As the Department of Justice has explained, ''[t]he strict scrutiny standard applicable to RFRA is exceptionally demanding,'' and ''[o]nly those interests of the highest order can outweigh legitimate claims to the free exercise of religion, and such interests must be evaluated not in broad generalities but as applied to the particular adherent.'' [17]

Second, since the day the contraceptive Mandate came into effect in 2011, the Mandate has not applied in many circumstances. To begin, the ACA does not apply the Mandate, or any part of the preventive services coverage requirements, to grandfathered plans. To continue, the Departments under the last Administration provided exemptions to the Mandate and expanded those exemptions through multiple rulemaking processes. Those rulemaking processes included an accommodation that effectively left employees of many non-exempt religious nonprofit entities without contraceptive coverage, in particular with respect to self-insured church plans exempt from ERISA. Under the previous accommodation, once a self-insured church plan filed a self-certification or notice, the accommodation relieved it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would generally have transferred the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments recognized that they lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to health insurance issuers, but does not apply to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs of those plans to provide such coverage, led to significant disparity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

Third party administrators for some, but not all, religious nonprofit organizations were subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they administer a self-insured church plan. Notably, many of those nonprofit organizations were not houses of worship or integrated auxiliaries. Under section 3(33)(C) of ERISA, organizations whose employees participate in self-insured church plans need not be churches so long as they are controlled by or ''share[ ] common religious bonds and convictions with'' a church or convention or association of churches. The effect is that many similar religious organizations were being treated differently with respect to their employees receiving contraceptive coverage based solely on whether organization employees participate in a church plan.

This arrangement encompassed potentially hundreds of religious non-profit organizations that were not covered by the exemption for houses of worship and integrated auxiliaries. For example, the Departments were sued by two large self-insured church plans—Guidestone and Christian Brothers.[18] Guidestone is a plan organized by the Southern Baptist convention that covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not. Christian Brothers is a plan that covers Catholic churches and integrated auxiliaries and has said in litigation that it covers about 500 additional entities that are not exempt as churches. In several other lawsuits challenging the Mandate, the previous Administration took the position that some plans established and maintained by houses of worship but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government ''has no authority to require the plaintiffs' TPAs to provide contraceptive coverage at this time.'' *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

Third, the Departments now believe the administrative record on which the Mandate rested was—and remains—insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. The Mandate is not narrowly tailored to advance the government's interests and appears both overinclusive and underinclusive. It includes some entities where a contraceptive coverage requirement seems unlikely to be effective, such as religious organizations of certain faiths, which, according to commenters, primarily hire persons who agree with their religious views or make their dedication to their religious views known to potential employees who are expected to respect those views. The Mandate also does not apply to a significant number of entities encompassing many employees and for-profit businesses, such as grandfathered plans. And it does not appear to target the population defined, at the time the Guidelines were developed, as being the most at-risk of unintended pregnancy, that is, ''women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority.'' [19] Rather than focusing on this group, the Mandate is a broad-sweeping requirement across employer-provided coverage and the individual and group health insurance markets.

The Department received conflicting comments on this issue. Some commenters agreed that the government does not have a compelling interest in applying the Mandate to objecting religious employers. They noted that the expanded exemptions will impact only a small fraction of women otherwise affected by the Mandate and argued that refusing to provide those exemptions would fail to satisfy the compelling interest test. Other commenters, however, argued that the government has a broader interest in the Mandate because all women should be considered at-risk of unintended pregnancy. But the Institute of Medicine (IOM), in discussing whether contraceptive coverage is needed, provided a very specific definition of the population of women most at-risk of unintended pregnancy.[20] The Departments believe it is appropriate to consider the government's interest in

[17] *Id.* at 49670.

[18] The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

[19] Institute of Medicine, ''Clinical Preventive Services for Women: Closing the Gaps'' at 102 (2011).

[20] Id.

the contraceptive coverage requirement using the definition that formed the basis of that requirement and the justifications the Departments have offered for it since 2011. The Mandate, by its own terms, applies not just to women most at-risk of unintended pregnancy as identified by the IOM, but applies to any non-grandfathered ''group health plan and a health insurance issuer offering group or individual health insurance coverage.'' PHS Act section 2713(a). Similarly, the exemptions and accommodation in previous rules, and the expanded exemptions in these rules, do not apply only to coverage for women most at-risk of unintended pregnancy, but to plans where a qualifying objection exists based on sincerely held religious beliefs without regard to the types of women covered in those plans. Seen in this light, the Departments believe there is a serious question whether the administrative record supports the conclusion that the Mandate, as applied to religious objectors encompassed by the expanded exemptions, is narrowly tailored to achieve the interests previously identified by the government. Whether and to what extent it is certain that an interest in health is advanced by refraining from providing expanded religious exemptions is discussed in more detail below in section II.F., Health Effects of Contraception and Pregnancy.

Fourth, the availability of contraceptive coverage from other possible sources—including some objecting entities that are willing to provide some (but not all) contraceptives, or from other governmental programs for low-income women—detracts from the government's interest to refuse to expand exemptions to the Mandate. The Guttmacher Institute recently published a study that concluded, ''[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy,'' and ''there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.'' [21] In discussing why they did not see such an effect from the Mandate, the authors suggested that ''[p]rior to the implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use. In addition, cost is not the only barrier to accessing a full range of method options,'' and ''[t]he fact that income is not associated with use of most other methods [besides male sterilization and withdrawal] obtained through health care settings may reflect broader access to affordable and/or free contraception made possible through programs such as Title X.''

Fifth, the Departments previously created the accommodation, in part, as a way to provide for payments of contraceptives and sterilization in a way that is ''seamless'' with the coverage that eligible employers provide to their plan participants and their beneficiaries. (80 FR 41318). As noted above, some commenters contended that seamlessness between contraceptive coverage and employer sponsored insurance is important and is a compelling governmental interest, while other commenters disagreed. Neither Congress, nor the Departments in other contexts, have concluded that seamlessness, as such, is a compelling interest in the federal government's delivery of contraceptive coverage. For example, the preventive services Mandate itself does not require contraceptive coverage and does not apply to grandfathered plans, thereby failing to guarantee seamless contraceptive coverage. The exemption for houses of worship and integrated auxiliaries, and the application of the accommodation to certain self-insured church plans, also represents a failure to achieve seamless contraceptive coverage. HHS's Title X program provides contraceptive coverage in a way that is not necessarily seamless with beneficiaries' employer sponsored insurance plans. After reviewing the public comments and reconsidering this issue, the Departments no longer believe that if a woman working for an objecting religious employer receives contraceptive access in ways that are not seamless to her employer sponsored insurance, a compelling government interest has nevertheless been undermined. Therefore the Departments conclude that guaranteeing seamlessness between contraceptive access and employer sponsored insurance does not constitute a compelling interest that overrides employers' religious objections to the contraceptive Mandate.

Some commenters contended that obtaining contraceptive coverage from other sources could be more difficult or more expensive for women than obtaining it from their group health plan or health insurance plan. The Departments do not believe that such differences rise to the level of a compelling interest or make it inappropriate for us to issue the expanded exemptions set forth in these final rules. Instead, after considering this issue, the Departments conclude that the religious liberty interests that would be infringed if we do not offer the expanded exemptions are not overridden by the impact on those who will no longer obtain contraceptives through their employer sponsored coverage as a result. This is discussed in more detail in following section, II.D., Burdens on Third Parties.

D. Burdens on Third Parties

The Departments received a number of comments on the question of burdens that these rules might impose on third parties. Some commenters asserted that the expanded exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might not otherwise receive contraceptive coverage with no cost-sharing. These included commenters agreeing with the Departments' explanations in the Religious IFC, stating that unintended pregnancies were decreasing before the Mandate was implemented, and asserting that any benefit that third parties might receive in getting contraceptive coverage does not justify forcing religious persons to provide such products in violation of their beliefs. Other commenters disagreed, asserting that the expanded exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more unintended pregnancies,[22] births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as those found in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as

[21] M.L. Kavanaugh et al., Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

[22] Some commenters attempted to quantify the costs of unintended pregnancy, but failed to persuasively estimate the population of women that this exemption may affect.

prioritizing religious liberty of exempted entities over the religious liberty, conscience, or choices of women who would not receive contraceptive coverage where an exemption is used.

The Departments note that the exemptions in the Religious IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these final rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. HHS exercised discretion granted to HRSA by the Congress to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: that the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits. But Congress did not create a right to receive contraceptive coverage from other private citizens through PHS Act section 2713, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to benefit other private parties, does not prevent the government from relieving some or all of the burden of its Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Religious IFC and these rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third-party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris* v. *McRae,* 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the Government refrain from requiring private citizens, in violation of their religious beliefs, to cover contraception for other citizens. *Cf. Rust* v. *Sullivan,* 500 U.S. 173, 192–93 (1991) (''A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.''). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting religious objections to such governmental mandates, especially where, as here, the mandate is not an explicit statutory requirement.[23] The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these final rules.

As the Department of Justice has observed, the fact that exemptions may relieve a religious adherent from conferring a benefit on a third party ''does not categorically render an exemption unavailable,'' and RFRA still applies.[24] The Departments conclusion on this matter is consistent with the Supreme Court's observation that RFRA may require exemptions even from laws requiring claimants ''to confer benefits on third parties.'' *See Hobby Lobby,* 134 S. Ct. at 2781 n.37. Here, no law contains such a requirement, but the Mandate is derived from an administrative exercise of discretion that Congress charged HRSA and the Departments with exercising. Burdens that may affect third parties as a result of revisiting the exercise of agency discretion may be relevant to the RFRA analysis, but they cannot be dispositive. ''Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).'' *Id.*

When government relieves burdens on religious exercise, it does not violate the Establishment Clause; rather, ''it follows the best of our traditions.'' *Zorach* v. *Clauson,* 343 U.S. 306, 314 (1952). The Supreme Court's cases ''leave no doubt that in commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice.'' *Board of Educ. of Kiryas Joel Village Sch. Dist.* v. *Grumet,* 512 U.S. 687, 705 (1994). Rather, the Supreme Court ''has long recognized that the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause.'' *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* 483 U.S. 327, 334 (1987) (quoting *Hobbie* v. *Unemployment Appeals Comm'n of Fla.,* 480 U.S. 136, 144–45 (1987)). ''[T]here is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.'' *Cutter* v. *Wilkinson,* 544 U.S. 709, 713 (2005) (internal quotation omitted). Thus, the Supreme Court has upheld a broad range of accommodations against Establishment Clause challenges, including the exemption of religious organizations from Title VII's prohibition against discrimination in employment on the basis of religion, *see Amos,* 483 U.S. at 335–39; a state property tax exemption for religious organizations, *see Walz* v. *Tax Comm'n of City of New York,* 397 U.S. 664, 672–80 (1970); and a state program releasing public school children during the school day to receive religious instruction at religious centers, *see Zorach,* 343 U.S. at 315.

Before 2012 (when HRSA's Guidelines went into effect), there was no federal women's preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA's Guidelines, and it did not require any preventive services required under PHS

[23] *See, for example, Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (''[A] woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'').

[24] See Federal Law Protections for Religious Liberty, 82 FR at 49670.

Act section 2713 to be covered by grandfathered plans. Many States do not impose contraceptive coverage mandates, or they offer religious exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or State courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters said that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others said that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to states or local governments. We are not aware of instances where the various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage (other than through the Religious and Moral IFCs), have been determined to cause a cognizable injury to state or local governments. Some states that were opposed to the IFCs submitted comments objecting to the potential impacts on their programs resulting from the expanded exemptions, but they did not adequately demonstrate that such impacts would occur, and they did not explain whether, or to what extent, they were impacted by the other kinds of instances mentioned above in which no federal mandate of contraceptive coverage has applied to certain plans. The Departments find no legal prohibition on finalizing these rules based on the speculative suggestion of an impact on state or local governments, and we disagree with the suggestion that once we have exercised our discretion to deny exemptions—no matter how recently or incompletely—we cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, these expanded exemptions apply only to a small fraction of entities to which the Mandate would otherwise apply—those with qualifying religious objections. Public comments did not provide reliable data on how many entities would use these expanded religious exemptions, in which states women in such plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would have to cover. As mentioned above, at least one study, published by the Guttmacher Institute, concluded the Mandate has caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the expanded exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates.

In the discussion below concerning estimated economic impacts of these rules, the Departments explain there is not reliable data available to accurately estimate the number of women who may lose contraceptive coverage under these rules, and the Departments set forth various reasons why it is difficult to know how many entities will use these exemptions or how many women will be impacted by those decisions. Solely for the purposes of determining whether the rules have a significant economic impact under Executive Order 12,866, and in order to estimate the broadest possible impact so as to determine the applicability of the procedures set forth in that Executive Order, the Departments propose that the rules will affect no more than 126,400 women of childbearing age who use contraceptives covered by the Guidelines, and conclude the economic impact falls well below $100 million. As explained below, that estimate assumes that a certain percentage of employers which did not cover contraceptives before the ACA will use these exemptions based on sincerely held religious beliefs. The Departments do not actually know that such entities will do so, however, or that they operate based on sincerely held religious beliefs against contraceptive coverage. The Departments also explain that other exemptions unaffected by these rules may encompass many or most women potentially affected by the expanded exemptions. In other words, the houses of worship and integrated auxiliaries exemption, the accommodation's failure to require contraceptive coverage in certain self-insured church plans, the non-applicability of PHS Act section 2713 to grandfathered plans, and the permanent injunctive relief many religious litigants have received against section 2713(a)(4), may encompass a large percentage of women potentially affected by religious objections, and therefore many women in those plans may not be impacted by these rules at all. In addition, even if 126,400 women might be affected by these rules, that number constitutes less than 0.1% of all women in the United States.[25] This suggests that if these rules have any impact on state or local governments, it will be statistically de minimus. The Departments conclude that there is insufficient evidence of a potential negative impact of these rules on state and local governments to override the appropriateness of deciding to finalize these rules.

Some commenters contended that the expanded exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions

[25] U.S. Census Bureau, ''Quick Facts: Population Estimates, July 1, 2017'' (estimating 325,719,178 persons in the U.S., 50.8% of which are female), available at *https://www.census.gov/quickfacts/fact/table/US/PST045217.*

would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these final rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The expanded exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead they allow entities that have sincerely held religious objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

These commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.,* 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII ''does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women''). Second, these rules create no disparate impact. The women's preventive services mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inures to the specific benefit of women—men are denied any benefit from that section. Both before and after these final rules, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or male contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions are expanded to encompass religious objections. The previous regulations, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that few women of childbearing age in the country will be affected by these expanded exemptions.[26] In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby*'s holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters observed that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some objected to the suggestion in the Religious IFC that many forms of contraceptives are available for around $50 per month and other forms, though they bear a higher one-time cost, cost a similar amount over the duration of use. But some of those commenters cited sources maintaining that birth control pills can cost up to $600 per year (that is, $50 per month), and said that IUDs, which can last three to six years or more,[27] can cost $1,100 (that is, less than $50 per month over the duration of use). Some commenters said that, for lower income women, contraceptives can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately insured individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, pointing out that some government programs that provide family planning have income and eligibility thresholds, so that women earning certain amounts above those levels would need to pay full cost for contraceptives if they were no longer covered in their health plans.

The Departments do not believe that these general considerations make it inappropriate to issue the expanded exemptions set forth in these rules. In addition, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed regulation to amend the regulations governing its Title X family planning program. The proposed regulation would amend the definition of ''low income family''—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions (see 83 FR 25502). If that regulation is finalized as proposed, it could further reduce any potential effect of these final rules on women's access to contraceptives. That proposal also demonstrates that the government has other means available to it for increasing women's access to contraception. Some of those means are less restrictive of religious exercise than imposition of the contraceptive Mandate on employers with sincerely held religious objections to providing such coverage.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS ''shall not promulgate any regulation'' that ''creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,'' ''impedes timely access to health care services,'' ''interferes with communications regarding a full range of treatment options between the patient and the provider,'' ''restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,'' ''violates the principles of informed consent and the ethical standards of health care professionals,'' or ''limits the

[26] Below, the Departments estimate that no more than 126,400 women of childbearing age will be affected by the expanded exemptions. As noted above, this is less than 0.1% of the over 165 million women in the United States. The Departments previously estimated that, at most 120,000 women of childbearing age would be affected by the expanded exemptions. *See* Religious IFC, 82 FR 47,823–84.

[27] *See, for example,* Planned Parenthood, ''IUD,'' *https://www.plannedparenthood.org/learn/birth-control/iud.*

availability of health care treatment for the full duration of a patient's medical needs.'' 42 U.S.C. 18114. Such commenters urged, for example, that the Religious IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections. The Departments, which administer both ACA section 1554 and PHS Act section 2713, did not conclude that the exemptions or accommodations in those regulations violated section 1554. Moreover, the decision not to impose a governmental mandate is not the ''creation'' of a ''barrier,'' especially when that mandate requires private citizens to provide services to other private citizens. Nor, in any event, are the exemptions from the Mandate unreasonable. Section 1554 of the ACA does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 prohibit the Departments from providing exemptions for burdens on religious exercise, or, as is the case here, from refraining to impose the Mandate in cases where religious exercise would be burdened by it. In light of RFRA and the First Amendment, providing religious exemptions is a reasonable administrative response in the context of this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts. Religious exemptions from federal mandates in sensitive health contexts have existed in federal laws for decades, and President Obama referenced them when he issued Executive Order 13535 (March 24, 2010), declaring that, under the ACA, ''longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact,'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.'' While the text of Executive Order 13535 does not require the expanded exemptions issued in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect religious beliefs.

In short, the Departments do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

Members of the public have widely divergent views on whether expanding the exemptions is good public policy. Some commenters said the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind expanding the exemptions and arguing that the exemptions would not interfere with the physician-patient relationship. For all the reasons explained at length in this preamble, the Departments have determined that these rules are good policy. Because of the importance of the religious liberty values being accommodated, the limited impact of these rules, and uncertainty about the impact of the Mandate overall according to some studies, the Departments do not believe these rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

E. Interim Final Rulemaking

The Departments received several comments about their decision to issue the Religious IFC as interim final rules with requests for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Religious IFC in that way, agreeing that the Departments had explicit statutory authority to do so, good cause under the Administrative Procedure Act (APA), or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe legal authority existed to issue the Religious IFC as interim final rules. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Religious IFC, the Departments issued three interim final rules implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Religious IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Religious IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules are being issued after receiving and thoroughly considering public comments as requested in the Religious IFC. These final rules therefore comply with the APA's notice and comment requirements.

F. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause or are associated with an increased risk of depression,[28] venous thromboembolic

[28] Commenters cited Charlotte Wessel Skovlund et al., ''Association of Hormonal Contraception with Depression,'' 73 *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) (''Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression,

disease,[29] fatal pulmonary embolism,[30] thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),[31] hypertension,[32] HIV–1 acquisition and transmission,[33] and breast, cervical, and liver cancers.[34] Some commenters also observed that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that contraceptive access does not reduce unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 IOM Report's discussions of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality.[35] Commenters also said studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer,[36] and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.[37] Some commenters said that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters said that, in the Religious IFC, the Departments made incorrect statements concerning scientific studies. For example, some commenters argued there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Religious IFC for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality Report No.: 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR at 47804, the 2013 Agency for Healthcare Research and Quality study, and others, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to take into account both of those studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,[38] the purpose for the Departments' reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or, more specifically, the part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some

suggesting depression as a potential adverse effect of hormonal contraceptive use.'').

[29] Commenters cited the Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception: Recent Advances and Controversies,'' 82 *Fertility and Sterility* S20, S26 (2004); V.A. Van Hylckama et al., ''The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study,'' 339 *Brit. Med. J.* 339b2921 (2009); Y. Vinogradova et al., ''Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases,'' 350 *Brit. Med. J.* 350h2135 (2015) (''Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year.''); Ø. Lidegaard et al., ''Hormonal contraception and risk of venous thromboembolism: national follow-up study,'' 339 *Brit. Med. J.* b2890 (2009): M. de Bastos et al., ''Combined oral contraceptives: venous thrombosis,'' Cochrane Database Syst. Rev. (no. 3, 2014). CD010813. doi: 10.1002/14651858.CD010813.pub2, available at *https://www.ncbi.nlm.nih.gov/pubmed?term=24590565;* L.J Havrilesky et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* and Robert A. Hatcher et al., *Contraceptive Technology* 405–07 (Ardent Media 18th rev. ed. 2004).

[30] Commenters cited N.R. Poulter, ''Risk of Fatal Pulmonary Embolism with Oral Contraceptives,'' 355 *Lancet* 2088 (2000).

[31] Commenters cited Ø. Lidegaard et al., ''Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception,'' 366 *N. Eng. J. Med.* 2257, 2257 (2012) (risks ''increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 μg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 μg''); Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception''; M. Vessey et al., ''Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking,'' 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, ''Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study,'' 349 *Lancet* 1202, 1202–09(1997); K.M. Curtis et al., Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review, 73 Contraception 73179, 179–88 (2006); L.A. Gillum et al., ''Ischemic stroke risk with oral contraceptives: A meta analysis,'' 284 *JAMA* 72, 72–78 (2000), available at *https://www.ncbi.nlm.nih.gov/pubmed/10872016;* and Robert A. Hatcher et al., *Contraceptive Technology* 404–05, 445 (Ardent Media 18th rev. ed. 2004).

[32] Commenters cited Robert A. Hatcher et al., *Contraceptive Technology* 407, 445 (Ardent Media 18th rev. ed. 2004).

[33] Commenters cited Renee Heffron et al., ''Use of Hormonal Contraceptives and Risk of HIV–1 Transmission: A Prospective Cohort Study,'' 12 *Lancet Infectious Diseases 19, 24* (2012) (''Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV–1 acquisition by women and HIV–1 transmission from women to men.''); and ''Hormonal Contraception Doubles HIV Risk, Study Suggests,'' *Science Daily* (Oct. 4, 2011), *https://www.sciencedaily.com/releases/2011/10/111003195253.htm.*

[34] Commenters cited ''Oral Contraceptives and Cancer Risk'' (Mar. 21, 2012, National Cancer Institute (reviewed Feb. 22, 2018), *https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet;* L.J Havrilesky et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* S.N. Bhupathiraju et al., ''Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study,'' 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, ''The Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment'', World Health Organization (Sept. 2005), *http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf;* and the American Cancer Society, ''Known and Probably Human Carcinogens,'' American Cancer Society (rev. Nov. 3, 2016), *https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html.*

[35] Citing, *e.g.,* Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. JAMA 2006;295:1809–23, and John Hopkins Bloomberg Public Health School of Health, Contraception Use Averts 272,000 Maternal Deaths Worldwide, *https://www.jhsph.edu/news/news-releases/2012/ahmed-contraception.html.*

[36] Citing, *e.g.,* Schindler, A.E. (2013). Non-contraceptive benefits of oral hormonal contraceptives. International Journal of Endocrinology and Metabolism, 11 (1), 41–47.

[37] Citing, *e.g.,* id., and American College of Obstetricians and Gynecologists, Committee on Health Care for Underserved Women. (2015, January). Committee Opinion Number 615: Access to Contraception. As discussed below, to the extent that contraceptives are prescribed to treat existing health conditions, and not for preventive purposes, the Mandate would not be applicable.

[38] 82 FR at 47803–04.

commenters agreed with the quotation, in the Religious IFC, of FDA materials [39] that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Religious IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Religious IFC that some persons believe those possible effects are ''abortifacient.''

The objection on this issue appears to be partially one of semantics. People disagree about whether to define ''conception'' or ''pregnancy'' to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items ''abortifacient''—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother's body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby,* 134 U.S. at 2765 (''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.'').

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere religious objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of a sincerely held religious belief under RFRA.[40] Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA's statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer expanded religious exemptions with respect to this Mandate.

The Departments also received comments about their discussion of the uncertain effects of the expanded exemptions on teen sexual activity. In this respect, the Departments stated, ''With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that '[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.' '' [41] Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that denying expanded exemptions to the Mandate is not a narrowly tailored way to advance the Government's interests in reducing teen pregnancy, and suggesting there are means of doing so that are less restrictive of religious exercise.[42] Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.[43]

Many commenters opposing the Religious IFC misunderstood the Departments' discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, we note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments' conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including but not limited to reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline), and concluded ''that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.'' [44] One

[39] FDA's guide ''Birth Control: Medicines To Help You,'' specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and ''may also work . . . by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

[40] ''Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You.'' *Hobby Lobby,* 134 S. Ct. at 2762–63. ''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.'' *Id.* at 2765–66.

[41] Citing J.S. Santelli & A.J. Melnikas, ''Teen fertility in transition: recent and historic trends in the United States,'' 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at *http://public.econ.duke.edu/~psarcidi/addicted13.pdf. See also* K. Buckles & D. Hungerman, ''The Incidental Fertility Effects of School Condom Distribution Programs,'' *Nat'l Bureau of Econ. Research* Working Paper No. 22322 (June 2016), available at *http://www.nber.org/papers/w22322* (''access to condoms in schools increases teen fertility by about 10 percent'' and increased sexually transmitted infections).

[42] *See* Helen Alvaré, ''No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom,'' 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[43] *See, for example,* Lindberg L., Santelli J., ''Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,'' 59 *J. Adolescent Health* 577–83 (Nov. 2016), *https://doi.org/10.1016/j.jadohealth.2016.06.024; see also* Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, *www.regulations.gov* (discussing teen pregnancy data from Colorado).

[44] Kearney MS and Levine PB, ''Investigating recent trends in the U.S. birth rate,'' 41 *J. Health*

study found that during the teen pregnancy decline between 2007–2012, teen sexual activity was also decreasing.[45] One study concluded that falling unemployment rates in the 1990s accounted for 85% of the decrease in rates of first births among 18–19 year-old African Americans.[46] Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.[47] One study concluded that an ''increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.'' [48] Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.[49] Some commenters also cited studies, which are not limited to the issue of teen pregnancy, that have found many women who have abortions report that they were using contraceptives when they became pregnant.[50]

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of the public comments has reinforced the Departments' conclusion that significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals. The uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing religious exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments for implementing the ACA.

G. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promotes the health and equality of women, especially low income women and promotes female participation and equality in the workforce. Other commenters contended that there was insufficient evidence that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed the study quoted above, published and revised by the Guttmacher Institute in October 2017, concluding that through 2014 there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy, that there was no significant shift from less effective to more effective methods, and that it was ''unclear'' whether this Mandate impacted contraceptive use because there was no significant increase in the use of contraceptive methods the Mandate covered.[51] These commenters also noted that, in the 29 States where contraceptive coverage mandates have been imposed statewide,[52] those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[53] Other commenters, however, disputed the significance of these state statistics, noting that of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the expanded exemptions in these rules might have on the Mandate more broadly. The state mandates apply to a very large number of plans and plan participants, notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups are, and have been, exempt from the federal Mandate prior to the Religious IFC. The exemptions as set forth in the Religious IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might

Econ. 15–29 (2015), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041.*

[45] *See, for example,* K. Ethier et al., ''Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,'' 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at *http://dx.doi.org/10.15585/mmwr.mm665152a1* (''Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall. . . .'').

[46] Colen CG, Geronimus AT, and Phipps MG, ''Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,'' 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at *https://www.sciencedirect.com/science/article/pii/S027795360600205X.*

[47] Atkins DN and Wilkins VM, ''Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,'' 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at *https://academic.oup.com/jpart/article-abstract/23/4/771/963674.*

[48] E. Collins & B. Herchbein, ''The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,'' *U. Mich. Pop. Studies Ctr.* Report 11–737 (May 2011), available at *https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf* (''[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women'').

[49] *See* D. Paton & L. Wright, ''The effect of spending cuts on teen pregnancy,'' 54 *J. Health Econ.* 135, 135–46 (2017), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551* (''Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates'').

[50] Commenters cited, for example, Guttmacher Institute, ''Fact Sheet: Induced Abortion in the United States'' (Jan. 2018) (''Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant''), available at *https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.*

[51] Kavanaugh, 97 *Contraception* at 14–21.

[52] *See* Guttmacher Institute, ''Insurance Coverage of Contraceptives'' (June 11, 2018); Kaiser Family Foundation, ''State Requirements for Insurance Coverage of Contraceptives,'' Henry J Kaiser Family Foundation (Jan. 1, 2018), *https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[53] *See* Michael J. New, ''Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,'' 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

result from a broad contraceptive coverage mandate.

Some commenters expressed concern that providing exemptions to the Mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, PHS Act section 2713(a)(2) requires coverage of ''immunizations,'' and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting religious beliefs from certain health care mandates concerning issues such as sterilization, abortion and birth control.

Some commenters took issue with the conclusion set forth in the Religious IFC, which is similar to that asserted in the 2017 Guttmacher study, that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.'' They observed that more women have coverage of contraceptives and contraception counseling under the Mandate and that more contraceptives are provided without co-pays than before. Still other commenters argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA [54] and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also argued that studies show that decreases in unintended pregnancies are due to broader access of contraceptives. Finally, some commenters argued that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on our review, it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, we conclude that the Religious IFC and these final rules—which merely withdraw the Mandate's requirement from what appears to be a small group of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. We also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, are an appropriate exercise of the Departments' discretion.

Moreover, we conclude that the best way to balance the various policy interests at stake in the Religious IFC and these final rules is to provide the expanded exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules will provide tangible protections for religious liberty, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a substantial burden on their religious exercise. The Departments view the provision of those protections to preserve religious exercise in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for religious exercise set forth in the Religious IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

[54] Citing, for example, Adelle Simmons et al., ''The Affordable Care Act: Promoting Better Health for Women,'' Table 1, Assistant Secretary for Planning and Evaluation (June 14, 2016), *https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf.*

III. Description of the Text of the Regulations and Response to Additional Public Comments

Here, the Departments describe the regulatory text set forth prior to the Religious IFC, the regulations from that IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments' response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. As noted above, various members of the public provided comments that were supportive, or critical, of the Religious IFC overall, or of significant policies pertaining to those regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

A. Restatement of Statutory Requirements of PHS Act Section 2713(a) and (a)(4) (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified these restatements to more closely align them with the text of PHS Act section 2713(a) and (a)(4).

Previous versions of these rules had varied from the statutory language. PHS Act section 2713(a) and (a)(4) require group health plans and health insurance issuers offering coverage to provide coverage without cost sharing for ''such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines'' supported by HRSA. In comparison, the previous version of regulatory restatements of this language (as drawn from 45 CFR 147.130(a)(1)

and (a)(1)(iv)) stated the coverage must include ''evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by'' HRSA. The Religious IFC amended this language to state, parallel to the language in section 2713(a)(4), that the coverage must include ''such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by'' HRSA.

These rules adopt as final, without change, the provisions in the Religious IFC amending 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). In this way, the regulatory text better conforms to the statutory language. In paragraph (a)(1) of the final regulations, instead of saying ''must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements . . . with respect to those items and services:'', the regulation now tracks the statutory language by saying ''must provide coverage for and must not impose any cost-sharing requirements . . . for—''. By eliminating the language ''coverage for all of the following items and services,'' and ''with respect to those items and services,'' the Departments do not intend that coverage for specified items and services will not be required, but we simply intend to simplify the text of the regulation to track the statute and avoid duplicative language.

By specifying that paragraph (a)(1)(iv) concerning the women's preventive services Guidelines encompasses ''such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132,'' the regulatory text also better tracks the statutory language that the Guidelines are for ''such additional'' preventive services as HRSA may ''provide[ ] for'' and ''support[ ].'' This text also eliminates language, not found in the statute, that the Guidelines are ''evidence-informed'' and ''binding.'' Congress did not include the word ''binding'' in PHS Act section 2713, and did include the words ''evidence-based'' or ''evidence-informed'' in section 2713(a)(1) and (a)(3), but omitted such terms from section 2713(a)(4). In this way, the regulatory text better comports with the scope of the statutory text. This text of paragraph (a)(1)(iv) also acknowledges that the Departments have decided Guidelines issued under section 2713(a)(4) will not be provided for or supported to the extent they exceed the exemptions and accommodation set forth in 45 CFR 147.131 and 147.132. Previous versions of the regulation placed that limit in 45 CFR 147.130(a)(1), but did not reiterate it in § 147.130(a)(1)(iv). To clearly set forth the applicability of the exemptions and accommodation, the Departments adopt as final the Religious IFC language, which included the language ''subject to §§ 147.131 and 147.132'' in both § 147.130(a)(1) and § 147.130(a)(1)(iv). Because these final rules adopt as final the Religious IFC language which includes the exemptions and accommodation in both §§ 147.131 and 147.132, and not just in § 147.131 as under the previous rules, the Departments correspondingly included references to both sections in this part.

Some commenters supported restoring the statutory language from PHS Act section 2713(a) and (a)(4) in the regulatory restatements of that language. Other commenters opposed doing so, asserting that Guidelines issued pursuant to section 2713(a)(4) must be ''evidence-informed'' and ''binding.'' The Departments disagree with the position that, even though Congress omitted those terms from section 2713(a)(4), their regulatory restatement of the statutory requirement should include those terms. Instead, the Departments conclude that it is more appropriate for the regulatory restatements of section 2713(a)(4) to track the statutory language in this regard, namely, ''as provided for in comprehensive guidelines supported by [HRSA] for purposes of'' that paragraph.

B. Prefatory Language of Religious Exemptions (45 CFR 147.132(a)(1))

These final rules adopt as final, with changes based on comments as set forth below, the regulatory provision in the Religious IFC that moved the religious exemption from 45 CFR 147.131(a) to 45 CFR 147.132.

In the previous regulations, the exemption stated, at § 147.131(a), that HRSA's Guidelines ''may establish an exemption'' for the health plan or coverage of a ''religious employer,'' defined as ''an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code.'' The Religious IFC moved the exemption to a new § 147.132, in which paragraph (a) discussed objecting entities, paragraph (b) discussed objecting individuals, paragraph (c) set forth a definition, and paragraph (d) discussed severability. The prefatory language to § 147.132(a)(1) stated that HRSA's Guidelines ''must not provide for or support the requirement of coverage or payments for contraceptive services'' for the health plan or coverage of an ''objecting organization,'' and thus that HRSA ''will exempt'' such an organization from the contraceptive coverage requirments of the Guidelines. The remainder of paragraph (a)(1), which is discussed in greater detail below, describes what entities are included as objecting organizations.

This language not only specifies that certain entities are ''exempt,'' but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women's preventive services coverage only ''as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.'' To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are ''exempt'' by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as ''exempt,'' and in referring to the ''exemption'' encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior regulations have worked by means of similar language. When sections § 147.132(a)(1) and (a)(1)(i) specify that ''[a] group health plan,'' ''health insurance coverage provided in connection with a group health plan,'' and ''health insurance coverage offered or arranged by an objecting organization'' are exempt ''to the extent'' of the objections ''as specified in paragraph (a)(2),'' that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv)), the plan

sponsor, issuer, and plan covered in the exemption of § 147.132(a)(1) and (a)(1)(i) would face no penalty as a result of omitting certain contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while the objection of a plan sponsor (or entity that arranges coverage under the plan, as applicable) removes penalties from that plan's issuer, it only does so for that plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.132(a)(1)(iii) is included below.

The exemptions in § 147.132(a)(1) apply ''to the extent'' of the objecting entities' sincerely held religious convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters said it was unclear whether the plans of entities or individuals that religiously object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite religious objection against some but not all contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects, and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules, the Departments finalize the prefatory language of § 147.132(a) with the following change, so that the final rules state that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, ''to the extent of the objections specified below.''

The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying ''to the extent'' of the objection(s).

C. Scope of Religious Exemptions and Requirements for Exempt Entities (45 CFR 147.132)

In 45 CFR 147.132(a)(1)(i) through (iii) and (b), the Religious IFC expands the exemption to plans of additional entities and individuals not encompassed by the exemption set forth in the regulations prior to the Religious IFC. Specific entities to which the expanded exemptions apply are discussed below.

The exemptions contained in previous regulations, at § 147.131(a), did not require exempt entities to submit any particular self-certification or notice, either to the government or to their issuer or third party administrator, in order to obtain or qualify for the exemption. Similarly, under the expanded exemptions in § 147.132, the Religious IFC did not require exempt entities to comply with a self-certification process. We finalize that approach in this respect without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[55] Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosure documents must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported the expanded exemption's approach which maintained the policy of the previous exemption in not requiring exempt entities to comply with a self-certification process. They suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to religious objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters, however, favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process. Some commenters asked that the government publish a list of entities that claim the exemption.

The Departments believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption. The Departments believe the approach under the previous exemption is appropriate for the expanded exemption. Adding a self-certification or notice to the exemption process would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices were to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries in plans that reduce or eliminate contraceptive benefits as a result of the exemption will know whether their health plan claims an exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these rules to continue to not require notices or self-certifications for using the exemption.

[55] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 102–3, & 104b–3(d), and 29 CFR 2590.715–2715. *See also* 45 CFR 147.200 (requiring disclosure of the ''exceptions, reductions, and limitations of the coverage,'' including group health plans and group and individual issuers).

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these rules. The expanded exemptions in these rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. The rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (Below, these rules discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that, where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed below, the Departments are including, in these final rules, language from the previous regulations protecting issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in and derived from the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators.

Regarding the Religious IFC's expansion of the exemption to other kinds of entities and individuals in general, commenters disagreed about the likely effects of the exemptions on the health coverage market. Some commenters said that expanding the exemptions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or offer only some contraceptives—to houses of worship and integrated auxiliaries; some commenters and litigants said that issuers were doing so. These cases where plans did not need to comply with the Mandate, and the Departments' previous accommodation process allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.[56]

Concerning the prospect raised by commenters of different risk pools between men and women, PHS Act section 2713(a) itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage would be required. These rules do not require issuers to offer products that satisfy religiously objecting entities or individuals; they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to religious entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

D. Plan Sponsors in General (45 CFR 147.132(a)(1)(i) Prefatory Text)

With respect to employers and others that sponsor group health plans, in § 147.132(a)(1)(i), the Religious IFC provided exemptions for non-governmental plan sponsors that object to coverage of all, or a subset of, contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs. The Departments finalize the prefatory text of § 147.132(a)(1)(i) without change.

The expanded exemptions covered any kind of non-governmental employer plan sponsor with the requisite objections, stating the exemption encompassed ''[a] group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section.'' For the sake of clarity, the expanded exemptions also stated that ''[s]uch non-governmental plan sponsors include, but are not limited to, the following entities,'' followed by an illustrative, non-exhaustive list of non-governmental organizations whose objections qualify the plans they sponsor for an exemption. Each type of such entities, and comments specifically concerning them, are discussed below.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.132(a)(1)(i). Some commenters suggested that the expanded religious exemptions should include government entities. Others disagreed. The Departments are not aware of reasons why it would be appropriate or necessary to offer a religious exemption to governmental employer plan sponsors with respect to the contraceptive Mandate. We are unaware of government entities that would attempt to assert a religious exemption to the Mandate, and it is not clear to us that a governmental entity could do so. Accordingly, we conclude that it is appropriate for us to not further expand the religious exemption to include governmental entities in the religious plan-sponsor exemption.

Nevertheless, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and, thus, to provide

[56] *See also Real Alternatives* v. *Sec'y, Dep't of Health & Human Servs.,* 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) (''Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny.'' (citation and internal quotation marks omitted)).

health coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union, or a sponsor of a multiemployer plan) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization. Some commenters objected to extending the exemption to such entities, arguing that they could not have the same kind of religious objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite religious objection. The Departments conclude that it is appropriate, where the plan sponsor of a union, multiemployer, or similar plan adopts a religious objection using the same procedures that such a plan sponsor might use to make other decisions, that the expanded exemptions should respect that decision by providing an exemption from the Mandate.

E. Houses of Worship and Integrated Auxiliaries (45 CFR 147.132(a)(1)(i)(A))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only ''an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.'' Section 6033(a)(3)(A)(i) or (iii) of the Code encompasses ''churches, their integrated auxiliaries, and conventions or associations of churches,'' and ''the exclusively religious activities of any religious order.''

The Religious IFC expanded the exemption to include, in § 147.132(a)(1)(i)(A), plans sponsored by ''[a] church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.'' Most commenters did not oppose the exemptions continuing to include these entities, although some contended that the Departments have no authority to exempt any entity or plan from the Mandate, an objection to which the Departments respond above. Notably, this exemption exempts ''a religious order,'' and not merely ''the exclusively religious activities of any religious order.'' In addition, section 6033(a)(3)(A)(i) specifies that it covers churches, not merely ''the exclusively religious activities'' of a church. Some religious people might express their beliefs through a church, others might do so through a religious order, and still others might do so through religious bodies that take a different form, structure, or nomenclature based on a different cultural or historical tradition. *Cf. Hosanna-Tabor Evangelical Lutheran Church and School* v. *E.E.O.C.,* 565 U.S. 171, 198 (2012) (Alito and Kagan, JJ., concurring) (''The term 'minister' is commonly used by many Protestant denominations to refer to members of their clergy, but the term is rarely if ever used in this way by Catholics, Jews, Muslims, Hindus, or Buddhists.''). For the purposes of respecting the exercise of religious beliefs, which the expanded exemptions in these rules concern, the Departments find it appropriate that this part of the exemption encompasses religious orders and churches similarly, without limiting the scope of the protection to the exclusively religious activities of either kind of entity. Based on all these considerations, the Departments finalize § 147.132(a)(1)(i)(A) without change.

Moreover, the Departments also finalize the regulatory text to exempt plans ''established or maintained by'' a house of worship or integrated auxiliary on a plan, not employer, basis. Under previous regulations, the Departments stated that ''the availability of the exemption or accommodation [was to] be determined on *an employer by employer basis,* which the Departments . . . believe[d] best balance[d] the interests of religious employers and eligible organizations and those of employees and their dependents.'' (78 FR 39886 (emphasis added)). Therefore, under the prior exemption, if an employer participated in a house of worship's plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not covered by the exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a ''plan established or maintained by a [house of worship].'' Upon further consideration, in the Religious IFC, the Departments changed their view on this issue and expanded the exemption for houses of worship and integrated auxiliaries. Under these rules, the Departments intend that, when this regulation text exempts a plan ''established or maintained by'' a house of worship or integrated auxiliary, such exemption will no longer ''be determined on an employer by employer basis,'' but will be determined on a plan basis—that is, by whether the plan is a ''plan established or maintained by'' a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices, but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the requirement of being integrated auxiliaries. Under this interpretation, houses of worship would not be faced with the potential of having to include, in the plans that they have established and maintained, coverage for services to which they have a religious objection for employees of an affiliated employer participating in the plans.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted to participate in its health plan but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior regulation where with respect to self-insured church plans, hundreds of nonprofit religious entities participating in those plans were provided a mechanism by which their plan participants would not receive contraceptive coverage through the plan or third party administrator.[57]

Therefore, the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

F. Nonprofit Organizations (45 CFR 147.132(a)(1)(i)(B))

The exemption under previous regulations did not encompass nonprofit religious organizations beyond one that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code. The Religious IFC expanded the exemption to include plans sponsored by any other

[57] See supra at II.A.3.

''nonprofit organization,'' § 147.132(a)(1)(i)(B), if it has the requisite religious objection under § 147.132(a)(2) (see § 147.132(a)(1)(i) introductory text). The Religious IFC also specified in § 147.132(a)(1)(i)(A), as under the prior exemption, that the exemption covers ''a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order.'' (Hereinafter ''houses of worship and integrated auxiliaries.'') These rules finalize, without change, the text of § 147.132(a)(1)(i)(A) and (B).

The Departments received comments in support of, and in opposition to, this expansion. Some commenters supported the expansion of the exemptions beyond houses of worship and integrated auxiliaries to other nonprofit organizations with religious objections (referred to herein as ''religious nonprofit'' organizations, groups or employers). They said that religious belief and exercise in American law has not been limited to worship, that religious people engage in service and social engagement as part of their religious exercise, and, therefore, that the Departments should respect the religiosity of nonprofit groups even when they are not houses of worship and integrated auxiliaries. Some public commenters and litigants have indicated that various religious nonprofit groups possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Other commenters did not support the expansion of exemptions to nonprofit organizations. Some of them described churches as having a special status that should not be extended to religious nonprofit groups. Some others contended that women at nonprofit religious organizations may support or wish to use contraceptives and that if the exemptions are expanded, it would deprive all or most of the employees of various religious nonprofit organizations of contraceptive coverage.

After evaluating the comments, the Departments continue to believe that an expanded exemption is the appropriate administrative response to the substantial burdens on sincere religious beliefs imposed by the contraceptive Mandate, as well as to the litigation objecting to the same. We agree with the comments that religious exercise in this country has long been understood to encompass actions outside of houses of worship and their integrated auxiliaries. The Departments' previous assertion that the exemptions were intended to respect a certain sphere of church autonomy (80 FR 41325) is not, in itself, grounds to refuse to extend the exemptions to other nonprofit entities with religious objections. Respect for churches does not preclude respect for other religious entities. Among religious nonprofit organizations, the Departments no longer adhere to our previous assertion that ''[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection.'' (78 FR 39874.) It is not clear to the Departments that the percentage of women who work at churches that oppose contraception, but who support contraception, is lower than the percentage of woman who work at nonprofit religious organizations that oppose contraception on religious grounds, but who support contraception. In addition, public comments and litigation reflect that many nonprofit religious organizations publicly describe their religiosity. Government records and those groups' websites also often reflect those groups' religious character. If a person who desires contraceptive coverage works at a nonprofit religious organization, the Departments believe it is sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit religious organization that opposes contraceptive coverage to hire a person who the organization knows disagrees with the organization's view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[58]

In addition, it is not at all clear to the Departments that expanding the exemptions would, as some commenters asserted, remove contraceptive coverage from employees of many large religious nonprofit organizations. Many large religious nonprofit employers, including but not limited to some Catholic hospitals, notified the Department under the last Administration that they had opted into the accommodation and expressed no objections to doing so. We also received public comments from organizations of similar nonprofit employers indicating that the accommodation satisfied their religious objections. These final rules leave the accommodation in place as an optional process. Thus, it is not clear to the Departments that all or most of such large nonprofit employers will choose to use the expanded exemption instead of the accommodation. If they continue to use the accommodation, their insurers or third party administrators would continue to be required to provide contraceptive coverage to the plan sponsors' employees through such accommodation.

Given the sincerely held religious beliefs of many nonprofit religious organizations, some commenters also contended that continuing to impose the contraceptive Mandate on certain nonprofit religious objectors might also undermine the Government's broader interests in ensuring health coverage by causing some entities to stop providing health coverage entirely.[59] Although the Departments do not know the extent to which that effect would result from not extending exemptions, we wish to avoid that potential obstacle to the general expansion of health coverage.

G. Closely Held For-Profit Entities (45 CFR 147.132(a)(1)(i)(C))

The previous regulations did not exempt plans sponsored by closely held for-profit entities; however, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(C), ''[a] closely held for-profit entity.'' These rules finalize § 147.132(a)(1)(i)(C) without change.

Some commenters supported including these entities in the exemption, saying owners of such entities exercise their religious beliefs through their businesses and should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise religion or should not have their religious opposition to contraceptive coverage protected by the exemption. Some said the entities should not be able to impose their beliefs about contraceptive coverage on their employees, and that doing so constitutes discrimination.

As set forth in the Religious IFC, the Departments believe it is appropriate to expand the exemptions to include closely held for-profit employers in

[58] Notably, ''the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.' '' *Boy Scouts of America* v. *Dale,* 530 U.S. 640, 655 (2000).

[59] See, *e.g.,* Manya Brachear Pashman, ''Wheaton College ends coverage amid fight against birth control mandate,'' Chicago Tribune, July 29, 2015; Laura Bassett, ''Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,'' HuffPost, May 15, 2012.

order to protect the religious exercise of those entities and their owners. The ACA did not apply the preventive services mandate to the many grandfathered health plans among closely held as well as publicly traded for-profit entities, encompassing tens of millions of women. As explained below, we are not aware of evidence showing that the expanded exemptions finalized here will impact such a large number of women. And, in the Departments' view, the decision by Congress to not apply the preventive services mandate to grandfathered plans did not constitute improper discrimination or an imposition of beliefs. We also do not believe RFRA or the large number of other statutory exemptions Congress has provided for religious beliefs (including those exercised for profit) in certain health contexts such as sterilization, contraception, or abortion have been improper.

Including closely held for-profit entities in the exemption is also consistent with the Supreme Court's ruling in *Hobby Lobby,* which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby,* the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization, and rejected the previous Administration's argument to the contrary. 134 S. Ct. at 2768–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby*.[60]

H. For-Profit Entities That Are Not Closely Held (45 CFR 147.132(a)(1)(i)(D))

The previous regulations did not exempt for-profit entities that are not closely held. However, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(D), ''[a] for-profit entity that is not closely held.'' These rules finalize § 147.132(a)(1)(i)(D) without change.

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. Some commenters supported including such entities, including publicly traded businesses, in the scope of the exemption. Some of them said that publicly traded entities have historically taken various positions on important public concerns beyond merely (and exclusively) seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to exercise religious views against contraceptive coverage. They also said that other protections for religious beliefs in federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines ''persons,'' protected under RFRA, to include corporations at 1 U.S.C. 1. Other commenters opposed including publicly traded companies in the expanded exemptions. Some of these commenters stated that such companies could not exercise religious beliefs, and opposed the effects on women if they could. These commenters also objected that including such employers, along with closely held businesses, would extend the exemptions to all or virtually all employers.

The Departments conclude it is appropriate to include entities that are not closely held within the expanded exemptions for entities with religious objection. RFRA prohibits the federal government from ''substantially burden[ing] a person's exercise of religion . . . .'' unless it demonstrates that the application of the burden to the person'' is the least restrictive means to achieve a compelling governmental interest. 42 U.S.C. 2000bb–1(a) & (b). As commenters noted, the definition of ''person'' applicable in RFRA is found at 1 U.S.C. 1, which defines ''person'' as including ''corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.'' Accordingly, the Departments' decision to extend the religious exemption to publicly traded for profit corporations is supported by the text of RFRA. The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held religious beliefs, is a matter of well-established State law with respect to corporate decision-making,[61] and the Departments expect that application of such laws would cabin the scope of this exemption.

As to the impact of so extending the religious exemption, the Departments are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief. As noted above, before the ACA, a substantial majority of employers covered contraceptives. Some commenters opposed to including publicly traded entities in these exemptions noted that there did not appear to be any known religiously motivated objections to the Mandate from publicly traded for-profit corporations. These comments support our estimates that including publicly traded entities in the exemptions will have little, if any effect, on contraceptive coverage for women. We likewise agree with the Supreme Court's statement in *Hobby Lobby* that it is unlikely that many publicly traded companies will adopt religious objections to offering women contraceptive coverage. *See* 134 S. Ct. at 2774. Some commenters contended that, because many closely held for-profit businesses expressed religious objections to the Mandate, or took advantage of the accommodation, it is likely that many publicly traded businesses will do so. The Departments agree it is possible that publicly traded businesses may use the expanded exemption. But while scores of closely held for-profit businesses filed suit against the Mandate, no publicly traded entities did so, even though they were not authorized to seek the accommodation. Based on these data points, we believe the impact of the extension of the exemption to publicly traded for-profit organizations will not be significant. Below, based on limited data, but on years of receiving public comments and defending litigation brought by organizations challenging the Mandate on the basis of their religious objections, our best estimate of the anticipated effects of these rules is that no publicly traded employers will invoke the religious exemption.

In the Departments' view, such estimate does not lead to the conclusion that the religious exemption should not be extended to publicly traded corporations. The Departments are generally aware that, in a country as large as the U.S., comprised of a supermajority of religious persons,[62] some publicly traded entities might claim a religious character for their company, or the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.[63] Thus we consider

[60] *See* Jennifer Haberkorn, ''Two years later, few Hobby Lobby copycats emerge,'' *Politico* (Oct. 11, 2016), *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627.*

[61] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which the organization is incorporated or organized.

[62] For example, in 2017, 74 percent of Americans said that religion is fairly important or very important in their lives, and 87 percent of Americans said they believe in God. Gallup, ''Religion,'' available at *https://news.gallup.com/poll/1690/religion.aspx.*

[63] *See, for example,* Kapitall, ''4 Publicly Traded Religious Companies if You're Looking to Invest in

it possible that a publicly traded company might have religious objections to contraceptive coverage. Moreover, as noted, there are many closely held for-profit corporations that do have religious objections to covering some or all contraceptives. The Departments do not want to preclude such a closely held corporation from having to decide between relinquishing the exemption or financing future growth by sales of stock, which would be the effect of denying it the exemption if it changes its status and became a publicly traded entity. The Departments also find it relevant that other federal conscience statutes, such as those applying to hospitals or insurance companies, do not exclude publicly traded businesses from protection.[64] As a result, the Departments continue to consider it appropriate not to exclude such entities from these expanded exemptions.

I. Other Non-Governmental Employers (45 CFR 147.132(a)(1)(i)(E))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order. The Religious IFC included, in its list of exempt plan sponsors at § 147.132(a)(1)(i)(E), ''[a]ny other non-governmental employer.'' These rules finalize § 147.132(a)(1)(i)(E) without change.

Some commenters objected to extending the exemption to other nongovernmental employers, asserting that it is not clear such employers should be protected, nor that they can assert religious objections. The Departments, however, agree with other commenters that supported that provision of the Religious IFC. The Departments believe it is appropriate that any nongovernmental employer asserting the requisite religious objections should be protected from the Mandate in the same way as other plan sponsors. Such other employers could include, for example, association health plans.[65] The reasons discussed above for providing the exemption to various specific kinds of employers, and for their ability to assert sincerely held religious beliefs using ordinary mechanisms of corporate decision-making, generally apply to other nongovernmental employers as well, if they have sincerely held religious beliefs opposed to contraceptive coverage and otherwise meet the requirements of these rules. We agree with commenters who contend there is not a sufficient basis to exclude other nongovernmental employers from the exemption.

J. Plans Established or Maintained by Objecting Nonprofit Entities (45 CFR 147.132(a)(1)(ii))

Based on the expressed intent in the Religious IFC, as discussed above, to expand the exemption to encompass plans established or maintained by nonprofit organizations with religious objections, and on public comments received concerning those exemptions, these rules finalize new language in § 147.132(a)(1)(ii) to better clarify the scope and application of the exemptions.

The preamble to the Religious IFC contained several discussions about the Departments' intent to exempt plans established or maintained by certain religious organizations that have the requisite objection to contraceptive coverage, including instances in which the plans encompass multiple employers. For example, as noted above, the Departments intended that the exemption for houses of worship and integrated auxiliaries be interpreted to apply on a plan basis, instead of on an employer-by-employer basis. In addition, the Departments discussed at length the fact that, under the prior regulations, where an entity was enrolled in a self-insured church plan exempt from ERISA under ERISA section 3(33) and the accommodation in the previous regulations was used, that accommodation process provided no mechanism to impose, or enforce, the accommodation requirement of contraceptive coverage against a third party administrator of such a plan. As a result, the prior accommodation served, in effect, as an exemption from requirements of contraceptive coverage for all organizations and employers covered under a self-insured church plan.

In response to these discussions in the Religious IFC, some commenters, including some church plans, supported the apparent intent to exempt such plans on a plan basis, but suggested that additional clarification is needed in the text of the rule to effect this intent. They observed that some plans are established or maintained by religious nonprofit entities that might not be houses of worship or integrated auxiliaries, and that some employers that adopt or participate in such plans may not be the ''plan sponsors.'' They recommended, therefore, that the final rules specify that the exemption applies on a plan basis when plans are established or maintained by houses of worship, integrated auxiliaries, or religious nonprofits, so as to shield employers that adopt such plans from penalties for noncompliance with the Mandate.

The text of the prefatory language of § 147.132(a)(1), as set forth in the Religious IFC, declared that the Guidelines would not apply ''with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization.'' We intended this language to exempt a plan and/or coverage where the entity that established or maintained a plan was an objecting organization, and not just to look at the views or status of individual employers (or other entities) participating in such plan. The Departments agree with commenters who stated that additional clarity is needed and appropriate in these final rules, in order to ensure that such plans are exempt on a plan basis, and that employers joining or adopting those plans are exempt by virtue of the plan itself being exempt. Doing so will make the application of the expanded exemption clearer, and protect employers (and other entities) participating in such plans from penalties for noncompliance with the Mandate. Clearer language will better realize the intent to exempt plans and coverage ''established or maintained by an objecting organization,'' and make the operation of that exemption simpler by specifying that the exemption applies based on the objection of the entity that established or maintains the plan. Such language would also resolve the anomaly that, under the previous rules, only self-insured church plans (not insured church plans) under ERISA section 3(33) were, in effect, exempt—but only indirectly through the Departments' inability to impose, or enforce, the accommodation process against the third party administrators of such plans, instead of being specifically exempt in the rules.

We believe entities participating in plans established or maintained by an objecting organization usually share the views of those organizations. Multiple lawsuits were filed against the Departments by churches that established or maintained plans, or the church plans themselves, and they generally declared that the entities or individuals participating in their plans

Faith'' (Feb. 7, 2014), *http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665.*

[64] *See, for example,* 42 U.S.C. 300a–7, 42 U.S.C. 238n, Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d), Public Law 115–141, and *id.* at Div. E, Sec. 808.

[65] See 29 CFR 2510.3–5.

are usually required to share their religious affiliation or beliefs. In addition, because, as we have stated before, ''providing payments for contraceptive services is cost neutral for issuers'' (78 FR 39877), we do not believe this clarification would produce any financial incentive for entities that do not have religious objections to contraceptive coverage to enter into plans established or maintained by an organization that does have such objections.

Therefore, the Departments finalize the text of § 147.132(a)(1) of the Religious IFC with the following change: adding a provision that makes explicit this understanding, in a new paragraph at § 147.132(a)(1)(ii). This language now specifies that the exemptions encompassed by § 147.132(a)(1) include: ''[a] group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan[.]''

K. Institutions of Higher Education (45 CFR 147.132(a)(1)(iii))

The previous regulations did not exempt student health plans arranged by institutions of higher education, although it did, for purposes of the accommodation, treat plans arranged by institutions of higher education similar to the way in which the regulations treated plans of nonprofit religious employers. *See* 80 FR at 41347. The Religious IFC included in its list of exemptions, at § 147.132(a)(1)(ii), ''[a]n institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to 'plan participants and beneficiaries' will be interpreted as references to student enrollees and their covered dependents.'' These rules finalize this language with a change to clarify their application, as discussed below, and by redesignating the paragraph as § 147.132(a)(1)(iii).

These rules treat the plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. These rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.132(a)(1)(iii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held religious beliefs, to their arrangement of student health insurance coverage in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer.

Some commenters supported including, in the expanded exemptions, institutions of higher education that provide health coverage for students through student health plans but have religious objections to providing certain contraceptive coverage. They said that religious exemptions allow freedom for certain religious institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemptions would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result among those women.

In the Departments' view, the reasons for extending the exemptions to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. Only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities.[66] It is necessarily true that an even smaller number receive such coverage from religious schools, and from religious or other private schools that object to arranging contraceptive coverage. Religious institutions of higher education are private entities with religious missions. Various commenters asserted the importance, to many of those institutions, of being able to adhere to their religious tenets. Indeed, many students who attend such institutions do so because of the institutions' religious tenets. No student is required to attend such an institution. At a minimum, students who attend private colleges and universities have the ability to ask those institutions in advance what religious tenets they follow, including whether the institutions will provide contraceptives in insurance plans they arrange. Some students wish to receive contraceptive coverage from a health plan arranged by an institution of higher education. But other students wish to attend an institution of higher education that adheres to its religious mission about contraceptives in health insurance. And still other students favor contraception, but are willing to attend a religious university without forcing it to violate its beliefs about contraceptive coverage. Exempting religious institutions that object to contraceptive coverage still allows contraceptive coverage to be provided by institutions of higher education more broadly. The exemption simply makes it legal under federal law for institutions to adhere to religious beliefs that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, and makes it more possible for students to attend institutions of higher education that hold those views.

In addition, under the previous exemption and accommodation, it was possible for self-insured church plans exempt from ERISA that have religious objection to certain contraceptives to avoid any requirement that either they or their third party administrators provide contraceptive coverage. As seen

[66] The American College Health Association estimates that, in 2014, student health insurance plans at colleges and universities covered ''more than two million college students nationwide.'' ''Do You Know Why Student Health Insurance Matters?'' available at *https://www.acha.org/documents/Networks/Coalitions/Why_SHIPs_Matter.pdf.* We assume for the purposes of this estimate that those plans covered 2,100,000 million students. Data from the Department of Education shows that in 2014, there were 20,207,000 students enrolled in degree-granting postsecondary institutions. National Center for Education Statistics, Table 105.20, ''Enrollment in elementary, secondary, and degree-granting postsecondary institutions, by level and control of institution, enrollment level, and attendance status and sex of student: Selected years, fall 1990 through fall 2026,'' available at *https://nces.ed.gov/programs/digest/d16/tables/dt16_105.20.asp?current=yes.*

in some public comments and litigation statements, some such self-insured church plans provide health coverage for students at institutions of higher education covered by those church plans. In order to avoid the situation where some student health plans sponsored by institutions with religious objections are effectively exempt from the contraceptive Mandate, and other student health plans sponsored by other institutions with similar religious objections are required to comply with the Mandate, the Departments consider it appropriate to extend the exemption, so that religious colleges and universities with objections to the Mandate would not be treated differently in this regard.

The Departments also note that the ACA does not require institutions of higher education to provide student health insurance coverage. As a result, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student health insurance plans, rather than comply with the Mandate or be subject to the accommodation.[67] Extending the exemption in these rules removes an obstacle to such entities deciding to offer student health insurance plans, thereby giving students another health insurance option.

As noted above, it is not clear that studies discussing various effects of birth control access clearly and specifically demonstrate a negative impact to students in higher education because of the expanded exemption in these final rules. The Departments consider these expanded exemptions to be an appropriate and permissible policy choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these expanded exemptions.

Finally, the Religious IFC specified that the plan sponsor exemption applied to ''non-governmental'' plan sponsors (§ 147.132(a)(1)(i)), including ''[a]ny other non-governmental employer'' (§ 147.132(a)(1)(i)(E)). Then, in § 147.132(a)(1)(ii), the rule specified that the institution of higher education exemption applicable to the arrangement of student health insurance coverage applied ''in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer.'' Consequently, the Religious IFC's expanded exemptions only applied to non-governmental institutions of higher education, including for student health insurance coverage, not to governmental institutions of higher education. Nevertheless, the term ''non-governmental,'' while appearing twice in § 147.132(a)(1)(i) concerning plan sponsors, was not repeated in in § 147.132(a)(1)(ii). To more clearly specify that this limitation was intended to apply to § 147.132(a)(1)(ii), we finalize this paragraph with a change by adding the phrase ''which is non-governmental'' after the phrase ''An institution of higher education as defined in 20 U.S.C. 1002''.

L. Health Insurance Issuers (45 CFR 147.132(a)(1)(iv))

The previous regulations did not exempt health insurance issuers. However, the Religious IFC included in its list of exemptions at § 147.132(a)(1)(iii), ''[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]'' These rules finalize this exemption with technical changes to clarify the language based on public comments, and redesignate the paragraph as § 147.132(a)(1)(iv).

The Religious IFC extends the exemption to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services. Under this exemption, the only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on their objection. An exempt issuer can then offer an exempt health insurance product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless it is also exempt from that requirement.

Under these rules, issuers that hold their own objections, based on sincerely held religious beliefs, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their religious beliefs, or on their moral convictions under the companion final rules published elsewhere in today's **Federal Register**. Likewise, issuers with sincerely held moral convictions, that are exempt under those companion final rules, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments provided a similar exemption for issuers in the context of moral objections, but we used slightly different operative language. There, in the second sentence, instead of saying ''the plan remains subject to any requirement to provide coverage for contraceptive services,'' the exemption stated, ''the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services.'' Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. Consequently, these rules finalize the issuer exemption paragraph from the Religious IFC with minor technical changes so that the final language will mirror language from the Moral IFC, stating that the exemption encompasses: ''[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iv) of this section, the group health plan established or maintained by the plan sponsor with

[67] See, *e.g.,* Manya Brachear Pashman, ''Wheaton College ends coverage amid fight against birth control mandate,'' Chicago Tribune, July 29, 2015; Laura Bassett, ''Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,'' HuffPost, May 15, 2012.

which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]''

Some commenters supported including this exemption for issuers in these rules, both to protect the religious exercise of issuers, and so that in the future religious issuers that may wish to specifically serve religious plan sponsors would be free to organize. Other commenters objected to including an exemption for issuers. Some objected that issuers cannot exercise religious beliefs, while others objected that exempting issuers would threaten contraceptive coverage for women. Some commenters said that it was arbitrary and capricious for the Departments to provide an exemption for issuers if we do not know that issuers with qualifying religious objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage. The issuer exemption therefore serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors and plans that independently qualify for an exemption, will remove a possible obstacle to religious issuers being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers from being required to issue policies that cover contraception in violation of the issuers' sincerely held religious beliefs, and from being required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise religious beliefs. First, since RFRA protects the religious exercise of corporations as persons, the religious exercise of health insurance issuers—which are generally organized as corporations—is protected by RFRA. In addition, many federal health care conscience laws and regulations specifically protect issuers or plans. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment specifically protects, among other entities, provider-sponsored organizations, health maintenance organizations (HMOs), health insurance plans, and ''any other kind of health care facilit[ies], organization[s], or plan[s]'' as a ''health care entity'' from being required to pay for, or provide coverage of, abortions. *See for example,* Consolidated Appropriations Act of 2018, Public Law 115–141, Div. H, Sec. 507(d), 132 Stat. 348, 764 (Mar. 23, 2018).[68] Congress also declared this year that ''it is the intent of Congress'' to include a ''conscience clause'' which provides exceptions for religious beliefs if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans.'' *See id.* at Div. E, Sec. 808, 132 Stat. at 603. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments' understanding that third party administrators are not typically designated as plan administrators, and, therefore, would not normally act as plan administrators, under section 3(16) of ERISA. Therefore, to the Departments' knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or decline to continue, contracts as third party administrators of such plans.

M. Description of the Religious Objection (45 CFR 147.132(a)(2))

The previous regulations did not specify what, if any, religious objection applied to its exemption; however, the Religious IFC set forth the scope of the religious objection of objecting entities in § 147.132(a)(2), as follows: ''The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.'' These rules finalize this description with technical changes to clarify the scope of the objection as intended in the Religious IFC, and based on public comments.

Throughout the exemptions for objecting entities, the rules specify that they apply where the entities object as specified in § 147.132(a)(2) of the Religious IFC. That paragraph describes the religious objection by specifying that exemptions for objecting entities will apply to the extent that an entity described in paragraph (a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

[68] ACA section 1553 protects an identically defined group of ''health care entities,'' including provider-sponsored organizations, HMOs, health insurance plans, and ''any other kind of . . . plan,'' from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(a)(2), provided a similar description of the scope of the objection based on moral convictions rather than religious beliefs, but we used slightly different operative language. There, instead of saying the entity ''objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services,'' the paragraph stated the entity ''objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments.'' Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. The Religious IFC explained that the intent of the expanded exemptions was to encompass entities that objected to providing or arranging for contraceptive coverage in their plans, and to encompass entities that objected to the previous accommodation process, by which their issuers or third party administrators were required to provide contraceptive coverage or payments in connection with their plans. In other words, an entity would be exempt from the Mandate if it objected to complying with the Mandate, or if it objected to complying with the accommodation. The language in the Religious IFC encompassed both circumstances by encompassing an objection to providing ''coverage [or] payments'' for contraceptive services, and by encompassing an objection to ''a plan that provides'' coverage or payments for contraceptive services. But the language describing the objection set forth in the Moral IFC does so more clearly, and restructuring the sentence could make it clearer still. Questions by commenters about the scope of the description suggests that we should restructure the description, in a non-substantive way, to provide more clarity. The Departments do this by breaking some of the text out into subparagraphs, and rearranging clauses so that it is clearer which words they modify. The new structure specifies that it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) coverage or payments for contraceptive services, and it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) a plan, issuer, or third party administrator that provides contraceptive coverage. This more clearly encompasses objections to complying with either the Mandate or the accommodation. Consequently, these rules finalize the paragraph describing the religious objection in the Religious IFC with minor technical changes so that the final language will essentially mirror language from the Moral IFC. The introductory phrase of the religious objection set forth in paragraph (a)(2) is finalized to state the exemption ''will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable)''. The remainder of the paragraph is broken into two sub-paragraphs, regarding either ''coverage or payments for some or all contraceptive services,'' or ''a plan, issuer, or third party administrator that provides or arranges such coverage or payments.''

Some commenters observed that by allowing exempt groups to object to ''some or all'' contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators. The Departments have concluded, however, that, just as the exemption under the previous regulations allowed entities to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. Notably, even where an entity or individual qualifies for an exemption under these rules, these rules do not require the issuer or third party administrator to contract with that entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual variation of a plan. These rules simply remove the federal Mandate that, in some cases, could have led to penalties for an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying religious objection. Similarly, under the previous exemption, the plans of houses of worship and integrated auxiliaries were exempt from offering some or all contraceptives, but the previous regulations did not require issuers and third party administrators to contract with those exempt entities if they chose not to do so.

N. Individuals (45 CFR 147.132(b))

The previous regulations did not provide an exemption for objecting individuals. However, the Religious IFC expanded the exemptions to encompass objecting individuals (referred to here as the ''individual exemption''), at § 147.132(b). These rules finalize the individual exemption from the Religious IFC with changes, which reflect both non-substantial technical revisions, and changes based on public comments to more clearly express the intent of the Religious IFC.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Religious IFC described what may be offered to objecting individuals as ''a separate benefit package option, or a separate policy, certificate or contract of insurance,'' the Moral IFC said a willing issuer and plan sponsor may offer ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects'' under the individual exemption. Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of ''a separate group health plan,'' as set forth in the version found in § 147.133(b), because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee's objection. Consequently, these rules finalize the individual

exemption by making a technical change to the language to adopt the formulation, ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects'' under the individual exemption.

Some commenters supported the individual exemption as providing appropriate protections for the religious beliefs of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to contraceptive coverage but is willing (and, as applicable, the issuer is also willing) to provide coverage that is consistent with an individual's religious objections. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage. Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. As discussed in the Religious IFC, the individual exemption only operates in the case where the group health plan sponsor or group or individual market health insurance issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases.

In addition, Congress has provided several protections for individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. *See for example,* Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–141, 132 Stat. 348, 593–94 (Mar. 23, 2018). While some commenters proposed to construe this provision narrowly, Congress likewise provided that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions''. *Id.* at Div. E, Sec. 808, 132 Stat. at 603. A religious exemption for individuals would not be effective if the government simultaneously made it illegal for issuers and group health plans to provide individuals with policies that comply with the individual's religious beliefs.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers.

By its terms, the individual exemption would also apply with respect to individuals in plans arranged by institutions of higher education, if the issuers offering those plans were willing to provide plans complying with the individuals' objections. Because federal law does not require institutions of higher education to arrange such plans, the institutions would not be required by these rules to arrange a plan compliant with an individual's objection if the institution did not wish to do so.

As an example, in one lawsuit brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees' religious beliefs, or against the individual employees who accept such offers. *See Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these final rules do not affect such other laws or terms.

Some individuals commented that they welcomed the individual exemption so that their religious beliefs were not forced to be in tension with their desire for health coverage. The Departments believe the individual exemption may help to meet the ACA's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.[69] At the same time, this individual exemption ''does not undermine the governmental interests furthered by the contraceptive

[69] See also, for example, *Wieland,* 196 F. Supp. 3d at 1017, and *March for Life,* 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to ''forgo health insurance altogether.''

coverage requirement,'' [70] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives. Other commenters expressed concern that there might be multiple variations in the kinds of contraceptive coverage to which individuals object, and this might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the religious beliefs of an exempt individual. As discussed above, where the individual exemption applies, it only affects the coverage of an individual. If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons they can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Religious IFC implied this conclusion, by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, this was different than the language applicable to the exemptions under § 147.132(a), which specifies that the exemptions apply ''to the extent'' of the religious objections, so that, as discussed above, the exemptions include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b) with the following change, by adding the following sentence at the end of the paragraph: ''Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the individual with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held religious beliefs objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to this employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under a policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with clarifying changes to reflect the Departments' intent.

O. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations set forth an accommodation process at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, as an alternative method of compliance with the Mandate. Under the accommodation, if a religious nonprofit entity, or a religious closely held for-profit business, objected to coverage of some or all contraceptive services in its health plan, it could file a notice or fill out a form expressing this objection and describing its objection to its plan and issuer or third party administrator. Upon doing so, the plan would not cover some or all contraceptive services, and the issuer or third party administrator would be responsible for providing or arranging for persons covered by the plan to receive coverage or payments of those services (except in the case of self-insured church plans exempt from ERISA, in which case no such obligation was imposed on the third party administrator). The accommodation was set forth in regulations of each of the Departments. Based on each Department's regulatory authority, HHS regulations applied to insured group health plans, and DOL and Treasury regulations applied to both insured group health plans and self-insured group health plans.

The Religious IFC maintained the accommodation process. Nevertheless, by virtue of expanding the exemptions to encompass all entities that were eligible for the accommodation process under the previous regulations, in addition to other newly exempt entities, the Religious IFC rendered the accommodation process optional. Entities could choose not just between the Mandate and the accommodation, but between the Mandate, the exemption, and the accommodation. These rules finalize the optional accommodation process and its location in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, but the Departments do so with several changes based on public comments.

Many commenters supported keeping the accommodation as an optional process, including some commenters who otherwise supported creating the expanded exemptions. Some commenters opposed making the accommodation optional, but asked the Departments to return to the previous regulations in which entities that did not meet the narrower exemption could only choose between the accommodation process or direct compliance with the Mandate. Some commenters believed there should be no exemptions and no accommodation process.

The Departments continue to consider it appropriate to make the accommodation process optional for entities that are otherwise also eligible for the expanded exemptions—that is, to keep it in place as an option that exempt entities can choose. The accommodation provides contraceptive access, which is a result many opponents of the expanded exemptions said they desire. The accommodation involves some regulation of issuers and third party administrators, but the previous

[70] 78 FR 39874.

regulations had already put that regulatory structure in place. These rules for the most part merely keep it in place and maintain the way it operates. The Religious IFC adds some additional paperwork burdens as a result of the new interaction between the accommodation and the expanded exemptions; those are discussed below.

Above, the Departments discussed public comments concerning whether we should have merely expanded the accommodation rather than expanding the exemptions. The Religious IFC and these final rules expand the kinds of entities that may use the optional accommodation, by expanding the exemptions and allowing any exempt entities to opt to make use of the accommodation. Consequently, under these rules, objecting employers may make use of the exemption or may choose to utilize the optional accommodation process. If an eligible organization uses the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

Some commenters asked that these final rules create an alternative payment mechanism to cover contraceptive services for third party administrators obligated to provide or arrange such coverage under the accommodation. These rules do not concern the payment mechanism, which is set forth in separate rules at 45 CFR 156.50. The Departments do not view an alternative payment mechanism as necessary. As discussed below, although the Departments do not know how many entities will use the accommodation, it is reasonably likely that some entities previously using it will continue to do so, while others will choose the expanded exemption, leading to an overall reduction in the use of the accommodation. The Departments have reason to believe that these final rules will not lead to a significant expansion of entities using the accommodation, since nearly all of the entities of which the Departments are aware that may be interested in doing so were already able to do so prior to the Religious IFC. Moreover, it is still the case under these rules that if an entity serving as a third party administrator does not wish to satisfy the obligations it would need to satisfy under an accommodation, it could choose not to contract with an entity that opts into the accommodation. This conflict is even less likely now that entities eligible for the accommodation are also eligible for the exemption. For these reasons, the Departments do not find it necessary to add an additional payment mechanism for the accommodation process.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these rules, and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation. Some commenters suggested HHS has not yet issued guidance on the revocation process, but CCIIO provided guidance concerning this process on November 30, 2017.[71] These rules supersede that guidance, and adopt or modify its specific guidelines as explained below. As a result, these rules delete references, set forth in the Religious IFC's accommodation regulations, to ''guidance issued by the Secretary of the Department of Health and Human Services.''

The guidance stated that an entity that was using the accommodation under the previous rules, or an entity that adopts the accommodation maintained by the IFCs, could revoke its use of the accommodation and use the exemption. This guideline applies under the final rules. This revocation process applies both prospectively to eligible organizations that decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that invoked the accommodation prior to the effective date of the Religious IFC either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies.

The guidance stated that, when the accommodation is revoked by an entity using the exemption, the issuer of the eligible organization must provide participants and beneficiaries written notice of such revocation. These rules adopt that guideline. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. The guidance further stated that the notice may be provided by the organization itself, its group health plan, or its third party administrator, as applicable. The guidance stated that, under the regulation at 45 CFR 147.200(b), ''[t]he notice of modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section,'' and (a)(4) has detailed rules on when electronic notice is permitted. These guidelines still apply under the final rules. These rules adopt those guidelines.

The guidance further specified that the revocation of the accommodation would be effective notice on the first day of the first plan year that begins on or after 30 days after the date of the revocation, or alternatively, whether or not the objecting entity's group health plan or issuer listed the contraceptive benefit in its Summary of Benefits of Coverage (SBC), the group health plan or issuer could revoke the accommodation by giving at least 60-days prior notice pursuant to section 2715(d)(4) of the PHS Act (incorporated into ERISA and the Code)[72] and applicable regulations thereunder to revoke the accommodation. The guidance noted that, unlike the SBC notification process, which can effectuate a modification of benefits in the middle of a plan year, provided it is allowed by State law and the contract of the policy, the 30 day notification process under the guidance can only effectuate a benefit modification at the beginning of a plan year. This part of the guidance is adopted in part and changed in part by these final rules, as follows, based on public comments on the issue.

Some commenters asked that revocations only be permitted to occur on the first day of the next plan year, or no sooner than January 2019, to avoid burdens on plans and because some states do not allow for mid-year plan changes. The Departments believe that providing 60-days notice pursuant to section 2715(d)(4) of the PHS Act, where applicable, is a mechanism that already exists for making changes in health benefits covered by a group health plan during a plan year; that process already takes into consideration any applicable state laws. However, in response to public comments, these rules change the accommodation provisions from the Religious IFC to indicate that, as a transitional rule, providing 60-days notice for revoking an accommodation is only available, if applicable, to plans that are using the accommodation at the time of the

[71] *See* Randy Pate, ''Notice by Issuer or Third Party Administrator for Employer/Plan Sponsor of Revocation of the Accommodation for Certain Preventive Services,'' CMS (Nov. 30, 2017), *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf.*

[72] *See also* 26 CFR 54.9815–2715(b); 29 CFR 2590.715–2715(b); 45 CFR 147.200(b).

publication of these final rules. As a general rule, for plans that use the accommodation in future plan years, the Departments believe it is appropriate to allow revocation of an accommodation only on the first day of the next plan year. Based on the objections of various litigants and public commenters, we believe that some entities already using the accommodation may have been doing so only because previous regulations denied them an exemption. For them, access to the transitional 60-days notice procedure (if applicable) is appropriate in the period immediately following the finalization of these rules. In future plan years, however—plan years that begin after the effective date of these final rules—plans and entities that qualify as exempt under these rules will have been on notice that they qualify for an exemption or the accommodation. If they have opted to enter or remain in the accommodation in those future plan years, when they could have chosen the exemption, the Departments believe it is appropriate for them to wait until the first day of the following plan year to change to exempt status.[73]

This change is implemented in the following manner. In the Religious IFC, the accommodation provisions addressing revocation were found at 45 CFR 147.131(c)(4), 26 CFR 54.9815–2713AT(a)(5),[74] and 29 CFR 2590.715–2713A(a)(5).

The provisions in the Religious IFC (with technical variations among the HHS, Labor, and Treasury rules) state that a written notice of revocation must be provided ''as specified in guidance issued by the Secretary of the Department of Health and Human Services.'' On November 30, 2017, HHS issued the guidance regarding revocation. These final rules incorporate this guidance, with certain clarifications, and state that the revocation notice must be provided ''as specified herein.'' The final rule incorporates the two sets of directions for revoking the accommodation initially set forth in the interim guidance in the following manner. The first, designated as subparagprah (1) as a ''[t]ransitional rule,'' explains that if contraceptive coverage is being offered through the accommodation process on the date on which these final rules go into effect, 60-days notice may be provided to revoke the accommodation process, or they revocation may occur ''on the first day of the first plan year that begins on or after 30 days after the date of the revocation'' consistent with PHS Act section 2715(d)(4), 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), or 29 CFR 2590.715–2715(b). The second direction, set forth in subparagraph (ii), explains the ''[g]eneral rule'' that, in plan years beginning after the date on which these final rules go into effect, revocation of the accommodation will be effective on ''the first day of the first plan year that begins on or after 30 days after the date of the revocation.''

The Religious IFC states that if an accommodated entity objects to some, but not all, contraceptives, an issuer for an insured group health plan that covers contraceptives under the accommodation may, at the issuer's option, choose to provide coverage or payments for all contraceptive services, instead of just for the narrower set of contraceptive services to which the entities object. Some commenters supported this provision, saying that it allows flexibility for issuers that might otherwise face unintended burdens from providing coverage under the accommodation for entities that object to only some contraceptive items. The Departments have maintained this provision in these final rules. Note that this provision is consistent with the other assertions in the rules saying that an entity's objection applies ''to the extent'' of the entity's religious beliefs, because in this instance, under the accommodation, the plan participant or beneficiary still receives coverage or payments for all contraceptives, and this provision simply allows issuers more flexibility in choosing how to help provide that coverage.

Some commenters asked that the Departments retain the ''reliance'' provision, contained in the previous accommodation regulations, under which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. The Departments omitted this provision from the Religious IFC, on the grounds that this provision was less necessary where any organization eligible for the optional accommodation is also exempt. Nevertheless, in order to respond to concerns in public comments, and to prevent any risk to issuers of a mistake or misrepresentation by an organization seeking the accommodation process, the Departments have finalized the Religious IFC with an additional change that restores this clause. The clause uses the same language that was in the regulations prior to the Religious IFC, and it is inserted at 45 CFR 147.131(f), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e). As a result, these rules renumber the subsequent paragraphs in each of those sections.

P. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under ''Contraceptive methods and counseling,'' ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' The previous regulations concerning the exemption and the accommodation used the terms contraceptive services and contraceptive coverage as catch-all terms to encompass all of those Guidelines' requirements. The 2016 update to the Guidelines are similarly worded. Under ''Contraception,'' they include the ''full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,'' ''instruction in fertility awareness-based methods,'' and ''[c]ontraceptive care'' to ''include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).'' [75]

To more explicitly state that the exemption encompasses any of the contraceptive or sterilization services, items, or information that have been required under the Guidelines, the Religious IFC included a definition at 45

[73] These final rules go into effect 60 days after they are published in the **Federal Register**. Some entities currently using the accommodation may have a plan year that begins less than 30 days after the effective date of these final rules. In such cases, they may be unable, after the effective date of these final rules, to provide a revocation notice 30 days prior to the start of their next plan year. However, these final rules will be published at least 60 days prior to the start of that plan year. Therefore, entities exempt under these final rules that have been subject to the accommodation on the date these final rules are published, that wish to revoke the accommodation, and whose next plan years start after these final rules go into effect, but less than 30 days thereafter, may submit their 30 day revocation notices after these final rules are published, before these final rules are in effect, so that they will have submitted the revocation at least 30 days before their next plan year starts. In such cases, even though the revocation notice will be submitted before these final rules are in effect, the actual revocation will not occur until after these final rules are in effect, and plan participants will have been provided with 30 days' notice of the revocation.

[74] The Department of the Treasury's rule addressing the accommodation is being finalized at 26 CFR 54.9815–2713A, superseding its temporary regulation at 26 CFR 54.9815–2713AT.

[75] *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713AT(e), and 29 CFR 2590.715–2713A(e). These rules finalize those definitions without change, but renumber them as 45 CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e), respectively.

Q. Severability

The Departments finalize without change (except for certain paragraph redesignations), the severability clauses in the interim final rules, namely, at paragraph (g) of 26 CFR 54.9815–2713A, the redesignated paragraph (g) of 29 CFR 2590.715–2713A, and 45 CFR 147.132(d).

R. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to ''preventive'' care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to ''preventive'' services or care.[76] The requirement in the Guidelines concerning ''contraception'' specifies several times that it encompasses ''contraceptives,'' that is, medical products, methods, and services applied for ''contraceptive'' uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage, without cost-sharing, of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[77] The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans' decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use, or for another use. Section 2713(a)(4), however, draws a distinction between preventive care and screenings and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of contraceptive methods or care unless such methods or care is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules also do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply to the extent the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that under section 2713(a)(4), exempt organizations must provide coverage for drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the expanded exemptions could take contraceptive coverage away from many or most women. Still others opposed expanding the exemptions and contended that accurately determining the number of women affected by the expanded exemptions is not possible.

After reviewing the public comments, the Departments agree with commenters who said that estimating the impact of these final rules is difficult based on the limited data available to us, and with commenters who agreed with the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women. The Departments do not find the estimates of large impacts submitted by some commenters more reliable than the estimates set forth in the Religious and Moral IFCs. Even certain commenters that ''strongly oppos[ed]'' the Religious IFC commented that merely ''thousands'' would be impacted, a number consistent with the Departments' estimate of the number of women who may be affected by the rule. The Departments' estimates of the impact of these final rules are discussed in more detail in the following section. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious IFC are still the best estimates available. Our estimates are discussed in more detail in the following section.

3. Interaction With State Laws

Some commenters asked the Departments to discuss the interaction between these final rules and state laws that either require contraceptive

[76] *Id.*

[77] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that ''there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy.'' 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act 2713(a)(4) or the Guidelines require coverage of ''contraceptive'' methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead, it was an observation that such drugs—generally referred to as ''contraceptives''—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the reference prior to the Religious IFC to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage for contraceptive use. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

coverage or provide religious exemptions from those and other requirements. Some commenters argued that providing expanded exemptions in these rules would negate state contraceptive requirements or narrower state religious exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage. The Department agrees that these rules concern only the applicability of the Federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state religious exemptions. If a plan is exempt under the Religious IFC and these rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the religious exemptions to declare that the Federal contraceptive Mandate will still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.[78]

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1). These rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with religious objections to cover contraceptives.

IV. Economic Impact and Paperwork Burden

The Departments have examined the impacts of the Religious IFC and the final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an ''economically significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding their anticipated effects, the Religious IFC and these rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These final rules adopt as final and further change the amendments made by the Religious IFC, which amended the Departments' July 2015 final regulations. The Religious IFC and these final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held religious beliefs, and they revise the accommodation process to make it optional for eligible organizations. The expanded exemption applies to certain individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action has been taken, among other reasons discussed above, to provide for participation in the health insurance market by certain entities or individuals, by freeing them from penalties they could incur if they follow their sincerely held religious beliefs against contraceptive coverage.

2. Anticipated Effects

a. Removal of Burdens on Religious Exercise

Regarding entities and individuals that are extended an exemption by the Religious IFC and these final rules, without that exemption the Guidelines would require many of them to either pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which

[78] Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the Federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. Elsewhere in this preamble, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

some entities also believe entangles them in the provision of such objectionable coverage; or pay tax penalties, or be subject to other adverse consequences, for non-compliance with these requirements. These final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections to, and exempting them on the basis of such objections from, the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

b. Notices When Revoking Accommodated Status

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption, a notice will need to be sent to enrollees (either by the objecting entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during the current plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of the entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be $302,036.

c. Impacts on Third Party Administrators and Issuers

The Departments estimate that these final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their new exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation to which they were not previously provided access. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations for serving the fewer number of entities that will now opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation. While these rules make it legal for issuers to offer insurance coverage that omits contraceptives to exempt entities and individuals, these final rules do not require issuers to do so.

The Departments anticipate that the effect of these rules on adjustments made to the federally facilitated Exchange user fees under 45 CFR 156.50 will be that fewer overall adjustments will be made using the accommodation process, because there will be more entities who previously were reluctant users of the accommodation that will choose to operate under the newly expanded exemption than there will be entities not previously eligible to use the accommodation that will opt into it. The Departments' estimates of each number of those entities is set forth in more detail below.

d. Impacts on Persons Covered by Newly Exempt Plans

These final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. As discussed in the Religious IFC, the Departments did not have sufficient data on a variety of relevant factors to precisely estimate how many women would be impacted by the expanded exemptions or any related costs they may incur for contraceptive coverage or the results associated with any unintended pregnancies.

i. Unknown Factors Concerning Impact on Persons in Newly Exempt Plans

As referenced above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- How many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- Which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby,* several objecting entities have still provided coverage for 14 of the 18 FDA-approved women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- How many women will be covered by plans of entities using their newly exempt status.
- Which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- Whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- The degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- The degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- The degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- The extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

ii. Public Comments Concerning Estimates in Religious IFC

In the public comments, some commenters agreed with the Departments' estimate that, at most, the economic impact would lead to a potential transfer cost, from employers (or other plan sponsors) to affected women, of $63.8 million. Some commenters said the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women.

These general comments do not, however, substantially assist us in

estimating how many women would be affected by these expanded exemptions specifically, or among them, how many unintended pregnancies would result, or how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the transfer costs the Departments estimate, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives. The Departments conclude, therefore, that our estimates of the anticipated effect in the Religious IFC are still the best estimates we have based on the limited data available to make those estimates. We do not believe that the higher estimates submitted by various public commenters sufficiently took into consideration, or analyzed, the various factors that suggest the small percentage of entities that will now use the expanded exemptions out of the large number of entities subject to the Mandate overall. Instead, the Departments agree with various public commenters providing comment and analysis that, for a variety of reasons, the best estimate of the impact of the expanded exemptions finalized in these rules is that most women receiving contraceptive coverage under the Mandate will not be affected. We agree with such commenters that the number of women covered by entities likely to make use of the expanded exemptions in these rules is likely to be very small in comparison to the overall number of women receiving contraceptive coverage as a result of the Mandate.

iii. Possible Sources of Information for Estimating Impact

The Departments have access to the following general sources of information that are relevant to this issue, but these sources do not provide a full picture of the impact of these final rules. First, the regulations prior to the Religious IFC already exempted certain houses of worship and their integrated auxiliaries and, as explained elsewhere, effectively did not apply contraceptive coverage requirements to various entities in self-insured church plans. The effect of those previous exemptions or limitations are not included as effects of these rules, which leave those impacts in place. Second, in the Departments' previous regulations creating or expanding exemptions and the accommodation process we concluded that no significant burden or costs would result. 76 FR 46625; 78 FR 39889. Third, some entities, including some for-profit entities, object to only some but not all contraceptives, and in some cases will cover 14 of 18 FDA-approved women's contraceptive and sterilization methods.[79] *See Hobby Lobby,* 134 S. Ct. at 2766. The effects of the expanded exemptions will be mitigated to that extent. No publicly traded for-profit entities sued challenging the Mandate, and the public comments did not reveal any that specifically would seek to use the expanded exemptions. Consequently, the Departments agree with the estimate from the Religious IFC that publicly traded companies would not likely make use of these expanded exemptions.

Fourth, HHS previously estimated that 209 entities would make use of the accommodation process. To arrive at this number, the Departments used, as a placeholder, the approximately 122 nonprofit entities that brought litigation challenging the accommodation process, and the approximately 87 closely held for-profit entities that filed suit challenging the Mandate in general. The Departments' records indicate, as noted in the Religious IFC, that approximately 63 entities affirmatively submitted notices to HHS to use the accommodation,[80] and approximately 60 plans took advantage of the contraceptive user fees adjustments, in the 2015 plan year, to obtain reimbursement for contraceptive service payments made for coverage of such services for women covered by self-insured plans that were accommodated. Overall, while recognizing the limited data available, the Departments assumed that, under an expanded exemption and accommodation, approximately 109 previously accommodated entities would use an expanded exemption, and about 100 would continue their accommodated status. We also estimated that another 9 entities would use the accommodation where the entities were not previously eligible to do so.

These sources of information were outlined in the Religious IFC. Some commenters agreed with the Departments' estimates based on those sources, and while others disagreed, the Departments conclude that commenters did not provide information that allows us to make better estimates.

iv. Estimates Based on Litigating Entities That May Use Expanded Exemptions

Based on these and other factors, the Departments considered two approaches in the Religious IFC to estimate the number of women affected among entities using the expanded exemptions. First, following the use in previous regulations of litigating entities to estimate the effect of the exemption and accommodation, the Departments attempted to estimate the number of women covered by plans of litigating entities that could be affected by expanded exemptions. Based on papers filed in litigation, and public sources, the Departments estimated in the Religious IFC that approximately 8,700 women of childbearing age could have their contraception costs affected by plans of litigating entities using these expanded exemptions. The Departments believe that number is lower based upon the receipt, by many of those litigating entities, of permanent injunctions against the enforcement of section 2713(a)(4) to the extent it supports a contraceptive Mandate, which have been entered by federal district courts since the issuance of the Religious IFC.[81] As a result, these final rules will not affect whether such entities will be subject to the contraceptive Mandate. Subtracting those entities from the total, the Departments estimate that the remaining litigating entities employ

[79] By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, *https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf,* Hobby Lobby and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). *See* 134 S. Ct. at 2765–66. Hobby Lobby was willing to cover: sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives (''the Pill''—combined pill); oral contraceptives (''the Pill''—extended/continuous use/combined pill); oral contraceptives (''the Mini Pill''—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that Hobby Lobby and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and ''[t]he pill and female sterilization have been the two most commonly used methods since 1982.'' *See* Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[80] This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. In addition, the Departments have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or the Departments were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage.

[81] *See, for example, Catholic Benefits Ass'n LCA* v. *Hargan,* No. 5:14–cv–00240–R (W.D. Okla. order filed Mar. 7, 2018), and *Dordt Coll.* v. *Burwell,* No. 5:13–cv–04100 (N.D. Iowa order filed June 12, 2018).

approximately 49,000 persons, male and female. The average percent of workers at firms offering health benefits that are actually covered by those benefits is 60 percent.[82] This amounts to approximately 29,000 employees covered under those plans. EBSA estimates that for each employee policyholder, there is approximately one dependent.[83] This amounts to approximately 58,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15 to 44—compose 20.2 percent of the general population.[84] Furthermore, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.[85] Therefore, the Departments estimate that approximately 5,200 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that might be affected by these final rules. The Departments also estimate that, for the educational institutions that brought litigation challenges objecting to the Mandate as applied to student coverage that they arranged—where (1) the institutions were not exempt under the prior rule, (2) their student plans were not self-insured, and (3) they have not received permanent injunctions preventing the application of the previous regulations—such student plans likely covered approximately 2,600 students. Thus, the Departments estimate the female members of those plans is 2,600 women.[86] Assuming, as referenced above, that 43.6 percent of such women use contraception covered by the Guidelines, the Departments estimate that 1,150 of those women would be affected by these final rules.

Together, this leads the Departments to estimate that approximately 6,400 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted previously, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do the Departments know how many would have alternative contraceptive access from a parent's or spouse's plan, or from federal, state, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

v. Estimates of Accommodated Entities That May Use Expanded Exemptions

In the Religious IFC, the Departments also examined data concerning user-fee reductions to estimate how many women might be affected by entities that are using the accommodation and would use the expanded exemptions under these final rules. Under the accommodation, HHS has received information from issuers that seek user fees adjustments under 45 CFR 156.50(d)(3)(ii), for providing contraceptive payments for self-insured plans that make use of the accommodation. HHS receives requests for fees adjustments both where Third Party Administrators (TPAs) for those self-insured accommodated plans are themselves issuers, and where the TPAs use separate issuers to provide the payments and those issuers seek fees adjustments. Where the issuers seeking adjustments are separate from the TPAs, the TPAs are asked to report the number of persons covered by those plans. Some users do not enter all the requested data, and not all the data for the 2017 plan year is complete. Nevertheless, HHS has reviewed the user fees adjustment data received for the 2017 plan year. HHS's best estimate from the data is that there were $38.4 million in contraception claims sought as the basis for user fees adjustments for plans, and that these claims were for plans covering approximately 1,823,000 plan participants and beneficiaries of all ages, male and female.

This number fluctuates from year to year. It is larger than the estimate used in the Religious IFC because, on closer examination of the data, this number better accounts for plans where TPAs were also issuers seeking user fees adjustments, in addition to plans where the TPA is separate from the issuer seeking user fees adjustments. The number of employers using the accommodation where user fees adjustments were sought cannot be determined from HHS data, because not all users are required to submit that information, and HHS does not necessarily receive information about fully insured plans using the accommodation. Therefore, the Departments still consider our previous estimate of 209 entities using the accommodation as the best estimate available.

As noted in the Religious IFC, HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly tens of thousands of persons each and are proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

The Departments continue to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.[87]

[82] See Kaiser Family Foundation and Health Research and Educational Trust, ''Employer Health Benefits: 2018 Annual Survey'' at 62, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.*

[83] Employee Benefits Security Administration, ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[84] United States Census Bureau, ''Age and Sex Composition: 2010'' (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies ''for all women with reproductive capacity.'' *https://www.hrsa.gov/womensguidelines/;* also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/*contraceptive-use-united-states.

[85] See *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states* (reporting that of 61,491,766 women aged 15–44, 26,809,5550 use women's contraceptive methods covered by the Guidelines).

[86] On average, the Departments expect that approximately half of those students (1,300) are female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. The Departments expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, the Departments assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 2,6,00. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, the Departments assume they are. Therefore, for the purposes of this estimate, the Departments assume that the effect of these expanded exemptions on student plans of litigating entities includes 2,600 women.

[87] See, *e.g., https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule* (''HHS has now established an accommodation that will allow our ministries to continue offering health

Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.[88] As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.[89] (The Departments take no view on the status of these particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.) Nevertheless, considering all these factors, it generally seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations, the Religious IFC and these final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.''). In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it ''is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia.'' Comments on CMS–9968–ANPRM (dated June 15, 2012).

[88] See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, Advocate Health Care Network, Nos. 16–74, 16–86, 16–258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) (''CHA members have relied for decades that the 'church plan' exemption contained in'' ERISA.).

[89] See *https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf;* see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

vi. Combined Estimates of Litigating and Accommodated Entities

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these final rules. In addition to the estimate of 6,400 women of childbearing age that use contraception covered by the Guidelines, who will be affected by use of the expanded exemption among litigating entities, the Departments calculate the following number of women who we estimate to be affected by accommodated entities using the expanded exemption. As noted above, approximately 1,823,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2017. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, the Departments do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, the Departments assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer-sponsored insurance in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans.[90] Therefore, corresponding to the approximately 1,823,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 1,084,000 persons were covered by fully insured plans using the accommodation. This yields approximately 2,907,000 persons of all ages and sexes whom the Departments estimate were covered in plans using the accommodation under the previous regulations.

Although recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the previous regulations will continue to opt into it under these final rules and that those entities will cover the substantial majority of persons previously covered in accommodated plans. The data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems and other entities likely to continue using the accommodation constitute over 60 percent of plans using the accommodation, and encompass more than 90 percent of the persons covered in accommodated plans.[91] In other words, plans sponsored by such entities appear to be a majority of plans using the accommodation, and also have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. Moreover, as cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these final rules would not impact the contraceptive coverage their employees receive.

The Departments do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which the Departments lack representative data. Based on these assumptions and without better data available, the Departments assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, the Departments assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons

[90] ''Health Insurance Coverage Bulletin'' Table 3A, page 14. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[91] The data also reflects a religious university using the accommodation that has publicly affirmed the accommodation is consistent with its religious views, and two houses of worship that are using the accommodation despite already qualifying for the previous exemption. We assume for the purposes of this estimate these three entities will also continue using the accommodation instead of the expanded exemption.

previously covered in accommodated plans.

Applying these percentages to the estimated 2,907,000 persons covered in previously accommodated plans, the Departments estimate that approximately 727,000 persons will be covered in the 109 plans that use the expanded exemption, and 2,180,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, women of childbearing age comprise 20.2 percent of the population, which means that approximately 147,000 women of childbearing age are covered in previously accommodated plans that the Departments estimate will use the expanded exemption. As noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that the Departments expect approximately 64,000 women that use contraception covered by the Guidelines will be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 6,400 women in plans of litigating entities that may be affected by these rules. In order to more broadly estimate the possible effects of these rules, the Departments assume there is no overlap between the two numbers, and therefore that these final rules would affect the contraceptive costs of approximately 70,500 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these final rules is approximately 0.1 percent of the 55.6 million women in private plans that HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated in 2015 received preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the previous accommodation process, the total amount of contraceptive claims sought for self-insured plans for the 2017 benefit year was $38.5 million.[92] These adjustments covered the cost of contraceptive coverage provided to women. As also discussed above, the Departments estimate that amount corresponded to plans covering 1,823,000 persons. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age, and of those, approximately 43.6 percent use women's contraceptive methods covered by the Guidelines. This amounts to approximately 161,000 women. Therefore, entities using contraceptive user fees adjustments received approximately $239 per year per woman of childbearing age that used contraception covered by the Guidelines and covered in their plans. But in the Religious IFC, we estimated that the average annual cost of contraception per woman per year is $584. As noted above, public commenters cited similar estimates of the annual cost of various contraceptive methods, if calculated for the life of the method's effectiveness. Therefore, to estimate the annual transfer effects of these final rules, the Departments will continue to use the estimate of $584 per woman per year. With an estimated impact of these final rules of 70,500 women per year, the financial transfer effects attributable to these final rules on those women would be approximately $41.2 million.

Some commenters suggested that the Departments' estimate of women affected among litigating entities was too low, but they did not support their proposed higher numbers with citations or specific data that could be verified as more reliable than the estimates in the Religious IFC. Their estimates appeared to be overinclusive, for example, by counting all litigating entities and not just those that may be affected by these rules because they are not in church plans, or by counting all plan participants and not just women of childbearing age that use contraception. Moreover, since the Religious IFC was issued, additional entities have received permanent injunctions against enforcement of any regulations implementing the contraceptive Mandate and so will not be affected by these final rules. Taking all of these factors into account, the Departments are not aware of a better method of estimating the number of women affected by these expanded exemptions.

vii. Alternate Estimates Based on Consideration of Pre-ACA Plans

To account for uncertainty in the estimates above, the Departments conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these final rules.

In 2015, ASPE estimated that 55.6 million women aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.[93] The Religious IFC used this estimate in this second analysis of the possible impact of the expanded exemptions in the interim final rules. ASPE has not issued an update to its report. Some commenters noted that a private organization published a fact sheet in 2017 claiming to make similar estimates based on more recent data, in which it estimated that 62.4 million aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.[94] The primary difference between these numbers appears to be a change in the number of persons covered by grandfathered plans.

The methodology of both reports do not fully correspond to the number the Departments seek to estimate here for the purposes of *Executive Orders 12866 and 13563.* These final rules will not affect all women aged 15 to 64 who are covered by private insurance and have coverage of preventive services under the Affordable Care Act. This is partly because the Departments do not have evidence to suggest that most employers will have sincerely held religious objections to contraceptive coverage and will use the expanded exemptions. In addition, both reports include women covered by plans that are not likely affected by the expanded exemptions for other reasons. For example, even though the estimates in those reports do not include enrollees in public plans such as Medicare or Medicaid, they do include enrollees in plans obtained on the health insurance marketplaces, purchased in the individual market, obtained by self-employed persons, or offered by government employers. Women who purchase plans in the marketplaces, the individual market, or as self-employed persons are not required to use the exemptions in these rules. Government employers are also not affected by the exemptions in these rules.

In response to public comments citing the more recent report, the Departments offer the following estimates based on more recent data than used in the Religious IFC. Data from the U.S. Census Bureau indicates that 167.6 million individuals, male and female, under 65 years of age, were covered by

[92] The amount of user fees adjustments provided was higher than this, since an additional administrative amount was added to the amount of contraceptive costs claimed.

[93] Available at *https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf.*

[94] The commenters cited the National Women's Law Center's Fact Sheet from September 2017, available at *https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf.*

employment-based insurance in 2017.[95] Of those, 50.1 percent were female, that is, 84 million.[96] The most recent Health Insurance Coverage Bulletin from EBSA states that, within employer-sponsored insurance, 76.5% are covered by private sector employers.[97] As noted above, these expanded exemptions do not apply to public sector employers. Assuming the same percentage applies to the Census data for 2017, 64.2 million women under 65 years of age were covered by private sector employment based insurance. EBSA's bulletin also states that, among those covered by private sector employer sponsored insurance, 5% receive health insurance coverage from a different primary source.[98] We assume for the purposes of this estimate that an exemption claimed by an employer under these rules need not affect contraceptive coverage of a person who receives health insurance coverage from a different primary source. Again assuming this percentage applies to the 2017 coverage year, we estimate that 61 million women under 65 years of age received primary health coverage from private sector, employment-based insurance. In conducting this analysis, the Departments also observed that for 3.8 percent of those covered by private sector employment sponsored insurance, the plan was purchased by a self-employed person, not by a third party employer. Self-employed persons who direct firms are not required to use the exemptions in these final rules, but if they do, they would not be losing contraceptive coverage that they want to have, since they would be using the exemption based on their sincerely held religious beliefs. If those persons have employees, the employees would be included in this estimate in the number of people who receive employer sponsored insurance from a third party. Assuming this percentage applies to the 2017 coverage year, we estimate that 58.7 million women under 65 years of age received primary health coverage from private sector insurance from a third party employer plan sponsor.

The Kaiser Family Foundation's Employer Health Benefits Annual Survey 2018 states that 16% of covered workers at all firms are enrolled in a plan grandfathered under the ACA (and thus not subject to the preventive services coverage requirements), but that only 14% of workers receiving coverage from state and local government employer plans are in grandfathered plans.[99] Using the data cited above in EBSA's bulletin concerning the number of persons covered in public and private sector employer sponsored insurance, this suggests 16.6% of persons covered by private sector employer sponsored plans are in grandfathered plans, and 83.4% in non-grandfathered plans.[100] Applying this percentage to the Census data, 49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based, non-grandfathered plans. Census data indicates that among women under age 65, 46.7% are of childbearing age (aged 15 to 44).[101] Therefore, we estimate that 22.9 million women aged 15–44 received primary health insurance coverage from private sector, third party employment based, non-grandfathered insurance plans.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.[102] The 6 percent may have included approximately 1.37 million of the women aged 15 to 44 primarily covered by employer-sponsored insurance plans in the private sector. And as noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore, the Departments estimate that 599,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.[103]

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for religious or other reasons. Despite the lack of information about their motives, the Departments attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, the Departments estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in *Hobby Lobby,* where the Court observed that ''HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable.'' 134 S. Ct. at 2774. The Departments are aware of several federal health care conscience

[95] See U.S. Census Bureau Current Population Survey Table HI–01, ''Health Insurance Coverage in 2017: All Races,'' available at *https://www2.census.gov/programs-surveys/cps/tables/hi-01/2018/hi01_1.xls.*

[96] *Id.*

[97] Table 1A, page 5 (stating that in coverage year 2015, 177.5 million persons of all ages were covered by employer sponsored insurance, with 135.7 million of those being covered by private sector employers), available at *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[98] *Id.* at Table 1C, page 8 (168.7 million persons received health insurance coverage from employer sponsored insurance as their primary source, compared to 177.5 million persons covered by employer sponsored insurance overall).

[99] ''Employer Health Benefits: 2018 Annual Survey'' at 211, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.*

[100] EBSA's bulletin shows 168.7 million persons with primary coverage from employer sponsored insurance, with 131.6 million in the private sector and 37.1 million in the public sector. 16% of 168.7 million is 26.9 million. 14% of 37.1 million is 5.2 million. 26.9 million − 5.2 million is 21.8 million, which is 16.6% of the 131.6 million persons with primary coverage from private sector employer sponsored insurance.

[101] U.S. Census Bureau, Table S0101 ''Age and Sex'' (available at *https://data.census.gov/cedsci/results/tables?q=S0101:%20AGE%20AND%20SEX&ps=table*currentPage@1*).

[102] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2010 Annual Survey'' at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf.*

[103] Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers' lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these final rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity's mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these final rules.

laws [104] that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but the Departments are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while the Departments consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those reasons used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions, the Departments agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.[105] That means that only approximately 411,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, because these final rules build on previous regulations that already exempted houses of worship and integrated auxiliaries and, as explained above, effectively eliminated obligations to provide contraceptive coverage within objecting self-insured church plans, the Departments attempt to estimate the number of such employers whose employees would not be affected by these rules. In attempting to estimate the number of such employers, the Departments consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the United States,[106] 197 Catholic dioceses,[107] 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.[108] Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so the Departments use the number of schools as an estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention covering 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.[109] Christian Brothers is a plan that covers Catholic organizations including Catholic churches and integrated auxiliaries, which are estimated above, but has also said in litigation that it covers about 500 additional entities that are not exempt as churches.[110] In total, therefore, without having certain data on the number of entities exempt under the previous rules, the Departments estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous regulations. The Departments do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include ''churches, mission-sending agencies, hospitals, educational institutions and other related ministries.'' Using that ratio, the Departments estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 women would be of childbearing age, and 32,100 may use contraceptives covered by the Guidelines.

Taking all of these factors into account, the Departments estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous regulations nor were participants in self-insured church plans that oppose contraceptive coverage, covered approximately 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines. But to estimate the likely actual transfer impact of these final rules, the Departments must estimate not just the number of such women covered by those entities, but how many of those entities would actually qualify for, and use, the expanded exemptions.

The Departments do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous regulations on this matter, the Departments are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, the Departments believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 126,400 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. Consequently, as explained below, the Departments believe that the potential impact of these final rules falls substantially below the $100 million threshold for an economically significant major rule.

First, as mentioned, the Departments are not aware of information, or of data from public comments, that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or, specifically, religious beliefs, as opposed to having done so for other reasons. It would seem reasonable to assume that many of those entities did not do so based on sincerely held religious beliefs. According to a 2016 poll, only 4% of Americans believe that using contraceptives is morally wrong (including from a religious perspective).[111] In addition,

[104] For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

[105] John Asker, et al., ''Corporate Investment and Stock Market Listing: A Puzzle?'' 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at *https://doi.org/10.1093/rfs/hhu077*. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, ''The number of publicly-traded US companies is down 46% in the past two decades,'' *Yahoo! Finance* (Aug. 8, 2016), available at *https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html*.

[106] Roman Catholic Diocese of Reno, ''Diocese of Reno Directory: 2016–2017,'' available at *http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf*.

[107] Wikipedia, ''List of Catholic dioceses in the United States,'' available at *https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States*.

[108] National Catholic Educational Association, ''Catholic School Data,'' available at *http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx*.

[109] Guidestone Financial Resources, ''Who We Serve,'' available at *https://www.guidestone.org/AboutUs/WhoWeServe*.

[110] The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

[111] Pew Research Center, ''Where the Public Stands on Religious Liberty vs. Nondiscrimination''

various reasons exist for some employers not to return to a pre-ACA situation in which they did not provide contraceptive coverage, such as avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.[112] Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees and, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

It may not be the case that all entities that objected on religious grounds to contraceptive coverage before the ACA brought suit against the Mandate. However, it is worth noting that, while less than 100 for-profit entities challenged the Mandate in court (and an unknown number joined two newly formed associational organizations bringing suit on their behalf), there are more than 3 million for-profit private sector establishments in the United States that offer health insurance.[113] Six percent of those would be 185,000, and one third of that number would be 62,000. The Departments consider it unlikely that tens or hundreds of thousands of for-profit private sector establishments omitted contraceptive coverage pre-ACA specifically because of sincerely held religious beliefs, when, after six years of litigation and multiple public comment periods, the Departments are aware of less than 100 such entities. The Departments do not know how many additional nonprofit entities would use the expanded exemptions, but as noted above, under the rules predating the Religious IFC, tens of thousands were already exempt as churches or integrated auxiliaries, or were covered by self-insured church plans that are not penalized if no contraceptive coverage is offered.

Finally, among entities that omitted contraceptive coverage based on sincerely held conscientious objections as opposed to other reasons, it is likely that some, albeit a minority, did so based on moral objections that are non-religious, and therefore would not be compassed by the expanded exemptions in these final rules.[114] Among the general public, polls vary about religious beliefs, but one prominent poll shows that 13 percent of Americans say they do not believe in God or have no opinion on the question.[115] Therefore, the Departments estimate that, of the entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, a small fraction did so based on sincerely held non-religious moral convictions, and therefore would not be affected by the expanded exemption provided by these final rules for religious beliefs.

For the reasons stated above, the Departments believe it would be incorrect to assume that all or even most of the plans that did not cover contraceptives before the ACA did so on the basis of religious objections. Instead, without data available on the reasons those plans omitted contraceptive coverage before the ACA, we assume that no more than one third of those plans omitted contraceptive coverage based on sincerely held religious beliefs. Thus, of the estimated 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines, who received primary coverage from plans of private, non-publicly traded, third party employers that did not cover contraception pre-Affordable Care Act, and whose plans were neither exempt nor omitted from mandatory contraceptive coverage under the previous regulations, we estimate that no more than 126,400 women would be in plans that will use these expanded exemptions.

viii. Final Estimates of Persons Affected by Expanded Exemptions

Based on the estimate of an average annual expenditure on contraceptive products and services of $584 per user, the effect of the expanded exemptions on 126,400 women would give rise to approximately $73.8 million in potential transfer impact. It is possible, however, that premiums would adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As referenced elsewhere in this analysis, such women may make up approximately 8.8 percent of the covered population,[116] in which case the offset would also be approximately 8.8 percent, yielding a potential transfer of $67.3 million.

Thus, in their most expansive estimate, the Departments conclude that no more than approximately 126,400 women would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. The Departments estimate this financial transfer to be approximately $67.3 million. This falls substantially below the $100 million threshold for an economically significant and major rule.

As noted above, the Departments view this alternative estimate as being the highest possible bound of the transfer effects of these rules, but believe the number of establishments that will actually exempt their plans as the result of these rules will be far fewer than contemplated by this estimate. The Departments make these estimates only for the purposes of determining whether the rules are economically significant under Executive Orders 12866 and 13563.

After reviewing public comments, both those supporting and those disagreeing with these estimates and similar estimates from the Religious IFC, and because the Departments do not have sufficient data to precisely

at page 26 (Sept. 28, 2016), available at *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.*

[112] On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered ''yes'' or ''don't know'' to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule's effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

[113] Tables I.A.1 and I.A.2, Medical Expenditure Panel Survey, ''Private-Sector Data by Firm Size, Industry Group, Ownership, Age of Firm, and Other Characteristics: 2017,'' HHS Agency for Healthcare Research and Quality (indicating total number of for-profit incorporated, for-profit unincorporated, and non-profit establishments in the United States, and the percentage of each that offer health insurance), available at *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia1.htm* and *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia2.htm.* 2523.

[114] Such objections may be encompassed by companion final rules published elsewhere in today's **Federal Register**. Those final rules, however, are narrower in scope than these final rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

[115] Gallup, ''Religion,'' available at *https://news.gallup.com/poll/1690/religion.aspx.*

[116] As cited above, women of childbearing age are 20.2 percent of woman aged 15–65, and 43.6 percent of women of childbearing age use contraceptives covered by the Guidelines.

estimate the amount by which these factors render our estimate too high, or too low, the Departments simply conclude that the financial transfer falls substantially below the $100 million threshold for an economically significant rule based on the calculations set forth above.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. The Religious IFC was an interim final rule with comment period, and in these final rules, the Departments adopt the Religious IFC as final with certain changes. These final rules are, thus, being issued after a notice and comment period.

The Departments also carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866 and do not expect that these final rules will have a significant economic effect on a substantial number of small entities. These final rules will not result in any additional costs to affected entities, and, in many cases, may relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization—businesses and organizations that would otherwise be faced with the dilemma of complying with the Mandate (and violating their religious beliefs) or following their beliefs (and incurring potentially significant financial penalties for noncompliance)—the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. In the October 13, 2017 (82 FR 47792) interim final rules, we solicited public comment on each of these issues for the following sections of the rule containing information collection requirements (ICRs). A description of the information collection provisions implicated in these final rules is given in the following section with an estimate of the annual burden. The burden related to these ICRs received emergency review and approval under OMB control number 0938–1344. They have been resubmitted to OMB in conjunction with these final rules and are pending re-approval. The Departments sought public comments on PRA estimates set forth in the Religious IFC, and are not aware of significant comments submitted that suggest there is a better way to estimate these burdens.

1. Wage Data

Average labor costs (including 100 percent fringe benefits and overhead) used to estimate the costs are calculated using data available derived from the Bureau of Labor Statistics.[117]

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupational code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Executive Secretaries and Executive Administrative Assistants	43–6011	$27.84	$27.84	$55.68
Compensation and Benefits Manager	11–3111	61.01	61.01	122.02
Legal Counsel	23–1011	67.25	67.25	134.50
Senior Executive	11–1011	93.44	93.44	186.88
General and Operations Managers	11–1021	58.70	58.70	117.40

2. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under these final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations (80 FR 41318).

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party

[117] May 2016 National Occupational Employment and Wage Estimates United States found at *https://www.bls.gov/oes/current/oes_nat.htm.*

administrator). As explained above, HHS assumes that, among the 209 entities the Departments estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.[118] HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of $55.68 per hour, 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour, 5 minutes for legal counsel at a cost of $134.50 per hour, and 5 minutes by a senior executive at a cost of $186.88 per hour) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost of approximately $74.96 for a total hour burden of approximately 7.5 hours and an associated equivalent cost of approximately $675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so that each will account for approximately 3.75 burden hours with an equivalent cost of approximately $337.

HHS estimates that each self-certification or notice to HHS will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be $0.55. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately $2.75 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so that each will account for $1.38 of the cost burden.

3. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations (80 FR 41318), a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language previously provided by HHS or substantially similar language.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at $55.68 per hour) and 15 minutes of management review (at $117.40 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an associated cost of approximately $85.03. The total burden for all 109 issuers or third party administrators will be 136 hours, with an associated cost of approximately $9,268. As DOL and HHS share jurisdiction, they are splitting the burden each will account for 68 burden hours with an associated cost of $4,634, with approximately 55 respondents.

The Departments estimate that approximately 2,180,000 plan participants and beneficiaries will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. We reach this estimate using calculations set forth above, in which we used 2017 data available to HHS for contraceptive user fees adjustments to estimate that approximately 2,907,000 plan participants and beneficiaries were covered by plans using the accommodation. We further estimated that the 100 entities that previously used the accommodation and will continue doing so will cover approximately 75 percent of the persons in all accommodated plans, based on HHS data concerning accommodated self-insured plans that indicates plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As noted above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans. The Departments do not have specific data on which plans of which employer sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data.

Based on these assumptions and without better data available, the Departments estimate that previously accommodated entities encompassed approximately 2,907,000 persons; the estimated 100 entities that previously used the accommodation and continue to use it will account for 75 percent of those persons (that is, approximately 2,180,000 persons); and the estimated 109 entities that previously used the accommodation and will now use their exempt status will account for 25 percent of those persons (that is, approximately 727,000 persons). It is not known how many persons will be covered in the plans of the 9 entities we estimate will newly use the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity as the 100 entities encompassing 2,180,000

[118] For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

persons, the Departments estimate that all 109 accommodated entities will encompass approximately 2,376,000 covered persons.

The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all participants and dependents. Among persons covered by insurance plans sponsored by large employers in the private sector, approximately 50.1 percent are participants and 49.9 percent are dependents.[119] For 109 entities, the total number of notices will be 1,190,613. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.[120] Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.55. The total cost for sending approximately 551,254 notices by mail will be approximately $303,190. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $151,595 of the cost burden.

4. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization that now wishes to take advantage of the expanded exemption may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to send the notification; the issuer or third party administrator can send the notice on behalf of the entity. For the purpose of calculating the ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke their use of the accommodation fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of $117.40 per hour, 30 minutes for legal counsel at a cost of $134.50 per hour, 1 hour for clerical staff at a cost of $55.68 per hour). The burden per respondent will be 2 hours with an associated cost of approximately $182; for 109 entities, the total hour burden will be 218 hours with an associated cost of approximately $19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an associated cost of approximately $9,899.

As discussed above, HHS estimates that there are approximately 727,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[121] As before, the Departments use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 364,102 notices will be distributed, of which 168,579 notices will be mailed. HHS estimates that each mailed notice will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.55. The total cost for sending approximately 168,579 notices by mail is approximately $93,545. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 182,051 notices, with an associated cost of approximately $46,772.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB Control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
Self-Certification or Notices to HHS	0938–1344	*5	5	0.83	3.75	$89.95	$337	$339
Notice of Availability of Separate Payments for Contraceptive Services	0938–1344	*55	595,307	1.25	68.13	68.02	4,634	156,229
Notice of Revocation of Accommodation	0938–1344	*55	182,051	2.00	109	90.82	9,899	56,671
Total		*115	777,363		180.88		14,870	213,239

*The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

[119] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[120] According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

[121] In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, the Departments indicated that we do not know the extent to which the number of women in accommodated plans affected by these final rules overlap with the number of women in plans offered by litigating entities that will be affected by these final rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

5. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov*. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

The Religious final rules amended the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer revokes their accommodation; these final rules confirm as final the Religious IFC provisions on the accommodation process. DOL submitted the ICRs to OMB in order to obtain OMB approval under the PRA for the regulatory revision. In an effort to consolidate the number of information collection requests, DOL is combining the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150 and discontinuing OMB control number 1210–0152. Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur $0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 1,190,613 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke their use of the accommodation (in favor of the expanded exemption) and will therefore be required to cause the Notice of Revocation of Accommodation to be sent, with the issuer or third party administrator able to send the notice on behalf of the entity. These entities will spend approximately two hours in preparation time and incur $0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 364,102 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114 [122] (combined with HHS total is 227).

Total Responses: 777,362 (combined with HHS total is 1,554,724).

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: $197,955 (combined with HHS total is $395,911).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, ''[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' In addition, agencies are directed to ''take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the states more flexibility and control to create a freer and open healthcare market.'' These final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these final rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.[123] However, in order to avoid double-counting with the Religious IFC, which has already been tallied as an Executive Order 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

[122] Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

[123] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (Dominic J. Mancini, ''Guidance Implementing Executive Order 13771, Titled ''Reducing Regulation and Controlling Regulatory Costs,'' Office of Mgmt. & Budget (Apr. 5, 2017), *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.'' In 2018, that threshold after adjustment for inflation is $150 million. For purposes of the Unfunded Mandates Reform Act, the Religious IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of $150 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These final rules do not have any federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

V. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code, and Public Law 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4).

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Pub. L. 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4); Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701); and Public Law 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

■ 2. Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 3. Section 54.9815–2713A is revised to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the

Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(b) *Optional accommodation—self-insured group health plans*—(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services) will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not

apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): ''Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].''

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be

incorrect, the issuer is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(f) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(g) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 54.9815–2713T [Removed]

■ 4. Section 54.9815–2713T is removed.

§ 54.9815–2713AT [Removed]

■ 5. Section 54.9815–2713AT is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor adopts as final the interim final rules amending 29 CFR part 2590 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read, as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713A is amended by:
■ a. Revising paragraph (a)(5);
■ b. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g); and
■ c. Adding new paragraph (e).

The revision and addition read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) * * *

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 8. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 9. Section 147.131 is amended by:
■ a. Revising paragraph (c)(4);
■ b. Redesignating paragraphs (f) and (g) as (g) and (h); and
■ c. Adding new paragraph (f).

The revision and addition read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

* * * * *

(c) * * *

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after January 14, 2019, if

contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(f) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

■ 10. Section 147.132 is amended by:
■ a. Revising paragraph (a)(1) introductory text;
■ b. Redesignating paragraphs (a)(1)(ii) and (iii) as paragraphs (iii) and (iv);
■ c. Adding new paragraph (a)(1)(ii);
■ d. Revising newly designated paragraph (a)(1)(iii);
■ e. Revising newly designated paragraph (a)(1)(iv); and
■ f. Revising paragraphs (a)(2) and (b).

The revisions and addition read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018–24512 Filed 11–7–18; 4:15 pm]
BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P

EXHIBIT B

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9841]

RIN 1545–BN91

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9925–F]

RIN 0938–AT46

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, the interim final rules issued in the **Federal Register** on October 13, 2017 concerning moral exemptions and accommodations regarding coverage of certain preventive services. These rules finalize expanded exemptions to protect moral beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an optional ''accommodation'' process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT:
Jeff Wu at (301) 492–4305 or *marketreform@cms.hhs.gov* for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
Amber Rivers or Matthew Litton at (202) 693–8335 for Employee Benefits Security Administration (EBSA), Department of Labor (DOL).
William Fischer at (202) 317–5500 for Internal Revenue Service, Department of the Treasury.
Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit DOL's website (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of these final rules is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47838), ''Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (the Moral IFC). The rules are necessary to protect sincerely held moral objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their moral beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, which was created by HHS through guidance promulgated by the Health Resources and Services

Administration (HRSA), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules finalize references to these moral exemptions in the previously created accommodation process that permit entities with certain objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's guidelines. The changes to the rules being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Moral Exemptions

These rules finalize exemptions provided in the Moral IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held moral convictions opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's guidelines. As in the Moral IFC, the exemptions include plan sponsors that are nonprofit organization plan sponsors or for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The exemptions also continue to include institutions of higher education in their arrangement of student health insurance coverage; health insurance issuers (but only with respect to plans that are otherwise also exempt under the rules); and objecting individuals with respect to their own coverage, where their health insurance issuer and plan sponsor, as applicable, are willing to provide coverage complying with the individual's moral objection. After considering public comments, the Departments have decided not to extend the moral exemptions to non-federal governmental entities at this time, although individuals receiving employer-sponsored insurance from a governmental entity may use the individual exemption if the other terms of the individual exemption apply, including that their employer is willing to offer them a plan consistent with their moral objection.

In response to public comments, various changes are made to clarify the intended scope of the language in the Moral IFC's exemptions. The prefatory exemption language is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to specify that the exemption for institutions of higher education applies to non-governmental entities. The Departments also modified language describing the moral objection applicable to the exemptions, to specify that the entity objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable) either: Coverage or payments for some or all contraceptive services; or a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The clarification is made to ensure that the HRSA guidelines do not prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. References to Moral Exemptions in Accommodation Regulations and in Regulatory Restatement of Statutory Language

These rules finalize without change the references to the moral exemptions that were inserted by the Moral IFC into the rules that regulatorily restate the statutory language from section 2713(a) and (a)(4) of the Public Health Service Act. Similarly, these rules finalize without change from the Moral IFC references to the moral exemptions that were inserted into the regulations governing the optional accommodation process. These references operationalize the effect of the moral exemptions rule, and they allow contraceptive services to be made available to women if any employers with non-religious moral objections to contraceptive coverage choose to use the optional accommodation process.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and Benefits	Costs
Finalizing insertion of references to moral exemptions into restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	These provisions, finalized without change, are for the purpose of inserting references to the moral exemptions into the regulatory restatement of section 2713(a) and (a)(4) of the Public Health Service Act, which already references the religious exemptions. This operationalizes the moral exemptions in each of the tri-agencies' rules. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.

Provision	Savings and Benefits	Costs
Finalized moral exemptions	The moral exemptions to the contraceptive coverage requirement are finalized with technical changes. Their purpose is to relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their moral beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage in violation of their sincerely held moral beliefs.	We estimate there will be only a small amount of costs for these exemptions, because they will primarily be used by organizations and individuals that do not want contraceptive coverage. To the extent some other employers will use the exemption where there will be transfer costs for women previously receiving contraceptive coverage who will no longer receive that coverage, we expect those costs to be minimal due to the small number of entities expected to use the exemptions with non-religious moral objections. We estimate the transfer costs will amount to $8,760.
Finalizing insertion of references to moral exemptions into optional accommodation regulations.	These provisions, finalized without change, will allow organizations with moral objections to contraceptive coverage on the basis of sincerely held moral convictions to use the accommodation as an optional process. These provisions will allow contraceptive coverage to be made available to women covered by plans of employers that object to contraceptive coverage but do not object to their issuers or third party administrators arranging for such coverage to be provided to persons covered by their plans.	We do not estimate any entities with non-religious moral objections to use the accommodation process at this time.

B. Background

Over many decades, Congress has protected conscientious objections including based on moral convictions in the context of health care and human services, and including health coverage, even as it has sought to promote access to health services.[1] In 2010, Congress enacted the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended PPACA. As amended by HCERA, PPACA is known as the Affordable Care Act (ACA).

The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter ''section 2713(a)(4)''), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women's preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, ''with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported'' by HRSA (the ''Guidelines'').

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.[2] In the same

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their ''religious beliefs or moral convictions''); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any ''health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion for any reason); *Id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions''); *Id.* at Div. E, Sec. 808 (regarding any requirement of ''the provision of contraceptive coverage by health insurance plans'' in the District of Columbia, ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.''); *Id.* at Div. K, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their ''religious or conscientious commitment to offer only natural family planning''); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on ''religious beliefs or moral objections''); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice, now Medicare Advantage, managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on ''conscience'' as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on ''religious beliefs or moral convictions''); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); *see also* 8 U.S.C. 1182(g) (protecting vaccination objections by ''aliens'' due to ''religious beliefs or moral convictions''); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on ''moral or religious convictions''); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their ''religious or moral objection'').

[2] The references in this document to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women's Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to ''Contraceptive Methods and Counseling'' as ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' *https://www.hrsa.gov/womens-guidelines/index.html.* The Guidelines as amended in December 2016 refer, under the header ''Contraception,'' to: ''the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family

time period, the administering agencies—HHS, the Department of Labor, and the Department of the Treasury (collectively, ''the Departments'' [3])—exercised discretion to allow exemptions to those requirements by issuing rulemaking various times, including issuing and finalizing three interim final regulations prior to 2017.[4] In those regulations, the Departments crafted exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Public comments were submitted on various iterations of the regulations issued before 2017, and some of those comments supported expanding the exemptions to include those who oppose the contraceptive coverage mandate for either religious ''or moral'' reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.[5]

During the period when the Departments were publishing and modifying the regulations, organizations and individuals filed dozens of lawsuits challenging the contraceptive coverage requirement and regulations (hereinafter, the ''contraceptive Mandate,'' or the ''Mandate''). Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. For-profit entities with religious objections won various court decisions leading to the Supreme Court's ruling in *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[6] Later, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On May 16, 2016, the Supreme Court issued a per curiam decision, vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments' favor—and remanding the cases ''in light of the substantial clarification and refinement in the positions of the parties'' that had been filed in supplemental briefs. *Zubik* v. *Burwell,* 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would ''allow the parties sufficient time to resolve any outstanding issues between them.'' *Id.*

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations stated that they believe some methods classified by the Food and Drug Administration (FDA) as contraceptives may have an abortifacient effect and, therefore, in their view, are morally equivalent to abortion to which they have a moral objection. Under regulations preceding October 2017, these organizations neither received an exemption from the Mandate nor qualified for the accommodation. For example, March for Life filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, 77 FR 8727, March for Life argued that the Departments' stated interests behind the Mandate were only advanced among women who ''want'' the coverage so as to prevent ''unintended'' pregnancy. March for Life contended that, because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments' interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and, therefore, was arbitrary and capricious in violation of the APA. March for Life further contended that, because the Departments concluded the government's interests were not undermined by exempting houses of worship and integrated auxiliaries (based on the assumption that such entities are relatively more likely than other nonprofits with religious objections to have employees that share their views against certain contraceptives), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and, therefore, violated their right of equal protection under the Due Process Clause.

March for Life's employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violated their rights under RFRA by making it impossible for them to obtain health coverage consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate's requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. *Real*

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planning practices, and sterilization procedures,'' ''contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.,* management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),'' and ''instruction in fertility awareness-based methods, including the lactation amenorrhea method.'' *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[3] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

[4] Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

[5] *See, for example,* Denise M. Burke, Re: file code CMS–9968–P, *Regulations.gov* (posted May 5, 2013), *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115;* Comment, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-54142;* David Sater, Re: CMS–9931–NC: Request for Information, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-54218;* Comment, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

[6] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. *See* 134 S. Ct. at 2774.

Alternatives, Inc. v. *Burwell,* 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims, while not specifically ruling on the APA claim, and issued a permanent injunction against the Departments that is still in place. *March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in *March for Life* is pending and has been stayed since early 2016. In another case, federal district and appellate courts in Pennsylvania disagreed with the reasoning in *March for Life,* and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. *Real Alternatives,* 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in *Real Alternatives* v. *Sec'y of HHS* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. 867 F.3d 338, 367 (3d Cir. 2017) (Jordan, J., dissenting).

The Departments most recently solicited public comments on these issues again in two interim final regulations with request for comments published in the **Federal Register** on October 13, 2017: The regulations (82 FR 47838) (the Moral IFC) that are being finalized with changes here, and the regulations (82 FR 47792) (the Religious IFC) published on the same day as the Moral IFC, which are being finalized with changes in the companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Moral IFC, the Departments explained several reasons why, after exercising our discretion to reevaluate the exemptions and accommodations for the contraceptive Mandate, we sought public comment on whether to protect moral convictions in the Moral IFC and these final rules. The Departments noted that we considered, among other things, Congress's history of providing protections for moral convictions regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); previously submitted public comments; and the extensive litigation over the contraceptive Mandate. The Departments concluded that it was appropriate that HRSA take into account the moral convictions of certain employers, individuals and health insurance issuers where the coverage of contraceptive services is concerned. Comments were requested on the interim final regulations.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Moral IFC, with changes based on comments as indicated herein.[7]

II. Overview of the Final Rules and Public Comments

During the 60-day comment period for the Moral IFC, which closed on December 5, 2017, the Departments received over 54,000 public comment submissions, which are posted to *www.regulations.gov*.[8] Below, the Departments provide an overview of the final rules and address the issues raised in the comments we received.

A. Moral Exemptions and Accommodation in General

These rules expand exemptions to protect certain entities and individuals with moral convictions that oppose contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also make available to exempt organizations the accommodation process, which was previously established in response to some objections of religious organizations, as an optional process for exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.[9]

1. The Departments' Authority To Mandate Coverage or Provide Exemptions

The Departments received conflicting comments on their legal authority to provide exemptions and accommodations to the Mandate. Some commenters agreed that the Departments are legally authorized to provide expanded exemptions and an accommodation for moral convictions, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing moral exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the religious exemptions that existed prior to the 2017 IFCs, but not to protect moral convictions.

The Departments conclude that we are legally authorized to provide the exemption and accommodation for moral convictions set forth in the Moral IFC and these final rules. These rules concern section 2713 of the PHS Act, as incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Where it applies, section 2713(a)(4) requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' guidelines developed by HHS acting through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a

[7] The Department of the Treasury and Internal Revenue Service published proposed and temporary regulations as part of the joint rulemaking of the Moral IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules in these final rules. The Department of the Treasury and Internal Revenue Service are finalizing their regulations.

[8] *See Regulations.gov* at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dktid=CMS-2017-0133* and *https://www.regulations.gov/docketBrowser?rpp=25&so=ASC&sb=postedDate&po=100&D=IRS-2017-0015.* Some of those submissions included form letters or attachments that, while not separately tabulated at regulations.gov, together included comments from, or were signed by, possibly over a hundred thousand separate persons. The Departments reviewed all of the public comments and attachments.

[9] *See, for example,* Family Planning grants in 42 U.S.C. 300, *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS to shape that development, as the administering agency of HRSA, and to all three agencies as the administering agencies of the statutes by which the Guidelines are enforced. *See* 26 U.S.C. 9833; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must ''provide for'' and ''support'' the application of Guidelines that it chooses to adopt. HRSA's authority to support ''comprehensive guidelines'' involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only ''as provided for in comprehensive guidelines supported by [HRSA].'' That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word ''as'' in the phrase ''as provided for,'' it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase ''as you like it.'' [10] When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See for example,* 42 U.S.C. 1395x (''The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.'') (emphasis added). Thus, the inclusion of ''as'' in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has discretion whether to support how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word ''as'' is missing from the other three provisions in section 2713(a) of the PHS Act. Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require ''evidence-based'' or ''evidence-informed'' coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The moral objections at issue here, like the religious objections prompting exemptions dating back to the inception of the Mandate in 2011, may, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive-coverage Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines ''exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,'' and ''it is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.'' *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a mandate that contraceptives be covered or that they be covered without any exemptions or exceptions, lead the Departments to conclude that we are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The Departments' conclusions are consistent with our interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4) to grant broad discretion to decide the extent to which HRSA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments created an exemption to the contraceptive Mandate when that Mandate was announced in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to plan participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrator of self-insured church plans (see 80 FR 41323). Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. In doing so, the Departments have been acting contrary to commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or its incorporation into ERISA and the Code, and who contended instead that the Departments must enforce Guidelines on the broadest spectrum of group health plans as possible, even including churches (see, for example, 2012 final regulations at 77 FR 8726).

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (see for

[10] See As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) (''[u]sed to indicate by comparison the way something happens or is done'').

example, 76 FR 46623). On the contrary, Congress carved out an exemption from section 2713 of the PHS Act (and from several other provisions) for grandfathered plans. In contrast, the grandfathering exemption is not applicable to many of the other provisions in Title I of the ACA—provisions previously referred to by the Departments as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.[11] Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, ''there is no legal requirement that grandfathered plans ever be phased out.'' *Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751, 2764 n.10 (2014).

Some commenters argue that Executive Order 13535's reference to implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions in the Guidelines. The Departments, however, believe that they are acting consistent with Executive Order 13535 by creating exemptions using HRSA's authority under section 2713(a)(4), and the Departments' administrative authority over the implementation of section 2713(a) of the PHS Act. Executive Order 13535, issued upon the signing of the ACA, specified that ''longstanding Federal laws to protect conscience . . . remain intact,'' including laws that protect holders of religious beliefs or moral convictions from certain requirements in health care contexts. Although the text of Executive Order 13535 does not require the expanded exemptions confirmed in these final rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect conscience objections, based on religious beliefs or moral convictions regarding certain health matters, and are consistent with the intent that the ACA be implemented in accordance with the conscience protections set forth in those laws.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities instead of to individuals, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for sincerely held moral convictions in sensitive healthcare contexts.[12] Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held moral convictions to the extent the Departments otherwise impose a contraceptive Mandate. These exemptions do not prohibit any services, nor authorize employers to prohibit employees from obtaining any services. The exemptions in the Moral IFC and these final rules simply refrain from imposing a federal mandate that employers cover contraceptives in their health plans even if they have sincerely held moral convictions against doing so.

Some commenters stated that the Supreme Court ruled that the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but that exemptions beyond those are not. But the Supreme Court did not rule on the question whether the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate unless RFRA prohibits us from doing so.

The appropriateness of including exemptions to protect moral convictions is informed by Congress's long history of providing exemptions for moral convictions, especially in certain health care contexts.

2. Congress's History of Protecting Moral Convictions

The Department received numerous comments about its decision in the Moral IFC to exercise its discretion to provide moral exemptions to, and an accommodation under, the contraceptive Mandate. Some commenters agreed with the Departments' decision in the Moral IFC, arguing that it is appropriate to exercise the Departments' discretion to protect moral convictions in light of Congress's history of protecting moral convictions in various contexts, especially concerning health care. Other commenters disagreed, saying that existing conscience statutes protecting moral convictions do not require these exemptions and, therefore, the exemptions should not be offered. Some commenters stated that because Congress has provided conscience protections, but did not specifically provide them in section 2713(a)(4), conscience protections are inappropriate in the implementation of that section. Still other commenters went further, disagreeing with conscience protections regarding contraceptives, abortions, or health care in general.

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on the most recent statements of Congress, along with nearly 50 years of statutes and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health coverage. Most recently, Congress expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.'' Consolidated Appropriations Act, 2018, Div. E, section 808, Public Law 115–141, 132 Stat. 348, 603 (Mar. 23, 2018); *see also*

[11] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' Henry J Kaiser Family Foundation (Sept. 19, 2017), *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017*.

[12] The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

Consolidated Appropriations Act, 2017, Div. C, section 808, Public Law 115–31 (May 5, 2017). The Departments consider it significant that Congress's most recent statements on the prospect of Government-mandated contraceptive coverage specifically intend that a conscience clause be included to protect moral convictions.

The Departments also consider significant the many statutes listed above, in section I—Background footnote 1, that show Congress's consistent protection of moral convictions alongside religious beliefs in the federal regulation of health care. These include laws such as the Church Amendments (dating back to 1973), which we discuss at length below, to the 2018 Consolidated Appropriations Act discussed above. Notably among those laws, and in addition to the Church Amendments, Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object ''on moral or religious grounds'' to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare + Choice (now Medicare Advantage) managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''). Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions.'' Consolidated Appropriations Act, 2018, Public Law 115–141, Division E, section 726(c); *see also* Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.[13]

The Departments disagree with commenters that suggested we should not consider Congress's history of protecting moral objections in certain health care contexts due to Congress's failure to explicitly include exemptions in section 2713(a)(4) itself. The argument by these commenters proves too much, since Congress also did not specifically require contraceptive coverage in section 2713 of the PHS Act. This argument would also negate not just these expanded exemptions, but the previous exemptions provided for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting moral convictions in the context of certain federal health care requirements.

a. The Church Amendments' Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations because they had received federal funds. These sections of the U.S. Code are known as the Church Amendments, named after their primary sponsor, Senator Frank Church (D-Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions, not just religious beliefs. Among other things, the amendments protect the recipients of certain federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object ''on the basis of religious beliefs or moral convictions,'' and they prohibit recipients of certain federal health funds from discriminating against any personnel ''because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions'' (42 U.S.C. 300a–7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to ''any lawful health service,'' or to ''any part of a health service program.'' (42 U.S.C. 300a–7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute ''any lawful health service'' or a ''part of a health service program.'' As such, the protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court's decision in *Roe* v. *Wade,* 410 U.S. 113 (1973). Although the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens facilitate its exercise. Indeed, *Roe* favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared, ''Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles.'' 410 U.S. at 144 & n.38 (1973). Likewise, in *Roe*'s companion case, *Doe* v. *Bolton,* the Court observed that, under state law, ''a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.'' 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions ''obviously . . . afford appropriate protection.'' *Id.* at 198. As an Arizona court later put it, ''a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'' *Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only *Roe* v. *Wade,* but also an instance where a federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D–IL) rose to ask that the amendment be changed to specify that it also protects objections to abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record records this discussion:

> Mr. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.
>
> One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or

[13] The Departments also note that, in protecting those individual and institutional health care entities that object to certain abortion-related services and activities regardless of the basis for such objection, the Coats-Snowe Amendment, PHS Act section 245 (42 U.S.C. 238n), and the Weldon Amendment, Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141, protect those whose objection is based on moral conviction.

participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.

As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?

Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words ''or moral''?

Mr. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words ''or moral conviction'' were added after ''religious belief.'' I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.

Mr. STEVENSON. The Senator's suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18

As the debate proceeded, Senator Church went on to quote *Doe* v. *Bolton*'s reliance on a Georgia statute that stated ''a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.'' 119 Congr. Rec. S5722 (quoting 410 U.S. at 197–98). Senator Church added, ''I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations.'' *Id.* Considering the scope of the protections, Senator Gaylord Nelson (D–WI) asked whether, ''if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, 'We are not going to bother with this kind of procedure in this hospital,' would the pending amendment permit that?'' 119 Congr. Rec. S5723. Senator Church responded that the amendment would not encompass such an objection. *Id.*

Senator James L. Buckley (C–NY), speaking in support of the amendment, added the following perspective:

Mr. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the recent Supreme Court decisions will likely unleash a series of court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic] [14] to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words ''moral conviction,'' because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. S5723

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R–MA) [15] likewise observed that ''the right of conscience has long been recognized in the parallel situation in which the individual's right to conscientious objector status in our selective service system has been protected'' and ''expanded by the Supreme Court to include moral conviction as well as formal religious belief.'' 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, ''We are concerned here only with the right of moral conscience, which has always been a part of our national tradition.'' *Id.* at 4149.

These first sections of the Church Amendments, codified at 42 U.S.C. 300a–7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions, as well as those who object to such services on the basis of religious beliefs. And, as noted above, subsequent statutes add protections for moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion. *See* 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141.
- Protections for entities and individuals that object to providing or covering contraceptives. *See id.* at Div. E, Sec. 808; *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act); *id.* at Div. K, Title III.
- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives. *See* 42 U.S.C. 290bb–36; 42 U.S.C. 1396a(w)(3); 42 U.S.C. 14406; 42 U.S.C. 18113 (adopted as part of the ACA).

The Departments believe that the intent behind Congress's protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports the Departments' decision in the Moral IFC and these final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

b. Court Precedents Relevant to These Expanded Exemptions

As reflected in the legislative history of the first Church Amendments, the Supreme Court has long afforded protection to moral convictions alongside religious beliefs. Indeed, Senator Church cited *Doe* v. *Bolton,* 410 U.S. 179, as a parallel instance of conscience protection and spoke of the Supreme Court generally giving ''comparable treatment to deeply held moral convictions.'' Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court's protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as *Welsh* v. *United States,* 398 U.S. 333 (1970), which the Supreme Court had decided just three years earlier.

Welsh involved what is perhaps the Government's paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on ''religious training and belief,'' that protection would also extend to avowedly non-religious objections to war held with the same moral strength.

[14] The Senator might have meant ''[forced] . . . against his will.''

[15] Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

Id. at 343. The Court declared, ''[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual 'a place parallel to that filled by . . . God' in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as much entitled to a 'religious' conscientious objector exemption . . . as is someone who derives his conscientious opposition to war from traditional religious convictions.''

In the context of this particular Mandate, it is also worth noting that, in *Hobby Lobby,* Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan's opinion in *Welsh,* 398 U.S. at 357–58, in support of her statement that ''[s]eparating moral convictions from religious beliefs would be of questionable legitimacy.'' 134 S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious beliefs constitute an illegitimate ''separat[ion]'' of moral convictions, nor do the Departments assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress's intent in the Church Amendments and in later federal statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

c. Conscience Protections in Other Federal and State Contexts

The tradition of protecting moral convictions in certain health contexts is not limited to laws passed by Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.[16] Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs in particular circumstances. The Equal Employment Opportunity Commission has consistently protected ''moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views'' alongside religious views under the ''standard [ ] developed in *United States* v. *Seeger,* 380 U.S. 163 (1965) and [*Welsh*].'' 29 CFR 1605.1. The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so ''is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such participation or attendance contrary to medical ethics.'' 28 CFR 26.5.[17]

Forty-five states have health care conscience protections covering objections to abortion; several of these also cover sterilization or contraception.[18] Most of those state laws protect objections based on ''moral,'' ''ethical,'' or ''conscientious'' grounds in addition to ''religious'' grounds. Particularly in the case of abortion, some federal and state conscience laws do not require any specified motive for the objection. 42 U.S.C. 238n; Consolidated Appropriations, 2018, Public Law 115–141, Div. H, section 507(d).

These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts. The contraceptive Mandate implicates that governmental interest. Many persons and entities object to the Mandate in part because they consider some forms of FDA-approved contraceptives to be morally equivalent to abortion due to the possibility that such items may prevent the implantation of a human embryo after fertilization.[19] The Supreme Court, in describing family business owners with religious objections, explained that ''[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions.'' *Hobby Lobby,* 134 S. Ct. at 2751. Based on pleadings in the litigation, all of the litigants challenging the Mandate and asserting purely non-religious objections share this view. And as Congress has implicitly recognized in providing health care conscience protections pertaining to sterilization, contraception, and other health care services and practices, individuals or entities may have additional moral objections to contraception.[20]

d. Founding Principles

The Departments also look to guidance from, and draw support for the Moral IFC and these final rules from, the broader history of respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. In supporting the protection of conscience based on non-religious moral convictions, Senator Buckley declared ''[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.'' Representative Heckler similarly stated that ''the right of moral conscience . . . has always been a part of our national tradition.'' This tradition is reflected, for example, in a letter President George Washington wrote saying that ''[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: A policy worthy of imitation. All possess alike liberty of conscience and immunities of

[16] *See, for example,* 42 CFR 422.206 (declaring that the general Medicare Advantage rule ''does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds.''); 42 CFR 438.102 (declaring that information requirements do not apply ''if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds''); 48 CFR 1609.7001 (''health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs.''); 48 CFR 352.270–9 (''Non-Discrimination for Conscience'' clause for organizations receiving HIV or Malaria relief funds).

[17] *See also* 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA's request will depend in part on ''[c]ultural, religious, or moral objections to the request'').

[18] According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). ''Refusing to Provide Health Services,'' The Guttmacher Institute (June 1, 2017), *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.*

[19] FDA, ''Birth Control,'' U.S. Food and Drug Administration (Mar. 6, 2018), *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm* (various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization, but ''may also work . . . by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization).

[20] *See supra* note 1.

citizenship.'' [21] Thomas Jefferson similarly declared that ''[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority.'' [22] Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience ''the most sacred of all property,'' and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that ''the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed.'' [23]

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context, and the Departments do not suggest that the specific protections offered in the Moral IFC and these final rules would be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These final rules do not address in any way how the Government would balance its interests with respect to other health services not encompassed by the contraceptive Mandate.[24] Instead, the Departments highlight this tradition of respect for conscience from the Nation's Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4), while protecting conscience in the exercise of moral convictions. The Departments believe that these final rules are consistent both with the American tradition of respect for conscience and with Congress's history of providing conscience protections in the kinds of health care matters involved in this Mandate.

e. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in these expanded exemptions and accommodation in these final rules, is consistent with recent executive orders. President Trump's Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for ''religious'' beliefs, but for ''conscience.'' We interpret that term to include both religious beliefs and moral convictions. Moreover, President Trump's first Executive Order, E.O. 13765, declared that ''the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' The exemption and accommodation adopted in these final rules relieves a regulatory burden imposed on entities with moral convictions opposed to providing certain contraceptive coverage and is therefore consistent with both Executive Orders.

f. Litigation Concerning the Mandate

The Departments have further taken into consideration the litigation surrounding the Mandate in exercising their discretion to adopt the exemption in these final rules. Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. *See March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court affirmed a district court ruling that allows the previous regulations to be imposed in a way that affects the moral convictions of a small nonprofit pro-life organization and its employees. *See Real Alternatives* v. *Sec'y, Dep't of Health & Human Servs.,* 867 F.3d 338 (3d Cir. 2017). The Departments' litigation of these cases has thus led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations, issuers, third party administrators, and employees and beneficiaries. The organizations that have sued seeking a moral exemption have adopted longstanding moral tenets opposed to certain FDA-approved contraceptives, and hire only employees who share this view. As a result, it is reasonable to conclude that employees of these organizations would not benefit from the Mandate. Thus, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, as well as the legal requirement to comply with permanent injunctive relief currently imposed in *March for Life,* provide substantial reasons for the Departments to protect moral convictions through these final rules. Although, as discussed below, the Departments assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, the Departments know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, the Departments consider it appropriate to issue the protections set forth in these final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so the Departments, too, believe that ''our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government'' in this situation. *See* 119 Congr. Rec. S5717–18.

The litigation concerning the Mandate has also underscored how important it is for the Government to tread carefully when engaging in regulation concerning sensitive health care areas. As demonstrated by the litigation, as well as the public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that certain contraceptive items may cause early abortions. Providing conscience protections advances the ACA's goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in *Hobby Lobby* declared that, if HHS requires owners of businesses to

[21] Letter from George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790) (available at *https://founders.archives.gov/documents/Washington/05-06-02-0135*).

[22] Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809) (available at *https://founders.archives.gov/documents/Jefferson/99-01-02-9714*).

[23] James Madison, ''Essay on Property'' (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

[24] As the Supreme Court stated in *Hobby Lobby,* the Court's decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer's religious beliefs. Nor does the Court's opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

cover procedures that the owners ''could not in good conscience'' cover, such as abortion, ''HHS would effectively exclude these people from full participation in the economic life of the Nation.'' 134 S. Ct. at 2783. That sort of outcome is one the Departments wish to avoid. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) in a way that respects the moral convictions of Americans so that they are freer to engage in ''full participation in the economic life of the Nation.'' The exemptions in these final rules do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

3. Whether Moral Exemptions Should Exist, and Whom They Should Cover

As noted above, the Department received comments expressing diverse views as to whether exemptions based on moral convictions should exist and, if so, whom they should cover.

Some commenters supported the expanded exemptions and accommodation in the Moral IFC, and the choice of entities and individuals to which they applied. They stated the expanded exemptions and accommodation would be an appropriate exercise of discretion and would be consistent with moral exemptions Congress has provided in many similar contexts. Similarly, commenters stated that the accommodation would be an inadequate means to resolve moral objections and that the expanded exemptions are needed. They contended that the accommodation process was objectionable because it was another method of complying with the Mandate, its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and the coverage for contraceptive services ''hijacked'' or flowed in connection with the objecting organizations' health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to moral objections that organizations would not have with an expanded exemption. Commenters also stated that, with respect to non-profit organizations that have moral objections and only hire persons who agree with those objections, the Mandate serves no legitimate government interest because the mandated coverage is neither wanted nor used and, therefore, would yield no benefits—it would only suppress the existence of non-profit organizations holding those views.

Several other commenters stated that the exemptions were still too narrow. They asked that the exemptions set forth in these final rules be as broad as the exemptions set forth in the Religious IFC concerning sincerely held religious beliefs. Some of these commenters also asked that HHS withdraw its Mandate of contraceptive coverage from the Guidelines entirely. They contended that fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of a preventive health service; that contraceptives can pose medical risks for women; and that studies do not show that contraceptive programs reduce abortion rates or unintended pregnancies. Some commented that many women report that they sought an abortion because their contraception failed. Some other commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacient and, therefore, violate federal conscience protections such as the Weldon Amendment, Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, § 507(d).

Other commenters contended that the exemptions in the Moral IFC were too broad. Some of these commenters expressed concern about the prospect of publicly traded for-profit entities also being afforded a moral exemption. One such commenter commented that allowing publicly traded for-profit entities a moral exemption could cause instability and confusion, as leadership changes at such a corporation may effectively change the corporation's eligibility for a moral exemption. Still others stated that the Departments should not exempt various kinds of entities such as businesses, issuers, or nonprofit entities, arguing that only individuals, not entities, can possess moral convictions. Some commenters were concerned that providing moral exemptions would contribute to population growth and related societal woes. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318), which did not encompass moral convictions. Other commenters stated that the Departments should not provide exemptions, but merely an accommodation process, to resolve moral objections to the Mandate.

Some commenters objected to providing any exemption or accommodation for moral objections at all. Some of these commenters contended that even the previous regulations allowing an exemption and accommodation were too broad and that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible. Other commenters did not go that far, but rejected the idea of exemptions or an accommodation based on moral convictions, contending that such exemptions or accommodation would contribute to population growth and related social woes. Some of these commenters also contended that the exemption in the Moral IFC would constitute an exemption covering every business and non-profit organization.

After considering these comments, and although the previous Administration declined to afford any exemption based on moral convictions, the Departments have concluded that it is appropriate to provide moral exemptions and access to the accommodation, as set forth in these final rules. Congress did not mandate contraceptive coverage, nor provide any explicit guidance about incorporating conscience exemptions into the Guidelines. But as noted above, it is a long-standing Congressional practice to provide consistent exemptions for both religious beliefs and moral convictions in many federal statutes in the health care context, and specifically concerning issues such as abortion, sterilization, and contraception. It is not clear to the Departments that, if Congress had expressly mandated contraceptive coverage in the ACA, it would have done so without providing for similar exemptions. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive Mandate by the exercise of agency discretion, that we also include an exemption for the protection of moral convictions in certain cases. The exemptions finalized in these final rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. As noted above, the Departments consider the exemptions in these final rules consistent with the intent of Executive Order 13535. The Departments also wish to avoid the stark disparity that may result from respecting religious objections to providing contraceptive coverage among certain entities and individuals, but not respecting parallel objections for moral convictions possessed by any entities and

individuals at all because those objections are not specifically religious.

In addition, the Departments note that a significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[25] Although the practice of states is by no means a limit on the discretion delegated to HRSA by the ACA, nor a statement about what the Federal Government may do consistent with other limitations in federal law, such state practices can inform the Departments' view that it is appropriate to provide conscience protections when exercising agency discretion.

The Departments decline to use these final rules to remove the contraceptive Mandate altogether, such as by declaring that HHS acting through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). HRSA's Guidelines were not issued, ratified, or updated through the regulations that preceded the Moral IFC and these final rules. Those Guidelines were issued in separate processes in 2011 and 2016, directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The regulations preceding these final rules attempted only to restate the statutory language of section 2713 in regulatory form, and delineate what exemptions and accommodations would apply if HRSA listed contraceptives in its Guidelines. We decline to use these final rules to direct the separate process that HRSA uses to determine what specific services are listed in the Guidelines generally. Some commenters stated that if contraceptives are not removed from the Guidelines entirely, entities or individuals with moral objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in these rules include a broad range of entities and individuals of whom we have notice may object based on moral convictions. The Departments are not aware of specific employers or individuals whose moral convictions would still be violated by compliance with the Mandate after the issuance of the Moral IFC and these final rules.

Some commenters stated that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions. Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These final rules focus on what moral exemptions and accommodation shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacient.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content and process of developing and updating the Guidelines, are welcome to communicate their views to HRSA, at *wellwomancare@hrsa.gov.*

The Departments also conclude that it would be inadequate to merely attempt to amend or expand the accommodation process to account for moral objectors, instead of providing the exemptions. In the past, the Departments stated in our regulations and court briefs that the previous accommodation required contraceptive coverage in a way that is ''seamless'' with the coverage provided by the objecting employer. As a result, in significant respects, the accommodation process did not actually accommodate the objections of many entities, as indicated by many entities with religious objections. The Departments have attempted to identify an accommodation that would eliminate the religious plaintiffs' objections, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but stated in January 2017 that we were unable to develop such an approach at that time.[26] Just as the Departments continue to believe merely amending the accommodation process would not adequately address religious objections to compliance with the Mandate, we do not believe doing so would adequately address similar moral objections. Furthermore, the few litigants raising non-religious moral objections have been non-profit organizations that assert they only hire persons who share the employers' objection to contraceptive coverage. Consequently, the Departments conclude that the most appropriate approach to resolve these concerns is to provide the exemptions set forth in the Moral IFC and these final rules. These final rules also finalize the modifications to the accommodation process to make it available to entities with moral objections, without forcing such entities to choose between compliance with either the Mandate or the accommodation.

Some commenters expressed concern over the lack of a definition of ''moral convictions'' in the Moral IFC, arguing that, without a definition, any objection could be encompassed by the exemptions even if it is not based on moral convictions. The Departments did not adopt a regulatory definition of ''moral convictions'' in the Moral IFC, and have decided not to adopt such a definition in response to public comments at this time. Nevertheless, the Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in the Moral IFC and these final rules. Neither these final rules or the Moral IFC, nor the Church Amendments or other Federal health care conscience statutes, define ''moral convictions'' (nor do they define ''religious beliefs''). But in issuing these final rules, we adopt the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as *Welsh* to support the addition of language protecting moral convictions. In protecting moral convictions in parallel to religious beliefs, *Welsh* describes moral convictions warranting such protection as ones: (1) That the ''individual deeply and sincerely holds''; (2) ''that are purely ethical or moral in source and content''; (3) ''but that nevertheless impose upon him a duty''; (4) and that ''certainly occupy in the life of that individual a place parallel to that filled by . . . God' in traditionally religious persons,'' such

[25] *See* ''Insurance Coverage of Contraceptives,'' The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

[26] *See* Departments of Labor, Health and Human Services, and the Treasury, FAQs About Affordable Care Act Implementation Part 36, (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

that one could say ''his beliefs function as a religion in his life.'' 398 U.S. at 339–40. As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises ''capriciously.'' Instead, along with the requirement that protected moral convictions must be ''sincerely held,'' this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

While moral convictions are the sort of principles that, in the life of an individual, occupy a place parallel to religion, sincerely held moral convictions can also be adopted by corporate bodies, not merely by individuals. Senators Church and Nelson, while discussing the fact that opposition to abortion or sterilization on the basis of ''moral questions'' does not include capricious opposition to abortion for no reason at all, were specifically talking about opposition to abortion by corporate entities: A ''hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise.'' [27] Corporate bodies operate by the decision-making actions of individuals. Thus, if individuals act in the governance of a corporate body so as to adopt a position for that body of adopting moral convictions against coverage of contraceptives, such an entity can be considered to have an objection to contraceptive coverage on the basis of sincerely held moral convictions.

4. The Departments' Rebalancing of Government Interests

The Departments also received comments on their rebalancing of interests as expressed and referenced in the Moral IFC. Some public commenters agreed with the Departments' conclusion that our interest in ensuring contraceptive coverage does not preclude the Departments from offering exemptions and an accommodation for entities, plans, and individuals with a qualifying objection to contraceptive coverage based on moral convictions. Some public commenters pointed out that protecting moral convictions serves to respect not only the interests of certain persons to access contraceptives, but also the interests of other persons to participate in a health coverage market consistent with their moral convictions. Other commenters disagreed with this rebalancing, and contended that the interest of women in receiving contraceptive coverage without cost-sharing is so great that it overrides private interests to the contrary, such that the government should or must force private entities to provide this coverage to other private citizens.

The Departments agree with the commenters who stated that the governmental interest in requiring contraceptive coverage does not override the interest in protecting moral convictions and does not make these expanded exemptions inappropriate. For additional discussion of the Government's balance of interests as applicable to religious beliefs, see section II.C.2.b. of the companion final rules concerning religious exemptions published by the Departments contemporaneously with these final rules elsewhere in today's **Federal Register**. There, and in the Religious and Moral IFCs, the Departments acknowledged the reasons why the Departments have changed the policies and interpretations previously adopted with respect to the Mandate and the governmental interests underlying it. For parallel reasons, the Departments believe the Government's legitimate interests in providing for contraceptive coverage do not require the Departments to violate sincerely held moral convictions while implementing the Guidelines. The Departments likewise believe Congress did not set forth interests that require us to violate sincerely held moral convictions if we otherwise require contraceptive coverage in our discretionary implementation of the women's preventive services Guidelines under section 2713(a)(4).

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4), added to the PHS Act in 2010. The Departments' expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after considering public comments on various sides of the issue, and reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant federal law, the Departments have determined that affording the exemptions to protect moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to invoke these exemptions and accommodation may be small, the Departments believe that it is important to provide such protection, given the long-standing recognition of such protections in law and regulation in the health care and health insurance contexts. The Moral IFC and these final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, including through such programs as Medicaid and Title X. The Departments also note that the exemptions created here, like the exemptions created by the previous Administration, do not burden third parties to a degree that counsels against providing the exemptions, as discussed below.

5. Burdens on Third Parties

The Department received a variety of comments about the effect that the exemptions and accommodation based on moral convictions would have on third parties. Some commenters stated that the exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might otherwise receive contraceptive coverage with no cost sharing. Other commenters disagreed, asserting that the exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more

[27] Nor was this recognition of the need to protect organizations that object to performance of certain health care procedures on the basis of moral conviction limited to the Church Amendments' legislative history. The first of the Church Amendments provides, in part, that the receipt of certain federal funds ''by any individual or entity does not authorize any court or any public official or other public authority to require— . . . (2) such entity to—(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or (B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.'' 42 U.S.C. 300a–7(b).

unintended pregnancies,[28] births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as prioritizing conscientious objection of exempted entities over the conscience, choices, or religious liberty of women who would not receive contraceptive coverage where an exemption is used. Some commenters disagreed and said the exemptions do not violate laws and constitutional protections, nor do they inappropriately prioritize the conscience of exempted entities over those of third parties.

The Departments note that the exemptions in the Moral IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. Agency discretion was exercised to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties whom the government chooses not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: That the government has an obligation to force private parties to benefit those third parties, and that the third parties have a right to those benefits. Congress did not create a right to receive contraceptive coverage from other private citizens through section 2713 of the PHS Act, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to which they morally object, to benefit other private parties, does not prevent the government from relieving some or all of the burden of that Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Moral IFC and these final rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through the grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris* v. *McRae,* 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the government refrain from requiring private citizens, in violation of their moral convictions, to cover contraception for other citizens. *Cf. Rust* v. *Sullivan,* 500 U.S. 173, 192–93 (1991) (''A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.''). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting moral objections to such governmental mandates, especially where, as here, the Mandate is not an explicit statutory requirement.[29] The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these rules.

Some commenters objected that the exemptions would violate the Establishment Clause of the First Amendment. The Moral IFC and these final rules create exemptions for moral convictions, not religious beliefs, and they do so for the same neutral purposes for which Congress has created similar exemptions for over four decades. Not only do these final rules not violate the Establishment Clause, but the Departments' decision to provide the exemptions and accommodation for moral convictions, instead of limiting the exemptions to identical objections based on religious beliefs, further demonstrates that neither the purpose nor the effect of these exemptions is to establish religion. The Establishment Clause does not force the Department to impose a contraceptive Mandate in violation of the moral convictions of entities and individuals protected by these rules.

American governmental bodies have, in many instances, refrained from requiring certain private parties to cover contraceptive services for other private parties. From 1789 through 2012 (when HRSA's Guidelines went into effect), there was no federal women's preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA's Guidelines, and it did not require any preventive services required under section 2713 of the PHS Act to be covered by grandfathered plans. Many states do not impose contraceptive coverage mandates, or they offer religious, and in some cases moral, exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or state courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. The Departments are not aware of federal courts declaring that the exemptions, safe harbor, or accommodations gave rise to third party burdens that required the government to mandate contraceptive coverage by entities eligible for an exemption or accommodation. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including

[28] Some commenters attempted to quantify the costs of unintended pregnancy, but were unable to provide estimates with regard to the number of women that this exemption may affect.

[29] *See, for example, Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (''[A] woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'').

under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters stated that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others commenters stated that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. Until 2012, there was no federal mandate of contraceptive coverage across health insurance and health plans nationwide. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to state or local governments. The various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage, have not been deemed to cause a cognizable injury to state or local governments. The Departments find no legal prohibition on finalizing these final rules based on the allegation of an impact on state or local governments, and disagree with the suggestion that once having exercised our discretion to deny exemptions—no matter how recently or incompletely—the Departments cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, the exemptions at issue here are available only to a tiny fraction of entities to which the Mandate would otherwise apply—those with qualifying moral objections. Public comments did not provide reliable data on how many entities would use these expanded moral exemptions, in which states women in those plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would potentially have to cover. As noted below, at least one study [30] has concluded the Mandate caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates. In addition, the only entities that have brought suit based on their moral objections to the Mandate are non-profit entities that have said they only hire persons who share their objections and do not use the contraceptives to which their employers object, so it is unlikely that exemptions for those entities would have any impact on safety net programs. Below, we predict that a small number of additional nonprofit and closely held for-profit entities will use the exemptions based on moral convictions. In light of the limited evidence of third party or state and local government impact of these final rules, the Departments consider it an appropriate policy option to provide the exemptions.

Some commenters contended that the exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead, they allow entities that have sincerely held moral objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

Those commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these final rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not in its capacity as an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.,* 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII ''does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women''). Second, these rules create no disparate impact. The women's preventive service mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inure to the specific benefit of women—men are denied any benefit from section 2713(a)(4). Both before and after these rules are in effect, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions encompass moral objections. The previous rules, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship and integrated auxiliaries, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby*'s holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women

[30] M.L. Kavanaugh et al., ''Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,'', 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters stated that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some commenters objected that the Moral IFC's estimate of a $584 yearly cost of contraceptives for women was too low. But some of those same commenters provided similar estimates, citing sources claiming that birth control pills can cost up to $600 per year, and stated that IUDs, which can last 3 to 6 years or more,[31] can cost $1,100 (that is, less than $50 per month over the duration of use). Some commenters stated that, for lower income women, contraceptives and related education and counseling can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately covered individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member, and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, emphasizing that income and eligibility thresholds could prevent some women from receiving contraceptives through certain government programs if they were no longer covered in their group health plans or health insurance plans.

The Departments do not believe that such differences make it inappropriate to issue the expanded exemptions set forth in these rules. As explained more fully below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. Moreover, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed rule to amend the regulations governing its Title X family planning program. The proposed rule would amend the definition of ''low income family''—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions. (83 FR 25502). If that rule is finalized as proposed, it would further reduce any potential effect of these final rules on women's access to contraceptives.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS ''shall not promulgate any regulation'' that ''creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,'' ''impedes timely access to health care services,'' ''interferes with communications regarding a full range of treatment options between the patient and the provider,'' ''restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,'' ''violates the principles of informed consent and the ethical standards of health care professionals,'' or ''limits the availability of health care treatment for the full duration of a patient's medical needs.'' 42 U.S.C. 18114. Such commenters urged, for example, that the Moral IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554 of the ACA. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections; multiple courts considered those regulations; and while many ruled that entities did not need to provide contraceptive coverage, none ruled that the exemptions or accommodations in the regulations violated section 1554 of the ACA. Moreover, the decision not to impose a governmental mandate is not the creation of a ''barrier,'' especially when that mandate requires private citizens to provide services to other private citizens. This would turn the assumptions of the United States' system of government on its head. *See, for example,* U.S. Constitution, Ninth Amendment. Section 1554 of the ACA likewise does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 of the ACA prohibit the Departments from providing exemptions to relieve burdens on moral convictions, or as is the case here, from refraining to impose the Mandate in cases where moral convictions would be burdened by the Mandate. Moral exemptions from federal mandates in certain health contexts, including sterilization, contraception, or items believed to be abortifacient, have existed in federal laws for decades. Some of those laws were referenced by President Obama in signing Executive Order 13535. In light of that Executive Order and Congress's long history of providing exemptions for moral convictions in the health context, providing moral exemptions is a reasonable administrative response to this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts.

In short, we do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered, or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

In summary, members of the public have widely divergent views on whether the exemptions in the Moral IFC and these final rules are good public policy. Some commenters stated that the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind the exemption, and arguing that the exemption would not interfere with the physician-patient relationship. The Departments have determined that these final rules are an appropriate exercise of public policy discretion. Because of the importance of the moral convictions being accommodated, the limited impact of these final rules, and uncertainty about

[31] *See, for example,* ''IUD,'' Planned Parenthood, *https://www.plannedparenthood.org/learn/birth-control/iud.*

the impact of the Mandate overall according to some studies, the Departments do not believe these final rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

6. Interim Final Rulemaking

The Departments received several comments about the decision to issue the Moral IFC as interim final rules with request for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Moral IFC in that way, agreeing with the Departments that there was explicit statutory authority to do so, good cause under the APA, or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe authority existed to issue the Moral IFC as interim final rules. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of that Act, and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Moral IFC, the Departments issued three interim final regulations implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Moral IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Moral IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules were issued after receiving and thoroughly considering public comments as requested in the Moral IFC. These final rules therefore comply with the APA's notice and comment requirements.

7. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause, or are associated with, an increased risk of depression,[32] venous thromboembolic disease,[33] fatal pulmonary embolism,[34] thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),[35] hypertension,[36] HIV–1 acquisition and transmission,[37] and breast, cervical, and liver cancers.[38] Some commenters also stated that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that it is not the case that contraceptive access reduces unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated

[32] Commenters cited Charlotte Wessel Skovlund, et al., ''Association of Hormonal Contraception with Depression,'' *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) (''Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression, suggesting depression as a potential adverse effect of hormonal contraceptive use.'').

[33] Commenters cited the Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception: Recent Advances and Controversies,'' 82 *Fertility and Sterility* S26, S30 (2004); V.A. Van Hylckama et al., ''The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study,'' 339 *Brit. Med. J.* b2921 (2009); Y. Vinogradova et al., ''Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases,'' 350 *Brit. Med. J.* h2135 (2015) (''Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year.''); Ø. Lidegaard et al., ''Hormonal contraception and risk of venous thromboembolism: national follow-up study,'' 339 *Brit. Med. J.* b2890 (2009): M. de Bastos et al., ''Combined oral contraceptives: venous thrombosis,'' Cochrane Database Syst. Rev., Mar. 3, 2014. doi: 10.1002/14651858.CD010813.pub2, available at *https://www.ncbi.nlm.nih.gov/pubmed?term=24590565;* L.J. Havrilesky et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* and Robert A. Hatcher et al., *Contraceptive Technology,* 405–07 (Ardent Media 18th rev. ed. 2004).

[34] Commenters cited N.R. Poulter, ''Risk of Fatal Pulmonary Embolism with Oral Contraceptives,'' 355 *Lancet* 2088 (2000).

[35] Commenters cited Ø. Lidegaard et al., ''Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception, 366 *N. Engl. J. Med.* 2257, 2257 (2012) (risks ''increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 μg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 μg''); Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception''; M. Vessey et al., ''Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking,'' 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, ''Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study,'' 349 *Lancet* 1202, 1202–09 (1997); K.M. Curtis et al., ''Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review,'' 73 Contraception 179, 179–188 (2006); L.A. Gillum et al., ''Ischemic stroke risk with oral contraceptives: A meta analysis,'' 284 *JAMA* 72, 72–78 (2000), available at *https://www.ncbi.nlm.nih.gov/pubmed/10872016;* and Robert A. Hatcher et al., *Contraceptive Technology,* 404–05, 445 (Ardent Media 18th rev. ed. 2004).

[36] Commenters cited Robert A. Hatcher et al., *Contraceptive Technology,* 407, 445 (Ardent Media 18th rev. ed. 2004).

[37] Commenters cited Renee Heffron et al., ''Use of Hormonal Contraceptives and Risk of HIV–1 Transmission: A Prospective Cohort Study,'' 12 *Lancet Infectious Diseases* 19, 24 (2012) (''Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV–1 acquisition by women and HIV–1 transmission from women to men.''); and ''Hormonal Contraception Doubles HIV Risk, Study Suggests,'' *Science Daily* (Oct. 4, 2011), *https://www.sciencedaily.com/releases/2011/10/111003195253.htm.*

[38] Commenters cited ''Oral Contraceptives and Cancer Risk,'' National Cancer Institute (Mar. 21, 2012), *https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet;* L.J Havrilesky et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* S. N. Bhupathiraju et al., ''Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study,'' 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, ''Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment,'' (Sept. 2005), available at *http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf;* and the American Cancer Society, ''Known and Probably Human Carcinogens,'' American Cancer Society (rev. Nov. 3, 2016), *https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html.*

with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 Report of the Institute of Medicine (IOM), ''Clinical Preventive Services for Women: Closing the Gaps,'' in its discussion of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality. Commenters also stated that studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer, and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.[39] Some commenters stated that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters stated that, in the Moral IFC, the Departments relied on incorrect statements concerning scientific studies. For example, some commenters stated that there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Departments for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR 47804, the 2013 Agency for Healthcare Research and Quality study, and other sources, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to consider these studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,[40] the purpose for the Departments' reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some commenters agreed with the quotation, in the Moral IFC, of FDA materials [41] that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Moral IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Moral IFC that some persons believe those possible effects are ''abortifacient.''

This objection on this issue appears to be partially one of semantics. People disagree about whether to define ''conception'' or ''pregnancy'' to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items ''abortifacient''—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother's body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby,* 134 U.S. at 2765 (''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.'').

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere moral objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of an objection based on sincerely held religious belief under RFRA.[42] Several litigants have separately raised non-religious moral objections to contraceptive coverage based on the same basic rationale. Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA's statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer moral exemptions with respect to this Mandate.

The Departments also received comments about their discussion, located in the Religious IFC but partly relied upon in the Moral IFC, concerning uncertainty about the effects the Mandate's expanded exemptions might have on teen sexual activity. In this respect, the Departments stated, ''With respect to teens, the Santelli and Melnikas study cited by IOM 2011

[39] To the extent that contraceptives are prescribed to treat health conditions, and not for preventive purposes, the Mandate would not be applicable.

[40] 82 FR at 47803–04.

[41] FDA's guide ''Birth Control'' specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and ''may also work . . . by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

[42] ''Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You.'' *Hobby Lobby,* 134 S. Ct. at 2762–63. ''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.'' *Id.* at 2765–66.

observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that '[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.' '' [43] Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that limiting the exemptions to the Mandate to those that existed prior to the Religious and Moral IFCs is not tailored towards advancing the Government's interests in reducing teen pregnancy. Instead they suggested there are means of reducing teen pregnancy that are less burdensome on conscientious objections.[44] Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.[45]

Many commenters opposing the moral exemptions misunderstood the Departments' discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, the Departments note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general make it difficult to establish causation between exemptions to the contraceptive Mandate, and an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including, but not limited to, reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline). It concluded that ''that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.'' [46] One study found that, during the teen pregnancy decline between 2007 through 2012, teen sexual activity was also decreasing.[47] One study concluded that falling unemployment rates in the 1990s accounted for 85 percent of the decrease in rates of first births among 18 to 19 year-old African Americans.[48] Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.[49] One study concluded that an ''increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.'' [50] Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.[51] Some commenters also cited studies—which are not limited to the issue of teen pregnancy—that have found that many women who have abortions report that they were using contraceptives when they became pregnant.[52]

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of public comments has reinforced the Departments' view that the uncertainty surrounding these weighty and important issues makes it appropriate to provide the moral exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing moral exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments to implement the ACA.

8. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promoted the health and equality of women, especially low income women, and promoted female participation and

[43] Citing J.S. Santelli & A.J. Melnikas, ''Teen fertility in transition: recent and historic trends in the United States,'' 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at *http://public.econ.duke.edu/~psarcidi/addicted13.pdf. See also* K. Buckles & D. Hungerman, ''The Incidental Fertility Effects of School Condom Distribution Programs,'' *Nat'l Bureau of Econ. Research* Working Paper No. 22322 (June 2016), available at *http://www.nber.org/papers/w22322* (''access to condoms in schools increases teen fertility by about 10 percent'' and increased sexually transmitted infections).

[44] *See* Helen Alvaré, ''No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom,'' 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[45] *See, e.g.,* Lindberg L., Santelli J., ''Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,'' 59 *J. Adolescent Health* 577–83 (Nov. 2016), *https://doi.org/10.1016/j.jadohealth.2016.06.024; see also* Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, *www.regulations.gov* (discussing teen pregnancy data from Colorado).

[46] Kearney MS and Levine PB, ''Investigating recent trends in the U.S. birth rate,'' 41 *J. Health Econ.* 15–29 (2015), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041.*

[47] *See, e.g.,* K. Ethier et al., ''Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,'' 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at *http://dx.doi.org/10.15585/mmwr.mm665152a1* (''Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall . . . .'').

[48] Colen CG, Geronimus AT, and Phipps MG, ''Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,'' 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at *https://www.sciencedirect.com/science/article/pii/S027795360600205X.*

[49] Atkins DN and Wilkins VM, ''Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,'' 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at *https://academic.oup.com/jpart/article-abstract/23/4/771/963674.*

[50] E. Collins & B. Herchbein, ''The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,'' *U. Mich. Pop. Studies Ctr.* Report 11–737 (May 2011), available at *https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf* (''[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women'').

[51] *See* D. Paton & L. Wright, ''The effect of spending cuts on teen pregnancy,'' 54 *J. Health Econ.* 135, 135–46 (2017), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551* (''Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates'').

[52] Commenters cited, for example, Guttmacher Institute, ''Fact Sheet: Induced Abortion in the United States'' (Jan. 2018) (''Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant''), available at *https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.*

equality in the workforce. Other commenters contended there was insufficient evidence showing that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence to show that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed a study published and revised by the Guttmacher Institute in October 2017, concluding that ''[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy.'' [53] This timeframe includes the first two years of the contraceptive Mandate's implementation. Despite some changes in the use of various methods of contraceptives, the study concluded that, ''[f]or the most part, women are changing method type within the group of most or moderately effective methods and not shifting from less effective to more effective methods.'' Regarding the effect of this Mandate in particular, the authors concluded that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.'' The authors observed that other ''[s]tudies have produced mixed evidence regarding the relationship between the implementation of the ACA and contraceptive use patterns.'' In explaining some possible reasons or no clear effect on contraceptive use, the authors suggested that ''existence of these safety net programs [publicly funded family planning centers and Medicaid] may have dampened any impact that the ACA could have had on contraceptive use,'' ''cost is not the only barrier to accessing a full range of method options,'' and ''access to affordable and/or free contraception made possible through programs such as Title X'' may have led to income not being associated with the use of most contraceptive methods.[54] In addition, commenters noted that in the 29 states where contraceptive coverage mandates have been imposed statewide,[55] those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[56]

Other commenters, however, disputed the significance of these state statistics, noting that, of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the exemption in these rules might have on the Mandate more broadly. The state mandates of contraceptive coverage still apply to a very large number of plans and plan participants notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups were already exempt from the federal Mandate prior to the 2017 Religious and Moral IFCs. The exemptions as set forth in the Moral IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might result from the contraceptive Mandate here.

Some commenters took a view that appears to disagree with the assertion in the 2017 Guttmacher study, that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.'' These commenters instead observed that, under the Mandate, more women have coverage of contraceptives and contraception counseling and that more contraceptives are provided without co-pays than before. Still others argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA [57] and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also stated that studies show that decreases in unintended pregnancies are due to broader access to contraceptives. Finally, some commenters also stated that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on that review, it is not clear that merely offering the exemption in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from contraceptive access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, the Departments

[53] M.L. Kavanaugh et al., ''Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,'' 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

[54] Id.

[55] See Guttmacher Institute, ''Insurance Coverage of Contraceptives'' (June 11, 2018); ''State Requirements for Insurance Coverage of Contraceptives,'' Henry J. Kaiser Family Foundation (Jan. 1, 2018), *https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[56] *See* Michael J. New, ''Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,'' 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

[57] Citing, for example, Adelle Simmons et al., ''The Affordable Care Act: Promoting Better Health for Women,'' Table 1, ASPE (June 14, 2016), *https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf.*

conclude that the Moral IFC and these final rules—which merely withdraw the Mandate's requirement from what appears to be a small number of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. The Departments also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, an appropriate exercise of the Departments' discretion.

Moreover, the Departments conclude that the best way to balance the various policy interests at stake in the Moral IFC and these final rules is to provide the exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules provide tangible conscience protections for moral convictions, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a burden on their moral convictions. The Departments view the provision of those protections to preserve conscience in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for moral convictions set forth in the Moral IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

9. Other General Comments

Some commenters expressed the view that the exemptions afforded in the Moral IFC and herein violate the RFRA rights of women who might not receive contraceptive coverage as the result of these final rules, by allowing their employers to impose their moral convictions on them by removing contraceptive coverage through use of the exemption. Still other commenters stated that employer payment of insurance premiums is part of any employee's compensation package, the benefits of which employers should not be able to limit. In the Departments' view, the expanded exemptions in these final rules do not prohibit employers from providing contraceptive coverage. Instead, they lift a government burden that was imposed on some employers to provide contraceptive coverage to their employees in violation of those employers' moral convictions. The Departments do not believe RFRA requires, or has ever required, the federal government to force employers to provide contraceptive coverage. The federal government's decision to exempt some entities from a requirement to provide no-cost-sharing services to private citizens does not constitute a federal government-imposed burden on the latter under RFRA.

Some commenters asked the Departments to discuss the interaction between these rules and state laws that either require contraceptive coverage or provide exemptions from those and other requirements. Some commenters argue that providing the exemptions in these rules would negate state contraceptive requirements or narrower state exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage.

The Departments agree that these rules only concern the applicability of the federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state exemptions. If a plan is exempt under the Moral IFC and these final rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the moral exemption rules to declare whether the federal contraceptive Mandate would still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.[58]

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1).

These final rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with moral objections to cover contraceptives.

Finally, some commenters expressed concern that providing moral exemptions to the mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, section 2713(a)(2) of the PHS Act requires coverage of ''immunizations,'' and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting moral convictions from certain health care mandates concerning issues such as sterilization, abortion and birth control.

B. Text of the Final Rules

In this section, the Departments describe the regulations from the Moral IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments' response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. We also note the regulatory text as it existed prior to the Religious and Moral IFCs, as appropriate. The Departments consider the exemptions finalized here to be an appropriate and permissible policy

[58] Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. In the preamble to the companion final rules concerning religious exemptions published elsewhere in today's **Federal Register**, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these exemptions.

As noted above, various members of the public provided comments that were supportive, or critical, of the regulations overall, or of significant policies pertaining to the regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

1. Restatement of Statutory Requirements of Section 2713(a) and (a)(4) of the PHS Act (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) and (a)(4) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified those restatements to more closely align them with the text of section 2713(a) and (a)(4) of the PHS Act. Those sections cross-reference the other sections of the Departments' rules that provide exemptions to the contraceptive Mandate. After the Religious IFC changed those sections, the Moral IFC inserted, within those cross-references, references to the new § 147.133, which contains the text of the moral exemptions. The insertions correspond to the cross-references to the religious exemptions added by the Religious IFC. The Departments finalize these parts of the Moral IFC without change.

2. Exemption for Objecting Entities Based on Moral Convictions (45 CFR 147.133(a))

The previous regulations contained no exemption concerning moral convictions, as distinct from religious beliefs. Instead, at 45 CFR 147.131(a), they offered an exemption for houses of worship and integrated auxiliaries. In the remaining part of § 147.131, the previous regulations described the accommodation process for organizations with religious objections. The Religious IFC moved the religious exemption to a new section 45 CFR 147.132, and expanded its scope. The Moral IFC created a new section 45 CFR 147.133, providing exemptions for moral convictions similar to, but not exactly the same as, the exemptions for religious beliefs set forth in § 147.132.

The prefatory language of § 147.133(a) not only specifies that certain entities are ''exempt,'' but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women's preventive services coverage only ''as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.'' To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are ''exempt'' by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as ''exempt,'' and in referring to the ''exemption'' encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.133(a) applies to several distinct entities involved in the provision of coverage to an objecting employer's employees. This explanation is consistent with how prior regulations have worked by means of similar language. When § 147.133(a)(1) and (a)(1)(i) specify that ''[a] group health plan,'' ''health insurance coverage provided in connection with a group health plan,'' and ''health insurance coverage offered or arranged by an objecting organization'' are exempt ''to the extent'' of the objections ''as specified in paragraph (a)(2),'' that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815 through 2713(a)(1)(iv) and 29 CFR 2590.715 through 2713(a)(1)(v)), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while a plan sponsor's or arranger's objection removes penalties from that group health plan's issuer, it only does so with respect to that group health plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.133(a)(1)(iii) is included below.

The exemptions in § 147.133(a)(1) apply ''to the extent'' of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters stated it was unclear whether the plans of entities or individuals that morally object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite moral objection to some, but not all, contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules the Departments finalize the prefatory language of § 147.133(a) so that the first sentence of that paragraph states that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, ''to the extent of the objections specified below.'' The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying ''to the extent'' of the objection(s).

The exemptions contained in previous regulations, at § 147.131(a), did not require an exempt entity to submit any particular self-certification or notice, either to the government or to the entity's issuer or third party administrator, in order to obtain or qualify for their exemption. Similarly, under the expanded exemptions in § 147.133, the Moral IFC did not require exempt entities to comply with a self-certification process. We finalize that approach without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan

document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[59] Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported this approach, while others did not. Those in favor suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use their exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process.

After considering the comments, the Departments continue to believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption, although there may have been thousands of houses of worship and integrated auxiliaries covered by the previous exemption and the Departments think it likely that only a small number of entities will use the moral exemption. Adding a self-certification or notice to the exemption would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices are to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement and accountability under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries will know whether their health plan claims a contraceptive Mandate exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these final rules to continue to not require notices or self-certifications for using the exemption.

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these final rules. The exemptions in these final rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. Final rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (In the companion rules concerning religious beliefs published elsewhere in today's **Federal Register**, the Departments discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed in the companion religious final rule published elsewhere in today's **Federal Register**, the Departments have added language from the previous regulations, in § 147.131(f), to protect issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in, and derived from, the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators. The Departments do not believe it necessary to do so in these final rules.

Commenters disagreed about the likely effects of the moral exemptions on the health coverage market. Some commenters stated that expanding the exemptions to encompass moral convictions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans, or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or only some contraceptives—to houses of worship and integrated auxiliaries, and some commenters and litigants said that issuers were doing so. These cases

[59] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b-3(d), and 29 CFR 2590.715–2715. See also 45 CFR 147.200 (requiring disclosure of the ''exceptions, reductions, and limitations of the coverage,'' including group health plans and group & individual issuers).

where plans did not need to comply with the Mandate, and the Departments' previous accommodation process which had the effect of allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.[60]

Concerning the prospect raised by some commenters of different risk pools between men and women, section 2713(a) of the PHS Act itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage will be required. The Moral IFC and these final rules do not require issuers to offer health insurance products that satisfy morally objecting entities, they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to objecting entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

3. Exemption for Certain Plan Sponsors (45 CFR 147.133(a)(1)(i))

The exemption in § 147.133(a)(1)(i) of the Moral IFC covers a group health plan and health insurance coverage for non-governmental plan sponsors that object as specified in paragraph (a)(2), and that are either nonprofit organizations, or are for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The Departments finalize this paragraph without change, and discuss each part of the paragraph in turn.

a. Plan Sponsors in General (45 CFR 147.133(a)(1)(i) Prefatory Text)

Under the plan sponsor exemption in § 147.132(a)(1)(i), the prefatory text in that paragraph specifies that it encompasses group health plans, and health insurance coverage provided in connection with such group health plans, that are sponsored by certain kinds of entities, namely, nonprofit organizations or for-profit entities that have no publicly traded ownership interests.

Such plan sponsors, if they are otherwise nonprofit organizations or for-profit entities that have no publicly traded ownership interests, can include entities that are not employers (for example, a union, or a sponsor of a multiemployer plan), where the plan sponsor objects based on sincerely held moral convictions to coverage of contraceptives or sterilization. Plan sponsors encompassed by the exemption can also include employers, and consistent with the definition of ''employer'' in 29 CFR 2510.3–5, can include association health plans, where the plan sponsor is a nonprofit organization or a for-profit entity that has no publicly traded ownership interests.

Some commenters objected to extending the exemption to plan sponsors that are not single employers, arguing that they could not have the same kind of moral objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite moral objection. The Departments conclude that it is appropriate, where a plan sponsor of a multiemployer plan or multiple employer plan adopts a moral objection using the same procedures that such a plan sponsor might use to make other decisions, to respect that decision by providing an exemption from the Mandate.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.133(a)(1)(i), which instead limits the moral exemptions to ''non-governmental plan sponsors.'' As noted above, the Departments sought public comment on whether to extend the exemptions to non-federal governmental plan sponsors. Some commenters suggested that the moral exemptions should include government entities because other conscience laws can include government entities, such as when they oppose offering abortions. Others disagreed, contending that governmental entities should not or cannot object based on moral convictions, or that it would be unlawful for them to do so.

The Departments are sympathetic to the arguments of commenters that favor including government entities in the exemption for moral convictions. The protections outlined in the first paragraph of the Church Amendments for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Both the Weldon and Coats-Snowe Amendments also protect state and local government entities from providing, promoting, or paying for abortions in particular ways.[61] Congress has generally not limited protections for conscience based on the nature of an entity—even in the case of governmental entities.

At the same time, the Departments do not at this time have information suggesting that an exemption for governmental entities is needed or desired. The Departments have not been sued by any governmental entities raising objections to the Mandate based on non-religious moral convictions. Although the Departments sought public comment on the issue, the Departments received no public comments identifying governmental entities that need or desire such an exemption. Rather, the Departments are aware of governmental entities that, despite not possessing their own objections to contraceptive coverage, have acted to protect their employees who have conscientious objections to receiving contraceptive coverage in their employer-provided health insurance plans. *See Wieland* v. *U.S. Dep't of Health & Human Servs.,* 196 F. Supp. 1010, 1015–16 (E.D. Mo. 2016) (quoting Mo. Rev. Stat. 191.724). The individual exemption adopted in these rules will ensure the Mandate is not an obstacle to those efforts.

Thus, in light of the balance of public comments, the Departments decline to extend the moral convictions exemption to governmental entities. As is the case with the Departments' decision not to extend the moral exemption to publicly traded for-profit entities, this decision does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions

[60] *See also Real Alternatives,* 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) (''Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny.'' (citation and internal quotation marks omitted)).

[61] Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), 132 Stat. at 764 (protecting any ''hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion); 42 U.S.C. 238n (protecting entities that object to abortion, including, but not limited to, any ''postgraduate physician training program'').

without categorically excluding governmental entities. The Departments remain open to the possibility of future rulemaking on this issue if the Departments become aware of a governmental entity seeking to be exempt from the contraceptive Mandate.

b. Nonprofit Organizations (45 CFR 147.133(a)(1)(i)(A))

As discussed above, some commenters opposed offering exemptions based on moral convictions to any plan sponsors, and/or objected to doing so for nonprofit organizations, on various grounds, including but not limited to arguments that the benefits of contraception access should override moral objections, entities cannot assert moral objections, and moral objections burden third parties. Other commenters supported the exemptions, generally defending the interest of nonprofit organizations not to be forced to violate their moral convictions, supporting the history of government protection of moral convictions in similar contexts, and disputing the claims of opponents of the exemptions.

The Departments are aware, through litigation, of only two non-religious nonprofit organizations with moral objections to the contraceptive Mandate. Many more nonprofit religious organizations have sued suggesting—as discussed below—that the effect of this exemption for non-religious nonprofit objections to the Mandate will be far less significant than commenters who oppose the exemption believe it will. The two non-religious nonprofit organizations that challenged the Mandate in court provide a good illustration of the reasons why the Department has decided to provide this exemption to nonprofit organizations. Both organizations have said in court they oppose certain contraceptives on non-religious moral grounds as being abortifacient and state that they only hire employees who share that view. Public comments and litigation reflect that many nonprofit organizations publicly describe their beliefs and convictions. Government records and many of those groups' websites also often reflect those groups' religious or moral character, as the case may be. If a person who desires contraceptive coverage works at a nonprofit organization, the Departments view it as sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit organization that opposes contraceptive coverage to hire a person who disagrees with the organization's view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[62]

The Departments agree with commenters who support offering the exemption to nonprofit organizations and believe that doing so is an appropriate protection and is not likely to have a significant impact on women who want contraceptive coverage.

c. For-Profit Entities (45 CFR 147.133(a)(1)(i)(B))

With respect to for-profit organizations addressed in § 147.133(a)(1)(i)(B), in the Moral IFC, the Departments did not limit the exemption to nonprofit organizations, but also included some for-profit entities. Some commenters supported including for-profit entities in the exemption, saying owners of such entities exercise their moral convictions through their businesses, and that such owners should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise moral convictions or should not have their moral opposition to contraceptive coverage protected by the exemption. Some commenters stated that the entities should not be able to impose their beliefs about contraceptive coverage on their employees and that doing so constitutes discrimination.

The Departments agree with commenters who support including some for-profit entities in the exemption. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities, without regard to whether they operate as nonprofit organizations or for-profit entities. In addition, nearly half of the states either impose no contraceptive coverage requirement or offer ''an almost unlimited'' exemption encompassing both ''religious and secular organizations.'' [63] States also generally protect moral convictions in other health care conscience laws whether or not an entity operates as a nonprofit.[64]

Extending the exemption to certain for-profit entities is also consistent with the Supreme Court's ruling in *Hobby Lobby,* which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby,* the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization and rejected the Departments' argument to the contrary. 134 S. Ct. at 2768–75. The mechanisms by which a for-profit company makes decisions of conscience, or resolves disputes on those issues among their owners, are problems that ''state corporate law provides a ready means'' of solving. *Id.* at 2774–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby.*[65] Because all of those appear to be informed by religious beliefs, extending the exemption to entities with non-religious moral convictions would seem to have an even smaller impact on access to contraceptive coverage.

The Moral IFC only extended the exemption covering for-profit entities to those that are closely held, not to for-profit entities that are publicly traded, but asked for comment on whether publicly traded entities should be included in the moral exemption. In this way the Moral IFC differed from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in the Religious IFC, at § 147.132(a)(1), finalized in companion rules published elsewhere in today's **Federal Register**.

Some commenters supported including publicly traded entities in the moral exemption, contending that publicly traded entities have historically taken various positions on important public concerns beyond merely seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to establish and exercise moral convictions against contraceptive coverage. They observed that large publicly traded entities are exempt from the contraceptive Mandate by means of the grandfathering provision of the ACA, so

[62] Notably, ''the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.' '' *Boy Scouts of America* v. *Dale,* 530 U.S. 640, 655 (2000).

[63] ''Insurance Coverage of Contraceptives,'' The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

[64] *See, e.g.,* ''Refusing to Provide Health Services,'' The Guttmacher Institute (June 1, 2018), *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.*

[65] See Jennifer Haberkorn, ''Two years later, few Hobby Lobby copycats emerge,'' *Politico* (Oct. 11, 2016), *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627.*

that it is inappropriate to refuse to exempt publicly traded entities that actually have sincerely held moral convictions against compliance with the Mandate. They further argued that in some instances there are closely held companies that are as large as publicly traded companies of significant size. They also stated that other protections for moral convictions in certain federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines ''persons'' to include all forms of corporations, not just closely held corporations, at 1 U.S.C. 1. Additionally, some commenters were concerned that not providing a moral exemption for publicly traded for-profit entities but allowing a religious exemption for publicly traded for-profit entities (as was allowed in the Religious IFC, and as is allowed in the companion religious final rules published elsewhere in today's **Federal Register**), may raise Establishment Clause questions, may cause confusion to the public, and may make the exemptions more difficult for the Departments and enforcing agencies to administer. They stated that it is incongruous to include publicly traded entities in the exemption for religious beliefs, but exclude them from the exemption for moral convictions.

Other commenters opposed including publicly traded companies in these moral exemptions. Some stated that such companies could not exercise moral convictions and opposed the effects on women if they would. They also objected that including such companies, along with closely held businesses, would extend the exemptions to all or virtually all companies. Some commenters stated that many publicly traded companies would use a moral exemption if available to them, because many closely held for-profit businesses expressed religious objections to the Mandate, or availed themselves of the religious accommodation.

As is the case for non-federal governmental employers, the Departments are sympathetic to the arguments of commenters that favor including publicly traded entities in the exemption for moral convictions. In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without regard to their ownership status. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations; the protections of the Church Amendments do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Thus, under section 300a–7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a–7(b), the protections of that section would apply. Other federal conscience protections in the health sector apply in the same manner:

- The Coats-Snowe Amendment (42 U.S.C. 238n) provides certain protections for health care entities and postgraduate physician training programs that, among other things, choose not to perform, refer for, or provide training for, abortions.
- The Weldon Amendment [66] provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans that do not provide, pay for, provide coverage of, or refer for abortions.
- The ACA provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing. (42 U.S.C. 18113).[67]
- Social Security Act sections 1852(j)(3)(B) (Medicare) and 1932(b)(3)(B) (Medicaid), 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B), provide protections so that the statutes cannot be construed to require organizations that offer Medicare Advantage and Medicaid managed care plans in certain contexts to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds.
- Congress's most recent statement on contraceptive coverage specified that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.'' Consolidated Appropriations Act, 2018, Public Law 115–141, Div. E, Sec. 808.

In all of these instances, Congress did not limit the protection for conscience based on the nature of the entity—and did not exclude publicly traded entities from protection.

At the same time, as stated in the Moral IFC, the Departments continue to lack significant information about whether there is a need to extend the expanded exemption to publicly traded entities. The Departments have been sued by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, as well as by closely held for-profit entities expressing religious objections, but not by any publicly traded entities. In addition, the Departments sought public comments on whether publicly traded entities might benefit from extending the moral exemption to them. No such entities were brought to the attention of the Department through the comment process. The Supreme Court concluded it is improbable that publicly traded companies with numerous ''unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs.'' *Hobby Lobby,* 134 S. Ct. at 2774. It would appear to be even less probable that publicly traded entities would adopt that view based on non-religious moral convictions.

In light of the balance of public comments, the Departments decline to extend the moral convictions exemption to publicly traded entities. Because the Departments are aware of so many closely-held for-profit entities with religious objections to contraceptive coverage, and of some nonprofit entities with non-religious moral objections to contraceptive coverage, the Departments believe it is reasonably possible that closely held for-profit entities with non-religious moral objections to contraceptive coverage might exist or come into being. The Departments have also concluded that it is reasonably possible, even if improbable, that publicly traded entities with religious objections to contraceptive coverage might exist or come into being. But the Departments conclude there is not a similar probability that publicly traded for-profit entities with non-religious moral objections to contraceptive

[66] See Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d) (Mar. 2018).

[67] The lack of the limitation in this provision may be particularly relevant since it was enacted in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—were promulgated.

coverage may exist and need to be included in these expanded exemptions. The decision to not extend the moral exemption to publicly traded for-profit entities in these rules does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions without categorically excluding publicly traded entities. The Departments remain open to the possibility of future rulemaking on this issue, if we become aware of the need to expand the exemptions to publicly traded corporations with non-religious moral objections to all (or a subset of) contraceptives.

In contrast, the Departments finalize, without change, the Moral IFC's extension of the exemptions in these rules to closely held for-profit entities with moral convictions opposed to offering coverage of some or all contraceptives. The Departments conclude that it is sufficiently likely that closely held for-profit entities exist or may come into being and may maintain moral objections to certain contraceptives, so as to support including them in these expanded exemptions. The Departments seek to remove an obstacle that might prevent individuals with moral objections from forming or maintaining such small or closely held businesses and providing health coverage to their employees in accordance with their moral convictions.

In defining what constitutes a closely held for-profit entity to which these exemptions extend, the Moral IFC used language derived from the July 2015 final regulations. Those regulations, in offering the accommodation (not an exemption) to religious (not moral) closely held for-profit entities, did so by attempting to positively define what constitutes a closely held entity, formulating a multi-factor, and partially open-ended, definition for that purpose. (80 FR 41313). Any such positive definition runs up against the myriad state differences in defining such entities and potentially intrudes into a traditional area of state regulation of business organizations. Instead of attempting to positively define closely held businesses in the Moral IFC, however, the Departments considered it much clearer, effective, and preferable to define the category negatively, by reference to one element of the previous definition: that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

4. Institutions of Higher Education (45 CFR 147.133(a)(1)(ii))

The previous regulations did not exempt plans arranged by institutions of higher education, although they did include, in the accommodation, plans arranged by institutions of higher education similarly to the way in which the regulations provided the accommodation to plans of nonprofit religious employers. (See 80 FR 41347). The Moral IFC provided an exemption, in § 147.133(a)(1)(ii), encompassing institutions of higher education that arrange student health insurance coverage, and stating the exemption would operate in a manner comparable to the exemption for employers with respect to plans they sponsor. In these final rules, the Departments finalize § 147.133(a)(1)(ii) with one change.

These rules treat the health plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. The rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held moral convictions, to their arrangement of student health insurance coverage, in a manner comparable to the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

Some commenters supported including, in the exemptions, institutions of higher education that provide health coverage for students through student health plans but have moral objections to providing certain contraceptive coverage. They stated that moral exemptions allow freedom for certain institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemption would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result.

In the Departments' view, the reasons for extending the exemption to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. The Departments are not aware of any institutions of higher education that arrange student health insurance coverage and object to the Mandate based on non-religious moral convictions. But because the Departments have been sued by several institutions of higher education that arrange student health insurance coverage and object to the Mandate based on religious beliefs and by several nonprofit organizations with moral objections, the Departments believe the existence of institutions of higher education with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible to justify including protections for such entities in these final rules.

The Departments conclude that this aspect of the exemption is likely to have a minimal impact on contraceptive coverage for women at institutions of higher education. As noted above, the Departments are not aware of any institutions of higher education that would currently qualify for the objection. In addition, only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities, as opposed to from other sources, and an even smaller number receive such coverage from schools objecting to contraceptive coverage. Exempting institutions of higher education that object to contraceptive coverage based on moral convictions does not affect student health insurance contraceptive coverage at the vast majority of institutions of higher education. The exemption simply makes it legal under federal law for institutions to adhere to moral convictions that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, because it makes it easier for students to attend institutions of higher education that hold those views, if the institutions exist or come into being and students choose to attend them. Moreover, because institutions of higher education have no legal obligation to sponsor student health insurance coverage, providing this moral exemption removes an obstacle to such institutions sponsoring student health insurance coverage, thus possibly encouraging

more widespread health insurance coverage.

As noted above, after seeking public comment on whether the final moral exemptions rules should be extended to include non-federal governmental entities, the Departments have concluded they should only include non-governmental entities. For the same reasons, the Departments are inserting a reference into § 147.133(a)(1)(ii) specifying that it includes an institution of higher education ''which is non-governmental.'' This language is parallel to the same limiting phrase used in the religious exemptions rule governing institutions of higher education, at § 147.132(a)(1)(ii). Thus, the first sentence of § 147.133(a)(1)(ii) is finalized to read: ''An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section.'' The remaining text of § 147.133(a)(1)(ii) is finalized without change.

5. Health Insurance Issuers (45 CFR 147.133(a)(1)(iii))

The Moral IFC extended the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services. The issuer exemption only applied to the group health plan if the plan itself was also exempt under an exemption for the plan sponsor or individuals. In these final rules, the Departments finalize § 147.133(a)(1)(iii) without change.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing contraceptive coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on that objection. An exempt issuer can then offer an exempt product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer under this paragraph (a)(1)(iii) that does not include some or all contraceptive services, are plan sponsors or individuals who themselves object and are exempt.

Under these rules, issuers that hold their own objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their moral convictions, or if they are exempt based on their religious beliefs under the companion final rules published elsewhere in today's **Federal Register**. Likewise, issuers with sincerely held religious beliefs, that are exempt under those companion final rules, could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Some commenters supported including this exemption for issuers in these rules, both to protect the moral convictions of issuers, and so that, in the future, issuers would be free to organize that may wish to specifically serve plan sponsors and individuals that object to contraception based on religious or moral reasons. Other commenters objected to including an exemption for issuers. Some commenters stated that issuers cannot exercise moral convictions, while others stated that exempting issuers would threaten contraceptive coverage for women. Some commenters stated that it was arbitrary and capricious for the Departments to provide an exemption for issuers if they do not know that issuers with qualifying moral objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage.

The issuer exemption serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors, plans, and individuals that independently qualify for an exemption, will remove a possible obstacle to issuers with moral convictions being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held moral convictions will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers both from being required to issue policies that cover contraception in violation of the issuers' sincerely held moral convictions and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise moral convictions. Many federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicare Advantage or Medicaid. The Weldon Amendment specifically protects, among other entities, HMOs, health insurance plans, and ''any other kind of health care facility[ies], organization[s] or plan[s]'' as a ''health care entity'' from being required to provide coverage of, or pay for, abortions. See, for example, Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d).[68] The most recently enacted Consolidated Appropriations Act declares that Congress supports a

[68] ACA section 1553 protects an identically defined group of ''health care entities,'' including provider-sponsored organizations, HMOs, health insurance plans, and ''any other kind of . . . plan,'' from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

''conscience clause'' to protect moral convictions concerning ''the provision of contraceptive coverage by health insurance plans.'' *See id.* at Div. E, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion Religious IFC and final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**.[69]

6. Description of the Moral Objection (45 CFR 147.133(a)(2))

The Moral IFC set forth the scope of the moral objection of objecting entities in § 147.133(a)(2), so that it applies to the extent an entity described in paragraph (a)(1), based on sincerely held moral convictions, objects to ''establishing, maintaining, providing, offering, or arranging'' either ''coverage or payments'' for contraceptives, or ''for a plan, issuer, or third party administrator that provides or arranges such coverage or payments.'' The Departments are finalizing this exemption with structural changes separating the second half of the sentence into separate subparagraphs, so as to more clearly specify, as set forth in the Moral IFC text, that the objection may pertain either to coverage or payments for contraceptives, or to a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

Some commenters observed that, by allowing exempt plan sponsors to object to ''some or all'' contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators.

The Departments have concluded, however, that just as the previous exemption rules allowed certain religious plan sponsors to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. These rules do not require any issuer or third party administrator to contract with an exempt entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual plan variation. These rules simply remove the federal Mandate, in some cases, where it could have led to penalties on an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying moral objection. That approach is consistent with the approach under the previous regulations, which did not require issuers and third party administrators to contract with exempt plans of houses of worship or integrated auxiliaries if they did not wish to do so.

The definition does not specify that the moral convictions that can support an exemption need to be non-religious moral convictions. We find it unnecessary to limit the definition in that way. Even though moral convictions need not be based on religious beliefs, religious beliefs can have a moral component. It is not always clear whether a moral conviction is based on religious tenets. As noted in *Welsh,* a moral conviction can be ''purely ethical or moral in source and content but that nevertheless . . . occupy in the life of that individual a place parallel to that filled by God [and] function as a religion in his life.'' 398 U.S at 340. One reason for providing exemptions for moral convictions is so that the government need not engage in the potentially difficult task of parsing which convictions are religious and which are not. If sincerely held moral convictions supporting an exemption are religious, they will be encompassed by the exemption for sincerely held religious beliefs. If the moral convictions are not also religious, or if their religious quality is unclear but they are ethical or moral, they can qualify as sincerely held moral convictions under these rules if the other requirements of these rules are met.

The Departments are not aware of any entities that qualify for an exemption under the religious exemptions finalized elsewhere in today's **Federal Register**, but not under the moral exemptions finalized here, such as publicly traded entities. If publicly traded entities object to the Mandate, it seems unlikely their objection is based on moral convictions and not religious beliefs, given that many more objections to the Mandate have been based on religious beliefs. Thus, the Departments find it unlikely that they would be faced with a situation where a publicly traded entity, for example, has an objection to the contraceptive Mandate, but it is not clear whether that objection is based on sincerely held religious beliefs or merely based on sincerely held moral convictions.

7. Individuals (45 CFR 147.133(b))

The previous regulations did not provide an exemption for objecting individuals. The Moral IFC provided such an exemption for objecting individuals (referred to here as the ''individual exemption''), using the following language at § 147.133(b): ''Objecting individuals''. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.''

The Departments finalize this language, with changes in response to public comments in some of the text and in a new sentence at the end of the paragraph that clarify how the exemption applies.

Section 147.133(b) sets forth a special rule pertaining to individuals (referred to here as the ''individual exemption''). This rule exempts plans of certain individuals with moral objections to contraceptive coverage where the plan sponsor and, as applicable, issuer is willing to provide a plan compliant with the individuals' objections to such plan sponsors or individuals, as applicable.

Some commenters supported this exemption as providing appropriate protections for the moral convictions of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to coverage of contraceptives but is willing (and, as applicable, the issuer is also willing) to provide coverage consistent with an individual's moral objections. They commented that this exemption

[69] The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for employers. Because the issuer exemption operates more narrowly than the exemption for plan sponsors operates, in the ways described here (*i.e.,* the issuer exemption does not operate unless the plan sponsor or individual, as applicable, is also exempt), and exists in part to help preserve market options for objecting plan sponsors and individuals, the Departments consider it appropriate to not draw such a distinction among issuers.

would free individuals from having their moral convictions placed in tension with their desire for health coverage. They also contended that the individual exemption would not undermine any government interests behind the contraceptive Mandate, since the individuals would be choosing not to have the coverage. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage.

Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. The Departments note that this individual exemption only operates in the case where the issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases. But the Departments do not wish to pose an obstacle to the offering of such coverage.

The Departments note that their decision is consistent with the decision by Congress to provide protections in certain contexts for individuals who object to prescribing or providing contraceptives contrary to their moral convictions. *See, for example,* Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Mar. 23, 2018). While some commenters argued that such express protections are narrow, Congress likewise provided that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions''. *Id.* at Div. E, Sec. 808. A moral exemption for individuals would not be effective if the government did not, at the same time, permit issuers and group health plans to provide individuals with policies that comply with their moral convictions.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers. Thus, this individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations ''does not undermine the governmental interests furthered by the contraceptive coverage requirement.'' (78 FR 39874). For parallel reasons, as the Departments stated in the Moral IFC (83 FR at 47853 through 47854), this individual exemption does not undermine the governmental interests furthered by the contraceptive coverage requirement, because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the state is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees' religious beliefs ''or moral convictions,'' or against the individual employees who accept such offers. *See Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption in these rules, employers sponsoring governmental plans would be free to honor the moral objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

In the separate companion IFC to the Moral IFC—the Religious IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Moral IFC said a willing issuer and plan sponsor may offer ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects'' under the individual exemption, the Religious IFC described what may be offered to objecting individuals as ''a separate benefit package option, or a separate policy, certificate or contract of insurance.'' Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of ''a separate group health plan,'' because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee's objection. Consequently, these rules finalize the individual exemption by making a technical change to the language to adopt the formulation, ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects.''

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of state law that requires coverage of such contraceptives or

sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held moral objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these rules do not affect such other laws or terms.

The Departments received numerous comments about the administrative burden from the potential variations in moral convictions held by individuals. Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives, while others expressed concern that the variations in the kinds of contraceptive coverage to which individuals object might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the moral convictions of an exempt individual.

If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Moral IFC implied this conclusion by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, that language differed from the language applicable to the exemptions under § 147.133(a), which specifies that those exemptions apply ''to the extent'' of the moral objections, so that, as discussed above, they include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b), with the following change, by adding the following sentence at the end of the paragraph: ''Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held moral convictions objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to the employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under her policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to do so. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with changes, to read as follows: ''(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

8. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations did not offer the accommodation process to entities with moral non-religious objections. The Religious IFC amended the accommodation regulations to offer it to all entities that are exempt on the basis of religious beliefs under § 147.132, as an optional process in which such entities could participate voluntarily. The Moral IFC did not change that accommodation process, but inserted references in it to the new section § 147.133, alongside the references to section § 147.132. These changes made entities eligible for the voluntary accommodation process if they are exempt on the basis of moral convictions. The references were inserted in 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A.

In these rules, the Departments finalize, without change, the Moral IFC's revisions of 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A. The operation of the accommodation process, changes made in the Religious IFC, and public comments concerning the accommodation, are more fully described in the Religious IFC, and in the companion final rules concerning the religious exemptions and accommodation, published elsewhere in today's **Federal Register**. Those descriptions are incorporated here by reference to the extent they apply to these rules.

Many commenters supported extending the accommodation process to entities with objections based on moral convictions. Others objected to doing so, raising arguments parallel to their objections to creating exemptions for group health plan sponsors with moral convictions. For much the same reasons discussed above concerning why the Departments find it appropriate to exempt entities with moral objections to contraceptive coverage, the Departments find it appropriate to extend the optional accommodation process to these entities. The Departments observe that, to the extent such entities wish to use the process, it will not be an obstacle to contraceptive coverage, but will instead help deliver contraceptive coverage to women who receive health coverage from such entities while respecting the moral convictions of the entities. The Departments are not aware of entities with non-religious moral convictions against contraceptive coverage that also consider the accommodation acceptable and would opt into it, but we are aware of a small number of entities with non-religious moral objections to the Mandate. The Departments, therefore, continue to consider it appropriate to extend the optional accommodation to such entities in case any wish to use it. Below, albeit based on very limited data, the Departments estimate that a small number of entities with non-religious moral objections may use the accommodation process.

9. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under ''Contraceptive methods and counseling,'' ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' The previous regulations concerning the exemption and the accommodation used the terms ''contraceptive services'' and ''contraceptive coverage'' as catch-all terms to encompass all of those Guidelines requirements. The 2016 update to the Guidelines are similarly worded. Under ''Contraception,'' they include the ''full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,'' ''instruction in fertility awareness-based methods,'' and ''[c]ontraceptive care'' to ''include contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.,* management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).'' [70]

To more explicitly state that the expanded exemptions encompass any of the contraceptive or sterilization services, items, procedures, or related patient education or information that have been required under the Guidelines, the Moral IFC included a definition of contraceptive services, benefits or coverage, at 45 CFR 147.133(c). These rules finalize that definition without change.

10. Severability

The Departments finalize, without change, the severability clause set forth at § 147.133(d).

C. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that moral objections to the Mandate should not be permitted in cases where contraceptive methods are used to treat such existing medical conditions and not for preventive purposes, even if those contraceptive methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to ''preventive'' care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to ''preventive'' services or care.[71] The requirement in the Guidelines concerning ''contraception'' specifies several times that it encompasses ''contraceptives,'' that is, medical products, methods, and services applied for ''contraceptive'' uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[72] The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans' decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so that plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use. Section 2713(a)(4), however, draws a distinction between preventive and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of care unless it is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are

[70] ''Women's Preventive Services Guidelines,'' HRSA (last reviewed Oct. 2017), *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[71] *Id.*

[72] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that ''there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy.'' 77 FR 8727 & n.7. This was not, however, an assertion that section 2713(a)(4) or the Guidelines require coverage of ''contraceptive'' methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead, it was an observation that such drugs—generally referred to as ''contraceptives''—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply if the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that, under section 2713(a)(4), exempt organizations must provide coverage for drugs or items prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Moral IFC that the moral exemptions are likely to affect only a very small number of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the exemptions could take contraceptive coverage away from many or most women. Still others opposed establishing the exemptions, but contended that accurately determining the number of women affected by the exemptions is not possible. Public comments included various statements that these exemptions would impact coverage for a large number of women, while others stated they would affect only a very small number. But few, if any, public commenters provided data predicting a precise number of entities that would make use of the exemptions for moral convictions nor a precise number of employees that would potentially be affected.

After reviewing the public comments, the Departments do not find the suggestions of commenters who predicted a very large impact any more reliable than the estimates set forth in the Religious and Moral IFCs. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious and Moral IFCs are still the best estimates available. The Departments' estimates are discussed in more detail in the following section.

III. Economic Impact and Paperwork Burden

The Departments have examined the impacts of these final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and an ''economically significant'' regulatory action is subject to review by OMB. As discussed below regarding their anticipated effects, the these final rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

The Religious IFC amended the Departments' July 2015 final regulations. The Moral IFC amended those regulations further, and added an additional rule at 45 CFR part 147.133. These final rules adopt as final, and further amend, the amendments made by the Moral IFC. The Departments do so in conjunction with the amendments made in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. These rules provide an exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4), section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, for certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process by making the accommodation applicable to organizations with such convictions as an option. The exemption applies to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action has been taken to provide for participation in the health insurance market by certain entities or individuals in a manner free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to ensure the preventive services coverage requirement is implemented in a way consistent with longstanding federal conscience statutes, to prevent lawsuits of the kind that were filed against the Departments when the expanded exemption in these final rules was not offered, and for the other reasons discussed above.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these final rules, we believe it to be small.

With respect to the exemption for nonprofit organizations with objections based on moral convictions, as noted

above, the Departments are aware of two small nonprofit organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree with their opposition to the nature of certain contraceptives subject to coverage under the Mandate.[73] One of them has obtained a permanent injunction against any regulations implementing the contraceptive Mandate, and so will not be affected by these final rules. Based on comments submitted in response to rulemakings prior to the Moral and Religious IFCs, the Departments believe that at least one other similar entity exists.[74] However, the Departments do not know how many similar entities exist and are currently unable to estimate the number of such entities. Lacking other information, we assume that the number is small. The Departments estimate it to be less than 10 and assume the exemption will be used by nine nonprofit entities.

The Departments also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with the conclusion in previous regulations that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (See 76 FR 46625 and 78 FR 39889). The Departments reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception and without requiring that such entities actually oppose contraception in order to be exempt (in contrast, the exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to contraceptive coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, the Departments relied on the assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is appropriate with respect to the expanded exemption for nonprofit organizations with objections based on moral convictions. To the knowledge of the Departments, the vast majority of organizations objecting to the Mandate assert objections based on religious beliefs. The only nonprofit organizations of which they are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It is possible that the exemption for nonprofit organizations with moral convictions in these final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under the Departments' previous regulations that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.[75] Although the Departments are unable to find sufficient data on this issue, we believe that there are far fewer nonprofit organizations opposed to contraceptive coverage on the basis of moral convictions than there are houses of worship or integrated auxiliaries with religious objections to such coverage. Based on the limited data available, the Departments believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose certain contraceptive coverage. Therefore, the Departments expect that the moral exemption for nonprofit entities will have a minimal effect of reducing contraceptive coverage with respect to employees who want such coverage.

These rules extend the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and make exempt entities with moral objections eligible to avail themselves of the accommodation. The Departments are not aware of any institutions of higher education with this kind of non-religious moral convictions. Moreover, the Departments believe the overall number of entities that would object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education. Public comments did not reveal the existence of any institutions of higher education with such moral convictions. Therefore, for the purposes of estimating the anticipated effect of these final rules on contraceptive coverage of women who wish to receive such coverage, the Departments assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no other entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might come into existence, based on reasons similar to those given above for why the exemptions and accommodations are extended to other entities.

The Departments believe that the exemption for issuers with objections based on moral convictions will not result in a distinct effect on contraceptive coverage for women who wish to receive it, because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein, or in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. The exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The moral exemption will also cover for-profit entities that do not have publicly traded ownership interests and that have non-religious moral objections to the Mandate, if such entities exist. Some commenters agreed that the impact of these final rules would be no more than the Departments estimated in the Moral IFC, and some commenters stated the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended

[73] Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

[74] See, for example, Americans United for Life (''AUL'') Comment on CMA-9992-IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496*, and AUL Comment on CMS-9968-P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115*.

[75] *Cf., for example,* Frank Newport, ''Americans, Including Catholics, Say Birth Control Is Morally OK,'' Gallup, (May 22, 2012), *http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx* (''Eighty-two percent of U.S. Catholics say birth control is morally acceptable'').

pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women. These general comments did not, however, substantially assist the Departments in estimating the number of women that would potentially be affected by these exemptions for moral convictions specifically, or among them, how many unintended pregnancies would result, how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the estimated transfer costs, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives.

Some of the comments opposing these exemptions assert that they will lead to a large number of entities dropping contraceptive coverage. The Departments disagree; they are aware of only two entities that hold non-religious moral convictions against contraceptive coverage. Both only hire employees that share their beliefs, and one will not be affected by these final rules because it is protected by an injunction from any regulations implementing the contraceptive Mandate. Commenters cited no other specific entities that might assert these moral convictions, and did not provide better data to estimate how many entities might exist. Likewise, the Departments find it unlikely that any of the vast majority of entities that covered contraceptives before this Mandate was announced in 2011 would terminate such coverage because of these exemptions based on moral convictions. The Departments also find it unlikely that a significant number of for-profit entities, whose plans include a significant number of women, omitted contraceptive coverage before the ACA on the basis of objections grounded in non-religious moral convictions, and would claim an exemption under these final rules. No such entities, or data concerning such entities, were identified by public commenters, nor are the Departments aware of any involved in litigation over the Mandate.

Numerous for-profit entities claiming religious objections have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—and both were nonprofit organizations. Among the general public, polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they believe in God.[76] Among non-religious persons, only a very small percentage of the population appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.[77] Combined, this suggests that 0.2 percent of Americans at most[78] might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. The Departments have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral convictions set forth in these final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, the Departments assume that some similar for-profit entities with non-religious moral objections exist. But the Departments expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities without publicly traded ownership interests and with sincere moral objections to the Mandate, the Departments expect that fewer than 10 entities, if any, will do so—so the Departments assume nine for-profit entities will use the exemption in these final rules.

The moral exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) to obtain an estimate of the number of policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.[79] The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known how many employees would be employed by the for-profit employers that might claim this exemption, but as discussed above these final rules do not include publicly traded companies, and both of the two nonprofit entities that challenged the Mandate based on moral objections included fewer than five policyholders in their group plans. Therefore, the Departments assume that the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For 9 entities, the total number of policyholders would be approximately 81. DOL estimates that for each policyholder, there is approximately one dependent.[80] This amounts to approximately 162 covered persons. Census data indicate that women of childbearing age, *i.e.,* women aged 15 to 44, comprise 20.2 percent of the general population.[81] This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.[82] Thus, the Departments estimate that approximately 15 women may incur contraceptive costs due to for-profit entities using the expanded moral exemption provided for in these final rules.[83] In the companion final

[76] Frank Newport, ''Most Americans Still Believe in God,'' Gallup (June 29, 2016), *http://www.gallup.com/poll/193271/americans-believe-god.aspx.*

[77] Pew Research Center, ''Where the Public Stands on Religious Liberty vs. Nondiscrimination,'' Pew Research Center, 26 (Sept. 28, 2016), *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.*

[78] The study defined religiously ''unaffiliated'' as agnostic, atheist or ''nothing in particular'', *id.* at 8, as distinct from several versions of Protestants, or Catholics. ''Nothing in particular'' might have included some theists.

[79] ''Health Insurance Coverage Bulletin,'' Dept. of Labor (June 28, 2016), Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.* Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey—Insurance.

[80] ''Health Insurance Coverage Bulletin'' Dept. of Labor'' (June 28, 2016), Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[81] U.S. Census Bureau, ''Age and Sex Composition: 2010'' (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies ''for all women with reproductive capacity.'' Women's Preventive Services Guidelines, HRSA (last reviewed Oct. 2017), *https://www.hrsa.gov/womensguidelines/; see also* 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. *See, e.g.,* ''Contraceptive Use in the United States,'' The Guttmacher Institute (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[82] *See* ''Contraceptive Use in the United States,'' The Guttmacher Institute (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[83] The Departments note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be

Continued

rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, in health plans that cover contraception, is $584. Consequently, the Departments estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded moral exemption in these final rules is approximately $8,760.

The Departments estimate that these final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will avail themselves of the accommodation, although the Departments wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to its plan participants and beneficiaries. While these final rules make it legal for issuers to offer insurance coverage that omits contraceptives to/for exempt entities and individuals, these final rules do not require issuers to do so. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, the Departments do not anticipate that these final rules will result in any burden from such entities acting to revoke their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the exemptions finalized in these final rules. The Departments acknowledge uncertainty in the estimate and, therefore, conducted a second analysis using an alternative framework, which is set forth in the companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, with reference to the analysis conducted in the Religious IFC. Under either estimate, these final rules are not deemed to be economically significant.

The Departments reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) imposes certain requirements with respect to federal regulations that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The Moral IFC was a set of interim final rules with comment, and in these final rules, the Departments finalize the Moral IFC with certain changes based on public comments. The Moral IFC was exempt from the notice and comment requirements of the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA did not apply to the Moral IFC. These final rules are, however, issued after a notice and comment period.

The Departments carefully considered the likely impact of the rules on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, by exempting from the Mandate small businesses and nonprofit organizations with moral objections to some or all contraceptives and/or sterilization—businesses and organizations which would otherwise be faced with the dilemma of complying with the Mandate (and violating their moral convictions), or of following their moral convictions and incurring potentially significant financial penalties for noncompliance—the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

The Departments estimate that these final rules will not result in additional burdens not accounted for as set forth in companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**. As discussed there, rules covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(e)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burden related to these information collection requirements (ICRs) received emergency review and approval under OMB Control Number 0938–1344. They have been resubmitted to OMB in conjunction with this final rule and are pending re-approval.

covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion —and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

As discussed above, however, the Departments assume that no entities with non-religious moral objections to the Mandate will use the accommodation. The Departments know that no such entities were eligible for it until now, so that no entity possesses an accommodated status that would need to be revoked. Therefore, the Departments believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1344, as described in the final rules concerning religious beliefs issued contemporaneously with these final rules.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. In an effort to consolidate the number of information collections the Department is combining OMB control numbers 1210–0150 and 1210–0152 under OMB control number 1210–0150 and discontinuing OMB control number 1210–0152.

A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov.* PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these final rules make entities with certain moral convictions eligible for the accommodation, the Department assumes (1) that no entities will use the accommodation rather than the exemption, and (2) entities using the moral exemption would not have to revoke an accommodation, because they previously were not eligible for it. Therefore, the Department believes these final rules do not involve additional burden not accounted for under OMB control number 1210–0150, which is published elsewhere in today's issue of the **Federal Register** in connection with the companion Religious Exemption and Accommodation Preventive Health Service final rule. The Department will publish a notice informing the public of OMB's action with respect to the Department's submission of the ICRs under OMB control number 1210–0150.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, ''[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [Affordable Care] Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' In addition, agencies are directed to ''take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.'' The Moral IFC and these final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.[84] However, in order to avoid double-counting with the Moral IFC, which has already been tallied as an E.O. 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) (Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year.'' In 2018, that threshold is approximately $150 million. For purposes of the Unfunded Mandates Reform Act, the Moral IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of $150 million or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

IV. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

[84] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to these final rules' medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October, 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§ 54.9815–2713 [Amended]

■ 2. Section 54.9815–2713, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraph (a)(1)(iv) by removing the reference ''147.131 and 147.132'' and adding in its place the reference ''147.131, 147.132, and 147.133''.

§ 54.9815–2713A [Amended]

■ 3. Section 54.9815–2713A, as amended elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (a)(1) by removing ''or (ii)'' and adding in its place ''or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)'';

■ b. In paragraph (a)(2) by removing the reference ''147.132(a)'' and adding in its place the reference ''147.132(a) or 147.133(a)'';

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ d. In paragraph (b)(1)(ii)(B) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ f. In paragraph (c)(1)(ii)(B) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133''; and

■ g. In paragraph (c)(2) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133''.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ For the reasons set forth in the preamble, the Department of Labor adopts, as final, the interim final rules amending 29 CFR part 2590, published October 13, 2017 (82 FR 47838), without change.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47838) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 4. The authority citation for part 147, as revised elsewhere in this issue of the **Federal Register**, continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 5. Section 147.133 is amended by revising paragraph (a)(1) introductory text, (a)(1)(ii), (a)(2), and (b) to read as follow:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health

insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

* * * * *

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018–24514 Filed 11–7–18; 4:15 pm]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P

EXHIBIT C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9827]

RIN 1545–BN92

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9940–IFC]

RIN 0938–AT20

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs and moral convictions. These interim final rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave the ''accommodation'' process in place as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These interim final rules and temporary regulations are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by ''Preventive Services,'' may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9940–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9940–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492–4305 or *marketreform@cms.hhs.gov* for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's Web site (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Congress has consistently sought to protect religious beliefs in the context of health care and human services, including health insurance, even as it has sought to promote access to health services.[1] Against that backdrop,

[1] See, for example, 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their ''religious beliefs or moral convictions''); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–31 (protecting any ''health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of ''the provision of

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, ''with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by'' by HRSA (the ''Guidelines''). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,[2] while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, ''the Departments'' [3])—exercised the same discretion to allow exemptions to those requirements. Through rulemaking, including three interim final rules, the Departments allowed exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the ''contraceptive Mandate,'' or the ''Mandate'') as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1. Much of that litigation continues to this day.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as the interests served by the existing Guidelines, regulations, and accommodation process; [4] the extensive litigation; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); protection of the free exercise of religion in the First Amendment and by Congress in the Religious Freedom Restoration Act of 1993; Congress' history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under section 2713(a)(4) of the PHS Act; the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; the regulatory process and comments submitted in various requests for public comments (including in the Departments' 2016 Request for Information).

In light of these factors, the Departments issue these new interim final rules to better balance the Government's interest in ensuring coverage for contraceptive and sterilization services in relation to the Government's interests, including as reflected throughout Federal law, to provide conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts, and to minimize burdens in our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, ''[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.''

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS Act requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

contraceptive coverage by health insurance plans'' in the District of Columbia, ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.''); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions''); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their ''religious or conscientious commitment to offer only natural family planning''); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on ''religious beliefs or moral objections''); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on ''conscience'' as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on ''religious beliefs or moral convictions''); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); also, see 8 U.S.C. 1182(g) (protecting vaccination objections by ''aliens'' due to ''religious beliefs or moral convictions''); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on ''moral or religious convictions''); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their ''religious or moral objection'').

[2] This document's references to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

[3] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

[4] In this document, we generally use ''accommodation'' and ''accommodation process'' interchangeably.

The Departments have consistently interpreted section 2714(a)(4) PHS Act's grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA's Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women's preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act's reference to ''comprehensive guidelines supported by HRSA for purposes of this paragraph'' to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines ''supported by HRSA for purposes of this paragraph,'' the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from ''the other guidelines referenced in section 2713(a) of the PHS Act, which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients.'' Id. Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4) of the PHS Act, the Departments have previously promulgated regulations defining the scope of permissible exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92)

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 of the PHS Act for grandfathered plans. In contrast, this exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include: Section 2704 of the PHS Act, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708 of the PHS Act, which prohibits excessive waiting periods (as of January 1, 2014); section 2711 of the PHS Act, which relates to lifetime limits; section 2712 of the PHS Act, which prohibits rescission of health insurance coverage; section 2714 of the PHS Act, which extends dependent coverage until age 26; and section 2718 of the PHS Act, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.[5] As the Supreme Court observed, ''there is no legal requirement that grandfathered plans ever be phased out.'' *Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments' interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments' own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that ''longstanding Federal laws to protect conscience * * * remain intact,'' including laws that protect religious beliefs (and moral convictions) from certain requirements in the health care context. While the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect religious beliefs regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in accordance with the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, ''Clinical Preventive Services for Women, Closing the Gaps'' (IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.[6]

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of ''contraceptives'' certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,[7] the IOM's recommendation included several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason

[5] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[6] Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings ''with respect to women,'' the Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

[7] FDA's guide ''Birth Control: Medicines To Help You,'' specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and ''may also work * * * by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

distinct from whether they also oppose contraception or sterilization.

One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He argued that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by the United States Preventive Services Task Force (USPSTF), HRSA's Bright Futures Project, and the Advisory Committee on Immunization Practices (ACIP) leads to lower rates of disability or disease and increased rates of well-being. He further argued that ''the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered,'' and that ''the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy.'' Dr. LoSasso also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.[8] (IOM 2011 at 231–32). In its response to Dr. LoSasso, the other 15 committee members stated, in part, that ''At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions.''

2. HRSA's 2011 Guidelines and the Departments' Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women's preventive services, adopting the recommendations of the IOM *https://www.hrsa.gov/womensguidelines/*. The Guidelines included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specify that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.[9] The 2011 interim final rules defined an exempt ''religious employer'' narrowly as one that: (1) Had the inculcation of religious values as its purpose; (2) primarily employed persons who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a nonprofit organization, as described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Those relevant sections of the Code include only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of a religious order. The practical effect of the rules' definition of ''religious employer'' was to create potential uncertainty about whether employers, including many of those houses of worship or their integrated auxiliaries, would fail to qualify for the exemption if they engaged in outreach activities toward persons who did not share their religious tenets.[10] As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some ''States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services.'' (76 FR 46623). That same day, HRSA exercised the discretion described in the 2011 interim final rules to provide the exemption.

3. The Departments' Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of ''religious employer'' in the 2011 interim final rules without modification (2012 final regulations).[11] (77 FR 8725). The exemption did not require religious employers to file any certification form or comply with any other information collection process.

Contemporaneous with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).[12] The guidance provided that the temporary safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. The temporary safe harbor did not apply to for-profit entities. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve ''two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services.'' (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of ''religious employer'' for purposes of the religious employer

[8] The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

[9] The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011 (76 FR 46621).

[10] See, for example, Comments of the United States Conference of Catholic Bishops on Interim Final Rules on Preventive Services, File Code CMS–9992–IFC2 (Aug. 31, 2011).

[11] The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

[12] Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: *http://www.lb7.uscourts.gov/documents/12cv3932.pdf*. The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled ''Student Health Insurance Coverage'' published March 21, 2012 (77 FR 16457).

exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer (1) have the inculcation of religious values as its purpose, (2) primarily employ persons who share its religious tenets, and (3) primarily serve persons who share its religious tenets.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible religious nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations ''may be less likely than'' employees of exempt houses of worship and integrated auxiliaries to share their employer's faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization's plan—and without any cost to the eligible organization.[13] In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries.

On August 15, 2012, the Departments also extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

[13] The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations ''does not undermine the governmental interests furthered by the contraceptive coverage requirement.'' (78 FR 39874). But, like the 2013 NPRM, the July 2013 regulations assumed that ''[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection'' to contraceptives (*Id.*).

The July 2013 regulations also finalized an accommodation for eligible organizations. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization's plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect.[14] With respect to fully insured group health plans, the issuer was expected to bear the cost of such payments,[15] and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations.

With respect to self-insured group health plans, the July 2013 final regulations specified that the self-certification was an instrument under which the plan was operated and that it obligated the third party administrator to provide or arrange for contraceptive coverage by operation of section 3(16) of ERISA. The regulations stated that, by submitting the self-certification form, the eligible organization ''complies'' with the contraceptive coverage requirement and does not have to contract, arrange, pay, or refer for contraceptive coverage. See, for example, Id. at 39874, 39896. Consistent with these statements, the Departments, through the Department of Labor, issued a self-certification form, EBSA Form 700. The form stated, in indented text labeled as a ''Notice to Third Party Administrators of Self-Insured Health Plans,'' that ''[t]he obligations of the third party administrator are set forth in 26 CFR 54.9815–2713A, 29 CFR 2510.3–16, and 29 CFR 2590.715–2713A'' and concluded, in unindented text, that ''[t]his form is an instrument under which the plan is operated.''

The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. The guidance extending the safe harbor included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary safe harbor if no prior form had been submitted.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others. Religious plaintiffs principally argued that the Mandate violated the Religious Freedom Restoration Act of 1993 (RFRA) by forcing them to provide coverage or payments for sterilization and contraceptive services, including what they viewed as early abortifacient items, contrary to their religious beliefs. Based on this claim, in July 2012 a

[14] See also 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was $33 million.

[15] ''[P]roviding payments for contraceptive services is cost neutral for issuers.'' (78 FR 39877).

Federal district court issued a preliminary injunction barring the Departments from enforcing the Mandate against a family-owned business. *Newland* v. *Sebelius,* 881 F. Supp. 2d. 1287 (D. Colo. 2012). Multiple other courts proceeded to issue similar injunctions against the Mandate, although a minority of courts ruled in the Departments' favor. *Compare Tyndale House Publishers, Inc.* v. *Sebelius,* 904 F. Supp. 2d 106 (D.D.C. 2012), and *The Seneca Hardwood Lumber Company, Inc.* v. *Sebelius* (sub nom *Geneva Coll.* v. *Sebelius),* 941 F. Supp. 2d 672 (W.D. Pa. 2013), with *O'Brien* v. *U.S. Dep't of Health & Human Servs.,* 894 F. Supp. 2d 1149 (E.D. Mo. 2012).

A circuit split swiftly developed in cases filed by religiously motivated for-profit businesses, to which neither the religious employer exemption nor the eligible organization accommodation (as then promulgated) applied. Several for-profit businesses won rulings against the Mandate before the Unites States Court of Appeals for the Tenth Circuit, sitting en banc, while similar rulings against the Departments were issued by the Seventh and District of Columbia (DC) Circuits. *Hobby Lobby Stores, Inc.* v. *Sebelius,* 723 F.3d 1114 (10th Cir. 2013); *Korte* v. *Sebelius,* 735 F.3d 654 (7th Cir. 2013); *Gilardi* v. *U.S. Dep't of Health & Human Servs.,* 733 F.3d 1208 (D.C. Cir. 2013). The Third and Sixth Circuits disagreed with similar plaintiffs, and in November 2013 the U.S. Supreme Court granted certiorari in *Hobby Lobby* and *Conestoga Wood Specialties Corp.* v. *Secretary of U.S. Department of Health & Human Services,* 724 F.3d 377 (3d Cir. 2013), to resolve the circuit split.

On June 30, 2014, the Supreme Court ruled against the Departments and held that, under RFRA, the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[16] *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Court held that the ''contraceptive mandate 'substantially burdens' the exercise of religion'' as applied to employers that object to providing contraceptive coverage on religious grounds, and that the plaintiffs were therefore entitled to an exemption unless the Mandate was the least restrictive means of furthering a compelling governmental interest. *Id.* at 2775. The Court observed that, under the compelling interest test of RFRA, the Departments could not rely on interests ''couched in very broad terms, such as promoting 'public health' and 'gender equality,' but rather, had to demonstrate that a compelling interest was served by refusing an exemption to the ''particular claimant[s]'' seeking an exemption. *Id.* at 2779. Assuming without deciding that a compelling interest existed, the Court held that the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner. The Court observed that ''[t]he most straightforward way of doing this would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections.'' *Id.* at 2780. The Court also observed that the Departments had ''not provided any estimate of the average cost per employee of providing access to these contraceptives,'' nor ''any statistics regarding the number of employees who might be affected because they work for corporations like Hobby Lobby, Conestoga, and Mardel''. *Id.* at 2780–81. But the Court ultimately concluded that it ''need not rely on the option of a new, government-funded program in order to conclude that the HHS regulations fail the least-restrictive means test'' because ''HHS itself ha[d] demonstrated that it ha[d] at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs.'' *Id.* at 2781–82. The Court explained that the ''already established'' accommodation process available to nonprofit organizations was a less-restrictive alternative that ''serve[d] HHS's stated interests equally well,'' although the Court emphasized that its ruling did not decide whether the accommodation process ''complie[d] with RFRA for purposes of all religious claims''. *Id.* at 2788–82.

Meanwhile, another plaintiff obtained temporary relief from the Supreme Court in a case challenging the accommodation under RFRA. Wheaton College, a Christian liberal arts college in Illinois, objected that the accommodation was a compliance process that rendered it complicit in delivering payments for abortifacient contraceptive services to its employees. Wheaton College refused to execute the EBSA Form 700 required under the July 2013 final regulations. It was denied a preliminary injunction in the Federal district and appellate courts, and sought an emergency injunction pending appeal from the Unites States Supreme Court on June 30, 2014. On July 3, 2014, the Supreme Court issued an interim order in favor of the College, stating that, ''[i]f the [plaintiff] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing [the Mandate] against the [plaintiff] . . . pending final disposition of appellate review.'' *Wheaton College* v. *Burwell.* 134 S. Ct. 2806, 2807 (2014). The order stated that Wheaton College did not need to use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for injunctive relief. *Id.*

In response to this litigation, on August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of the Department of Health and Human Services that an eligible organization had religious objections to coverage of all or a subset of contraceptive services. (79 FR 51092). In response to *Hobby Lobby,* the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations. (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption, and neither added a certification requirement for exempt entities.

In October 2014, based on an interpretation of the Supreme Court's interim order, HHS deemed Wheaton College as having submitted a sufficient notice to HHS. HHS conveyed that interpretation to the DOL, so as to trigger the accommodation process.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The preamble to the July 2015 final regulations stated that, through the accommodation, payments

[16] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. See 134 S. Ct. at 2774.

for contraceptives and sterilization would be provided in a way that is ''seamless'' with the coverage that eligible employers provide to their plan participants and beneficiaries. *Id.* at 41328. The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

When an eligible organization maintains an insured group health plan or student health plan and provides the alternative notice, the July 2015 final regulations provide that HHS will inform the health insurance issuer of its obligations to cover contraceptive services to which the eligible organization objects. Where an eligible organization maintains a self-insured plan under ERISA and provides the alternative notice, the regulations provide that DOL will work with HHS to send a separate notification to the self-insured plan's third party administrator(s). The regulations further provide that such notification is an instrument under which the plan is operated for the purposes of section 3(16) of ERISA, and the instrument would designate the third party administrator as the entity obligated to provide or arrange for payments for contraceptives to which the eligible organization objects. The July 2015 final regulations continue to apply the amended notice requirement to eligible organizations that sponsor church plans exempt from ERISA pursuant to section 4(b)(2) of ERISA, but acknowledge that, with respect to the operation of the accommodation process, section 3(16) of ERISA does not provide a mechanism to impose an obligation to provide contraceptive coverage as a plan administrator on those eligible organizations' third party administrators. (80 FR 41323).

Meanwhile, a second split among Federal appeals courts had developed involving challenges to the Mandate's accommodation. Many religious nonprofit organizations argued that the accommodation impermissibly burdened their religious beliefs because it utilized the plans the organizations themselves sponsored to provide services to which they objected on religious grounds. They objected to the self-certification requirement on the same basis. Federal district courts split in the cases, granting preliminary injunction motions to religious groups in the majority of cases, but denying them to others. In most appellate cases, religious nonprofit organizations lost their challenges, where the courts often concluded that the accommodation imposed no substantial burden on their religious exercise under RFRA. For example, *Priests for Life* v. *U.S. Dep't of Health and Human Servs.,* 772 F. 3d 229 (D.C. Cir. 2014); *Little Sisters of the Poor Home for the Aged* v. *Burwell,* 794 F.3d 1151 (10th Cir. 2015); *Geneva Coll.* v. *Sec'y U.S. Dep't of Health & Human Servs.,* 778 F.3d 422 (3d Cir. 2015). But the Eighth Circuit disagreed and ruled in favor of religious nonprofit employers. *Dordt College* v. *Burwell,* 801 F.3d 946, 949–50 (8th Cir. 2015) (relying on *Sharpe Holdings, Inc.* v. *U.S. Dep't of Health & Human Servs.,* 801 F.3d 927 (8th Cir. 2015)).

On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik* v. *Burwell.* The Court held oral argument on March 23, 2016, and, after the argument, asked the parties to submit supplemental briefs addressing ''whether and how contraceptive coverage may be obtained by petitioners' employees through petitioners' insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees''. In a brief filed with the Supreme Court on April 12, 2016, the Government stated on behalf of the Departments that the accommodation process for eligible organizations with insured plans could operate without any self-certification or written notice being submitted by eligible organizations.

On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik,* vacating the judgments of the Courts of Appeals and remanding the cases ''in light of the substantial clarification and refinement in the positions of the parties'' in their supplemental briefs. (136 S. Ct. 1557, 1560 (2016).) The Court stated that it anticipated that, on remand, the Courts of Appeals would ''allow the parties sufficient time to resolve any outstanding issues between them.'' *Id.* The Court also specified that ''the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice'' while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, some meetings were held between attorneys for the Government and for the plaintiffs in those cases. Separately, at various times after the Supreme Court's remand order, HHS and DOL sent letters to the issuers and third party administrators of certain plaintiffs in *Zubik* and other pending cases, directing the issuers and third party administrators to provide contraceptive coverage for participants in those plaintiffs' group health plans under the accommodation. The Departments also issued a Request for Information (RFI) on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016.

On December 20, 2016, HRSA updated the Guidelines via its Web site, *https://www.hrsa.gov/womensguidelines2016/index.html.* HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the contraceptive method). They also specified that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women's Preventive Services' Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process.

On January 9, 2017, the Departments issued a document entitled, ''FAQs About Affordable Care Act Implementation Part 36'' (FAQ).[17] The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. Thus, the

[17] Available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

litigation on remand from the Supreme Court remains unresolved.

A separate category of unresolved litigation involved religious employees as plaintiffs. For example, in two cases, the plaintiff-employees work for a nonprofit organization that agrees with the employees (on moral grounds) in opposing coverage of certain contraceptives they believe to be abortifacient, and that is willing to offer them insurance coverage that omits such services. See *March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015); *Real Alternatives,* 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). In another case, the plaintiff-employees work for a State government entity that the employees claim is willing, under State law, to provide a plan omitting contraception consistent with the employees' religious beliefs. See *Wieland* v. *HHS,* 196 F. Supp. 3d 1010 (E.D. Mo. 2016). Those and similar employee-plaintiffs generally contend that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from their willing employer or in the individual market, because the Departments offer no exemptions encompassing either circumstance. Such challenges have seen mixed success. Compare, for example, *Wieland,* 196 F. Supp. 3d at 1020 (concluding that the Mandate violates the employee plaintiffs' rights under RFRA and permanently enjoining the Departments) and *March for Life,* 128 F. Supp. 3d at 133–34 (same), with *Real Alternatives,* 2017 WL 3324690 at *18 (affirming dismissal of employee plaintiffs' RFRA claim).

On May 4, 2017, the President issued an ''Executive Order Promoting Free Speech and Religious Liberty.'' Regarding ''Conscience Protections with Respect to Preventive-Care Mandate,'' that order instructs ''[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services [to] consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code.''

II. RFRA and Government Interests Underlying the Mandate

RFRA provides that the Government ''shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability'' unless the Government ''demonstrates that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.'' 42 U.S.C. 2000bb–1(a) and (b). In *Hobby Lobby,* the Supreme Court had ''little trouble concluding'' that, in the absence of an accommodation or exemption, ''the HHS contraceptive mandate 'substantially burden[s]' the exercise of religion. 42 U.S.C. 2000bb–1(a).'' 134 S. Ct. at 2775. And although the Supreme Court did not resolve the RFRA claims presented in *Zubik* on their merits, it instructed the parties to consider alternative accommodations for the objecting plaintiffs, after the Government suggested that such alternatives might be possible.

Despite multiple rounds of rulemaking, however, the Departments have not assuaged the sincere religious objections to contraceptive coverage of numerous organizations, nor have we resolved the pending litigation. To the contrary, the Departments have been litigating RFRA challenges to the Mandate and related regulations for more than 5 years, and dozens of those challenges remain pending today. That litigation, and the related modifications to the accommodation, have consumed substantial governmental resources while creating uncertainty for objecting organizations, issuers, third party administrators, employees, and beneficiaries. Consistent with the President's Executive Order and the Government's desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.

These interim final rules (and the companion interim final rules published elsewhere in this **Federal Register**) are the result of that reexamination. The Departments acknowledge that coverage of contraception is an important and highly sensitive issue, implicating many different views, as reflected in the comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. After reconsidering the interests served by the Mandate in this particular context, the objections raised, and the applicable Federal law, the Departments have determined that an expanded exemption, rather than the existing accommodation, is the most appropriate administrative response to the religious objections raised by certain entities and organizations concerning the Mandate. The Departments have accordingly decided to revise the regulations channeling HRSA authority under section 2713(a)(4) of the PHS to provide an exemption from the Mandate to a broader range of entities and individuals that object to contraceptive coverage on religious grounds, while continuing to offer the existing accommodation as an optional alternative. The Departments have also decided to create a process by which a willing employer and issuer may allow an objecting individual employee to obtain health coverage without contraceptive coverage. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

In addition to relying on the text of section 2713(a)(4) of the PHS Act and the Departments' discretion to promulgate rules to carry out the provisions of the PHS Act, the Departments also draw on Congress' decision in the Affordable Care Act neither to specify that contraception must be covered nor to require inflexible across-the-board application of section 2713 of the PHS Act. The Departments further consider Congress' extensive history of protecting religious objections when certain matters in health care are specifically regulated—often specifically with respect to contraception, sterilization, abortion, and activities connected to abortion.

Notable among the many statutes (listed in footnote 1 in Section I-Background) that include protections for religious beliefs are, not only the Church Amendments, but also protections for health plans or health care organizations in Medicaid or Medicare Advantage to object ''on moral or religious grounds'' to providing coverage of certain counseling or referral services. (42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1396u–2(b)(3)). In addition, Congress has protected individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31 (May 5, 2017). Congress likewise provided that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for

religious beliefs and moral convictions''. *Id.* at Division C, Title VIII, Sec. 808. In light of the fact that Congress did not require HRSA to include contraception in Guidelines issued under section 2713 of the PHS Act, we consider it significant, in support of the implementation of those Guidelines by the expanded exemption in these interim final rules, that Congress' most recent statement on the prospect of Government mandated contraceptive coverage was to express the specific intent that a conscience clause be provided and that it should protect religious beliefs.

The Departments' authority to guide HRSA's discretion in determining the scope of any contraceptive coverage requirement under section 2713(a)(4) of the PHS Act includes the authority to provide exemptions and independently justifies this rulemaking. The Departments have also determined that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance violates their rights under RFRA.

A. Elements of RFRA

1. Substantial Burden

The Departments believe that agencies charged with administering a statute or associated regulations or guidance that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining how to avoid the imposition of such burden. The Departments have previously contended that the Mandate does not impose a substantial burden on entities and individuals. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with religious objections, our argument was rejected in *Hobby Lobby,* which held that the Mandate imposes a substantial burden. (134 S. Ct. at 2775–79.) With respect to whether the Mandate imposes a substantial burden on entities that may choose the accommodation, but must choose between the accommodation, the Mandate, or penalties for noncompliance, a majority of Federal appeals courts have held that the accommodation does not impose a substantial burden on such entities (mostly religious nonprofit entities).

The Departments have reevaluated our position on this question, however, in light of all the arguments made in various cases, public comments that have been submitted, and the concerns discussed throughout these rules. We have concluded that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA. We believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing a substantial burden, to the burdens that an entity faces when it religiously opposes participating in the accommodation process or the straightforward Mandate, and is subject to penalties or disadvantages that apply in this context if it chooses neither. As the Eighth Circuit stated in *Sharpe Holdings,* ''[i]n light of [nonprofit religious organizations'] sincerely held religious beliefs, we conclude that compelling their participation in the accommodation process by threat of severe monetary penalty is a substantial burden on their exercise of religion. . . . That they themselves do not have to arrange or pay for objectionable contraceptive coverage is not determinative of whether the required or forbidden act is or is not religiously offensive''. (801 F.3d at 942.)

Our reconsideration of these issues has also led us to conclude, consistent with the rulings in favor of religious employee plaintiffs in *Wieland* and *March for Life* cited above, that the Mandate imposes a substantial burden on the religious beliefs of individual employees who oppose contraceptive coverage and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because of the Mandate's prohibition on that employer and/or issuer providing them with such a plan.

Consistent with our conclusion earlier this year after the remand of cases in *Zubik* and our reviewing of comments submitted in response to the 2016 RFI, the Departments believe there is not a way to satisfy all religious objections by amending the accommodation. Accordingly, the Departments have decided it is necessary and appropriate to provide the expanded exemptions set forth herein.

2. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Under such circumstances, the Departments are required by law to alleviate the substantial burden created by the Mandate. Here, informed by the Departments' reassessment of the relevant interests, as well as by our desire to bring to a close the more than 5 years of litigation over RFRA challenges to the Mandate, the Departments have determined that the appropriate administrative response is to create a broader exemption, rather than simply adjusting the accommodation process.

RFRA requires the Government to respect religious beliefs under ''the most demanding test known to constitutional law'': Where the Government imposes a substantial burden on religious exercise, it must demonstrate a compelling governmental interest and show that the law or requirement is the least restrictive means of furthering that interest. *City of Boerne* v. *Flores,* 521 U.S. 507, 534 (1997). For an interest to be compelling, its rank must be of the ''highest order''. *Church of the Lukumi Babalu Aye, Inc.* v. *City of Hialeah,* 508 U.S. 520, 546 (1993); see also *Sherbert* v. *Verner,* 374 U.S. 398, 406–09 (1963); *Wisconsin* v. *Yoder,* 406 U.S. 205, 221–29 (1972). In applying RFRA, the Supreme Court has ''looked beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants.'' *Gonzales* v. *O Centro Espirita Beneficente Uniao do Vegetal,* 546 U.S. 418, 431 (2006). To justify a substantial burden on religious exercise under RFRA, the Government must show it has a compelling interest in applying the requirement to the ''particular claimant[s] whose sincere exercise of religion is being substantially burdened.'' *Id.* at 430–31. Moreover, the Government must meet the ''exceptionally demanding'' least-restrictive-means standard. *Hobby Lobby,* 134 S. Ct. at 2780. Under that standard, the Government must establish that ''it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by the objecting parties.'' *Id.*

Upon further examination of the relevant provisions of the Affordable Care Act and the administrative record on which the Mandate was based, the Departments have concluded that the application of the Mandate to entities with sincerely held religious objections to it does not serve a compelling governmental interest. The Departments have reached that conclusion for multiple reasons, no one of which is dispositive.

First, Congress did not mandate that contraception be covered at all under the Affordable Care Act. Instead, Congress merely provided for coverage

of ''such additional preventive care and screenings'' for women ''provided for in comprehensive guidelines supported by [HRSA].'' Congress, thus, left the identification of any additional required preventive services for women to administrative discretion. The fact that Congress granted the Departments the authority to promulgate all rules appropriate and necessary for the administration of the relevant provisions of the Code, ERISA, and the PHS Act, including by channeling the discretion Congress afforded to HRSA to decide whether to require contraceptive coverage, indicates that the Departments' judgment should carry particular weight in considering the relative importance of the Government's interest in applying the Mandate to the narrow population of entities exempted in these rules.

Second, while Congress specified that many health insurance requirements added by the Affordable Care Act—including provisions adjacent to section 2713 of the PHS Act—were so important that they needed to be applied to all health plans immediately, the preventive services requirement in section 2713 of the PHS Act was not made applicable to ''grandfathered plans.'' That feature of the Affordable Care Act is significant: As cited above, seven years after the Affordable Care Act's enactment, approximately 25.5 million people are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act. We do not suggest that a requirement that is inapplicable to grandfathered plans or otherwise subject to exceptions could never qualify as a serving a compelling interest under RFRA. For example, ''[e]ven a compelling interest may be outweighed in some circumstances by another even weightier consideration.'' *Hobby Lobby,* 134 S. Ct. at 2780. But Congress' decision not to apply section 2713 of the PHS Act to grandfathered plans, while deeming other requirements closely associated in the same statute as sufficiently important to impose immediately, is relevant to our assessment of the importance of the Government interests served by the Mandate. As the Departments observed in 2010, those immediately applicable requirements were ''particularly significant.'' (75 FR 34540). Congress' decision to leave section 2713 out of that category informs the Departments' assessment of the weight of the Government's interest in applying the Guidelines issued pursuant to section 2713 of the PHS Act to religious objectors.

Third, various entities that brought legal challenges to the Mandate (including some of the largest employers) have been willing to provide coverage of some, though not all, contraceptives. For example, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of 14 of 18 FDA-approved women's contraceptive and sterilization methods. (134 S. Ct. at 2766.) With respect to organizations and entities holding those beliefs, the fact that they are willing to provide coverage for various contraceptive methods significantly detracts from the government interest in requiring that they provide coverage for other contraceptive methods to which they object.

Fourth, the case for a compelling interest is undermined by the existing accommodation process, and how it applies to certain similarly situated entities based on whether or not they participate in certain self-insured group health plans, known as church plans, under applicable law. The Departments previously exempted eligible organizations from the contraceptive coverage requirement, and created an accommodation under which those organizations bore no obligation to provide for such coverage after submitting a self-certification or notice. Where a non-exempt religious organization uses an insured group health plan instead of a self-insured church plan, the health insurance issuer would be obliged to provide contraceptive coverage or payments to the plan's participants under the accommodation. Even in a self-insured church plan context, the preventive services requirement in section 2713(a)(4) of the PHS Act applies to the plan, and through the Code, to the religious organization that sponsors the plan. But under the accommodation, once a self-insured church plan files a self-certification or notice, the accommodation relieves it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would normally transfer the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but not as they pertain to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs to become administrators of those plans to provide such coverage, has led to significant incongruity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

More specifically, issuers and third party administrators for some, but not all, religious nonprofit organizations are subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they participate in a self-insured church plan. Notably, many of those nonprofit organizations are not houses of worship or integrated auxiliaries. Under section 3(33)(C)(iv) of ERISA, many organizations in self-insured church plans need not be churches, but can merely ''share[] common religious bonds and convictions with [a] church or convention or association of churches''. The effect is that many similar religious organizations are being treated very differently with respect to their employees receiving contraceptive coverage—depending on whether the organization is part of a church plan—even though the Departments claimed a compelling interest to deny exemptions to all such organizations. In this context, the fact that the Mandate and the Departments' application thereof ''leaves appreciable damage to [their] supposedly vital interest unprohibited'' is strong evidence that the Mandate ''cannot be regarded as protecting an interest 'of the highest order.' '' *Lukumi,* 508 U.S. at 520 (citation and quotation marks omitted).

Fifth, the Departments' previous assertion that the exemption for houses of worship was offered to respect a certain sphere of church autonomy (80 FR 41325) does not adequately explain some of the disparate results of the existing rules. And the desire to respect church autonomy is not grounds to prevent the Departments from expanding the exemption to other religious entities. The Departments previously treated religious organizations that operate in a similar fashion very differently for the purposes of the Mandate. For example, the Departments exempted houses of worship and integrated auxiliaries that may conduct activities, such as the

operating of schools, that are also conducted by non-exempt religious nonprofit organizations. Likewise, among religious nonprofit groups that were not exempt as houses of worship or integrated auxiliaries, many operate their religious activities similarly even if they differ in whether they participate in self-insured church plans. As another example, two religious colleges might have the same level of religiosity and commitment to defined ideals, but one might identify with a specific large denomination and choose to be in a self-insured church plan offered by that denomination, while another might not be so associated or might not have as ready access to a church plan and so might offer its employees a fully insured health plan. Under the accommodation, employees of the college using a fully insured plan (or a self-insured plan that is not a church plan) would receive coverage of contraceptive services without cost sharing, while employees of the college participating in the self-insured church plan would not receive the coverage where that plan required its third party administrator to not offer the coverage.

As the Supreme Court recently confirmed, a self-insured church plan exempt from ERISA through ERISA 3(33) can include a plan that is not actually established or maintained by a church or by a convention or association of churches, but is maintained by ''an organization . . . the principal purpose or function of which is the administration or funding of a plan or program for the provision of retirement benefits or welfare benefits, or both, for the employees of a church or a convention or association of churches, if such organization is controlled by or associated with a church or a convention or association of churches'' (a so-called ''principal-purpose organization''). See *Advocate Health Care Network* v. *Stapleton,* 137 S. Ct. 1652, 1656–57 (U.S. June 5, 2017); ERISA 3(33)(C). While the Departments take no view on the status of these particular plans, the Departments acknowledge that the church plan exemption not only includes some non-houses-of-worship as organizations whose employees can be covered by the plan, but also, in certain circumstances, may include plans that are not themselves established and maintained by houses of worship. Yet, such entities and plans—if they file a self-certification or notice through the existing accommodation—are relieved of obligations under the contraceptive Mandate and their third party administrators are not subject to a requirement that they provide contraceptive coverage to their plan participants and beneficiaries.

After considering the differential treatment of various religious nonprofit organizations under the previous accommodation, the Departments conclude that it is appropriate to expand the exemption to other religious nonprofit organizations with sincerely held religious beliefs opposed to contraceptive coverage. We also conclude that it is not appropriate to limit the scope of a religious exemption by relying upon a small minority of State laws that contain narrow exemptions that focus on houses of worship and integrated auxiliaries. (76 FR 46623.)

Sixth, the Government's interest in ensuring contraceptive coverage for employees of particular objecting employers is undermined by the characteristics of many of those employers, especially nonprofit employers. The plaintiffs challenging the existing accommodation include, among other organizations, religious colleges and universities, and religious orders that provide health care or other charitable services. Based in part on our experience litigating against such organizations, the Departments now disagree with our previous assertion that ''[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection.'' [18] (78 FR 39874.) Although empirical data was not required to reach our previous conclusion, we note that the conclusion was not supported by any specific data or other source, but instead was intended to be a reasonable assumption. Nevertheless, in the litigation and in numerous public comments submitted throughout the regulatory processes described above, many religious nonprofit organizations have indicated that they possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Some of the religious nonprofit groups challenging the accommodation claim that their employees are required to adhere to a statement of faith which includes the entities' views on certain contraceptive items.[19] The Departments recognize, of course, that not all of the plaintiffs challenging the accommodation require all of their employees (or covered students) to share their religious objections to contraceptives. At the same time, it has become apparent from public comments and from court filings in dozens of cases—encompassing hundreds of organizations—that many religious nonprofit organizations express their beliefs publicly and hold themselves out as organizations for whom their religious beliefs are vitally important. Employees of such organizations, even if not required to sign a statement of faith, often have access to, and knowledge of, the views of their employers on contraceptive coverage, whether through the organization's published mission statement or statement of beliefs, through employee benefits disclosures and other communications with employees and prospective employees, or through publicly filed lawsuits objecting to providing such coverage and attendant media coverage. In many cases, the employees of religious organizations will have chosen to work for those organizations with an understanding—explicit or implicit—that they were being employed to advance the organization's goals and to be respectful of the organization's beliefs even if they do not share all of those beliefs. Religious nonprofit organizations that engage in expressive activity generally have a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[20]

Given the sincerely held religious beliefs of many religious organizations, imposing the contraceptive-coverage requirement on those that object based on such beliefs might undermine the Government's broader interests in ensuring health coverage by causing the entities to stop providing health coverage. For example, because the Affordable Care Act does not require

[18] In changing its position, an agency ''need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates.'' *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009).

[19] See, for example, *Geneva College* v. *Sebelius,* 929 F. Supp. 2d 402, 411 (W.D. Pa. 2013); *Grace Schools* v. *Sebelius,* 988 F. Supp. 2d 935, 943 (N.D. Ind. 2013); Comments of the Council for Christian Colleges & Universities, re: CMS–9968–P (filed Apr. 8, 2013) (''On behalf of [] 172 higher education institutions . . . a requirement for membership in the CCCU is that full-time administrators and faculty at our institutions share the Christian faith of the institution.'').

[20] Notably, ''the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.'' *Boy Scouts of America* v. *Dale,* 530 U.S. 640, 655 (2000).

institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or be subject to the accommodation with respect to such populations.[21]

Seventh, we now believe the administrative record on which the Mandate rests is insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. To begin, in support of the IOM's recommendations, which HRSA adopted, the IOM identified several studies showing a preventive services gap because women require more preventive care than men. (IOM 2011 at 19–21). Those studies did not identify contraceptives or sterilization as composing a specific portion of that gap, and the IOM did not consider or establish in the report whether any cost associated with that gap remains after all other women's preventive services are covered without cost-sharing. *Id.* Even without knowing what the empirical data would show about that gap, the coverage of the other women's preventive services required under both the HRSA Guidelines and throughout section 2713(a) of the PHS Act—including annual well-woman visits and a variety of tests, screenings, and counseling services—serves at a minimum to diminish the cost gap identified by IOM for women whose employers decline to cover some or all contraceptives on religious grounds.[22]

Moreover, there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women. Such Federal programs include, among others, Medicaid (with a 90 percent Federal match for family planning services), Title X, community health center grants, and Temporary Assistance for Needy Families. According to the Guttmacher Institute, government-subsidized family planning services are provided at 8,409 health centers overall.[23] The Title X program, for example, administered by the HHS Office of Population Affairs (OPA), provides a wide variety of voluntary family planning information and services for clients based on their ability to pay, through a network that includes nearly 4,000 family planning centers. *http://www.hhs.gov/opa/title-x-family-planning/* Individuals with family incomes at or below the HHS poverty guideline (for 2017, $24,600 for a family of four in the 48 contiguous States and the District of Columbia) receive services at no charge unless a third party (governmental or private) is authorized or obligated to pay for these services. Individuals with incomes in excess of 100 percent up to 250 percent of the poverty guideline are charged for services using a sliding fee scale based on family size and income. Unemancipated minors seeking confidential services are assessed fees based on their own income level rather than their family's income. The availability of such programs to serve the most at-risk women (as defined in the IOM report) diminishes the Government's interest in applying the Mandate to objecting employers. Many forms of contraception are available for around $50 per month, including long-acting methods such as the birth control shot and intrauterine devices (IUDs).[24] Other, more permanent forms of contraception like implantables bear a higher one-time cost, but when calculated over the duration of use, cost a similar amount.[25] Various State programs supplement the Federal programs referenced above, and 28 States have their own mandates of contraceptive coverage as a matter of State law. This existing inter-governmental structure for obtaining contraceptives significantly diminishes the Government's interest in applying the Mandate to employers over their sincerely held religious objections.

The record also does not reflect that the Mandate is tailored to the women most likely to experience unintended pregnancy, identified by the 2011 IOM report as ''women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority''. (IOM 2011 at 102). For example, with respect to religiously objecting organizations, the Mandate applies in employer-based group health plans and student insurance at private colleges and universities. It is not clear that applying the Mandate among those objecting entities is a narrowly tailored way to benefit the most at-risk population. The entities appear to encompass some such women, but also appear to omit many of them and to include a significantly larger cross-section of women as employees or plan participants. At the same time, the Mandate as applied to objecting employers appears to encompass a relatively small percentage of the number of women impacted by the Mandate overall, since most employers do not appear to have conscientious objections to the Mandate.[26] The Guttmacher Institute, on which the IOM relied, further reported that 89 percent of women who are at risk of unintended pregnancy and are living at 0 through 149 percent of the poverty line are already using contraceptives, as are 92 percent of those with incomes of 300 percent or more of the Federal poverty level.[27]

The rates of—and reasons for—unintended pregnancy are notoriously difficult to measure.[28] In particular, association and causality can be hard to disentangle, and the studies referred to by the 2011 IOM Report speak more to association than causality. For example, IOM 2011 references Boonstra, et al.

[21] See, for example, Manya Brachear Pashman, ''Wheaton College ends coverage amid fight against birth control mandate,'' Chicago Tribune (July 29, 2015); Laura Bassett, ''Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,'' HuffPost (May 15, 2012).

[22] The Departments are not aware of any objectors to the contraceptive Mandate that are unwilling to cover any of the other preventive services without cost sharing as required by PHS Act section 2713.

[23] ''Facts on Publicly Funded Contraceptive Services in the United States,'' March 2016.

[24] See, for example, Caroline Cunningham, ''How Much Will Your Birth Control Cost Once the Affordable Care Act Is Repealed?'' *Washingtonian* (Jan. 17, 2017), available at *https://www.washingtonian.com/2017/01/17/how-much-will-your-birth-control-cost-once-the-affordable-care-act-is-repealed/*; also, see *https://www.plannedparenthood.org/learn/birth-control.*

[25] *Id.*

[26] Prior to the implementation of the Affordable Care Act approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2010 Annual Survey'' at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf.* It is not clear whether the minority of employers who did not cover contraception refrained from doing so for conscientious reasons or for other reasons. Estimates of the number of women who might be impacted by the exemptions offered in these rules, as compared to the total number of women who will likely continue to receive contraceptive coverage, is discussed in more detail below.

[27] ''Contraceptive Use in the United States,'' September 2016.

[28] The IOM 2011 Report reflected this when it cited the IOM's own 1995 report on unintended pregnancy, ''The Best Intentions'' (IOM 1995). IOM 1995 identifies various methodological difficulties in demonstrating the interest in reducing unintended pregnancies by means of a coverage mandate in employer plans. These include: The ambiguity of intent as an evidence-based measure (does it refer to mistimed pregnancy or unwanted pregnancy, and do studies make that distinction?); ''the problem of determining parental attitudes at conception'' and inaccurate methods often used for that assessment, such as ''to use the request for an abortion as a marker''; and the overarching problem of ''association versus causality,'' that is, whether intent causes certain negative outcomes or is merely correlated with them. IOM 1995 at 64–66. See also IOM 1995 at 222 (''the largest public sector funding efforts, Title X and Medicaid, have not been well evaluated in terms of their net effectiveness, including their precise impact on unintended pregnancy'').

(2006), as finding that, ''as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined,'' [29] and Santelli and Melnikas as finding that ''increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use''. IOM 2011 at 105.[30] In this respect, the report does not show that access to contraception causes decreased incidents of unintended pregnancy, because both of the assertions rely on association rather than causation, and they associate reduction in unintended pregnancy with increased use of contraception, not merely with increased access to such contraceptives.

Similarly, in a study involving over 8,000 women between 2012 and 2015, conducted to determine whether contraceptive coverage under the Mandate changed contraceptive use patterns, the Guttmacher Institute concluded that ''[w]e observed no changes in contraceptive use patterns among sexually active women.'' [31] With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship).[32] Another study, which proposed an economic model for the decision to engage in sexual activity, stated that ''[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.'' [33] Regarding emergency contraception in particular, ''[i]ncreased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates.''[34] In the longer term—from 1972 through 2002—while the percentage of sexually experienced women who had ever used some form of contraception rose to 98 percent,[35] unintended pregnancy rates in the Unites States rose from 35.4 percent[36] to 49 percent.''[37] The Departments note these and other studies[38] to observe the complexity and uncertainty in the relationship between contraceptive access, contraceptive use, and unintended pregnancy.

Contraception's association with positive health effects might also be partially offset by an association with negative health effects. In 2013 the National Institutes of Health indicated, in funding opportunity announcement for the development of new clinically useful female contraceptive products, that ''hormonal contraceptives have the disadvantage of having many undesirable side effects[,] are associated with adverse events, and obese women are at higher risk for serious complications such as deep venous thrombosis.'' [39] In addition, IOM 2011 stated that ''[l]ong-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011).'' (IOM 2011 at 107). However, after IOM 2011 made this statement, AHRQ (a component of HHS) completed its systematic evidence review.[40] Based on its review, AHRQ stated that: ''[o]varian cancer incidence was significantly reduced in OC [oral contraceptive] users''; ''[b]reast cancer incidence was slightly but significantly increased in OC users''; ''[t]he risk of cervical cancer was significantly increased in women with persistent human papillomavirus infection who used OCs, but heterogeneity prevented a formal meta-analysis''; ''[i]ncidences of both colorectal cancer [] and endometrial cancer [] were significantly reduced by OC use''; ''[t]he risk of vascular events was increased in current OC users compared with nonusers, although the increase in myocardial infarction was not statistically significant''; ''[t]he overall strength of evidence for ovarian cancer prevention was moderate to low''; and ''[t]he simulation model predicted that the combined increase in risk of breast and cervical cancers and vascular events was likely to be equivalent to or greater than the decreased risk in ovarian cancer.''[41] Based on these findings, AHRQ concluded that ''[t]here is insufficient evidence to recommend for or against the use of OCs solely for the primary prevention of ovarian cancer . . . . the harm/benefit ratio for ovarian cancer prevention alone is uncertain, particularly when the

[29] H. Boonstra, et al., ''Abortion in Women's Lives'' at 18, *Guttmacher Inst.* (2006).

[30] Citing John S. Santelli & Andrea J. Melnikas, ''Teen Fertility in Transition: Recent and Historic Trends in the United States,'' 31 *Ann. Rev. Pub. Health* 371 (2010).

[31] Bearak, J.M. and Jones, R.K., ''Did Contraceptive Use Patterns Change after the Affordable Care Act? A Descriptive Analysis,'' 27 *Women's Health Issues* 316 (Guttmacher Inst. May–June 2017), available at *http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.*

[32] 31 *Ann. Rev. Pub. Health* at 375–76.

[33] Peter Arcidiacono, et al., ''Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?'' (2005), *available at http://public.econ.duke.edu/~psarcidi/teensex.pdf.*

[34] G. Raymond et al., ''Population effect of increased access to emergency contraceptive pills: a systematic review,'' 109 Obstet. Gynecol. 181 (2007).

[35] William D. Mosher & Jo Jones, U.S. Dep't of HHS, CDC, National Center for Health Statistics, ''Use of Contraception in the United States: 1982–2008'' at 5 fig. 1, 23 *Vital and Health Statistics* 29 (Aug. 2010), available at *https://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf.*

[36] Helen M. Alvaré, ''No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom,'' 58 *Vill. L. Rev.* 379, 404–05 & n.128 (2013), available at *http://digitalcommons.law.villanova.edu/vlr/vol58/iss3/2* (quoting Christopher Tietze, ''Unintended Pregnancies in the United States, 1970–1972,'' 11 *Fam. Plan. Persp.* 186, 186 n.* (1979) (''in 1972, 35.4 percent percent of all U.S. pregnancies were 'unwanted' or 'wanted later'''')).

[37] *Id.* (citing Lawrence B. Finer & Stanley K. Henshaw, ''Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001'' 38 *Persp. on Sexual Reprod. Health* 90 (2006) (''In 2001, 49 percent of pregnancies in the United States were unintended'')).

[38] See, for example, J.L Dueñas, et al., ''Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997–2007,'' 83 *Contraception* 82 (2011) (as use of contraceptives increased from 49 percent to 80 percent, the elective abortion rate more than doubled); D. Paton, ''The economics of family planning and underage conceptions,'' 21 *J. Health Econ.* 207 (2002) (data from the UK confirms an economic model which suggests improved family planning access for females under 16 increases underage sexual activity and has an ambiguous impact on underage conception rates); T. Raine et al., ''Emergency contraception: advance provision in a young, high-risk clinic population,'' 96 *Obstet. Gynecol.* 1 (2000) (providing advance provision of emergency contraception at family planning clinics to women aged 16–24 was associated with the usage of less effective and less consistently used contraception by other methods); M. Belzer et al., ''Advance supply of emergency contraception: a randomized trial in adolescent mothers,'' 18 *J. Pediatr. Adolesc. Gynecol.* 347 (2005) (advance provision of emergency contraception to mothers aged 13–20 was associated with increased unprotected sex at the 12-month follow up).

[39] NIH, ''Female Contraceptive Development Program (U01)'' (Nov. 5, 2013), available at *https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-14-024.html.* Thirty six percent of women in the United States are obese. *https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity.* Also see ''Does birth control raise my risk for health problems?'' and ''What are the health risks for smokers who use birth control?'' HHS Office on Women's Health, available at *https://www.womenshealth.gov/a-z-topics/birth-control-methods*; Skovlund, CW, ''Association of Hormonal Contraception with Depression,'' 73 *JAMA Psychiatry* 1154 (Nov. 1, 2016), available at *https://www.ncbi.nlm.nih.gov/pubmed/27680324.*

[40] Havrilesky, L.J, et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No.: 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html.*

[41] *Id.*

potential quality-of-life impact of breast cancer and vascular events are considered.''[42]

In addition, in relation to several studies cited above, imposing a coverage Mandate on objecting entities whose plans cover many enrollee families who may share objections to contraception could, among some populations, affect risky sexual behavior in a negative way. For example, it may not be a narrowly tailored way to advance the Government interests identified here to mandate contraceptive access to teenagers and young adults who are not already sexually active and at significant risk of unintended pregnancy.[43]

Finally, evidence from studies that post-date the Mandate is not inconsistent with the observations the Departments make here. In 2016, HRSA awarded a 5-year cooperative agreement to the American College of Obstetricians and Gynecologists to develop recommendations for updated Women's Preventive Services Guidelines. The awardee formed an expert panel called the Women's Preventive Services Initiative that issued a report (the WPSI report).[44] After observing that ''[p]rivate companies are increasingly challenging the contraception provisions in the Affordable Care Act,'' the WPSI report cited studies through 2013 stating that application of HRSA Guidelines had applied preventive services coverage to 55.6 million women and had led to a 70 percent decrease in out-of-pocket expenses for contraceptive services among commercially insured women. *Id.* at 57–58. The WPSI report relied on a 2015 report of the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''The Affordable Care Act Is Improving Access to Preventive Services for Millions of Americans,'' which estimated that persons who have private insurance coverage of preventive services without cost sharing includes 55.6 million women.[45]

As discussed above and based on the Departments' knowledge of litigation challenging the Mandate, during the time ASPE estimated the scope of preventive services coverage (2011–2013), houses of worship and integrated auxiliaries were exempt from the Mandate, other objecting religious nonprofit organizations were protected by the temporary safe harbor, and hundreds of accommodated self-insured church plan entities were not subject to enforcement of the Mandate through their third party administrators. In addition, dozens of for-profit entities that had filed lawsuits challenging the Mandate were protected by court orders pending the Supreme Court's resolution of *Hobby Lobby* in June 2014. It would therefore appear that the benefits recorded by the report occurred even though most objecting entities were not in compliance.[46] Additional data indicates that, in 28 States where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[47]

The Departments need not take a position on these empirical questions. Our review is sufficient to lead us to conclude that significantly more uncertainty and ambiguity exists in the record than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals as set forth herein, and that no compelling interest exists to counsel against us extending the exemption.

During public comment periods, some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions. The IOM similarly stated that ''the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain.'' IOM 2011 at 107. Consequently, some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes. Section 2713(a)(4) of the PHS Act does not, however, apply to non-preventive care provided solely for treatment of an existing condition. It applies only to ''such additional preventive care and screenings . . . as provided for'' by HRSA (Section 2713(a)(4) of the PHS Act). HRSA's Guidelines implementing this section state repeatedly that they apply to ''preventive'' services or care, and with respect to the coverage of contraception specifically, they declare that the methods covered are ''contraceptive'' methods as a ''Type of Preventive Service,'' and that they are to be covered only ''[a]s prescribed'' by a physician or other health care provider. *https://www.hrsa.gov/womensguidelines/* The contraceptive coverage requirement in the Guidelines also only applies for ''women with reproductive capacity.'' *https://www.hrsa.gov/womensguidelines/*; (80 FR 40318). Therefore, the Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that the FDA has approved for contraceptive use is prescribed in whole or in part for such use. The Guidelines and section 2713(a)(4) of the PHS Act do not require coverage of such drugs where they are prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[48] As discussed above, the last

[42] *Id.* Also, see Kelli Miller, ''Birth Control & Cancer: Which Methods Raise, Lower Risk,'' *The Am. Cancer Society,* (Jan. 21, 2016), available at *http://www.cancer.org/cancer/news/features/birth-control-cancer-which-methods-raise-lower-risk.*

[43] For further discussion, see Alvaré, 58 *Vill. L. Rev.* at 400–02 (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[44] ''WPSI 2016 Recommendations: Evidence Summaries and Appendices,'' at 54–64, *available at https://www.womenspreventivehealth.org/wp-content/uploads/2016/12/Evidence-Summaries-and-Appendices.pdf.*

[45] Available at *https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans*; also, see Abridged Report, available at *https://www.womenspreventivehealth.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf.*

[46] In addition, as in IOM 2011, the WPSI report bases its evidentiary conclusions relating to contraceptive coverage, use, unintended pregnancy, and health benefits, on conclusions that the phenomena are ''associated'' with the intended outcomes, without showing there is a causal relationship. For example, the WPSI report states that ''[c]ontraceptive counseling in primary care may increase the uptake of hormonal methods and [long-acting reversible contraceptives], although data on structured counseling in specialized reproductive health settings demonstrated no such effect.'' *Id.* at 63. The WPSI report also acknowledges that a large-scale study evaluating the effects of providing no-cost contraception had ''no randomization or control group.'' *Id.* at 63.

The WPSI report also identifies the at-risk population as young, low-income, and/or minority women: ''[u]nintended pregnancies disproportionately occur in women age 18 to 24 years, especially among those with low incomes or from racial/ethnic minorities.'' *Id.* at 58. The WPSI report acknowledges that many in this population are already served by Title X programs, which provide family planning services to ''approximately 1 million teens each year.'' *Id.* at 58. The WPSI report observes that between 2008 and 2011—before the contraceptive coverage requirement was implemented—unintended pregnancy decreased to the lowest rate in 30 years. *Id.* at 58. The WPSI report does not address how to balance contraceptive coverage interests with religious objections, nor does it specify the extent to which applying the Mandate among commercially insured at objecting entities serves to deliver contraceptive coverage to women most at risk of unintended pregnancy.

[47] See Michael J. New, ''Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,'' 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

[48] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that ''there are demonstrated preventive health benefits

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Administration decided to exempt houses of worship and their integrated auxiliaries from the Mandate, and to relieve hundreds of religious nonprofit organizations of their obligations under the Mandate and not further require contraceptive coverage to their employees. In several of the lawsuits challenging the Mandate, some religious plaintiffs stated that they do not object and are willing to cover drugs prescribed for the treatment of an existing condition and not for contraceptive purposes—even if those drugs are also approved by the FDA for contraceptive uses. Therefore, the Departments conclude that the fact that some drugs that are approved for preventive contraceptive purposes can also be used for exclusively non-preventive purposes to treat existing conditions is not a sufficient reason to refrain from expanding the exemption to the Mandate.

An additional consideration supporting the Departments' present view is that alternative approaches can further the interests the Departments previously identified behind the Mandate. As noted above, the Government already engages in dozens of programs that subsidize contraception for the low-income women identified by the IOM as the most at risk for unintended pregnancy. The Departments have also acknowledged in legal briefing that contraception access can be provided through means other than coverage offered by religious objectors, for example, through ''a family member's employer,'' ''an Exchange,'' or ''another government program.'' [49]

Many employer plan sponsors, institutions of education arranging student health coverage, and individuals enrolled in plans where their employers or issuers (as applicable) are willing to offer them a religiously acceptable plan, hold sincerely held religious beliefs against (respectively) providing, arranging, or participating in plans that comply with the Mandate either by providing contraceptive coverage or by using the accommodation. Because we have concluded that requiring such compliance through the Mandate or accommodation has constituted a substantial burden on the religious exercise of many such entities or individuals, and because we conclude requiring such compliance did not serve a compelling interest and was not the least restrictive means of serving a compelling interest, we now believe that requiring such compliance led to the violation of RFRA in many instances. We recognize that this is a change of position on this issue, and we make that change based on all the matters discussed in this preamble.

B. Discretion To Provide Religious Exemptions

Even if RFRA does not compel the religious exemptions provided in these interim final rules, the Departments believe they are the most appropriate administrative response to the religious objections that have been raised. RFRA identifies certain circumstance under which government must accommodate religious exercise-when a government action imposes a substantial burden on the religious exercise of an adherent and imposition of that burden is not the least restrictive means of achieving a compelling government interest. RFRA does not, however, prescribe the accommodation that the government must adopt. Rather, agencies have discretion to fashion an appropriate and administrable response to respect religious liberty interests implicated by their own regulations. We know from *Hobby Lobby* that, in the absence of any accommodation, the contraceptive-coverage requirement imposes a substantial burden on certain objecting employers. We know from other lawsuits and public comments that many religious entities have objections to complying with the accommodation based on their sincerely held religious beliefs. Previously, the Departments attempted to develop an accommodation that would either alleviate the substantial burden imposed on religious exercise or satisfy RFRA's requirements for imposing that burden.

Now, however, the Departments have reassessed the relevant interests and determined that, even if exemptions are not required by RFRA, they would exercise their discretion to address the substantial burden identified in *Hobby Lobby* by expanding the exemptions from the Mandate instead of revising accommodations previously offered. In the Departments' view, a broader exemption is a more direct, effective means of satisfying all bona fide religious objectors. This view is informed by the fact that the Departments' previous attempt to develop an appropriate accommodation did not satisfy all objectors. That previous accommodation consumed Departmental resources not only through the regulatory process, but in persistent litigation and negotiations. Offering exemptions as described in these interim final rules is a more workable way to respond to the substantial burden identified in *Hobby Lobby* and bring years of litigation concerning the Mandate to a close.

C. General Scope of Expanded Religious Exemptions

1. Exemption and Accommodation for Religious Employers, Plan Sponsors, and Institutions of Higher Education

For all of these reasons, and as further explained below, the Departments now believe it is appropriate to modify the scope of the discretion afforded to HRSA in the July 2015 final regulations to direct HRSA to provide the expanded exemptions and change the accommodation to an optional process if HRSA continues to otherwise provide for contraceptive coverage in the Guidelines. As set forth below, the expanded exemption encompasses non-governmental plan sponsors that object based on sincerely held religious beliefs, and institutions of higher education in their arrangement of student health plans. The accommodation is also maintained as an optional process for exempt employers, and will provide contraceptive availability for persons covered by the plans of entities that use it (a legitimate program purpose).

The Departments believe this approach is sufficiently respectful of religious objections while still allowing the Government to advance other interests. Even with the expanded exemption, HRSA maintains the discretion to require contraceptive coverage for nearly all entities to which the Mandate previously applied (since most plan sponsors do not appear to possess the requisite religious objections), and to reconsider those interests in the future where no covered objection exists. Other Government subsidies of contraception are likewise not affected by this rule.

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from contraceptives relating to conditions other than pregnancy.'' 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act section 2713(a)(4) or the Guidelines require coverage of ''contraceptive'' methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead it was an observation that such drugs—generally referred to as ''contraceptives''—also have some alternate beneficial uses to treat existing conditions. For the purposes of these interim final rules, the Departments clarify here that our previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines.

[49] Brief for the Respondents at 65, *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016) (No. 14–1418).

2. Exemption for Objecting Individuals Covered by Willing Employers and Issuers

As noted above, some individuals have brought suit objecting to being covered under an insurance policy that includes coverage for contraceptives. See, for example, *Wieland* v. *HHS,* 196 F. Supp. 3d 1010 (E.D. Mo. 2016); *Soda* v. *McGettigan,* No. 15–cv–00898 (D. Md.). Just as the Departments have determined that the Government does not have a compelling interest in applying the Mandate to employers that object to contraceptive coverage on religious grounds, we have also concluded that the Government does not have a compelling interest in requiring individuals to be covered by policies that include contraceptive coverage when the individuals have sincerely held religious objections to that coverage. The Government does not have an interest in ensuring the provision of contraceptive coverage to individuals who do not wish to have such coverage. Especially relevant to this conclusion is the fact that the Departments have described their interests of health and gender equality as being advanced among women who ''want'' the coverage so as to prevent ''unintended'' pregnancy. (77 FR 8727).[50] No asserted interest is served by denying an exemption to individuals who object to it. No unintended pregnancies will be avoided or costs reduced by imposing the coverage on those individuals.

Although the Departments previously took the position that allowing individual religious exemptions would undermine the workability of the insurance system, the Departments now agree with those district courts that have concluded that an exemption that allows—but does not require—issuers and employers to omit contraceptives from coverage provided to objecting individuals does not undermine any compelling interest. See *Wieland,* 196 F. Supp. 3d at 1019–20; *March for Life,* 128 F. Supp. 3d at 132. The individual exemption will only apply where the employer and issuer (or, in the individual market, the issuer) are willing to offer a policy accommodating the objecting individual. As a result, the Departments consider it likely that where an individual exemption is invoked, it will impose no burdens on the insurance market because such burdens may be factored into the willingness of an employer or issuer to offer such coverage. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments' previous exemption for houses of worship and integrated auxiliaries, and our lack of authority to enforce the accommodation with respect to self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.[51] Furthermore, granting exemptions to individuals who do not wish to receive contraceptive coverage where the plan and, as applicable, issuer and plan sponsor are willing, does not undermine the Government's interest in ensuring the provision of such coverage to other individuals who wish to receive it. Nor do such exemptions undermine the operation of the many other programs subsidizing contraception. Rather, such exemptions serve the Government's interest in accommodating religious exercise. Accordingly, as further explained below, the Departments have provided an exemption to address the concerns of objecting individuals.

D. Effects on Third Parties of Exemptions

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 of the PHS Act requirements on grandfathered plans that cover millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have other avenues for obtaining contraception, including the various governmental programs discussed above. As the Government is under no constitutional obligation to fund contraception, *cf. Harris* v. *McRae,* 448 United States 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their religious beliefs. *Cf. Rust* v. *Sullivan,* 500 U.S. 173, 192–93 (1991) (''A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.'').[52]

That conclusion is consistent with the Supreme Court's observation that RFRA may require exemptions even from laws requiring claimants ''to confer benefits on third parties.'' *Hobby Lobby,* 134 S. Ct. at 2781 n.37. The burdens imposed on such third parties may be relevant to the RFRA analysis, but they cannot be dispositive. ''Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).'' *Id.* Where, as here, contraceptives are readily accessible and, for many low income persons, are available at reduced cost or for free through various governmental programs, and contraceptive coverage may be available through State sources or family plans obtained through non-objecting employers, the Departments have determined that the expanded exemptions rather than accommodations are the appropriate response to the substantial burden that the Mandate has placed upon the religious exercise of many religious employers.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including prior interim final rules), public comments, and litigation throughout the Federal court system. The interim final rules seek to resolve this matter and the long-running litigation with respect to religious

[50] In this respect, the Government's interest in contraceptive coverage is different than its interest in persons receiving some other kinds of health coverage or coverage in general, which can lead to important benefits that are not necessarily conditional on the recipient's desire to use the coverage and the specific benefits that may result from their choice to use it.

[51] Also, see *Real Alternatives,* 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) (''Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the Affordable Care Act) would be unworkable, it has not satisfied strict scrutiny.'' (citation and internal quotation marks omitted)).

[52] *Cf. also Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (''a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'').

objections by extending the exemption under the HRSA Guidelines to encompass entities, and individuals, with sincerely held religious beliefs objecting to contraceptive or sterilization coverage, and by making the accommodation process optional for eligible organizations.

The Departments acknowledge that the foregoing analysis represents a change from the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlie the Mandate. These changes in policy are within the Departments' authority. As the Supreme Court has acknowledged, ''[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change.'' *Encino Motorcars, LLC* v. *Navarro,* 136 S. Ct. 2117, 2125 (2016). This ''reasoned analysis'' requirement does not demand that an agency ''demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates''. *United Student Aid Funds, Inc.* v. *King,* 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)); also, see *New Edge Network, Inc.* v. *FCC,* 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that ''an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance'').

Here, for all of the reasons discussed above, the Departments have determined that the Government's interest in the application of contraceptive coverage requirements in this specific context to the plans of certain entities and individuals does not outweigh the sincerely held religious objections of those entities and individuals based on the analyses set forth above. Thus, these interim final rules amend the Departments' July 2015 final regulations to expand the exemption to include additional entities and persons that object based on sincerely held religious beliefs. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no such objection exists, and to the extent that section 2713 of the PHS Act applies. These interim final rules also maintain the existence of an accommodation process, but consistent with our expansion of the exemption, we make the process optional for eligible organizations. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.[53]

A. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules modify the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) introductory text and (a)(1)(iv), so that they conform to the statutory text of section 2713 of the PHS Act.

B. Prefatory Language of the Exemption in 45 CFR 147.132

These interim final rules move the religious exemption from 45 CFR 147.131 to a new § 147.132 and expand it as follows. In the prefatory language of § 147.132, these interim final rules specify that not only are certain entities ''exempt,'' but the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such entities. This is an acknowledgement that section 2713(a)(4) of the PHS Act requires women's preventive services coverage only ''as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.'' To the extent the HRSA Guidelines do not provide for or support the application of such coverage to exempt entities, the Affordable Care Act does not require the coverage. Section 147.132 not only describes the exemption of certain entities and plans, but does so by specifying that the HRSA Guidelines do not provide for, or support the application of, such coverage to exempt entities and plans.

C. General Scope of Exemption for Objecting Entities

In the new 45 CFR 147.132 as created by these interim final rules, these rules expand the exemption that was previously located in § 147.131(a). With respect to employers that sponsor group health plans, the new language of § 147.132(a)(1) introductory text and (a)(1)(i) provides exemptions for employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption created in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.132(a)(1) introductory text and (a)(1)(i), by specifying that ''[a] group health plan and health insurance coverage provided in connection with a group health plan'' is exempt ''to the extent the plan sponsor objects as specified in paragraph (a)(2),'' exempt the group health plans the sponsors of which object, and exempt their health insurance issuers from providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[54] Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage,

[53] See *https://www.hrsa.gov/womensguidelines/* and *https://www.hrsa.gov/womensguidelines2016/index.html.*

[54] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. Also, see 45 CFR 147.200 (requiring disclosure of the ''exceptions, reductions, and limitations of the coverage,'' including group health plans and group & individual issuers).

otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.132(a) apply ''to the extent'' of the objecting entities' sincerely held religious beliefs. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.132(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsor has no qualifying objection. The objection of a health insurance issuer in § 147.132(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

D. Exemption of Employers and Institutions of Higher Education

The scope of the exemption is expanded for non-governmental plan sponsors and certain entities that arrange health coverage under these interim final rules. The Departments have consistently taken the position that section 2713(a)(4) of the PHS Act grants HRSA authority to issue Guidelines that provide for and support exemptions from a contraceptive coverage requirement. Since the beginning of rulemaking concerning the Mandate, HRSA and the Departments have repeatedly exercised their discretion to create and modify various exemptions within the Guidelines.[55]

The Departments believe the approach of these interim final rules better aligns our implementation of section 2713(a)(4) of the PHS Act with Congress' intent in the Affordable Care Act and throughout other Federal health care laws. As discussed above, many Federal health care laws and regulations provide exemptions for objections based on religious beliefs, and RFRA applies to the Affordable Care Act. Expanding the exemption removes religious obstacles that entities and certain individuals may face when they otherwise wish to participate in the health care market. This advances the Affordable Care Acts goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate. These rules also leave in place many Federal programs that subsidize contraceptives for women who are most at risk of unintended pregnancy and who may have more limited access to contraceptives.[56] These interim final rules achieve greater uniformity and simplicity in the regulation of health insurance by expanding the exemptions to include entities that object to the Mandate based on their sincerely held religious beliefs.

The Departments further conclude that it would be inadequate to merely attempt to amend the accommodation process instead of expand the exemption. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way ''seamless'' to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. The Departments have engaged in an effort to attempt to identify an accommodation that would eliminate the plaintiffs' religious objections, including seeking public comment through an RFI, but we stated in January 2017 that we were unable to develop such an approach at that time.

1. Plan Sponsors Generally

The expanded exemptions in these interim final rules cover any kind of non-governmental employer plan sponsor with the requisite objections but, for the sake of clarity, they include an illustrative, non-exhaustive list of employers whose objections qualify the plans they sponsor for an exemption.

Under these interim final rules, the Departments do not limit the Guidelines exemption with reference to nonprofit status or to sections 6033(a)(3)(A)(i) or (iii) of the Code, as previous rules have done. A significant majority of States either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[57] Although the practice of States is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor a statement about what the Federal Government may do consistent with RFRA or other limitations in federal law, such State practice can be informative as to the viability of broad protections for religious liberty. In this case, such practice supports the Departments' decision to expand the federal exemption, bringing the Federal Government's practice into greater alignment with the practices of the majority of the States.

2. Section 147.132(a)(1)(i)(A)

Despite not limiting the exemption to certain organizations referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, the exemption in these rules includes such organizations. Section 147.132(a)(1)(i)(A) specifies, as under the prior exemption, that the exemption covers ''a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order.'' In the preamble to rules setting forth the prior exemption at § 147.132(a), the Departments interpreted this same language used in those rules by declaring that ''[t]he final regulations continue to provide that the availability of the exemption or accommodation be determined on an employer by employer basis, which the Departments continue to believe best balances the interests of religious employers and eligible organizations and those of employees and their dependents.'' (78 FR 39886). Therefore, under the prior exemption, if an employer participated in a house of worship's plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not considered to be covered by the

[55] ''The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.'' *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837, 863–64 (1984).

[56] See, for example, Family Planning grants in 42 U.S.C. 300, *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[57] See Guttmacher Institute, ''Insurance Coverage of Contraceptives'' available at *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a ''plan established or maintained by a [house of worship].''

Under these interim final rules, however, the Departments intend that, when this regulation text exempts a plan ''established or maintained by'' a house of worship or integrated auxiliary, such exemption will no longer ''be determined on an employer by employer basis,'' but will be determined on a plan basis—that is, by whether the plan is a ''plan established or maintained by'' a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these interim final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the threshold of being integrated auxiliaries. Moreover, under this interpretation, houses of worship would not be faced with the potential prospect of services to which they have a religious objection being covered for employees of an associated employer participating in a plan they have established and maintain.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted participation in its health plan, but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior rule, to the extent that, in practice and as discussed elsewhere herein, it does not force contraceptive coverage to be provided on behalf of the plan participants of many religious organizations in a self-insured church plan exempt from ERISA—which are exempt in part because the plans are established and maintained by a church. (Section 3(33)(A) of ERISA) In several lawsuits challenging the Mandate, the Departments took the position that some plans established and maintained by houses of worship, but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government ''has no authority to require the plaintiffs' TPAs to provide contraceptive coverage at this time.'' *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013). Therefore the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

3. Section 147.132(a)(1)(i)(B)

Section 147.132(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of plan sponsors that are nonprofit organizations.

4. Section 147.132(a)(1)(i)(C)

Under § 147.132(a)(1)(i)(C), the rules extend the exemption to the plans of closely held for-profit entities. This is consistent with the Supreme Court's ruling in *Hobby Lobby,* which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby,* religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the Departments' argument to the contrary. (134 S. Ct. 2768–75) Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.[58]

5. Section 147.132(a)(1)(i)(D)

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. The Departments implicitly recognized the difficulty of providing an affirmative definition of closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely ''substantially similar'' to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. The exemptions in these interim final rules do not need to address this difficulty because they include both for-profit entities that are closely held and for-profit entities that are not closely held.[59] The mechanisms for determining whether a company has adopted and holds such principles or views is a matter of well-established State law with respect to corporate decision-making,[60] and the Departments expect that application of such laws would cabin the scope of this exemption.

In including entities in the exemption that are not closely held, these interim final rules provide for the possibility that some publicly traded entities may use the exemption. Even though the Supreme Court did not extend its holding in *Hobby Lobby* to publicly traded corporations (the matter could be resolved without deciding that question), the Court did instruct that RFRA applies to corporations because they are ''persons'' as that term is defined in 1 U.S.C. 1. Given that the definition under 1 U.S.C. 1 applies to any corporation, the Departments consider it appropriate to extend the exemption set forth in these interim final rules to for-profit corporations whether or not they are closely held. The Departments are generally aware that in a country as large as America comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.[61] The fact that such a company is religious does not mean that it will have an objection to contraceptive coverage, and there are many fewer publicly traded companies than there are closely held ones. But our experience with closely held companies is that some, albeit a small minority, do have religious objections to contraceptive coverage. Thus we consider it possible, though very unlikely, that a religious publicly

[58] See Jennifer Haberkorn, ''Two years later, few Hobby Lobby copycats emerge,'' *Politico* (Oct. 11, 2016), available at *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627*.

[59] In the companion interim final rules published elsewhere in this **Federal Register**, the Departments provide an exemption on an interim final basis to closely held entities by using a negative definition: entities that do not have publicly traded ownership interests as defined by certain securities required to be registered under section 12 of the Securities Exchange Act of 1934. Although this is a more workable definition than set forth in our previous rules, we have determined that it is appropriate to offer the expanded religious exemptions to certain entities whether or not they have publicly traded ownership interests.

[60] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

[61] *See, e.g., Nasdaq.com,* ''4 Publicly Traded Religious Companies if You're Looking to Invest in Faith'' (Feb. 7, 2014), available at *http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665*.

traded company might have objections to contraceptive coverage. At the same time, we are not aware of any publicly traded entities that challenged the Mandate specifically either publicly or in court. The Departments agree with the Supreme Court that it is improbable that many publicly traded companies with numerous ''unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs'' and thereby qualify for the exemption. (134 S. Ct. at 2774)

6. Section 147.132(a)(1)(i)(E)

Under § 147.132(a)(1)(i)(E), the rules extend the exemption to the plans of any other non-governmental employer. The plans of governmental employers are not covered by the plan sponsor exemption of § 147.132(a)(1)(i). The Departments are not aware of reasons why it would be appropriate or necessary to offer religious exemptions to governmental employer plan sponsors in the United States with respect to the contraceptive Mandate. But, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and thus to provide health insurance coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these interim final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization.

7. Section 147.132(a)(1)(ii)

As in the previous rules, the plans of institutions of higher education that arrange student health insurance coverage will continue to be treated similarly to the way in which the plans of employers are treated, but for the purposes of such plans being exempt or electing the optional accommodation, rather than merely being eligible for the accommodation as in the previous rule. These interim final rules specify, in § 147.132(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor. As mentioned above, because the Affordable Care Act does not require institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or use the accommodation. Extending the exemption in these interim final rules may remove an obstacle to such entities deciding to offer student plans, thereby giving students another health insurance option.

E. Exemption for Issuers

These interim final rules extend the exemption, in § 147.132(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services.

The Departments are not currently aware of health insurance issuers that possess their own religious objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations are protected from being required to provide coverage or pay for abortions. See, for example, Consolidated Appropriations Act of 2017, Public Law 115–31, Div. H, Title V, Sec. 507(d). Congress also declared this year that ''it is the intent of Congress'' to include a ''conscience clause'' which provides exceptions for religious beliefs if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans.'' See *Id.* at Div. C, Title VIII, Sec. 808. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.132(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. As set forth in these interim final rules, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection. Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under 42 CFR 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include coverage for some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt. Issuers that hold religious objections should identify to plan sponsors the lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers' sincerely held religious beliefs, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to

continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4) of the PHS Act or related provisions for their failure to provide contraceptive coverage.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these interim final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these interim final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) of the PHS Act to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments' understanding that third party administrators are not typically designated as plan administrators under section 3(16) of ERISA and, therefore, would not normally act as plan administrators under section 3(16) of ERISA. Therefore, to the Departments' knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These interim final rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or continue, contracts as third party administrators of such plans. For these reasons, these interim final rules do not otherwise exempt third party administrators. The Departments solicit public comment, however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have religious beliefs implicated by the Mandate.

F. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.132(a)(2). That paragraph specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.132(a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

G. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the ''individual exemption''). Section 147.132(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held religious beliefs. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' religious beliefs, or against the individual employees who accept such offers. See *Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This ''individual exemption'' cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other Federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.[62] At the same time, this individual exemption ''does not undermine the governmental interests furthered by the contraceptive coverage requirement,''[63] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

H. Optional Accommodation

Despite expanding the scope of the exemption, these rules also keep the accommodation process, but revise it so as to make it optional. In this way, objecting employers are no longer required to choose between direct compliance or compliance through the accommodation. These rules maintain the location of the accommodation process in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A. These rules, by virtue of expanding the plan sponsor exemption beyond houses of worship and integrated auxiliaries that were

[62] See, for example, *Wieland,* 196 F. Supp. 3d at 1017, and *March for Life,* 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to ''forgo health insurance altogether.''

[63] 78 FR 39874.

previously exempt, and beyond religious nonprofit groups that were previously accommodated, and by defining eligible organizations for the accommodation with reference to those covered by the exemption, likewise expand the kinds of entities that may use the optional accommodation. This includes plan sponsors with sincerely held religious beliefs for the reasons described above. Consequently, under these interim final rules, objecting employers may make use of the exemption, or may choose to pursue the optional accommodation process. If an eligible organization pursues the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

The fees adjustment process for qualifying health issuers or third party administrators pursuant to 45 CFR 156.50 is not modified, and (as specified therein) requires for its applicability that an exception under OMB Circular No. A–25R be in effect as the Secretary of the Department of Health and Human Services requests.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these interim final rules and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. This revocation process applies both prospectively to eligible organizations who decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that were included in the accommodation prior to the effective date of these interim final rules either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. If contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the 1st day of the 1st plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act,[64] if applicable, to revoke its use of the accommodation process.

The Departments have eliminated the provision in the previous accommodation under which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. Because any organization with a sincerely held religious objection to contraceptive coverage is now eligible for the optional accommodation under these interim final rules and is also exempt, the Departments believe there is minimal opportunity for mistake or misrepresentation by the organization, and the reliance provision is no longer necessary.

I. Definition of Contraceptive Services for the Purpose of These Rules

The interim final rules specify that when the rules refer to ''contraceptive'' services, benefits, or coverage, such terms include contraceptive or sterilization items, services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv). This was the case under the previous rules, as expressed in the preamble text of the various iterations of the regulations, but the Departments wish to make the scope clear by specifying it in the regulatory text.

J. Conclusion

The Departments believe that the Guidelines and the exemptions expanded herein will advance the limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress' well-established record of allowing for religious exemptions with respect to especially sensitive health care and health insurance requirements. These interim final rules leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. These interim final rules also maintain HRSA's discretion to decide whether to continue to require contraceptive coverage under the Guidelines (in plans where Congress applied section 2713 of the PHS Act) if no objection exists. The Departments believe this array of programs and requirements better serves the interest of providing contraceptive coverage while protecting the conscience rights of entities that have sincerely held religious objections to some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

V. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; 79 FR 51092).

Section 553(b) of the Administrative Procedure Act (APA) requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated

[64] See also 26 CFR 54.9815–2715(b); 29 CFR 2590.715–2715(b); 45 CFR 147.200(b).

those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to continue to update the Guidelines.

Dozens of lawsuits over the Mandate have been pending for nearly 5 years. The Supreme Court remanded several of those cases more than a year ago, stating that on remand ''[w]e anticipate that the Courts of Appeals will allow the parties sufficient time to resolve any outstanding issues between them''. *Zubik,* 136 S. Ct. at 1560. During that time, Courts of Appeals have been asking the parties in those cases to submit status reports every 30 through 90 days. Those status reports have informed the courts that the parties were in discussions, and about the RFI issued in late 2016 and its subsequent comment process and the FAQ the Departments issued indicating that we could not find a way at that time to amend the accommodation process so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. Since then, several courts have issued orders setting more pressing deadlines. For example, on March 10, 2017, the United States Court of Appeals for the Seventh Circuit ordered that, by May 1, 2017, ''the court expects to see either a report of an agreement to resolve the case or detailed reports on the parties' respective positions. In the event no agreement is reported on or before May 1, 2017, the court will plan to schedule oral argument on the merits of the case on short notice after that date''. The Departments submitted a status report but were unable to set forth their specific position because this interim final rule was not yet on public display. Instead, the Departments informed the Court that we ''are now considering whether further administrative action would be appropriate''. In response, the court extended the deadline to June 1, 2017, again declaring the court expected ''to see either a report of an agreement to resolve the case or detailed reports on the parties' respective positions''. The Departments were again unable to set forth their position in that status report, but were able to state that the ''Departments of Health and Human Services, Labor, and the Treasury are engaged in rulemaking to reconsider the regulations at issue here,'' citing *https://www.reginfo.gov/public/do/eoDetails?rrid=127381*.

As discussed above, the Departments have concluded that, in many instances, requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncomplaince has violated RFRA. Good cause exists to issue the expanded exemption in these interim final rules in order to cure such violations (whether among litigants or among similarly situated parties that have not litigated), to help settle or resolve cases, and to ensure, moving forward, that our regulations are consistent with any approach we have taken in resolving certain litigation matters.

The Departments have also been subject to temporary injunctions protecting many religious nonprofit organizations from being subject to the accommodation process against their wishes, while many other organizations are fully exempt, have permanent court orders blocking the contraceptive coverage requirement, or are not subject to section 2713 of the PHS Act and its enforcement due to Congress' limited application of that requirement. Good cause exists to change the Departments' previous rules to direct HRSA to bring its Guidelines in accord with the legal realities and remove the threat of a future violation of religious beliefs, including where such violations are contrary to Federal law.

Other objecting entities similarly have not had the protection of court injunctions. This includes some nonprofit entities that have sued the Departments, but it also includes some organizations that do not have lawsuits pending against us. For example, many of the closely held for-profit companies that brought the array of lawsuits challenging the Mandate leading up to the decision in *Hobby Lobby* are not protected by injunctions from the current rules, including the requirement that they either fully comply with the Mandate or subject themselves to the accommodation. Continuing to apply the Mandate's regulatory burden on individuals and organizations with religious beliefs against it could serve as a deterrent for citizens who might consider forming new entities—nonprofit or for-profit—and to offering health insurance in employer-sponsored plans or plans arranged by institutions of higher education. Delaying the protection afforded by these interim final rules would be contrary to the public interest because it would serve to extend for many months the harm caused to all entities and individuals with religious objections to the Mandate. Good cause exists to provide immediate resolution to this myriad of situations rather than leaving them to continued uncertainty, inconsistency, and cost during litigation challenging the previous rules.

These interim final rules provide a specific policy resolution that courts have been waiting to receive from the Departments for more than a year. If the Departments were to publish a notice of proposed rulemaking instead of these interim final rules, many more months could pass before the current Mandate is lifted from the entities receiving the expanded exemption, during which time those entities would be deprived of the relief clearly set forth in these interim final rules. In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and by what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed.

As the United States Court of Appeals for the D.C. Circuit stated with respect to an earlier interim final rule promulgated with respect to this issue in *Priests for Life* v. *U.S. Department of Health and Human Services,* 772 F.3d 229, 276 (D.C. Cir. 2014), vacated on other grounds, *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016), ''[S]everal reasons support HHS's decision not to engage in notice and comment here''. Among other things, the Court noted that ''the agency made a good cause finding in the rule it issued''; that ''the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues''; that ''HHS will expose its interim rule to notice and comment before its permanent implementation''; and that ''delay in implementation of the rule would interfere with the prompt availability of contraceptive coverage and delay the implementation of the alternative opt-out for religious objectors''. *Id.* at 277.

Delaying the availability of the expanded exemption would delay the ability of those organizations and individuals to avail themselves of the relief afforded by these interim final rules. Good cause is supported by

providing relief for entities and individuals for whom the Mandate operates in violation of their sincerely held religious beliefs, but who would have to experience that burden for many more months under the prior regulations if these rules are not issued on an interim final basis. Good cause is also supported by the effect of these interim final rules in bringing to a close the uncertainty caused by years of litigation and regulatory changes made under section 2713(a)(4) of the PHS Act. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

Delaying the availability of the expanded exemption would also increase the costs of health insurance. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover contraception. They wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. They are refraining from making those changes—and therefore are continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. Issuing these rules on an interim final basis is necessary in order to help reduce the costs of health insurance for such entities and their plan participants.

These interim final rules also set forth an optional accommodation process, and expand eligibility for that process to a broader category of entities. Delaying the availability of the optional accommodation process would delay the ability of organizations that do not now qualify for the accommodation, but wish to opt into it, to be able to do so and therefore to provide a mechanism for contraceptive coverage to be provided to their employees while the organization's religious objections are accommodated.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final rules effective immediately upon filing at the Office of the Federal Register.

VI. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an ''economically significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of $100 million or more in any 1 year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations to expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, and to revise the accommodation process to make it optional for eligible organizations. The expanded exemption would apply to individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action is taken, among other reasons, to provide for participation in the health insurance market by certain entities or individuals free from penalties for violating sincerely held religious beliefs opposed to providing or receiving coverage of contraceptive services, and to resolve many of the lawsuits that have been filed against the Departments.

2. Anticipated Effects

The Departments assess this interim final rule together with a companion interim final rule concerning moral but non-religious conscientious objections to contraception, published elsewhere in this **Federal Register**. Regarding entities that are extended an exemption, absent expansion of the exemption the Guidelines would require many of these entities and individuals to either: Pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which some entities also believe entangles them in the provision of such objectionable coverage; or, pay tax penalties or be

subject to other adverse consequences for non-compliance with these requirements. These interim final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections and exempting them—on the basis of such objections—from the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption immediately, a notice will need to be sent to enrollees (either by the entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during a plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these interim final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be $51,990.

The Departments estimate that these interim final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their newly exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation that were not provided access to it previously. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations on issuers and third party administrators serving the fewer number of entities that will newly opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation.

These interim final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. The Departments do not have sufficient data to determine the actual effect of these rules on plan participants and beneficiaries, including for costs they may incur for contraceptive coverage, nor of unintended pregnancies that may occur. As discussed above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- how many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby,* several objecting entities still provide coverage for 14 of the 18 women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- how many women will be covered by plans of entities using their newly exempt status.
- which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- the degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- the degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- the degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- the extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

The Departments have access to sources of information discussed in the following paragraphs that are relevant to this issue, but those sources do not provide a full picture of the impact of these interim final rules.

First, the prior rules already exempted certain houses of worship and their integrated auxiliaries. Further, as discussed above, the prior accommodation process allows hundreds of additional religious nonprofit organizations in self-insured church plans that are exempt from ERISA to file a self-certification or notice that relieves not only themselves but, in effect, their third party administrators of any obligation to provide contraceptive coverage or payments. Although in the latter case, third party administrators are legally permitted to provide the coverage, several self-insured church plans themselves have expressed an objection in litigation to allowing such contraceptive coverage to be provided, and according to information received during litigation, it appears that such contraceptive coverage has not been provided. In addition, a significant portion of the lawsuits challenging the Mandate were brought by a single firm representing Catholic dioceses and related entities covered by their diocese-sponsored plans. In that litigation, the Departments took the position that, where those diocese-sponsored plans are self-insured, those plans are likely church plans exempt from ERISA.[65] For the purposes of considering whether the expanded exemption in these rules affects the persons covered by such diocese-sponsored plans, the Departments continue to assume that such plans are similar to other objecting entities using self-insured church plans with respect to their third party administrators being unlikely to provide contraceptive coverage to plan participants and beneficiaries under the previous rule. Therefore the

[65] See, for example, Brief in Opp. To Pls.' Mot. for Prelim. Inj., *Brandt* v. *Burwell,* No. 2:14–cv–681–AJS, doc. #23 (W.D. Pa. filed June 10, 2014) (arguing that ''plaintiffs have not established an injury in fact to the degree plaintiffs have a self-insured church plan,'' based on the fact that ''the same law firm representing the plaintiffs here has suggested in another similar case that all 'Catholic entities like the Archdiocese participate in ''church plans.'' '); *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013) (''because plaintiffs' self-insured plans are church plans, their third party administrators would not be required to provide contraceptive coverage'').

Departments estimate that these interim final rules have no significant effect on the contraceptive coverage of women covered by plans of houses of worship and their integrated auxiliaries, entities using a self-insured church plan, or church dioceses sponsoring self-insured plans.

It is possible that an even greater number of litigating or accommodated plans might have made use of self-insured church plan status under the previous accommodation. Notably, one of the largest nonprofit employers that had filed suit challenging the Mandate had, under these prior rules, shifted most of their employees into self-insured church plans, and the Departments have taken the position that various other employers that filed suit were eligible to assume self-insured church plan status.[66] The Supreme Court's recent decision in *Advocate Health Care Network,* while not involving this Mandate, also clarifies certain circumstances under which religious hospitals may be eligible for self-insured church plan status. See 137 S. Ct. at 1656–57, 1663 (holding that a church plan under ERISA can be a plan not established and maintained by a church, if it is maintained by a principal-purpose organization).

Second, when the Departments previously created the exemption, expanded its application, and provided an accommodation (which, as mentioned, can lift obligations on self-insured church plans for hundreds of nonprofit organizations), we concluded that no significant burden or costs would result at all. (76 FR 46625; 78 FR 39889.) We reached this conclusion despite the impact, just described, whereby the previous rule apparently lead to women not receiving contraceptive coverage through hundreds of nonprofit entities using self-insured church plans. We also reached this conclusion without counting any significant burden or cost to some women covered in the plans of houses of worship or integrated auxiliaries that might want contraceptive coverage. This conclusion was based in part on the assertion, set forth in previous regulations, that employees of houses of worship and integrated auxiliaries likely share their employers' opposition to contraception. Many other religious nonprofit entities, however, both adopt and implement religious principles with similar fervency. For the reasons discussed above, the Departments no longer believe we can distinguish many of the women covered in the plans of religious nonprofit entities from the women covered in the plans of houses of worship and integrated auxiliaries regarding which the Departments assumed share their employers' objection to contraception, nor from women covered in the plans of religious entities using self-insured church plans regarding which we chose not to calculate any anticipated effect even though we conceded we were not requiring their third party administrators to provide contraceptive coverage. In the estimates and assumptions below, we include the potential effect of these interim rules on women covered by such entities, in order to capture all of the anticipated effects of these rules.

Third, these interim final rules extend the exemption to for-profit entities. Among the for-profit employers that filed suit challenging the Mandate, the one with the most employees was *Hobby Lobby.*[67] As noted above, and like some similar entities, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of various contraceptive services: 14 of 18 FDA-approved women's contraceptive and sterilization methods.[68] (134 S. Ct. at 2766.) The effect of expanding the exemption to for-profit entities is therefore mitigated to the extent many of the persons covered by such entities' plans may receive coverage for at least some contraceptive services. No publicly traded for-profit entities have filed lawsuits challenging the Mandate. The Departments agree with the Supreme Court's expectation in this regard: ''it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable''. *Hobby Lobby,* 134 S. Ct. at 2774. Therefore, although publicly traded entities could make use of exempt status under these interim final rules, the Departments do not expect that very many will do so, as compared to the 87 religious closely held for-profit entities that brought litigation challenging the Mandate (some of which might be content with the accommodation).

Fourth, the Departments have a limited amount of information about entities that have made use of the accommodation process as set forth in the previous rules. HHS previously estimated that 209 entities would make use of the accommodation process. That estimate was based on HHS's observation in its August 2014 interim final rules and July 2015 final regulations that there were 122 eligible entities that had filed litigation challenging the accommodation process, and 87 closely held for-profit entities that had filed suit challenging the Mandate in general. (79 FR 51096; 80 FR 41336). The Departments acknowledged that entities that had not litigated might make use of the accommodation, but we stated we did not have better data to estimate how many might use the accommodation overall.

After issuing those rules, the Departments have not received complete data on the number of entities actually using the accommodation, because the accommodation does not require many accommodated entities to submit information to us. Our limited records indicate that approximately 63 entities have affirmatively submitted notices to HHS to use the accommodation. This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. We have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being

[66] See *https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf.*; see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

[67] Verified Complaint ¶ 34, *Hobby Lobby Stores, Inc., et al.* v. *Sebelius,* No. 5:12–cv–01000–HE (Sept. 12, 2012 W.D. Okla.) (13,240 employees).

[68] By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, *https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf*, Hobby Lobby and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). See 134 S. Ct. at 2765–66. Hobby Lobby was willing to cover: Sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives (''the Pill''—combined pill); oral contraceptives (''the Pill''—extended/continuous use/combined pill); oral contraceptives (''the Mini Pill''—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that Hobby Lobby and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and ''[t]he pill and female sterilization have been the two most commonly used methods since 1982.'' See Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or we were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage. Our records also indicate that 60 plans used the contraceptive user fees adjustments in the 2015 plan year, the last year for which we have data. This includes only self-insured plans, and it includes some plans that self-certified through submitting notices and other plans that, presumably, self-certified through the EBSA form 700.

These sets of data are not inconsistent with our previous estimate that 209 entities would use the accommodation, but they indicate that some non-litigating entities used the accommodation, and some litigating entities did not, possibly amounting to a similar number. For this reason, and because we do not have more complete data available, we believe the previous estimate of 209 accommodated entities is still the best estimate available for how many entities have used the accommodation under the previous rule. This assumes that the number of litigating entities that did not use the accommodation is approximately the same as the number of non-litigating entities that did use it.

In considering how many entities will use the voluntary accommodation moving forward—and how many will use the expanded exemption—we also do not have specific data. We expect the 122 nonprofit entities that specifically challenged the accommodation in court to use the expanded exemption. But, as noted above, we believe a significant number of them are not presently participating in the accommodation, and that some nonprofit entities in self-insured church plans are not providing contraceptive coverage through their third party administrators even if they are using the accommodation. Among the 87 for-profit entities that filed suit challenging the Mandate in general, few if any filed suit challenging the accommodation. We do not know how many of those entities are using the accommodation, how many may be complying with the Mandate fully, how many may be relying on court injunctions to do neither, or how many will use the expanded exemption moving forward. Among entities that never litigated but used the accommodation, we expect many but not all of them to continue using the accommodation, and we do not have data to estimate how many such entities there are or how many will choose either option.

Overall, therefore, without sufficient data to estimate what the estimated 209 previously accommodated entities will do under these interim final rules, we assume that just over half of them will use the expanded exemption, and just under half will continue their accommodated status under the voluntary process set forth in these rules. Specifically, we assume that 109 previously accommodated entities will make use of their exempt status, and 100 will continue using the accommodation. This estimate is based in part on our view that most litigating nonprofit entities would prefer the exemption to the accommodation, but that many of either have not been using the accommodation or, if they have been using it, it is not providing contraceptive coverage for women in their plans where they participate in self-insured church plans. This estimate is also consistent with our lack of knowledge of how many for-profit entities were using the accommodation and will choose the exemption or the accommodation, given that many of them did not bring legal challenges against the accommodation after *Hobby Lobby.* This estimate is further consistent with our view, explained in more detail below, that some entities that are using the accommodation and did not bring litigation will use the exemption, but many accommodated, non-litigating entities—including the ones with the largest relative workforces among accommodated entities—will continue using the accommodation. The Departments recognize that we do not have better data to estimate the effects of these interim final rules on such entities.

In addition to these factors, we recognize that the expanded exemption and accommodation are newly available to religious for-profit entities that are not closely held and some other plan sponsors. As explained above, the Departments believe religious for-profit entities that are not closely held may exist, or may wish to come into being. HHS does not anticipate that there will be significant number of such entities, and among those, we believe that very few if any will use the accommodation. All of the for-profit entities that have challenged the Mandate have been religious closely held entities.

It is also possible that religious nonprofit or closely held for-profit entities that were already eligible for the accommodation but did not previously use it will opt into it moving forward, but because they could have done so under the previous rules, their opting into the accommodation is not caused by these rules.

Without any data to estimate how many of any entities newly eligible for and interested in using the accommodation might exist, HHS assumes for the purposes of estimating the anticipated effect of these rules that less than 10 entities (9) will do so. Therefore, we estimate that 109 entities will use the voluntary accommodation moving forward, 100 of which were already using the previous accommodation, and that 109 entities that have been using the previous accommodation will use the expanded exemption instead.

Fifth, in attempting to estimate the anticipated effect of these interim final rules on women receiving contraceptive coverage, the Departments have limited information about the entities that have filed suit challenging the Mandate. Approximately 209 entities have brought suit challenging the Mandate over more than 5 years. They have included a broad range of nonprofit entities and closely held for-profit entities. We discuss a number of potentially relevant points:

First, the Departments do not believe that out-of-pocket litigation costs have been a significant barrier to entities choosing to file suit. Based on the Departments' knowledge of these cases through public sources and litigation, nearly all the entities were represented pro bono and were subject to little or no discovery during the cases, and multiple public interest law firms publicly provided legal services for entities willing to challenge the Mandate.[69] (It is noteworthy, however, that such pro bono arrangements and minimization of discovery do not eliminate 100 percent of the time costs of participating in litigation or, as discussed in more detail below, the potential for negative

[69] See, for example, Catholic Diocese of Pittsburgh, ''Award-winning attorney 'humbled' by recognition,'' *Pittsburgh Catholic* (''Jones Day is doing the cases 'pro bono,' or voluntarily and without payment.'') (quoting Paul M. Pohl, Partner, Jones Day), available at *http://diopitt.org/pittsburgh-catholic/award-winning-attorney-humbled-recognition*; ''Little Sisters Fight for Religious Freedom,'' *National Review* (Oct. 2, 2013) (''the Becket Fund for Religious Liberty is representing us pro bono, as they do all their clients.'') (quoting Sister Constance Veit, L.S.P., communications director for the Little Sisters of the Poor), available at *http://www.nationalreview.com/article/360103/little-sisters-fight-religious-freedom-interview*; Suzanne Cassidy, ''Meet the major legal players in the Conestoga Wood Specialties Supreme Court case,'' *LancasterOnline* (Mar. 25, 2014) (''Cortman and the other lawyers arguing on behalf of Conestoga Wood Specialties and Hobby Lobby are offering their services pro bono.''), available at *http://lancasteronline.com/news/local/meet-the-major-legal-players-in-the-conestoga-wood-specialties/article_302bc8e2-b379-11e3-b669-001a4bcf6878.html.*

publicity. Both concerns could have dissuaded participation in lawsuits, and the potential for negative publicity may also dissuade participation in the expanded exemptions.)

Second, prior to the Affordable Care Act, the vast majority of entities already covered contraception, albeit not always without cost-sharing The Departments do not have data to indicate why entities that did not cover contraception prior to the Affordable Care Act chose not to cover it. As noted above, however, the Departments have maintained that compliance with the contraceptive Mandate is cost-neutral to issuers, which indicates that no significant financial incentive exists to omit contraceptive coverage. As indicated by the report by HHS ASPE discussed above, we have assumed that millions of women received preventive services after the Mandate went into effect because nearly all entities complied with the Guidelines. We are not aware of expressions from most of those entities indicating that they would have sincerely held religious objections to complying with the Mandate, and therefore that they would make use of the expanded exemption provided here.

Third, omitting contraceptive coverage has subjected some entities to serious public criticism and in some cases organized boycotts or opposition campaigns that have been reported in various media and online outlets regarding entities that have filed suit. The Departments expect that even if some entities might not receive such criticism, many entities will be reluctant to use the expanded exemption unless they are committed to their views to a significant degree.

Overall, the Departments do not know how many entities will use the expanded exemption. We expect that some non-litigating entities will use it, but given the aforementioned considerations, we believe it might not be very many more. Moreover, many litigating entities are already exempt or are not providing contraceptive coverage to women in their plans due to their participating in self-insured church plans, so the effect of the expanded exemption among litigating entities is significantly lower than it would be if all the women in their plans were already receiving the coverage.

To calculate the anticipated effects of this rule on contraceptive coverage among women covered by plans provided by litigating entities, we start by examining court documents and other public sources.[70] These sources provide some information, albeit incomplete, about how many people are employed by these entities. As noted above, however, contraceptive coverage among the employees of many litigating entities will not be affected by these rules because some litigating entities were exempt under the prior rule, while others were or appeared to be in self-insured church plans so that women covered in their plans were already not receiving contraceptive coverage.

Among litigating entities that were neither exempt nor likely using self-insured church plans, our best estimate based on court documents and public sources is that such entities employed approximately 65,000 persons, male and female.[71] The average number of workers at firms offering health benefits that are actually covered by those benefits is 62 percent.[72] This amounts to approximately 34,000 employees covered under those plans. DOL estimates that for each employee policyholder, there is approximately one dependent.[73] This amounts to approximately 68,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—compose 20.2 percent of the general population.[74] In addition, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.[75] Therefore, we estimate that approximately 7,221 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that have filed lawsuits challenging the Mandate, where those plans are neither exempt under the prior rule nor are self-insured church plans.

We also estimate that for the educational institutions objecting to the Mandate as applied to student coverage that they arranged, where the entities were neither exempt under the prior rule nor were their student plans self-insured, such student plans likely covered approximately 3,300 students. On average, we expect that approximately half of those students (1,650) are female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. We expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, we assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 3,300. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, we assume they are. Therefore, for the purposes of this estimate, we assume that the effect of these expanded exemptions on student plans of litigating entities includes 3,300 women. Assuming that 44.3 perecent of such women use contraception covered by the Guidelines,[76] we estimate that

[70] Where complaints, affidavits, or other documents filed in court did not indicate the number of employees that work for an entity, and that entity was not apparently exempt as a house of worship or integrated auxiliary, and it was not using the kind of plan that we have stated in litigation qualifies for self-insured church plan status (see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013)), we examined employment data contained in some IRS form W–3's that are publicly available online for certain nonprofit groups, and looked at other Web sites discussing the number of people employed at certain entities.

[71] In a small number of lawsuits, named plaintiffs include organizations claiming to have members that seek an exemption. We have very little information about the number, size, and types of entities those members. Based on limited information from those cases, however, their membership appears to consist mainly, although not entirely, of houses of worship, integrated auxiliaries, and participants in self-insured plans of churches. As explained above, the contraceptive coverage of women covered by such plans is not likely to be affected by the expanded exemption in these rules. However, to account for plans subject to contraceptive coverage obligations among those members we have added 10,000 to our estimate of the number of persons among litigants that may be impacted by these rules.

[72] See Kaiser Family Foundation and Health Research and Educational Trust, ''Employer Health Benefits: 2017 Annual Survey'' at 57, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[73] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[74] United States Census Bureau, ''Age and Sex Composition: 2010'' (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies ''for all women with reproductive capacity.'' *https://www.hrsa.gov/womensguidelines/*; also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[75] See *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states* (reporting that of 60,877,000 women aged 15–44, 26,945,000 use women's contraceptive methods covered by the Guidelines).

[76] It would appear that a smaller percentage of college-aged women use contraception—and use more expensive methods such as long acting methods or sterilization—than among other women of childbearing age. *See* NCHS Data Brief, ''Current Contraceptive Status Among Women Aged 15–44: United States, 2011–2013'' (Dec. 2014), available at

Continued

1,462 of those women would be affected by these rules.

Together, this leads the Departments to estimate that approximately 8,700 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted above, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do we know how many would have alternative contraceptive access from a parent's or spouse's plan, or from Federal, State, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

Sixth, in a brief filed in the *Zubik* litigation, the Departments stated that ''in 2014, [HHS] provided user-fee reductions to compensate TPAs for making contraceptive coverage available to more than 600,000 employees and beneficiaries,'' and that ''[t]hat figure includes both men and women covered under the relevant plans.'' [77] HHS has reviewed the information giving rise to that estimate, and has received updated information for 2015. In 2014, 612,000 persons were covered by plans claiming contraceptive user fees adjustments, and in 2015, 576,000 persons were covered by such plans. These numbers include all persons in such plans, not just women of childbearing age.

HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly 100,000 persons each, and several others cover approximately 40,000 persons each. In other words, these plans were proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

There are two reasons to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.[78] Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these interim final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.[79] As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.[80] (The Departments take no view on the status of these particular plans under ERISA, but simply make this observation for the purpose of seeking to estimate the impact of these interim final rules.) Nevertheless, overall it seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these interim final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations these interim final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these interim final rules. The Departments begin with the 8,700 women of childbearing age that use contraception who we estimate will be affected by use of the expanded exemption among litigating entities. In addition to that number, we calculate the following number of women affected by accommodated entities using the expanded exemption. As noted above, approximately 576,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2014. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, we do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, we assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer sponsored insurance, 56.1 percent are covered by self-insured plans and 43.9 percent are covered by fully insured plans.[81] Therefore, corresponding to the 576,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 451,000 persons were covered by fully insured plans using the accommodation. This yields an estimate of 1,027,000 covered persons of all ages and sexes in plans using the previous accommodation.

As discussed below, and recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the prior rule

https://www.cdc.gov/nchs/data/databriefs/db173.pdf.

[77] Brief of Respondents at 18–19 & n.7, *Zubik* v. *Burwell,* No. 14–1418, et al. (U.S. filed Feb. 10, 2016). The actual number is 612,487.

[78] See, for example, *https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule* (''HHS has now established an accommodation that will allow our ministries to continue offering health insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.'') In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it ''is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia.'' Comments on CMS–9968–ANPRM (dated June 15, 2012).

[79] See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, *Advocate Health Care Network,* Nos. 16–74, 16–86, 16–258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) (''CHA members have relied for decades that the 'church plan' exemption contained in'' ERISA.).

[80] See supra note 66.

[81] ''Health Insurance Coverage Bulletin'' Table 3A, page 15. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

will continue to opt into it under these interim final rules. Notably, however, the data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As also cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these interim final rules would not impact the contraceptive coverage their employees receive. We do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. We assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data. Based on these assumptions and without better data available, we assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, we assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons previously covered in accommodated plans.

Applying these percentages to the total number of 1,027,000 persons we estimate are covered in accommodated plans, we estimate that approximately 257,000 persons previously covered in accommodated plans will be covered in the 109 plans that use the expanded exemption, and 770,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, 20.2 percent of these persons are women of childbearing age, which amounts to approximately 51,900 women of childbearing age in previously accommodated plans that we estimate will use the expanded exemption. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that we expect approximately 23,000 women that use contraception covered by the Guidelines to be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 8,700 women in plans of litigating entities that may be affected by these rules. Based on our limited information from the litigation and accommodation notices, we expect that the overlap is significant. Nevertheless, in order to estimate the possible effects of these rules, we assume there is no overlap between these two numbers, and therefore that these interim final rules would affect the contraceptive costs of approximately 31,700 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these interim final rules is less than 0.1 percent of the 55.6 million women in private plans that HHS ASPE estimated [82] receive preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the prior accommodation process, the total user fee adjustment amount for self-insured plans for the 2015 benefit year was $33 million. These adjustments covered the cost of contraceptive coverage provided to women participants and beneficiaries in self-insured plans where the employer objected and made use of the accommodation, and where an authorizing exception under OMB Circular No. A–25R was in effect as the Secretary of the Department of Health and Human Services requests. Nine percent of that amount was attributable to administrative costs and margin, according to the provisions of 45 CFR 156.50(d)(3)(ii). Thus the amount of the adjustments attributable to the cost of contraceptive services was about $30 million. As discussed above, in 2015 that amount corresponded to 576,000 persons covered by such plans. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age—that is, approximately 116,000 women. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, which includes 51,400 women in those plans. Therefore, entities using contraceptive user fees adjustments received approximately $584 per year per woman of childbearing age that use contraception covered by the Guidelines and are covered in their plans.

As discussed above, the Departments estimate that the expanded exemptions will impact the contraceptive costs of approximately 31,700 women of childbearing age that use contraception covered by the Guidelines. At an average of $584 per year, the financial transfer effects attributable to the interim final rules on those women would be approximately $18.5 million.[83] [84]

To account for uncertainty in the estimate, we conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these interim final rules.

As noted above, the HHS ASPE report estimated that 55.6 million women aged 15 to 64 and covered by private insurance had preventive services coverage under the Affordable Care Act. Approximately 16.2 percent of those women were enrolled in plans on exchanges or were otherwise not covered by employer sponsored insurance, so only 46.6 million women aged 15 to 64 received the coverage through employer sponsored private insurance plans.[85] In addition, some of those private insurance plans were offered by government employers, encompassing approximately 10.5 million of those women aged 15 to 64.[86]

[82] Available at *https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans*; also, see Abridged Report, available at *https://www.womenspreventivehealth.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf*.

[83] As noted above, the Departments have taken the position that providing contraceptive coverage is cost neutral to issuers. (78 FR 39877). At the same time, because of the up-front costs of some contraceptive or sterilization methods, and because some entities did not cover contraception prior to the Affordable Care Act, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent × 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent.

[84] Describing this impact as a transfer reflects an implicit assumption that the same products and services would be used with or without the rule. Such an assumption is somewhat oversimplified because the interim final rules shift cost burden to consumption decision-makers (that is, the women who choose whether or not to use the relevant contraceptives) and thus can be expected to lead to some decrease in use of the affected drugs and devices and a potential increase in pregnancy—thus leading to a decrease and an increase, respectively, in medical expenditures.

[85] Available at *https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf*.

[86] The ASPE study relied on Census data of private health insurance plans, which included plans sponsored by either private or public sector

Continued

The expanded exemption in these interim final rules does not apply to government plan sponsors. Thus we estimate that the number of women aged 15 to 64 covered by private sector employer sponsored insurance who receive preventive services coverage under the Affordable Care Act is approximately 36 million.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.[87] The 6 percent may have included approximately 2.16 million of the women aged 15–64 covered by employer sponsored insurance plans in the private sector. According to Census data, 59.9 percent of women aged 15 to 64 are of childbearing age (aged 15 to 44), in this case, 1.3 million. And as noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore we estimate that 574,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.[88]

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for conscientious reasons, or for other reasons. Despite our lack of information about their motives, we attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, we estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in *Hobby Lobby,* where the Court observed that ''HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable''. 134 S. Ct. at 2774. The Departments are aware of several Federal health care conscience laws[89] that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but we are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while we consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions we agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.[90] That means that only approximately 394,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, these interim final rules build on existing rules that already exempt houses of worship and integrated auxiliaries and, as explained above, effectively remove obligations to provide contraceptive coverage within objecting self-insured church plans. These rules will therefore not effect transfers to women in the plans of such employers. In attempting to estimate the number of such employers, we consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the

employers. See Table 2, notes 2 & 3 (explaining the scope of private plans and government plans for purposes of Table 2), available at *https://www.census.gov/content/dam/Census/library/publications/2014/demo/p60-250.pdf*.

According to data tables from the Medical Expenditure Panel Survey (MEPS) of the Agency for Healthcare Research and Quality of HHS (*https://meps.ahrq.gov/mepsweb/*), State and local governments employ 19,297,960 persons; 99.2 percent of those employers offer health insurance; and 67.4 percent of employees that work at such entities where insurance is offered are enrolled in those plans, amounting to 12.9 million persons enrolled. DOL estimates that in the public sector, for each policyholder there is an average of slightly less than one dependent. ''Health Insurance Coverage Bulletin'' Table 4, page 21. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf*. Therefore, State and local government employer plans cover approximately 24.8 million persons of all ages. Census data indicates that on average, 12 percent of persons covered by private insurance plans are aged 65 and older. Using these numbers, we estimate that State and local government employer plans cover approximately 21.9 million persons under age 65.

The Federal Government has approximately 8.2 million persons covered in its employee health plans. According to information we received from the Office of Personnel Management, this includes 2.1 million employees having 3.2 million dependents, and 1.9 million retirees (annuitants) having 1 million dependents. We do not have information about the ages of these policyholders and dependents, but for the purposes of this estimate we assume the annuitants and their dependents are aged 65 or older and the employees and their dependents are under age 65, so that the Federal Government's employee health plans cover 5.3 million persons under age 65.

Thus, overall we estimate there are 27.2 million persons under age 65 enrolled in private health insurance sponsored by government employers. Of those, 38.3 percent are women aged 15–64, that is, 10.5 million.

[87] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2010 Annual Survey'' at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf*.

[88] Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers' lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity's mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these interim final rules.

[89] For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

[90] John Asker, et al., ''Corporate Investment and Stock Market Listing: A Puzzle?'' 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at *https://doi.org/10.1093/rfs/hhu077*. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, ''The number of publicly-traded US companies is down 46% in the past two decades,'' *Yahoo! Finance* (Aug. 8, 2016), available at *https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html*.

United States,[91] 197 Catholic dioceses,[92] 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.[93] Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so we use the number of schools to estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention. It covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.[94] Christian Brothers is a plan that covers Catholic organizations. It covers Catholic churches and integrated auxiliaries, which are estimated above, but also it has said in litigation that it also covers about 500 additional entities that are not exempt as churches. In total, therefore, we estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous rules. We do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include ''churches, mission-sending agencies, hospitals, educational institutions and other related ministries.'' Using that ratio, we estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 would be of childbearing age, and 32,100 would use contraceptives covered by the Guidelines. Therefore, we estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous rules nor were participants in self-insured church plans that oppose contraceptive coverage, covered 362,100 women aged 15 to 44 that use contraceptives covered by the Guidelines. As noted above, we estimate an average annual expenditure on contraceptive products and services of $584 per user. That would amount to $211.5 million in potential transfer impact among entities that did not cover contraception pre- Affordable Care Act for any reason.

We do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these interim final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous rules on this matter, we are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, we believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 120,000 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these interim final rules. Consequently, as explained below, we believe that the potential impact of these interim final rules falls substantially below the $100 million threshold for economically significant and major rules.

First, as mentioned, we are not aware of information that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or religious beliefs specifically, as opposed to having done so for other reasons. Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees. Also, avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts, all provide reasons for some employers not to return to pre-Affordable Care Act lack of contraceptive coverage. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.[95] Furthermore, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

In addition, not all sincerely held conscientious objections to contraceptive coverage are likely to be held by persons with religious beliefs as distinct from persons with sincerely held non-religious moral convictions, whose objections would not be encompassed by these interim final rules.[96] We do not have data to indicate, among entities that did not cover contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, which ones did so based on religious beliefs and which ones did so instead based on non-religious moral convictions. Among the general public, polls vary about religious beliefs but one prominent poll shows that 89 percent of Americans say they believe in God, while 11 percent say they do not or are agnostic.[97] Therefore, we estimate that for every ten entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, one did so based on sincerely held non-religious moral convictions, and therefore are not affected by the expanded exemption provided by these interim final rules for religious beliefs.

Based on our estimate of an average annual expenditure on contraceptive products and services of $584 per user,

[91] Roman Catholic Diocese of Reno, ''Diocese of Reno Directory: 2016–2017,'' available at *http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf.*

[92] Wikipedia, ''List of Catholic dioceses in the United States,'' available at *https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States.*

[93] National Catholic Educational Association, ''Catholic School Data,'' available at *http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx.*

[94] Guidestone Financial Resources, ''Who We Serve,'' available at *https://www.guidestone.org/AboutUs/WhoWeServe.*

[95] On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered ''yes'' or ''don't know'' to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule's effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

[96] Such objections may be encompassed by companion interim final rules published elsewhere in this **Federal Register**. Those rules, however, as an interim final matter, are more narrow in scope than these rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

[97] Gallup, ''Most Americans Still Believe in God'' (June 14–23, 2016), available at *http://www.gallup.com/poll/193271/americans-believe-god.aspx.*

the effect of the expanded exemptions on 120,000 women would give rise to approximately $70.1 million in potential transfer impact. This falls substantially below the $100 million threshold for economically significant and major rules. In addition, as noted above, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent × 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent, yielding a potential transfer of $63.8 million.

We request comment on all aspects of the preceding regulatory impact analysis, as well as on how to attribute impacts to this interim final rule and the companion interim final rule concerning exemptions provided based on sincerely held (non-religious) moral convictions published elsewhere in this **Federal Register**.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments anticipate that there will be more entities reluctantly using the existing accommodation that will choose to operate under the newly expanded exemption, than entities that are not currently eligible to use the accommodation that will opt into it. The effect of this rule will therefore be that fewer overall adjustments are made to the Federally facilitated Exchange user fees for entities using the accommodation process, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect, than would have occurred under the previous rule if this rule were not finalized. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities, and in many cases will relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization, the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

However, we are requesting an emergency review of the information collection referenced later in this section. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we have submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting an emergency review and approval under both 5 CFR 1320.13(a)(2)(i) and (iii) of the implementing regulations of the PRA in order to implement provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). In accordance with 5 CFR 1320.13(a)(2)(i), we believe public harm is reasonably likely to ensue if the normal clearance procedures are followed. The use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information. Similarly, in accordance with 5 CFR 1320.13(a)(2)(iii), we believe the use of normal clearance procedures is reasonably likely to cause a statutory or court ordered deadline to be missed. Many cases have been on remand for over a year from the Supreme Court, asking the Departments and the parties to resolve this matter. These interim final rules extend exemptions to entities, which involves no collection of information and which the Departments have statutory authority to do by the use of interim final rules. If the information collection involved in the amended accommodation process is not approved on an emergency basis, newly exempt entities that wish to opt into the amended accommodation process might not be able to do so until normal clearance procedures are completed.

A description of the information collection provisions implicated in these interim final rules is given in the following section with an estimate of the annual burden. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.[98]

a. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under

[98] May 2016 National Occupational Employment and Wage Estimates United States found at *https://www.bls.gov/oes/current/oes_nat.htm.*

these interim final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these interim final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations. The burden related to the notice to HHS is currently approved under OMB Control Number 0938–1248 and the burden related to the self-certification (EBSA Form 700) is currently approved under OMB control number 0938–1292.

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these interim final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party administrator). As explained above, HHS assumes that, among the 209 entities we estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes, as it did in its August 2014 interim final rules, that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.[99] HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of $55.68 per hour,[100] 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour,[101] 5 minutes for legal counsel at a cost of $134.50 per hour,[102] and 5 minutes by a senior executive at a cost of $186.88 per hour[103]) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately $74.96 for a total hour burden of approximately 7.5 hours with an equivalent cost of approximately $675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for approximately 3.75 burden hours with an equivalent cost of approximately $337.

HHS estimates that each self-certification or notice to HHS will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be $0.54. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately $2.70 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so each will account for $1.35 of the cost burden.

b. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language set forth previously by HHS or substantially similar language. The burden for this ICR is currently approved under OMB control number 0938–1292.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at $55.68 per hour)[104] and 15 minutes of management review (at $117.40 per hour)[105] to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately $85.03. The total burden for all issuers or third party administrators will be 136 hours, with an equivalent cost of $9,268. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 68 burden hours with an equivalent cost of $4,634, with approximately 55 respondents.

As discussed above, the Departments estimate that 770,000 persons will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. It is not known how many persons will be covered in the plans of the 9 entities newly using the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity, we estimate that all 109 accommodated entities will encompass 839,300 covered persons. We assume that sending one notice to each participant will satisfy the need to send the notices to all participants and dependents. Among persons covered by plans, approximately 50.1 percent are participants and 49.9 percent are

[99] For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

[100] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84, *https://www.bls.gov/oes/current/oes436011.htm.*

[101] Occupation code 11–3111 for Compensation and Benefits Managers with mean hourly wage $61.01, *https://www.bls.gov/oes/current/oes113111.htm.*

[102] Occupation code 23–1011 for Lawyers with mean hourly wage $67.25, *https://www.bls.gov/oes/current/oes231011.htm.*

[103] Occupation code11–1011 for Chief Executives with mean hourly wage $93.44, *https://www.bls.gov/oes/current/oes111011.htm.*

[104] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84.

[105] Occupation code 11–1021 General and Operations Managers with mean hourly wage $58.70.

dependents.[106] For 109 entities, the total number of notices will be 420,490. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.[107] Therefore, approximately 194,687 notices will be mailed. HHS estimates that each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54. The total cost for sending approximately 194,687 notices by mail is approximately $105,131. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $52,565 of the cost burden.

c. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to cause the notification to be sent (the issuer or third party administrator can send the notice on behalf of the entity). For the purpose of calculating ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke it fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of $117.40 per hour,[108] 30 minutes for legal counsel at a cost of $134.50 per hour [109], 1 hour for clerical labor at a cost of $55.68 per hour [110]). The burden per respondent will be 2 hours with an equivalent cost of $181.63; for 109 entities, the total burden will be 218 hours with an equivalent cost of approximately $19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an equivalent cost of approximately $9,899.

As discussed above, HHS estimates that there are 257,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[111] As before, we use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 128,757 notices will be sent, of which 59,615 notices will be mailed. HHS estimates that each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54. The total cost for sending approximately 59,615 notices by mail is approximately $32,192. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 64,379 notices, with an equivalent cost of approximately $16,096.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
Self-Certification or Notices to HHS	0938—NEW	*5	5	0.83	3.75	$89.95	$337.31	$338.66
Notice of Availability of Separate Payments for Contraceptive Services.	0938—NEW	*55	210,245	1.25	68.13	68.02	4,634.14	57,199.59
Notice of Revocation of Accommodation	0938—NEW	*55	64,379	2.00	109	90.82	9,898.84	25,994.75
Total		*115	274,629	4.08	180.88		14,870.29	83,533.00

*The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

We are soliciting comments on all of the information collection requirements contained in these interim final rules. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938–1292 and 0938–1248. HHS is requesting a new OMB control number that will ultimately contain the approval for the new information collection requirements contained in these interim

[106] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[107] According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the Internet outside of work. According to a Pew Research Center survey, 61 percent of Internet users use online banking, which is used as the proxy for the number of Internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

[108] Occupation code 11–1021 for General and Operations Managers with mean hourly wage $58.70, *https://www.bls.gov/oes/current/oes111021.htm.*

[109] Occupation code 23–1011 for Lawyers with mean hourly wage $67.25, *https://www.bls.gov/oes/current/oes231011.htm.*

[110] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84, *https://www.bls.gov/oes/current/oes436011.htm.*

[111] In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, we indicated that we do not know the extent to which the number of women in accommodated plans affected by these rules overlap with the number of women in plans offered by litigating entities that will be affected by these rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

final rules as well as the related requirements currently approved under 0938–1292 and 0938–1248. In an effort to consolidate the number of information collection requests, we will formally discontinue the control numbers 0938–1292 and 0938–1248 once the new information collection request associated with these interim final rules is approved.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of these interim final rules with comment period.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov*. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

These interim final rules amend the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer who revokes their accommodation. DOL submitted the ICRs in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. In an effort to consolidate the number of information collection requests, DOL will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once the ICR is approved DOL will discontinue 1210–0152. A copy of the information collection request may be obtained free of charge on the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001*. This approval will allow respondents to temporarily utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden.

Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur $0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 420,489 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke its use and will therefore be required to cause the Notice of Revocation of Accommodation to be sent (the issuer or third party administrator can send the notice on behalf of the entity). These entities will spend approximately two hours in preparation time and incur $0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 128,757 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114 [112] (combined with HHS total is 227).

Total Responses: 274,628 (combined with HHS total is 549,255).

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: $68,662 (combined with HHS total is $137,325).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, ''[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' In addition, agencies are directed to ''take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.'' These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting

[112] Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

costs.[113] Therefore, this interim final rule is considered an Executive Order 13771 deregulatory action.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflater for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.

G. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VII. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ 2. Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* [Reserved]. For further guidance, see § 54.9815–2713T(a)(1) introductory text.

* * * * *

(iv) [Reserved]. For further guidance, see § 54.9815–2713T(a)(1)(iv).

* * * * *

■ 3. Section 54.9815–2713T is added to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of § 54.9815–2713 and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i)–(iii) [Reserved]. For further guidance, see § 54.9815–2713(a)(1)(i) through (iii).

[113] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of § 54.9815–2713 as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

(2)–(c) [Reserved]. For further guidance, see § 54.9815–2713(a)(2) through (c).

(d) *Effective/Applicability date.* (1) Paragraphs (a) through (c) of this section are applicable beginning on April 16, 2012, except—

(2) Paragraphs (a)(1) introductory text and (a)(1)(iv) of this section are effective on October 6, 2017.

(e) *Expiration date.* This section expires on October 6, 2020.

■ 4. Section 54.9815–2713A is revised to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) through (f) [Reserved]. For further guidance, see § 54.9815–2713AT.

(b)

■ 5. Section 54.9815–2713AT is added to read as follows:

§ 54.9815–2713AT Accommodations in connection with coverage of preventive health services (temporary).

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give sixty-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group

health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): ''Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].''

(e) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(g) *Expiration date.* This section expires on October 6, 2020.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 2590.715–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 8. Section 2590.715–2713A is revised to read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its exempt status under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in § 2510.3–16 of this chapter and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under § 2510.3–16 of this chapter and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715–2713.

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) for plan participants and beneficiaries

for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 715 of ERISA. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): ''Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].''

(e) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 2590.715–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 10. Section 147.130 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131 and 147.132, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132.

* * * * *

■ 11. Section 147.131 is revised to read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

(c) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process.

(d) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Deparement of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) ''Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments . If you have any questions about this notice, contact [contact information for health insurance issuer].''

(f) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(g) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ 12. Add § 147.132 to read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(c) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[FR Doc. 2017–21851 Filed 10–6–17; 11:15 am]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P; 6325–64–P

EXHIBIT D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9828]

RIN 1545–BN91

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9925–IFC]

RIN 0938–AT46

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs or moral convictions. These interim final rules expand exemptions to protect moral convictions for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the United States Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also provide certain morally objecting entities access to the voluntary ''accommodation'' process regarding such coverage. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES:

Effective date: These interim final rules are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by ''Preventive Services,'' may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9925–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9925–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492–4305 or *marketreform@cms.hhs.gov* for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's Web site (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the context of legal requirements touching on certain sensitive health care issues—including health coverage of contraceptives—Congress has a consistent history of supporting conscience protections for moral convictions alongside protections for religious beliefs, including as part of its efforts to promote access to health services.[1] Against that backdrop,

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their ''religious beliefs or moral convictions''); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS,

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, ''with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by'' HRSA (the ''Guidelines''). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,[2] while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, ''the Departments''),[3] exercised both the discretion granted to HHS through HRSA, its component, in PHS Act section 2713(a)(4), and the authority granted to the Departments as administering agencies (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92) to issue regulations to guide HRSA in carrying out that provision. Through rulemaking, including three interim final rules, the Departments exempted and accommodated certain religious objectors, but did not offer an exemption or accommodation to any group possessing non-religious moral objections to providing coverage for some or all contraceptives. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the ''contraceptive Mandate,'' or the ''Mandate'') as being inconsistent with various legal protections. These challenges included lawsuits brought by some non-religious organizations with sincerely held moral convictions inconsistent with providing coverage for some or all contraceptive services, and those cases continue to this day. Various public comments were also submitted asking the Departments to protect objections based on moral convictions.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as: The interests served by the existing Guidelines, regulations, and accommodation process; [4] the extensive litigation; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); Congress' history of providing protections for moral convictions alongside religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under PHS Act section 2713(a)(4); the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; and the history of the regulatory process and comments submitted in various requests for public comments (including in the Departments' 2016 Request for Information). Elsewhere in this issue of the **Federal Register**, the Departments published, contemporaneously with these interim final rules, companion interim final rules expanding exemptions to protect sincerely held religious beliefs in the context of the contraceptive Mandate.

In light of these considerations, the Departments issue these interim final rules to better balance the Government's interest in promoting coverage for contraceptive and sterilization services with the Government's interests in providing conscience protections for individuals and entities with sincerely held moral convictions in certain health care contexts, and in minimizing burdens imposed by our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, ''[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the Department of Health and Human Services (HHS).'' Those laws protect objections based on moral convictions in addition to religious beliefs.

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS

and Education, and Related Agencies Appropriations Act), Public Law 115–31 (protecting any ''health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of ''the provision of contraceptive coverage by health insurance plans'' in the District of Columbia, ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.''); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions''); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their ''religious or conscientious commitment to offer only natural family planning''); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on ''religious beliefs or moral objections''); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on ''conscience'' as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on ''religious beliefs or moral convictions''); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); *see also* 8 U.S.C. 1182(g) (protecting vaccination objections by ''aliens'' due to ''religious beliefs or moral convictions''); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on ''moral or religious convictions''); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their ''religious or moral objection'').

[2] This document's references to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

[3] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

[4] In this IFR, we generally use ''accommodation'' and ''accommodation process'' interchangeably.

Act requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

The Departments have consistently interpreted section 2713(a)(4)'s of the PHS Act grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA's Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women's preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act reference to ''comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph'' to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines ''supported by the Health Resources and Services Administration for purposes of this paragraph,'' the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from ''the other guidelines referenced in section 2713(a), which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients.'' *Id.* Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4), the Departments have previously promulgated regulations defining the scope of permissible religious exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority delegated to the Departments as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. The Congress did not intend to require entirely uniform coverage of preventive services. (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 for grandfathered plans. This exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include: Section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime limits; section 2712, which prohibits rescissions of health insurance coverage; section 2714, which extends dependent coverage until age 26; and section 2718, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.[5] As the Supreme Court observed, ''there is no legal requirement that grandfathered plans ever be phased out.'' *Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments' interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments' own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that ''longstanding Federal laws to protect conscience . . . remain intact,'' including laws that protect religious beliefs and moral convictions from certain requirements in the health care context. Although the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect conscience regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in consideration of the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS Act.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, ''Clinical Preventive Services for Women, Closing the Gaps'' (IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation, pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.[6]

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of ''contraceptives'' certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,[7] the IOM's recommendation included

[5] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[6] Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings ''with respect to women,'' the Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

[7] FDA's guide ''Birth Control: Medicines To Help You,'' specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and ''may also work . . . by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason distinct from whether they also oppose contraception or sterilization. One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He stated that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by section 2713(a)(1) through (3) of the PHS Act leads to lower rates of disability or disease and increased rates of well-being, such that the IOM should recommend additional services to be included under Guidelines issued under section 2713(a)(4) of the PHS Act. He further stated that ''the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered,'' and that ''the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy.'' He also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.[8] IOM 2011 at 231–32. In its response to Dr. LoSasso, the other 15 committee members stated in part that ''At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions.''

2. HRSA's 2011 Guidelines and the Departments' Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women's preventive services, adopting the recommendations of the IOM. *https://www.hrsa.gov/womensguidelines/* The Guidelines included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (hereinafter ''the Mandate'').

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules. (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specified that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.[9] The 2011 interim final rules only offered the exemption to a narrow scope of employers, and only if they were religious. As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some ''States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services.'' (76 FR 46623). Several comments were submitted asking that the exemption include those who object to contraceptive coverage based on non-religious moral convictions, including pro-life, non-profit advocacy organizations.[10]

3. The Departments' Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of ''religious employer'' in the 2011 interim final rules without modification (2012 final regulations).[11] (77 FR 8725). The exemption did not require exempt employers to file any certification form or comply with any other information collection process.

Contemporaneously with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).[12] The temporary safe harbor did not include nonprofit organizations that had an objection to contraceptives based on moral convictions but not religious beliefs, nor did it include for-profit entities of any kind. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve ''two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services.'' (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of ''religious employer'' for purposes of the religious employer exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer—(1) have the inculcation of religious values as its purpose; (2) primarily employ persons who share its religious tenets; and (3) primarily serve persons who share its religious tenets. The proposed expanded

[8] The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

[9] The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011. (76 FR 46621).

[10] *See, for example,* Americans United for Life (''AUL'') Comment on CMA–9992–IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496.*

[11] The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

[12] Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: *http://www.lb7.uscourts.gov/documents/12cv3932.pdf.* The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled ''Student Health Insurance Coverage'' published March 21, 2012 (77 FR 16457).

definition still encompassed only religious entities.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations ''may be less likely than'' employees of exempt houses of worship and integrated auxiliaries to share their employer's faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization's plan—and without any cost to the eligible organization.[13] In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries. The proposed accommodation process was not to be offered to non-religious nonprofit organizations, nor to any for-profit entities. Public comments again included the request that exemptions encompass objections to contraceptive coverage based on moral convictions and not just based on religious beliefs.[14] On August 15, 2012, the Departments extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations ''does not undermine the governmental interests furthered by the contraceptive coverage requirement.'' (78 FR 39874). However, like the 2013 NPRM, the July 2013 regulations assumed that ''[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection'' to contraceptives. *Id.*

The July 2013 regulation also finalized an accommodation for eligible organizations, which were then defined to include solely organizations that are religious. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization's plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the HHS Secretary requests and an authorizing exception under OMB Circular No. A–25R is in effect.[15] With respect to fully insured group health plans, the issuer was expected to bear the cost of such payments,[16] and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations. The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. Religious for-profit entities won various court decisions leading to the Supreme Court's ruling in *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[17]

On August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of HHS that an eligible organization had religious objections to coverage of all or a subset of contraceptive services (79 FR 51092). In response to *Hobby Lobby,* the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption; neither added a certification requirement for

[13] The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

[14] *See,for example,* AUL Comment on CMS–9968–P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115.*

[15] *See also* 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally-facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was $33 million.

[16] ''[P]roviding payments for contraceptive services is cost neutral for issuers.'' (78 FR 39877).

[17] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. *See* 134 S. Ct. at 2774.

exempt entities; and neither encompassed objections based on non-religious moral convictions.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

Meanwhile, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik* v. *Burwell.* On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik,* vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments' favor—and remanding the cases ''in light of the substantial clarification and refinement in the positions of the parties'' that had been filed in supplemental briefs. 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would ''allow the parties sufficient time to resolve any outstanding issues between them.'' *Id.* The Court also specified that ''the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice'' while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, meetings were held between attorneys for the Government and for the plaintiffs in those cases. The Departments also issued a Request for Information (''RFI'') on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016. Those comments included the request that the exemption be expanded to include those who oppose the Mandate for either religious ''or moral'' reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.[18]

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations asserted that they believe some methods classified by FDA as contraceptives may have an abortifacient effect and therefore, in their view, are morally equivalent to abortion. These organizations have neither received an exemption from the Mandate nor do they qualify for the accommodation. For example, the organization that since 1974 has sponsored the annual March for Life in Washington, DC (March for Life), filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, (77 FR 8727), March for Life argued that the Departments' stated interests behind the Mandate were only advanced among women who ''want'' the coverage so as to prevent ''unintended'' pregnancy. March for Life contended that because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments' interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and therefore doing so was arbitrary and capricious in violation of the APA. March for Life further contended that because the Departments concluded the government's interests were not undermined by exempting houses of worship and integrated auxiliaries (based on our assumption that such entities are relatively more likely than other religious nonprofits to have employees that share their views against contraception), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and therefore violated their right of equal protection under the Due Process Clause.

March for Life's employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate's requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. *Real Alternatives, Inc.* v. *Burwell,* 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the Federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims (not specifically ruling on the APA claim), and issued a permanent injunction against the Departments that is still in place. *March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in *March for Life* is pending and has been stayed since early 2016. In another case, Federal district and appellate courts in Pennsylvania disagreed with the reasoning from *March for Life* and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. *Real Alternatives,* 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in *Real Alternatives* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. *Id.* at *18.

On December 20, 2016, HRSA updated the Guidelines via its Web site, *https://www.hrsa.gov/womensguidelines2016/index.html.* HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the

[18] *See, for example, https://www.regulations.gov/document?D=CMS-2016-0123-54142; see also https://www.regulations.gov/document?D=CMS-2016-0123-54218* and *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

contraceptive method). They also specified, for the first time, that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women's Preventive Services' Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process, nor did they extend the exemption or accommodation process to organizations or individuals that oppose certain forms of contraception (and coverage thereof) on moral grounds.

On January 9, 2017, the Departments issued a document entitled, ''FAQs About Affordable Care Act Implementation Part 36.'' [19] The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. The Departments did not adopt the approach requested by certain commenters, cited above, to expand the exemption to include those who oppose the Mandate for moral reasons.

On May 4, 2017, the President issued Executive Order 13798, ''Promoting Free Speech and Religious Liberty.'' Section 3 of that order declares, ''Conscience Protections with Respect to Preventive-Care Mandate. The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code.''

II. Expanded Exemptions and Accommodations for Moral Convictions

These interim final rules incorporate conscience protections into the contraceptive Mandate. They do so in part to bring the Mandate into conformity with Congress's long history of providing or supporting conscience protections in the regulation of sensitive health-care issues, cognizant that Congress neither required the Departments to impose the Mandate nor prohibited them from providing conscience protections if they did so. Specifically, these interim final rules expand exemptions to the contraceptive Mandate to protect certain entities and individuals that object to coverage of some or all contraceptives based on sincerely held moral convictions but not religious beliefs, and these rules make those exempt entities eligible for accommodations concerning the same Mandate.

A. Discretion To Provide Exemptions Under Section 2713(a)(4) of the PHS Act and the Affordable Care Act

The Departments have consistently interpreted HRSA's authority under section 2713(a)(4) of the PHS Act to allow for exemptions and accommodations to the contraceptive Mandate for certain objecting organizations. Section 2713(a)(4) of the PHS Act gives HRSA discretion to decide whether and in what circumstances it will support Guidelines providing for additional women's preventive services coverage. That authority includes HRSA's discretion to include contraceptive coverage in those Guidelines, but the Congress did not specify whether or to what extent HRSA should do so. Therefore, section 2713(a)(4) of the PHS Act allows HRSA to not apply the Guidelines to certain plans of entities or individuals with religious or moral objections to contraceptive coverage, and by not applying the Guidelines to them, to exempt those entities from the Mandate. These rules are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Our protection of conscience in these interim final rules is consistent with the structure and intent of the Affordable Care Act. The Affordable Care Act refrains from applying section 2713(a)(4) of the PHS Act to millions of women in grandfathered plans. In contrast, we anticipate that conscientious exemptions to the Mandate will impact a much smaller number of women. President Obama emphasized in signing the Affordable Care Act that ''longstanding Federal law to protect conscience''—laws with conscience protections encompassing moral (as well as religious) objections—specifically including (but not limited to) the Church Amendments (42 U.S.C. 300a–7), ''remain intact.'' Executive Order 13535. Nothing in the Affordable Care Act suggests Congress' intent to deviate from its long history, discussed below, of protecting moral convictions in particular health care contexts. The Departments' implementation of section 2713(a)(4) of the PHS Act with respect to contraceptive coverage is a context similar to those encompassed by many other health care conscience protections provided or supported by Congress. This Mandate concerns contraception and sterilization services, including items believed by some citizens to have an abortifacient effect—that is, to cause the destruction of a human life at an early stage of embryonic development. These are highly sensitive issues in the history of health care regulation and have long been shielded by conscience protections in the laws of the United States.

B. Congress' History of Providing Exemptions for Moral Convictions

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on nearly 50 years of statutory law and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health insurance coverage. Congress very recently expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.'' Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808, Public Law 115–31 (May 5, 2017). In support of these interim final rules, we consider it significant that Congress' most recent statement on the prospect of Government mandated contraceptive coverage specifically intends that a conscience clause be included to protect moral convictions.

The many statutes listed in Section I-Background under footnote 1, which show Congress' consistent protection of moral convictions alongside religious beliefs in the Federal regulation of health care, includes laws such as the 1973 Church Amendments, which we discuss at length below, all the way to the 2017 Consolidated Appropriations Act discussed above. Notably among those laws, the Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object ''on moral or religious grounds'' to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w–

[19] Available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''). The Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions.'' Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.

C. The Church Amendments' Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations. These sections of the United States Code are known as the Church Amendments, named after their primary sponsor Senator Frank Church (D–Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions. Among other things, the amendments protect the recipients of certain Federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object ''on the basis of religious beliefs or moral convictions,'' and they prohibit recipients of certain Federal health funds from discriminating against any personnel ''because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions'' (42 U.S.C. 300a–7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to ''any lawful health service,'' or to ''any part of a health service program.'' (42 U.S.C. 300a–7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute ''any lawful health service'' or a ''part of a health service program.'' As such, the protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court's decision in *Roe* v. *Wade,* 410 U.S. 113 (1973). Even though the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens must facilitate its exercise. Thus, *Roe* favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared ''Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles.'' 410 U.S. at 144 & n.38 (1973). Likewise in *Roe*'s companion case, *Doe* v. *Bolton,* the Court observed that, under State law, ''a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.'' 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions ''obviously . . . afford appropriate protection.'' *Id.* at 198. As an Arizona court later put it, ''a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'' *Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains relevant discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only *Roe* v. *Wade* but also an instance where a Federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D–IL) rose to ask that the amendment be changed to specify that it also protects objections to abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record is particularly relevant to this discussion:

> Mr. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.
>
> One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.
>
> As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?
>
> Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words ''or moral''?
>
> Mr. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words ''or moral conviction'' were added after ''religious belief.'' I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.
>
> Mr. STEVENSON. The Senator's suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18.

As the debate proceeded, Senator Church went on to quote *Doe* v. *Bolton*'s reliance on a Georgia statute that stated ''a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.'' 119 Congr. Rec. at S5722 (quoting 410 U.S. at 197–98). Senator Church added, ''I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations.'' *Id.* Considering the scope of the protections, Senator Gaylord Nelson (D–WI) asked whether, ''if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, 'We are not going to bother with this kind of procedure in this hospital,' would the pending amendment permit that?'' 119 Congr. Rec. at S5723. Senator Church responded that the amendment would not encompass such an objection. *Id.*

Senator James L. Buckley (C–NY), speaking in support of the amendment, added the following perspective:

> Mr. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the

recent Supreme Court decisions will likely unleash a series of court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic] [20] to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words ''moral conviction,'' because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. at S5723.

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R–MA) [21] likewise observed that ''the right of conscience has long been recognized in the parallel situation in which the individual's right to conscientious objector status in our selective service system has been protected'' and ''expanded by the Supreme Court to include moral conviction as well as formal religious belief.'' 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, ''We are concerned here only with the right of moral conscience, which has always been a part of our national tradition.'' *Id.* at 4149.

These first of the Church Amendments, codified at 42 U.S.C. 300a–7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions. And, as noted above, subsequent statutes add protections for moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion: See 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31;
- Protections for entities and individuals that object to providing or covering contraceptives: See id. at Div. C, Title VIII, Sec. 808; id. at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act); and id. at Div. I, Title III; and
- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives: See 42 U.S.C. 290bb–36; 42 U.S.C. 14406; 42 U.S.C. 18113; and 42 U.S.C. 1396a(w)(3).

The Departments believe that the intent behind Congress' protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports our decision in these interim final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

D. Court Precedents Relevant to These Expanded Exemptions

The legislative history of the protection of moral convictions in the first Church Amendments shows that Members of Congress saw the protection as being consistent with Supreme Court decisions. Not only did Senator Church cite the abortion case *Doe* v. *Bolton* as a parallel instance of conscience protection, but he also spoke of the Supreme Court generally giving ''comparable treatment to deeply held moral convictions.'' Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court's protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as *Welsh* v. *United States,* 398 U.S. 333 (1970), which the Supreme Court decided just 3 years earlier.

Welsh involved what is perhaps the Government's paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on ''religious training and belief,'' that protection would also extend to avowedly non-religious objections to war held with the same moral strength. *Id.* at 343. The Court declared, ''[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual 'a place parallel to that filled by . . . God' in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as much entitled to a 'religious' conscientious objector exemption . . . as is someone who derives his conscientious opposition to war from traditional religious convictions.''

The Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in these interim final rules. Neither these interim final rules, nor the Church Amendments or other Federal health care conscience statutes, define ''moral convictions'' (nor do they define ''religious beliefs''). But in issuing these interim final rules, we seek to use the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as *Welsh* to support the addition of language protecting moral convictions. In protecting moral convictions parallel to religious beliefs, *Welsh* describes moral convictions warranting such protection as ones: (1) That the ''individual deeply and sincerely holds''; (2) ''that are purely ethical or moral in source and content; (3) ''but that nevertheless impose upon him a duty''; (4) and that ''certainly occupy in the life of that individual a place parallel to that filled by . . . God' in traditionally religious persons,'' such that one could say ''his beliefs function as a religion in his life.'' (398 U.S. at 339–40). As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises ''capriciously.'' Instead, along with the requirement that protected moral convictions must be ''sincerely held,'' this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

In the context of this particular Mandate, it is also worth noting that, in *Hobby Lobby,* Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan's opinion in *Welsh,* 398 U.S. at 357–58, in support of her statement that ''[s]eparating moral convictions from religious beliefs would be of questionable legitimacy.'' 134 S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious

[20] The Senator might have meant ''[forced] . . . against his will.''

[21] Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

beliefs constitute an illegitimate ''separat[ion]'' of moral convictions, nor do we assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress' intent in the Church Amendments and in later Federal conscience statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

E. Conscience Protections in Regulations and Among the States

The tradition of protecting moral convictions in certain health contexts is not limited to Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.[22] Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs when they have determined that it is appropriate to do so in particular circumstances. The Equal Employment Opportunity Commission has consistently protected ''moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views'' alongside religious views under the ''standard [] developed in *United States* v. *Seeger,* 380 U.S. 163 (1965) and [*Welsh*].'' (29 CFR 1605.1). The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so ''is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such participation or attendance contrary to medical ethics.'' (28 CFR 26.5).[23]

Forty-five States have health care conscience protections covering objections to abortion, and several of those also cover sterilization or contraception.[24] Most of those State laws protect objections based on ''moral,'' ''ethical,'' or ''conscientious'' grounds in addition to ''religious'' grounds. Particularly in the case of abortion, some Federal and State conscience laws do not require any specified motive for the objection. (42 U.S.C. 238n). These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts.

The contraceptive Mandate implicates that governmental interest. Many persons and entities object to this Mandate in part because they consider some forms of FDA-approved contraceptives to be abortifacients and morally equivalent to abortion due to the possibility that some of the items may have the effect of preventing the implantation of a human embryo after fertilization. Based on our knowledge from the litigation, all of the current litigants asserting purely non-religious objections share this view, and most of the religious litigants do as well. The Supreme Court, in describing family business owners with religious objections, explained that ''[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions.'' *Hobby Lobby,* 134 S. Ct. at 2751. Outside of the context of abortion, as cited above, Congress has also provided health care conscience protections pertaining to sterilization, contraception, and other health care services and practices.

F. Founding Principles

The Departments also look to guidance from the broader history of respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. As quoted above, in supporting protecting conscience based on non-religious moral convictions, Senator Buckley declared ''[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.'' Rep. Heckler similarly stated that ''the right of moral conscience . . . has always been a part of our national tradition.'' This tradition is reflected, for example, in a letter President George Washington wrote saying that ''[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: A policy worthy of imitation. All possess alike liberty of conscience and immunities of citizenship.'' [25] Thomas Jefferson similarly declared that ''[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority.'' [26] Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience ''the most sacred of all property,'' and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that ''the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed.'' [27]

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context. We do not suggest that the specific protections offered in this rule would also be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These interim final rules do not address in any way how the Government would balance its interests with respect to

[22] *See, for example,* 42 CFR 422.206 (declaring that the general Medicare Advantage rule ''does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds.''); 42 CFR 438.102 (declaring that information requirements do not apply ''if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds''); 48 CFR 1609.7001 (''health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs.''); 48 CFR 352.270–9 (''Non-Discrimination for Conscience'' clause for organizations receiving HIV or Malaria relief funds).

[23] *See also* 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA's request will depend in part on ''[c]ultural, religious, or moral objections to the request'').

[24] According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). ''Refusing to Provide Health Services'' (June 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.*

[25] From George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790), available at *https://founders.archives.gov/documents/Washington/05-06-02-0135.*

[26] Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809), available at *https://founders.archives.gov/documents/Jefferson/99-01-02-9714.*

[27] James Madison, ''Essay on Property'' (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

other health services not encompassed by the contraceptive Mandate.[28] Instead we highlight this tradition of respect for conscience from our Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4) of the PHS Act, while protecting conscience in the exercise of moral convictions. We believe that these interim final rules are consistent both with the American tradition of respect for conscience and with Congress' history of providing conscience protections in the kinds of health care matters involved in this Mandate.

G. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in the expanded exemptions and accommodations of these rules, is consistent with recent executive orders. President Trump's Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for ''religious'' beliefs, but for ''conscience.'' We interpret that term to include moral convictions and not just religious beliefs. Likewise, President Trump's first Executive Order, EO 13765, declared that ''the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' This Mandate imposes both a cost, fee, tax, or penalty, and a regulatory burden, on individuals and purchasers of health insurance that have moral convictions opposed to providing contraceptive coverage. These interim final rules exercise the Departments' discretion to grant exemptions from the Mandate to reduce and relieve regulatory burdens and promote freedom in the health care market.

H. Litigation Concerning the Mandate

The sensitivity of certain health care matters makes it particularly important for the Government to tread carefully when engaging in regulation concerning those areas, and to respect individuals and organizations whose moral convictions are burdened by Government regulations. Providing conscience protections advances the Affordable Care Act's goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in *Hobby Lobby* declared that, if HHS requires owners of businesses to cover procedures that the owners ''could not in good conscience'' cover, such as abortion, ''HHS would effectively exclude these people from full participation in the economic life of the Nation.'' 134 S. Ct. at 2783. That would be a serious outcome. As demonstrated by litigation and public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that some of those items may cause early abortions. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) of the PHS Act in a way that respects the moral convictions of our citizens so that they are more free to engage in ''full participation in the economic life of the Nation.'' These expanded exemptions do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. *See March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court recently affirmed a district court ruling that allows the previous regulations to be imposed in a way that violates the moral convictions of a small nonprofit pro-life organization and its employees. *See Real Alternatives,* 2017 WL 3324690. Our litigation of these cases has led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations, issuers, third party administrators, and employees and beneficiaries. The organizations that have sued seeking a moral exemption have all adopted moral tenets opposed to contraception and hire only employees who share this view. It is reasonable to conclude that employees of these organizations would therefore not benefit from the Mandate. As a result, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, and our requirement to comply with permanent injunctive relief currently imposed in *March for Life,* provide substantial reasons for the Departments to protect moral convictions through these interim final rules. Even though, as discussed below, we assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, we know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, we consider it appropriate to issue the protections set forth in these interim final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so we, too, believe that ''our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government'' in this situation.

I. The Departments' Rebalancing of Government Interests

For additional discussion of the Government's balance of interests concerning religious beliefs issued contemporaneously with these interim final rules, see the related document published by the Department elsewhere in this issue of the **Federal Register**. There, we acknowledge that the Departments have changed the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlying it, and we assert that we now believe the Government's legitimate interests in providing for contraceptive coverage do not require us to violate sincerely held religious beliefs while implementing the Guidelines. For parallel reasons, the Departments believe Congress did not set forth—and we do not possess—interests that require us to violate sincerely held moral convictions in the course of generally requiring contraceptive coverage. These changes in policy are

[28] As the Supreme Court stated in *Hobby Lobby,* the Court's decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer's religious beliefs. Nor does the Court's opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

within the Departments' authority. As the Supreme Court has acknowledged, ''[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change.'' *Encino Motorcars, LLC* v. *Navarro,* 136 S. Ct. 2117, 2125 (2016). This ''reasoned analysis'' requirement does not demand that an agency ''demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates.'' *United Student Aid Funds, Inc.* v. *King,* 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)); *see also New Edge Network, Inc.* v. *FCC,* 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that ''an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance'').[29]

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. In addition to the apparent fact that many entities with non-religious moral objections to the Mandate appear to only hire persons that share those objections, Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 requirements on grandfathered plans benefitting millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have other avenues for obtaining contraception, including through various other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, and which these interim final rules leave unchanged.[30] As the Government is under no constitutional obligation to fund contraception, *cf. Harris* v. *McRae,* 448 U.S. 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their moral convictions. *Cf. Rust* v. *Sullivan,* 500 U.S. 173, 192–93 (1991) (''A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.'').

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. Our expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant Federal law, the Departments have determined that expanding the exemptions to include protections for moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to take advantage of these exemptions and accommodations may be small, we believe that it is important formally to codify such protections for objections based on moral conviction, given the long-standing recognition of such protections in health care and health insurance context in law and regulation and the particularly sensitive nature of these issues in the health care context. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including 3 previous interim final rules), public comments, and the long-running litigation from non-religious moral objectors to the Mandate, as well as the information contained in the companion interim final rules issued elsewhere in this issue of the **Federal Register**. These interim final rules seek to resolve these matters by directing HRSA, to the extent it requires coverage for certain contraceptive services in its Guidelines, to afford an exemption to certain entities and individuals with sincerely held moral convictions by which they object to contraceptive or sterilization coverage, and by making the accommodation process available for certain organizations with such convictions.

For all of the reasons discussed and referenced above, the Departments have determined that the Government's interest in applying contraceptive coverage requirements to the plans of certain entities and individuals does not outweigh the sincerely held moral objections of those entities and individuals. Thus, these interim final rules amend the regulations amended in both the Departments' July 2015 final regulations and in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

These interim final rules expand those exemptions to include additional entities and persons that object based on sincerely held moral convictions. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no objection specified in the regulations exists, and if section 2713 of the PHS Act otherwise applies. These interim final rules also maintain the existence of an accommodation process as a voluntary option for organizations with moral objections to contraceptive coverage, but consistent with our expansion of the exemption, we expand eligibility for the accommodation to include organizations with sincerely held moral convictions concerning contraceptive coverage. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.[31]

[29] *See also Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837, 863–64 (1984) (''The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.'')

[30] *See, for example,* Family Planning grants in 42 U.S.C. 300, *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[31] *See https://www.hrsa.gov/womensguidelines/* and *https://www.hrsa.gov/womensguidelines2016/index.html.*

1. Exemption for Objecting Entities Based on Moral Convictions

In the new 45 CFR 147.133 as created by these interim final rules, we expand the exemption that was previously located in § 147.131(a), and that was expanded in § 147.132 by the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

With respect to employers that sponsor group health plans, § 147.133(a)(1) and (a)(1)(i) provide exemptions for certain employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held moral convictions.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption in § 147.133(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.133(a)(1) and (a)(1)(i), by specifying that ''[a] group health plan and health insurance coverage provided in connection with a group health plan'' is exempt ''to the extent the plan sponsor objects as specified in paragraph (a)(2),'' exempt the group health plans the sponsors of which object, and exempt their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713T(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[32] Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures should reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.133(a) apply ''to the extent'' of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.133(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsors have no qualifying objection. The objection of a health insurance issuer in § 147.133(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

2. Exemption of Certain Plan Sponsors

The rules cover certain kinds of non-governmental employer plan sponsors with the requisite objections, and the rules specify which kinds of entities qualify for the exemption.

Under these interim final rules, the Departments do not limit the exemption with reference to nonprofit status as previous rules have done. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities without regard to whether they operate as nonprofits or for-profit entities. In addition, a significant majority of states either impose no contraceptive coverage requirement, or offer broader exemptions than the exemption contained in the July 2015 final regulations.[33] States also generally protect moral convictions in health care conscience laws, and they often offer those protections whether or not an entity operates as a nonprofit.[34] Although the practice of states is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor is it a statement about what the Federal Government may do consistent with other protections or limitations in federal law, such state practice can be informative as to the viability of offering protections for conscientious objections in particularly sensitive health care contexts. In this case, the existence of many instances where conscience protections are offered, or no underlying mandate of this kind exists that could violate moral convictions, supports the Departments' decision to expand the Federal exemption concerning this Mandate as set forth in these interim final rules.

Section 147.133(a)(1)(i)(A) of the rules specifies that the exemption includes the plans of a plan sponsor that is a nonprofit organization with sincerely held moral convictions.

Section 147.133(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of a plan sponsor that is a for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

Extending the exemption to certain for-profit entities is consistent with the Supreme Court's ruling in *Hobby Lobby,* which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby,* religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the

[32] *See, for example,* 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. *See also* 45 CFR 147.200 (requiring disclosure of the ''exceptions, reductions, and limitations of the coverage,'' including group health plans and group & individual issuers).

[33] *See* Guttmacher Institute, ''Insurance Coverage of Contraceptives'' (Aug. 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

[34] *See, for example,* Guttmacher Institute, ''Refusing to Provide Health Services'' (Aug. 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.*

Departments' argument to the contrary. 134 S. Ct. 2768–75. Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.[35] The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held moral convictions, is a matter of well-established State law with respect to corporate decision-making,[36] and the Departments expect that application of such laws would cabin the scope of this exemption.

The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. Any such positive definition runs up against the myriad state differences in defining such entities, and potentially intrudes into a traditional area of state regulation of business organizations. The Departments implicitly recognized the difficulty of defining closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely ''substantially similar'' to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. Instead of attempting to positively define closely held businesses for the purpose of this rule, the Departments consider it much more clear, effective, and preferable to define the category negatively by reference to one element of our previous definition, namely, that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

In this way, these interim final rules differ from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in § 147.132(a)(1)—those extend to for-profit entities whether or not they are closely held or publicly traded. The Departments seek public comment on whether the exemption in § 147.133(a)(1)(i) for plan sponsors with moral objections to the Mandate should be finalized to encompass all of the types of plan sponsors covered by § 147.132(a)(1)(i), including publicly traded corporations with objections based on sincerely held moral convictions, and also non-federal governmental plan sponsors that may have objections based on sincerely held moral convictions.

In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without precluding publicly traded and governmental entities from using those protections. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 300a–7(b)). Thus, under section 300a–7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a–7(b), the protections of that section would apply. The Coats-Snowe Amendment likewise provides certain protections for health care entities and postgraduate physician training programs that choose not to perform, refer for, or provide training for abortions, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 238n).

The Weldon Amendment[37] provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans that do not provide, pay for, provide coverage of, or refer for abortions, and the statute does not limit those protections based on whether the entity is publicly traded or governmental. The Affordable Care Act provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing, and the statute similarly does not limit those protections based on whether the entity is publicly traded or governmental. (42 U.S.C. 18113).[38]

Sections 1395w–22(j)(3)(B) and 1396u–2(b)(3) of 42 U.S.C. protect organizations that offer Medicaid and Medicare Advantage managed care plans from being required to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds, and those paragraphs do not further specify that publicly traded entities do not qualify for the protections. Congress' most recent statement on Government requirements of contraceptive coverage specified that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.'' Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808. Congress expressed no intent that such a conscience should be limited based on whether the entity is publicly traded.

At the same time, the Departments lack significant information about the need to extend the expanded exemption further. We have been subjected to litigation by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, and we have been sued by closely held for-profit entities expressing religious objections. This combination of different types of plaintiffs leads us to believe that there may be a small number of closely held for-profit entities that would seek to use an exemption to the contraceptive Mandate based on moral convictions. The fact that many closely held for-profit entities brought challenges to the Mandate has led us to offer protections that would include publicly traded entities with religious objections to the Mandate if such entities exist. But the combined lack of any lawsuits challenging the Mandate by for-profit entities with non-religious moral convictions, and of any lawsuits by any kind of publicly traded entity, leads us to not extend the expanded exemption in these interim final rules to publicly traded entities, but rather to invite public comment on whether to do so in

[35] See Jennifer Haberkorn, ''Two years later, few Hobby Lobby copycats emerge,'' *Politico* (Oct. 11, 2016), available at *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627*.

[36] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

[37] Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Pub. L. 115–31.

[38] The lack of the limitation in this provision may be particularly relevant since it is contained in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—are promulgated.

a way parallel to the protections set forth in § 147.132(a)(1)(i). We agree with the Supreme Court that it is improbable that many publicly traded companies with numerous ''unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs'' (or moral convictions) and thereby qualify for the exemption. *Hobby Lobby,* 134 S. Ct. at 2774. We are also not aware of other types of plan sponsors (such as non-Federal governmental entities) that might possess moral objections to compliance with the Mandate, including whether some might consider certain contraceptive methods as having a possible abortifacient effect. Nevertheless, we would welcome any comments on whether such corporations or other plan sponsors exist and would benefit from such an exemption.

Despite our a lack of complete information, the Departments know that nonprofit entities have challenged the Mandate, and we assume that a closely held business might wish to assert non-religious moral convictions in objecting to the Mandate (although we anticipate very few if any will do so). Thus we have chosen in these interim final rules to include them in the expanded exemption and thereby remove an obstacle preventing such entities from claiming an exemption based on non-religious moral convictions. But we are less certain that we need to use these interim final rules to extend the expanded exemption for moral convictions to encompass other kinds of plan sponsors not included in the protections of these interim final rules. Therefore, with respect to plan sponsors not included in the expanded exemptions of § 147.133(a)(1)(i), and non-federal governmental plan sponsors that might have moral objections to the Mandate, we invite public comment on whether to include such entities when we finalize these rules at a later date.

The Departments further conclude that it would be inadequate to merely provide entities access to the accommodation process instead of to the exemption where those entities object to the Mandate based on sincerely held moral convictions. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way ''seamless'' to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. This has led many religious groups to challenge the accommodation in court, and we expect similar challenges would come from organizations objecting to the accommodation based on moral convictions if we offered them the accommodation but not an exemption. When we took that narrow approach with religious nonprofit entities it led to multiple cases in many courts that we needed to litigate to the Supreme Court various times. Although objections to the accommodation were not specifically litigated in the two cases brought by nonprofit non-religious organizations (because we have not even made them eligible for the accommodation), those organizations made it clear that they and their employees strongly oppose coverage of certain contraceptives in their plans and in connection with their plans.

3. Exemption for Institutions of Higher Education

The plans of institutions of higher education that arrange student health insurance coverage will be treated similarly to the way that plans of employers are treated for the purposes of such plans being exempt or accommodated based on moral convictions. These interim final rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

The Departments are not aware of institutions of higher education that arrange student coverage and object to the Mandate based on non-religious moral convictions. We have been sued by several institutions of higher education that arrange student coverage and object to the Mandate based on religious beliefs. We believe the existence of such entities with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible so that we should provide protections for them in these interim final rules. But based on a lack of information about such entities, we assume that none will use the exemption concerning student coverage at this time.

4. Exemption for Issuers

These interim final rules extend the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection (whether the objection is based on moral convictions, as set forth in these rules, or on religious beliefs, as set forth in exemptions created by the companion interim final rules published elsewhere in this issue of the **Federal Register**). Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt.

Under the rules as amended, issuers with objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions, and issuers with sincerely held religious beliefs could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Issuers that hold moral objections should identify to plan sponsors the

lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers' sincerely held moral convictions, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Protecting issuers that object to offering contraceptive coverage based on sincerely held moral convictions will help preserve space in the health insurance market for certain issuers so that exempt plan sponsors and individuals will be able to obtain coverage.

The Departments are not currently aware of health insurance issuers that possess their own religious or moral objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations from being required to provide coverage or pay for abortions. *See, for example,* Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31. The most recently enacted Consolidated Appropriations Act declares that Congress supports a ''conscience clause'' to protect moral convictions concerning ''the provision of contraceptive coverage by health insurance plans.'' *See id.* at Div. C, Title VIII, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. The Departments solicit public comment; however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have moral convictions implicated by the Mandate.[39]

5. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.133(a)(2). That section specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.133(a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) for coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held moral convictions.

6. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the ''individual exemption''). Section 147.133(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713T(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan and/or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held moral convictions. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' moral convictions, or against the individual employees who accept such offers. *See Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the sincerely held moral objections of individual employees by offering them plans that omit contraception, even if those governmental entities do not object to offering contraceptive coverage in general.

This ''individual exemption'' cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of state law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held moral objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held moral convictions.[40] At the same

[39] The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for business entities. Because the issuer exemption operates more narrowly than the exemption for business plan sponsors operates, in the ways described here, and exists in part to help preserve market options for objecting plan sponsors, the Departments consider it appropriate to not draw such a distinction among issuers.

[40] This prospect has been raised in cases of religious individuals—see, for example, *Wieland,*

Continued

time, this individual exemption ''does not undermine the governmental interests furthered by the contraceptive coverage requirement,'' [41] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered. In addition, because the individual exemption only operates when the employer and/or issuer, as applicable, are willing, the exemption will not undermine any governmental interest in the workability of the insurance market, because we expect that any workability concerns will be taken into account in the decision of whether to be willing to offer the individual morally acceptable coverage.

For similar reasons, we have changed our position and now believe the individual exemption will not undermine any Government interest in uniformity in the health insurance market. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. The Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments' previous exemption for houses of worship and integrated auxiliaries, and our accommodation of self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.[42]

With respect to operationalizing this provision of these rules, as well as the similar provision protecting individuals with religious objections to purchasing insurance that covers some or all contraceptives, in the interim final rules published elsewhere in this issue of the **Federal Register**, the Departments note that a plan sponsor or health insurance issuer is not required to offer separate and different benefit package options, or separate and different forms of policy, certificate, or contract of insurance with respect to those individuals who object on moral bases from those who object on religious bases. That is, a willing employer or issuer may offer the same benefit package option or policy, certificate, or contract of insurance—which excludes the same scope of some or all contraceptive coverage—to individuals who are exempt from the Mandate because of their moral convictions (under these rules) or their religious beliefs (under the regulations as amended by the interim final rules pertaining to religious beliefs).

7. Optional Accommodation

In addition to expanding the exemption to those with sincerely held moral convictions, these rules also expand eligibility for the optional accommodation process to include employers with objections based on sincerely held moral convictions. This is accomplished by inserting references to the newly added exemption for moral convictions, 45 CFR 147.133, into the regulatory sections where the accommodation process is codified, 45 CFR 147.131, 26 CFR 54.9815–2713AT, and 29 CFR 2590.715–2713A. In all other respects the accommodation process works the same as it does for entities with objections based on sincerely held religious beliefs, as described in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

The Departments are not aware of entities with objections to the Mandate based on sincerely held moral convictions that wish to make use of the optional accommodation, and our present assumption is that no such entities will seek to use the accommodation rather than the exemption. But if such entities do wish to use the accommodation, making it available to them will both provide contraceptive coverage to their plan participants and respect those entities' objections. Because entities with objections to the Mandate based on sincerely held non-religious moral convictions have not previously had access to the accommodation, they would not be in a position to revoke their use of the accommodation at the time these interim final rules are issued, but could do so in the future under the same parameters set forth in the accommodation regulations.

8. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules insert references to 45 CFR 147.133 into the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713T(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv).

9. Conclusion

The Departments believe that the Guidelines, and the expanded exemptions and accommodations set forth in these interim final rules, will advance the legitimate but limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress' well-established record of allowing for moral exemptions with respect to various health care matters. These interim final rules maintain HRSA's discretion to decide whether to continue to require contraceptive coverage under the Guidelines if no regulatorily recognized exemption exists (and in plans where Congress applied section 2713 of the PHS Act). As cited above, these interim final rules also leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. The Departments believe this array of programs and requirements better serves the interests of providing contraceptive coverage while protecting the moral convictions of entities and individuals concerning coverage of some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

IV. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; and 79 FR 51092).

Section 553(b) of the APA requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior

196 F. Supp. 3d at 1017, and *March for Life,* 128 F. Supp. 3d at 130—where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to ''forgo health insurance altogether.''

[41] 78 FR 39874.

[42] *See also Real Alternatives,* 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) (''Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny.'' (citation and internal quotation marks omitted)).

to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to so continue to update the Guidelines.

Two lawsuits have been pending for several years by entities raising non-religious moral objections to the Mandate.[43] In one of those cases, the Departments are subject to a permanent injunction and the appeal of that case has been stayed since February 2016. In the other case, Federal district and appeals courts ruled in favor of the Departments, denying injunctive relief to the plaintiffs, and that case is also still pending. Based on the public comments the Departments have received, we have reason to believe that some similar nonprofit entities might exist, even if it is likely a small number.[44]

For entities and individuals facing a burden on their sincerely held moral convictions, providing them relief from Government regulations that impose such a burden is an important and urgent matter, and delay in doing so injures those entities in ways that cannot be repaired retroactively. The burdens of the existing rules undermine these entities' and individuals' participation in the health care market because they provide them with a serious disincentive—indeed a crisis of conscience—between participating in or providing quality and affordable health insurance coverage and being forced to violate their sincerely held moral convictions. The existence of inconsistent court rulings in multiple proceedings has also caused confusion and uncertainty that has extended for several years, with different federal courts taking different positions on whether entities with moral objections are entitled to relief from the Mandate. Delaying the availability of the expanded exemption would require entities to bear these burdens for many more months. Continuing to apply the Mandate's regulatory burden on individuals and organizations with moral convictions objecting to compliance with the Mandate also serves as a deterrent for citizens who might consider forming new entities consistent with their moral convictions and offering health insurance through those entities.

Moreover, we separately expanded exemptions to protect religious beliefs in the companion interim final rules issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. Because Congress has provided many statutes that protect religious beliefs and moral convictions similarly in certain health care contexts, it is important not to delay the expansion of exemptions for moral convictions set forth in these rules, since the companion rules provide protections for religious beliefs on an interim final basis. Otherwise, our regulations would simultaneously provide and deny relief to entities and individuals that are, in the Departments' view, similarly deserving of exemptions and accommodations consistent, with similar protections in other federal laws. This could cause similarly situated entities and individuals to be burdened unequally.

In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and to what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. As noted above, the public comments in response to both the RFI and various prior rulemaking proceedings included specific requests that the exemptions be expanded to include those who oppose the Mandate for either religious or ''moral'' reasons.[45] In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

As the U.S. Court of Appeals for the D.C. Circuit stated with respect to an earlier IFR promulgated with respect to this issue in *Priests for Life* v. *U.S. Department of Health and Human Services,* 772 F.3d 229, 276 (D.C. Cir. 2014), *vacated on other grounds, Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016), ''[S]everal reasons support HHS's decision not to engage in notice and comment here.'' Among other things, the Court noted that ''the agency made a good cause finding in the rule it issued''; that ''the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues''; that ''HHS will expose its interim rule to notice and comment before its permanent implementation''; and that not proceeding under interim final rules would ''delay the implementation of the alternative opt-out for religious objectors.'' *Id.* at 277. Similarly, not proceeding with exemptions and accommodations for moral objectors here would delay the implementation of those alternative opt-outs for moral objectors.

Delaying the availability of the expanded exemption could also increase the costs of health insurance for some entities. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover

[43] *March for Life,* 128 F. Supp. 3d 116; *Real Alternatives,* 867 F.3d 338.

[44] *See, for example,* Americans United for Life (''AUL'') Comment on CMA–9992–IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496,* and AUL Comment on CMS–9968–P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115.*

[45] *See, for example, http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496, http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115, https://www.regulations.gov/document?D=CMS-2016-0123-54142, https://www.regulations.gov/document?D=CMS-2016-0123-54218,* and *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

contraception. As such, they may wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. To the extent that entities with objections to the Mandate based on moral convictions but not religious beliefs fall into this category, they may be refraining from making those changes—and therefore may be continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. We are not aware of the extent to which such entities exist, but 17 percent of all covered workers are in grandfathered health plans, encompassing tens of millions of people.[46] Issuing these rules on an interim final basis reduces the costs of health insurance and regulatory burdens for such entities and their plan participants.

These interim final rules also expand access to the optional accommodation process for certain entities with objections to the Mandate based on moral convictions. If entities exist that wish to use that process, the Departments believe they should be able to do so without the delay that would be involved by not offering them the optional accommodation process by use of interim final rules. Proceeding otherwise could delay the provision of contraceptive coverage to those entities' employees.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final rules effective immediately upon filing for public inspection at the Office of the Federal Register.

V. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an ''economically significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations and do so in conjunction with the amendments made in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. These interim final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process to make entities with such convictions eligible to use it. The expanded exemption would apply to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to providing coverage for some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action is taken, among other reasons, to provide for conscientious participation in the health insurance market free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to resolve lawsuits that have been filed against the Departments by some such entities, and to avoid similar legal challenges.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these interim final rules, they believe it to be small.

With respect to the expanded exemption for nonprofit organizations, as noted above the Departments are aware of two small nonprofit

[46] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017*.

organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree with their opposition to the coverage.[47] Based on comments submitted in response to prior rulemakings on this subject, we believe that at least one other similar entity exists. However, we do not know how many similar entities exist. Lacking other information we assume that the number is small. Without data to estimate the number of such entities, we believe it to be less than 10, and assume the exemption will be used by nine nonprofit entities.

We also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with our conclusion in previous rules that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (*See* 76 FR 46625 and 78 FR 39889). We reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception, and without even requiring that such entities actually oppose contraception in order to be exempt (in contrast, the expanded exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to the coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, we relied on our assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is supported with respect to the expanded exemption for nonprofit organizations. To our knowledge, the vast majority of organizations objecting to the Mandate assert religious beliefs. The only nonprofit organizations of which we are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It is possible that the exemption for nonprofit organizations with moral convictions in these interim final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under our previous rules that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.[48] Although we are unable to find sufficient data on this issue, we believe that there are far fewer non-religious moral nonprofit organizations opposed to contraceptive coverage than there are churches with religious objections to such coverage. Based on our limited data, we believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose the coverage. Therefore, we expect that the expanded exemption for nonprofit entities will have no effect of reducing contraceptive coverage to employees who want that coverage.

These interim final rules expand the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and they make exempt entities with moral objections eligible to use the accommodation. The Departments are not aware of either kind of entity. We believe the number of entities that object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education, and appear to hold objections that we assume would likely lead them to reject the accommodation process. Therefore, for the purposes of estimating the anticipated effect of these interim final rules on contraceptive coverage of women who wish to receive such coverage, we assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might come into existence, based on similar reasons to those given above for why the exemptions and accommodations are extended to other entities. We invite public comment on whether and how many such entities will make use of these interim final rules.

The expanded exemption for issuers will not result in a distinct effect on contraceptive coverage for women who wish to receive it because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein. The expanded exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The expanded moral exemption would also cover for-profit entities that do not have publicly traded ownership interests, and that have non-religious moral objections to the Mandate. The Departments are not aware of any for-profit entities that possess non-religious moral objections to the Mandate. However, scores of for-profit entities have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—both were nonprofit. Among the general public polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they believe in God.[49] Among non-religious persons, only a very small percentage appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.[50] Combined, this suggests that 0.2 percent of Americans at most[51] might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. We have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral

[47] Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

[48] *Cf., for example,* Gallup, ''Americans, Including Catholics, Say Birth Control Is Morally OK,'' (May 22, 2012) (''Eighty-two percent of U.S. Catholics say birth control is morally acceptable''), available at *http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx.*

[49] Gallup, ''Most Americans Still Believe in God'' (June 14–23, 2016), available at *http://www.gallup.com/poll/193271/americans-believe-god.aspx.*

[50] Pew Research Center, ''Where the Public Stands on Religious Liberty vs. Nondiscrimination'' at page 26 (Sept. 28, 2016), available at *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.*

[51] The study defined religiously ''unaffiliated'' as agnostic, atheist or ''nothing in particular'' (*id.* at 8), as distinct from several versions of Protestants, or Catholics. ''Nothing in particular'' might have included some theists.

convictions set forth in these interim final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, we assume that some similar for-profit entities with non-religious moral objections exist. But we expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities that do not have publicly traded ownership interests and that have objections to the Mandate based on sincerely held moral convictions, we expect that fewer than 10 entities, if any, will do so—we assume nine for-profit entities will use the exemption in these interim final rules.

The expanded exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) to obtain an estimate of the number of policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.[52] The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known what size the for-profit employers will be that might claim this exemption, but as discussed above these interim final rules do not include publicly traded companies (and we invite public comments on whether to do so in the final rules), and both of the two nonprofit entities that challenged the Mandate included fewer than five policyholders in each entity. Therefore we assume the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For nine entities, the total number of policyholders would be 81. DOL estimates that for each policyholder, there is approximately one dependent.[53] This amounts to 162 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—comprise 20.2 percent of the general population.[54] This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.[55] Thus we estimate that 15 women may incur contraceptive costs due to for-profit entities using the expanded exemption provided in these interim final rules.[56] In the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, within health plans that cover contraception, is $584. Consequently, we estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded exemption in these interim final rules is approximately $8,760.

The Departments estimate that these interim final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will use the accommodation, although we wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to its plan participants and beneficiaries. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, we do not anticipate that these interim final rules will result in any burden from such entities revoking their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the rules expanded exemptions. The Departments acknowledge uncertainty in the estimate and therefore conducted a second analysis using an alternative framework, which is set forth in the companion interim final rule concerning religious beliefs issued contemporaneously with this interim final rule and published elsewhere in this issue of the **Federal Register**. Under either estimate, this interim final rule is not economically significant.

We reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

We request comment on all aspects of the preceding regulatory impact analysis.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments estimate that the likely effect of these interim final rules will be that entities will use the exemption and not the accommodation. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public

[52] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf*Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey—Insurance

[53] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[54] U.S. Census Bureau, ''Age and Sex Composition: 2010'' (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies ''for all women with reproductive capacity.'' *https://www.hrsa.gov/womensguidelines/; see also* 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. *See,* Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[55] *See https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[56] We note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion—and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, by exempting from the Mandate small businesses and nonprofit organizations with moral objections to some or all contraceptives and/or sterilization, the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We estimate that these interim final rules will not result in additional burdens not accounted for as set forth in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. As discussed there, regulations covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burdens related to those ICRs are currently approved under OMB Control Numbers 0938–1248 and 0938–1292. These interim final rules amend the accommodation regulations to make entities with moral objections to the Mandate eligible to use the same accommodation processes. The Departments will update the forms and model notices regarding these processes to reflect that entities with sincerely held moral convictions are eligible organizations.

As discussed above, however, we assume that no entities with non-religious moral objections to the Mandate will use the accommodation, and we know that no such entities were eligible for it until now, so that they do not possess accommodated status to revoke. Therefore we believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1248 and 0938–1292, as described in the interim final rules concerning religious beliefs issued contemporaneously with these interim final rules.

We are soliciting comments on all of the possible information collection requirements contained in these interim final rules, including those discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, for which these interim final rules provide eligibility to entities with objections based on moral convictions. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938–1292 and 0938–1248.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of these interim final rules with comment period.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov*. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these interim final rules make entities with certain moral convictions eligible for the accommodation, we assume that no entities will use it rather than the exemption, and such entities were not previously eligible for the accommodation so as to revoke it. Therefore we believe these interim final rules do not involve additional burden not accounted for under OMB control number 1210–0150.

Regarding the ICRs discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, the forms for which would be used if any entities with moral objections used the accommodation process in the future, DOL submitted those ICRs in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. OMB approved the ICRs under the emergency clearance process. In an effort to consolidate the number of information collection requests, DOL indicated it will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once

the ICR is approved, DOL indicated it will discontinue 1210–0152. OMB approved the ICR under control number 1210–0150 through [DATE]. A copy of the information collection request may be obtained free of charge on the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001.* This approval allows respondents temporarily to utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden. Contemporaneously with the publication of these interim final rules, DOL will publish a notice in the **Federal Register** informing the public of its intention to extend the OMB approval.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, ''[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' In addition, agencies are directed to ''take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.'' These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting costs.[57] Therefore, this interim final rule is considered an EO 13771 deregulatory action.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VI. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping

[57] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§ 54.9815–2713T [Amended]

■ 2. Section 54.9815–2713T, as added elsewhere in this issue of the **Federal Register**, is amended in paragraph (a)(1)(iv) by removing the reference ''147.131 and 147.132'' and adding in its place the reference ''147.131, 147.132, and 147.133''.

§ 54.9815–2713AT [Amended]

■ 3. Section 54.9815–2713AT, as added elsewhere in this issue of the **Federal Register**], is amended—

■ a. In paragraph (a)(1) by removing ''or (ii)'' and adding in its place ''or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)'';

■ b. In paragraph (a)(2) by removing the reference ''147.132(a)'' and adding in its place the reference ''147.132(a) or 147.133(a)'';

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ d. In paragraph (b)(1)(ii)(B) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ f. In paragraph (c)(1)(ii)(B) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133''; and

■ g. In paragraph (c)(2) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133''.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

§ 2590.715–2713 [Amended]

■ 4. Section 2590.715–2713, as amended elsewhere in this issue of the **Federal Register**], is further amended in paragraph (a)(1)(iv) by removing the reference ''147.131 and 147.132'' and adding in its place the reference ''147.131, 147.132, and 147.133''.

§ 2590.715–2713A [Amended]

■ 5. Section 2590.715–2713A, as revised elsewhere in this issue of the **Federal Register**], is further amended—

■ a. In paragraph (a)(1) by removing ''(ii)'' and adding in its place ''(ii), or 45 CFR 147.133(a)(1)(i) or (ii)'';

■ b. In paragraph (a)(2) by removing the reference ''147.132(a)'' and adding in its place the reference ''147.132(a) or 147.133(a)'';

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ d. In paragraph (b)(1)(ii)(B) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133'';

■ f. In paragraph (c)(1)(ii)(B) by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133''; and

■ g. In paragraph (c)(2) introductory text by removing the reference ''147.132'' and adding in its place the reference ''147.132 or 147.133''.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 6. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

§ 147.130 [Amended]

■ 7. Section 147.130, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraphs (a)(1) introductory text and (a)(1)(iv) by removing the reference ''§§ 147.131 and 147.132'' and adding in its place the reference ''§§ 147.131, 147.132, and 147.133''.

§ 147.131 [Amended]

■ 8. Section 147.131, as revised elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (c)(1) by removing the reference ''(ii)'' and adding in its place the reference ''(ii), or 45 CFR 147.133(a)(1)(i) or (ii)''.

■ b. In paragraph (c)(2) by removing the reference ''§ 147.132(a)'' and adding in its place the reference ''§ 147.132(a) or 147.133''; and

■ c. In paragraphs (d)(1)(ii) introductory text, (d)(1)(ii)(B) and (d)(2) by removing the reference ''§ 147.132'' and to adding in its place the reference ''§ 147.132 or 147.133''.

■ 9. Add § 147.133 to read as follows:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus

the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(c) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[FR Doc. 2017–21852 Filed 10–6–17; 11:15 am]

BILLING CODE 4830–01–P; 4510–029–P; 4120–01–P; 6325–64–P

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, **Plaintiff,** **v.** **DONALD J. TRUMP, *et al.*,** **Defendants.**	**NO. 2:17-cv-04540-WB**

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

JOSH SHAPIRO
Attorney General
Commonwealth of Pennsylvania

JONATHAN SCOTT GOLDMAN
Executive Deputy Attorney General
MICHAEL J. FISCHER
Chief Deputy Attorney General
NICOLE VAN ORDER
Senior Deputy Attorney General
NICOLE J. BOLAND
PATRICK GREENE
Deputy Attorneys General
Office of Attorney General
Strawberry Square
Harrisburg, PA 17120
(717) 787-3391
jgoldman@attorneygeneral.gov

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PRELIMINARY STATEMENT

The Commonwealth of Pennsylvania respectfully asks this Court to enjoin the "Religious Exemption Rule" and the "Moral Exemption Rule," which the Defendants issued earlier this month in violation of the United States Constitution and other laws.[1] As set forth herein, the Commonwealth satisfies all criteria necessary for an immediate injunction: it is likely to win the underlying case, it faces irreparable harm in the absence of preliminary relief, and the public interest strongly favors an injunction to avoid imminent, direct and irreparable harm to the Commonwealth and its female citizens and their families. Accordingly, this Court should grant the Commonwealth's Motion and enjoin the Rules so they do not go into effect before a full trial on the merits.

In this case, the President of the United States and various secretaries and agencies of the federal government under his direction targeted a class of citizens that is protected under the Civil Rights Act, the Pregnancy Discrimination Act and the equal protection guarantee of the Fifth Amendment. They eliminated rights to which these citizens are entitled under the law. In so doing, the Defendants used the arm of the state to permit employers to impose their religious beliefs on their female employees and insureds, thereby violating the Establishment Clause of the First Amendment. And they did all of this in violation of the Administrative Procedure Act, the law that governs how such regulations must be issued.

---

[1] *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (filed Oct. 6, 2017) (attached hereto as Exhibit A) (the "Religious Exemption"); and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (filed Oct. 6, 2017) (the "Moral Exemption") (attached hereto as Exhibit B). These two rules, which are collectively referred to as the "Exemption Rules" or the "Rules," were subsequently published in the Federal Register on October 13, 2017. *See* 82 Fed. Reg. 47611, 47792 and 47838. The Rules are codified at 45 C.F.R. §§ 147.130-147.133.

Under the law, health care plans are required to cover contraceptive care, cost-free, for those they insure. Yet by Executive Order, the President specifically directed the other Defendants to pursue additional "conscience-based objections" to mandated coverage of these services under the Women's Health Amendment to the Affordable Care Act.

To be clear, a reasonable exemption and accommodation already allowed employers to opt out of providing this mandated contraceptive coverage on religious grounds. If an employer (other than churches and certain affiliated organizations) opted out of paying for contraceptive coverage, its insurer had to provide coverage directly to the employees to comply with the law. The new Rules that the Defendants issued in response to the President's Executive Order do away with this requirement and allow any employer to claim an absolute exemption from providing mandated contraceptive coverage. They are the "exceptions that swallow the rule."

Millions of women need and rely on contraception. It enables women to plan their families, participate fully in the workforce, and exercise greater control over their lives and health. For some women, pregnancy can be life-threatening. And contraception is not only birth control – it is frequently prescribed to treat menstrual disorders, acne, pelvic pain and other medical concerns. Long-term use of oral contraceptives reduces a woman's risk of endometrial cancer, and protects against pelvic inflammatory disease and some benign breast diseases. In fact, more than half of all women who use contraception use it to manage health issues unrelated to birth control.[2]

Despite this, under the new Rules, the Defendants allow employers to prevent women from receiving otherwise legally mandated coverage under their health care plans based on the

[2] *See* Jones, Rachel K., *Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills* (Nov. 2011), available at https://www.guttmacher.org/sites/default/files/report_pdf/beyond-birth-control.pdf.

employers' own religious or moral beliefs. And under the Rules, a "moral belief" can be just about anything. As a result, virtually any private employer can opt out of providing basic medical care that is mandated under the law without any explanation or oversight by regulators charged with enforcing this mandate. If employers opt out under the Religious Exemption Rule, their insurers will no longer provide that coverage.

As a result, many women who are otherwise insured will no longer be covered for preventive contraceptive services – and the Commonwealth of Pennsylvania (and other States around the Country) will face irreparable harm. If the women who lose contraceptive coverage cannot get it elsewhere, they will have to pay up to $1200 per year in out-of-pocket costs to purchase contraception directly – assuming they can afford it.[3] The Commonwealth will face increased costs of providing contraceptive care services through already over-burdened state programs. And, where women do not seek or cannot get contraceptive care, these state programs will face additional costs in connection with the medical outcomes that result. Some women will face unintended pregnancies and potentially life-threatening medical consequences. The Commonwealth of Pennsylvania, its female citizens, and their families will face irreparable harm.

The Commonwealth's Motion should be granted and an injunction should issue.

BACKGROUND

During debate over the Affordable Care Act, the U.S. Senate passed the "Women's Health Amendment" to expand women's access to preventive health services and reduce gender disparities in out-of-pocket costs. *See* S. Amdt. 2791, 111th Congress (2009-2010). It was included in the final

[3] *See* Center for American Progress, *The High Costs of Birth Control* (Feb. 15, 2010), *available at* https://www.americanprogress.org/issues/women/news/2012/02/15/11054/the-high-costs-of-birth-control/.

version of the law, which was signed by the President on March 23, 2010. *See* Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 *et seq.* (2010) (the "ACA" or "Affordable Care Act"); *see also* Public Health Service Act (as amended by the ACA) § 2713, 42 U.S.C. § 300gg–13(a)(4). The Women's Health Amendment mandated that group health plans and health insurance issuers offering group or individual health insurance coverage provide coverage for preventive health services and screenings for women – and that they do so with no cost-sharing responsibilities, or further cost to patients. *See* 42 U.S.C. § 300gg-13(a)(4).[4] Exactly which "preventive health services and screenings" were required to be included was to be determined by guidelines issued by the Health Resources and Services Administration (the "HRSA"), an agency of Defendant United States Department of Health and Human Services ("HHS"). *Id.* This was required under the law.

A. The Institute of Medicine Determines That Contraception Is Necessary Preventive Care for Women and Coverage Should Be Provided to Women Cost-Free.

The HRSA commissioned the Institute of Medicine (the "Institute"), a widely respected organization of medical professionals, to issue recommendations identifying what specific preventive women's health services should be covered under the ACA's mandate. The Institute, in turn, convened a committee of sixteen members, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations (the "Committee"). After conducting an extensive study, the Institute, through the Committee, issued a comprehensive report that identified eight evidence-based preventive health services, which it recommended be included. *See* Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps* 105 (2011) (the "Report") (attached hereto as

[4] Like many other requirements of the ACA, the Women's Health Amendment did not apply to so-called "grandfathered plans" in which the participant was enrolled prior to passage of the ACA. *See* 29 C.F.R. § 2590.715-1251 (2010).

Exhibit C); *see also* Declaration of Carol S. Weisman, Ph.D. (the "Weisman Decl.") (attached hereto as Exhibit D). Consistent with the Women's Health Amendment to the ACA, these recommended preventive health services were unique to women. *See* Report, Exh. C at 105.

Among other things, the Institute found that contraceptive care should be covered under the ACA's mandate. *See* Report, Exh. C at 109-10. In making this finding, the Institute cited evidence that "contraception and contraceptive counseling" are "effective at reducing unintended pregnancies" and considered that "[n]umerous health professional associations," including the American Academy of Pediatrics, the Society of Adolescent Medicine, the American Medical Association, the American Public Health Association, and the Association of Women's Health, Obstetric and Neonatal Nurses, recommend that such family planning services be included as mandated preventive care for women. *See id.* at 109. Based on its analysis, the Institute recommended that health plans cover the "the *full range* of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." Report, Exh. C at 109-10 (emphasis added).

The Institute based its recommendation on several important factors, among them:

1. Unintended Pregnancy Is Prevalent in the United States. As stated in the Institute's Report, in 2001, an estimated "49 percent of all pregnancies in the United States were unintended – defined as unwanted or mistimed at the time of conception." Report, Exh. C at 102 (internal citations omitted). These unintended pregnancies disproportionately impact the most vulnerable, including the young and lower-income women. *Id.* And unintended pregnancies are more likely to result in abortions: "In 2001, 42 percent of [] unintended pregnancies [in the United States] ended in abortion." *Id.* Moreover, women carrying babies to term are less likely to

follow best health practices where those pregnancies are unintended, resulting in adverse pregnancy outcomes. *Id.*

2. For Some Women, Pregnancy is Especially Dangerous. Further, while all pregnancies carry inherent health risks, the Institute found that some women have serious medical conditions for which pregnancy is strictly contraindicated or ill-advised. It specifically found that "women with serious medical conditions such as pulmonary hypertension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and … Marfan Syndrome," are advised against becoming pregnant. Report, Exh. C at 103. For these women, contraception is not a convenience; it is necessary, lifesaving medical care.

3. Pregnancies Should Be "Spaced" at Least 18 Months Apart. The Institute found that contraceptives promote medically recommended "spacing" between pregnancies. Such spacing is important because of the "increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy)." Report, Exh. C at 103. This is true for all women.

4. Contraceptives Are Effective at Preventing Unintended Pregnancies. The Institute also found that contraceptives are, in fact, effective at preventing unintended pregnancies. Put simply, "greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally." Report, Exh. C at 105. The Report highlighted a study showing that, as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, their rates of unintended pregnancy and abortion declined. *Id.* Other studies show that increased rates of contraceptive use by adolescents were associated with a "decline in teen pregnancies" and, conversely, that "periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use." *Id.* at 105.

5. Contraceptives Have Other Significant Health Benefits. In addition, the Institute recognized that contraceptives have other significant health benefits unrelated to preventing unintended pregnancy. The Report states that these "non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain." Report, Exh. C at 104. Long-term use of oral contraceptives has also been shown to "reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases." *Id.*

6. Cost Is A Meaningful Barrier to Contraceptive Access. Importantly, the Institute found that *cost* is a meaningful barrier to contraceptive access. It stated that "[d]espite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years" and, citing to a Kaiser Permanente study, noted that reduced cost brings more effective contraceptive care: "when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods." Report, Exh. C at 109.[5]

B. The HRSA Adopts the Institute's Recommendations and Requires Plans to Cover Contraceptive Care without Additional Cost.

On August 1, 2011, the HRSA promulgated the Women's Preventive Service Guidelines, which adopted the Institute's recommendation that contraceptive care services be covered under the Women's Health Amendment to the Affordable Care Act. *See* Health Resources & Services

[5] The fact that the Report is based upon sound scientific and empirical evidence is confirmed by experts in the field. *See e.g.,* Declaration of Cynthia H. H. Chuang, M.D., MSc (the "Chuang Decl.") (attached hereto as Exhibit E); Weisman Decl., Exh. D; and, Declaration of Samantha F. Butts, M.D., MSCE (the "Butts Decl.") (attached hereto as Exhibit F).

Administration, *Women's Preventive Service Guidelines* (2011), *available a*t https://www.hrsa.gov/womens-guidelines/index.html#2 (attached hereto as Exhibit G) (the "Guidelines").[6] The Guidelines required that plans must cover "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity," without any cost-sharing or payment by the insureds. *Id.* (the "Contraceptive Care Mandate"). This requirement applied to all health insurance issuers offering individual or group insurance as well as all group health plans, with the exception of those plans that were "grandfathered" under the ACA. *See* 29 C.F.R. § 2590.715-1251 (2010). As a result, employers, colleges and universities, and other organizations that provide health plans were required to comply with the mandate.

C. Religious Objectors Are Granted a Limited Exemption and Accommodation.

The Affordable Care Act does not contain a "conscience clause" that would allow employers and other plan sponsors to opt out of providing the preventive contraceptive services required by the statute. Nevertheless, in 2011, the Administration undertook regulatory action to accommodate religious objectors. It issued regulations in August 2011 that exempt "churches, their integrated auxiliaries, and conventions or associations of churches" from the ACA's requirement that employers cover contraceptive services – provided these objectors satisfied certain specified criteria[7] (the "Original Religious Exemption"). *See* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable

[6] The Guidelines were updated in 2016, but continued to identify contraception as covered preventive care. *See* Health Resources & Services Administration, *Women's Preventive Service Guidelines*, *available a*t https://www.hrsa.gov/womens-guidelines-2016/index.html (2016) (attached hereto as Exhibit H) (the "2016 Guidelines").

[7] Specifically, the purpose of the organization had to be "[t]he inculcation of religious values," the organization had to primarily employ and serve "persons who share the religious tenets of the organization," and the organization had to be a nonprofit entity. 76 Fed. Reg. 46621.

Care Act, 76 Fed. Reg. 46621 (Aug. 3, 2011). When employers in this discrete group claim this exemption, their employees do not receive the otherwise mandated contraceptive coverage from any source. This Original Religious Exemption went into effect August 1, 2011, years before the new Rules were issued.

The next year, the Administration issued additional regulations to accommodate religious nonprofit organizations that were not already exempt under the Original Religious Exemption but objected to the ACA's Contraceptive Care Mandate. *See* Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41318 (2015) (the "Religious Non-Profit Accommodation" or the "Accommodation"). Under the Accommodation, an objecting employer could notify its health insurance provider (in the case of fully insured plans) or third-party administrator (in the case of self-insured plans) of a religious objection. Then the insurer or administrator, rather than the objecting employer, would have to provide the legally required contraceptive services directly to women covered under the employer's plan. *Id.*[8] In this way, women still had access to legally mandated no-cost contraceptive care, but employers did not have

[8] Employer-sponsored health coverage is generally categorized as "self-insured" or "fully insured." Self-insured plans, which are typically offered by larger companies, are those in which the plan sponsor pays for enrollees' health benefits directly. A self-insured plan will typically contract with a third party to administer the plan, but the plan sponsor will bear the financial risks associated with the plan. A fully insured plan, by contrast, is one in which the plan sponsor contracts with an insurance company to provide benefits to plan participants. In the case of a fully insured plan, the insurance company bears the risks associated with the plan.

Both types of plans are subject to the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq.* ("ERISA"), which regulates employee benefit plans. While ERISA preempts state laws that "relate to any employee benefits plan," it contains an exception for laws that regulate "insurance, banking, or securities." *Id.* § 1144(b)(2)(A). As a result, states may regulate the benefits offered under fully insured plans, which are provided by insurance companies. They may not, however, regulate the benefits offered by self-insured plans, which are provided by the plan sponsor itself. *See generally* Declaration of Seth Mendelsohn (the "Mendelsohn Decl.") (attached hereto as Exhibit I).

to pay for it. This Accommodation was different from the Original Religious Exemption, under which employees did not get insurance coverage for preventive contraceptive services at all.

D. Employers Challenge the Contraceptive Care Mandate.

Following enactment of the ACA and the relevant implementing regulations, several employers, including some in Pennsylvania, filed lawsuits to challenge the scope of the Contraceptive Care Mandate, the Original Religious Exemption and the Religious Non-Profit Accommodation. Two of these cases were argued before the Supreme Court:

In *Burwell v. Hobby Lobby Stores, Inc*., 134 S. Ct. 2751 (2014), the Supreme Court concluded that applying the ACA's Contraceptive Care Mandate to closely held corporations that objected on the basis of sincerely held religious beliefs violated the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb–1 ("RFRA"). Under RFRA, the government may not "substantially burden a person's exercise of religion" unless it is acting "is in furtherance of a compelling governmental interest" and employing the "least restrictive means" to further that interest. 42 U.S.C. § 2000bb–1(a) & (b). Therefore, following *Hobby Lobby*, the Administration began allowing such employers to take advantage of the Religious Non-Profit Accommodation, which had previously been available to nonprofit employers only.

Two years later, in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), the Supreme Court considered several consolidated challenges to the Accommodation process itself. The plaintiffs in these cases were employers and other plan sponsors who were eligible for the Accommodation but alleged that the act of notifying their insurer so the insurer could pay for contraception directly substantially burdened their exercise of religion. Ultimately, the Supreme Court did not decide this issue but instead remanded the cases to provide the parties with "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage,

including contraceptive coverage.'" *Id.* at 1560 (citation omitted). On January 9, 2017, however, the Department of Labor announced that "no feasible approach has been identified … that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage." Department of Labor, *FAQs about Affordable Care Act Implementation Part 36* (Jan. 9, 2017), *available at* https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf.

E. Defendant Donald Trump Issues an Executive Order "Promoting Free Speech and Religious Liberty."

On May 4, 2017, President Donald Trump issued an Executive Order entitled "Promoting Free Speech and Religious Liberty." *See* President Donald Trump, Executive Order No. 13798, "Promoting Free Speech and Religious Liberty," (May 4, 2017) (the "Executive Order"), 82 Fed. Reg. 21675 (attached hereto as Exhibit J). Among other things, this Executive Order directed the other Defendants to "consider issuing amended regulations" to address "conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of Title 42, United States Code" – *the Women's Health Amendment*. *Id*. § 3. To be clear, the Executive Order did not address the Affordable Care Act as a whole. Rather, the President directed his co-Defendants to target amended regulations at services provided under the Women's Health Amendment only.

F. The Defendant Departments Issue the New Rules Without Engaging in Required Notice-and-Comment Rulemaking.

On October 6, 2017, the Departments simultaneously issued both the Religious Exemption Rule and the Moral Exemption Rule. The Departments issued the Rules without any advance public notice and without inviting or providing opportunity for comment. These new Rules significantly expanded exemptions to the Contraceptive Care Mandate – they are the proverbial exceptions that swallow the rule.

1. The Religious Exemption Rule.

The Religious Exemption Rule significantly expands the scope of the existing Original Religious Exemption Rule for certain religious employers. Specifically, it allows *all* employers and other plan sponsors – including large, publicly traded corporations – to opt out of providing no-cost contraceptive coverage to their employees on the basis of "sincerely held religious beliefs." Religious Exemption, Exh. A at 74. In fact, the Rule suggests that if owners of a majority of a company's shares oppose contraceptive coverage, the company can refuse to provide it. *Id.* at 68-69.

In addition, the Religious Exemption Rule renders the Accommodation process optional. *See id.* at 54. As a result, any employer, university, or other plan sponsor can simply stop providing contraceptive coverage; there is no longer any obligation that the sponsor inform its insurer so the insurer can provide the coverage itself. *See id.* at 58 ("[T]he Departments have determined that the expanded exemptions rather than accommodations are the appropriate response to the substantial burden that the Mandate has placed upon the religious exercise of many religious employers.").

Employers that stop providing contraceptive coverage under the Religious Exemption Rule have no obligation to explain their decision, and the Rules provide for no oversight to determine whether employers are abusing the Exemption. In fact, the Rules do not require plans to provide any notice of their decision beyond what is already required by ERISA and the ACA. Entities that stop providing contraceptive care "do not need to file notices or certifications of their exemption, and [the Exemption Rules] do not impose any new notice requirements on them." *Id.* at 62. Under existing notice requirements, a plan need only provide 30 days' notice of any reduction in benefits occurring at the beginning of a plan year, and only 60 days' notice of a reduction imposed during the plan year. *See id.* at 138 ("[T]he revocation will be effective on the first day of the first plan

year that begins on or after 30 days after the date of the revocation …. Alternatively, an eligible organization may give sixty-days' notice."); *see also* 26 C.F.R. § 54.9815–2715(a)(i)(C)(2) & (b).

2. The Moral Exemption Rule.

The Moral Exemption Rule creates a new exemption that allows employers to refuse to provide their employees with contraceptive coverage "based on sincerely held moral convictions." Moral Exemption, Exh. B at 8. This Rule applies to nonprofit entities *and* for-profit entities whose shares are not publicly traded, but unlike the Religious Exemption Rule, it does not allow publicly traded companies to opt out of the Mandate. As with the Religious Exemption Rule, there is no mandatory accommodation process, and no notice requirement beyond those in other provisions of law.

G. The New Rules Cause Specific and Irreparable Harm to the Commonwealth of Pennsylvania and Its Citizens.

For every employer, college, or other health plan sponsor who claims either of these new, certification-free exemptions, women will lose contraceptive coverage otherwise required under the Contraceptive Care Mandate.[9] Not only will these women face imminent medical harm for lack of contraceptive care or financial harm if they are able to and choose to self-fund their contraceptive needs, but the loss of ACA-mandated contraceptive care will result in significant, direct and proprietary harm to the Commonwealth.

[9] Just last week, the University of Notre Dame informed faculty, staff, and students that it would no longer provide contraceptive coverage as a result of the Exemption Rules. *See* Fosmoe, Margaret, *Notre Dame to end no-cost contraceptive coverage for employees*, South Bend Tribune, Oct. 31, 2017, *available at* https://www.southbendtribune.com/news/politics/notre-dame-to-end-no-cost-contraceptive-coverage-foremployees/article_512017b8-f873-50b0-841a-5158296b36aa.html (attached hereto as Exhibit O). Not only will the many Pennsylvania residents that attend Notre Dame be directly affected, but Notre Dame's decision is likely a harbinger that many of Pennsylvania's religiously-affiliated colleges and universities will follow.

1. The Commonwealth Faces Additional Economic Harm Because Women Will Seek More Contraceptive Care Funded by the State.

In Pennsylvania, the Commonwealth will bear increased costs because of the new Rules. Some women who lose employer-sponsored contraceptive coverage will seek coverage through state-funded programs, including Medicaid (known as Medical Assistance in Pennsylvania) and Pennsylvania's Family Planning Services program. Medical Assistance provides health insurance, including contraceptive coverage, for individuals and families with incomes up to 138% of the federal poverty limit. Family Planning Services provides preventive screenings and contraceptives for individuals who are not eligible for full Medicaid benefits but have incomes at or below 215% of the federal poverty limit. *See* Declaration of Leesa Allen ¶¶ 14-17 (the "Allen Decl.") (attached hereto as Exhibit K). If employers eliminate contraceptive coverage, women will seek coverage from these programs. In fact, practitioners in the field specifically direct women without contraceptive coverage to state-funded programs. *See, e.g.,* Chuang Decl., Exh. E ¶ 22 ("I direct low-income patients without insurance to the Medicaid program (if eligible).").

Others will seek contraceptive care from health clinics that receive funding from both Commonwealth sources and the federal government's Title X program. *See* Declaration of Dayle Steinberg (the "Steinberg Decl.") (attached hereto as Exhibit L); *see also* Chuang Decl., Exh. E ¶ 22 ("I direct other uninsured or underinsured women without contraceptive coverage to seek care through Planned Parenthood, or another Federally Qualified Health Center (FQHC), where they may qualify for contraceptive coverage under Title X."). In this way, the Rules will further increase the financial burden on the Commonwealth.

2. The Commonwealth Also Faces Additional Economic Harm Because It Will Share the Increased Economic Burden of Its Citizens Having Unintended Pregnancies and Negative Health Outcomes.

Other women will forgo contraceptive health services altogether, because the loss of ACA-mandated coverage under the Rules will make their contraceptive care unaffordable or inaccessible. *See* Weisman Decl., Exh. D ¶¶ 45-48 ("[C]ost has been shown to be a barrier to access to contraceptive care…. For these reasons, some women who lose contraceptive coverage through their employers as a result of the Rules, will choose a less effective contraceptive option for their medical needs, will use contraception inconsistently, or will discontinue using contraceptives entirely"); Butts Decl., Exh. F ¶ 55 ("Based upon my own experience and existing scientific and empirical information that I have reviewed and am aware of, under the new Rules, cost will, again, become a barrier to women's access to and use of the contraceptive that is medically recommended for them"); and Chuang Decl., Exh. E ¶ 38 ("This harm will manifest itself in the disruption of these patients' medical treatment, whether by substituting a less effective but cheaper method of contraception or by being forced to stop using contraceptives at all, due to financial reasons").

Women who stop using contraception entirely will experience more unintended pregnancies and negative health outcomes. *See* Butts Decl., Exh. F ¶¶ 56-58 (confirming that the Rules will result in some women facing unintended pregnancy and other adverse medical consequences). These outcomes will impose additional costs on Pennsylvania's state-funded health programs. *See* Steinberg Decl., Exh. L ¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births).

3. The Contraceptive Care Mandate Has Resulted in Significant Savings for Women.

In contrast to the new Rules, by requiring employers to provide cost-free contraception, the Contraceptive Care Mandate has saved Pennsylvania women a significant amount of money. A recent study conducted by the University of Pennsylvania found, for example, that average out-of-pocket savings from the ACA's Contraceptive Care Mandate were "$248 for the intrauterine device and $255 annually for the oral contraceptive pill." *See* Becker, Nora V. & Daniel Polsky, *Women Saw Large Decrease In Out-Of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing*, Health Affairs, July 2015, at 1204 (attached hereto as Exhibit M); *see also* Mendelsohn Decl., Exh. I ¶ 11 ("The [Insurance] Department estimates that the women in Pennsylvania who have benefitted from the Contraceptive Care Mandate have saved over $250 million annually as a result."); *see also* Weisman Decl., Exh. D ¶ 50 ("[A]t least one study has shown that, under the ACA's contraceptive mandate, women have saved approximately $1 billion dollars per year on oral contraceptives alone."). But if employers opt out under the Exemption Rules, these savings will vanish and Pennsylvania women and the Commonwealth itself will be harmed as a result.

ARGUMENT

This Court should grant the Commonwealth's Motion and order immediate injunctive relief. In the Third Circuit, a party seeking a preliminary injunction must first satisfy two "gateway" factors: "that it can win on the merits" and "that it is more likely than not to suffer irreparable harm in the absence of preliminary relief." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017). Satisfying the first requirement "requires a showing significantly better than negligible but not necessarily more likely than not" that the movant can prevail. *Id.* Here, the Commonwealth has a strong likelihood of prevailing on several of its claims, any one of which is sufficient to require that the Rules be struck down. To satisfy the irreparable harm requirement, a plaintiff must demonstrate "a significant risk that he or she will experience harm that cannot adequately be compensated after the fact by monetary damages." *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484-85 (3d Cir. 2000). The Commonwealth also satisfies this requirement: if the Rules are not struck down, it will suffer direct proprietary harm as well as harm to its quasi-sovereign interests. These damages cannot be remedied after the fact.

Once a movant has satisfied these "gateway" factors, a court should then consider the possibility of harm to other interested persons and any public interest, balancing both these and the gateway factors in deciding whether preliminary injunctive relief is appropriate. *Reilly*, 858 F.3d at 176, 179. Here, these factors tip strongly in favor of the Commonwealth: if the Rules remain in effect, substantial harm will result to women and families. If they are enjoined, the Defendants and others will be in no different position than they were before the rules were issued. The public interest, particularly the strong interest in promoting access to necessary preventive medicine, would be best served by granting the Commonwealth's Motion.

In sum, this Court should grant the Motion and issue an injunction for the following three reasons: (1) the Commonwealth will prevail in this litigation; (2) if relief is not granted, the Commonwealth will be irreparably injured; and (3) the public interest demands it.

I. THE COMMONWEALTH WILL PREVAIL IN THIS LITIGATION.

The Commonwealth will prevail in this litigation because the Rules are unlawful. They violate the Administrative Procedure Act; the Affordable Care Act; Title VII of the Civil Rights Act (as amended by the Pregnancy Discrimination Act); the equal protection guarantee of the Fifth Amendment to the Constitution; and the Establishment Clause of the First Amendment. Any *one* of these flaws would justify striking down the Rules. Together, they plainly establish that the Commonwealth "can win on the merits" of this case. *Reilly*, 858 F.3d at 179.

A. The Rules Violate the Administrative Procedure Act.

The Rules violate both the procedural and substantive requirements of the Administrative Procedure Act, 5 USC § 551 *et seq.* (the "APA").

1. The Rules Are Procedurally Flawed.

The APA sets forth clear requirements that an agency must follow in issuing a new rule. It first must publish a "[g]eneral notice of proposed rule making" in the *Federal Register*. 5 U.S.C. § 553(b). That notice "shall include (1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id*. Then, the agency "shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c). And "[a]fter consideration of the relevant matter presented," the agency "shall incorporate" within the adopted rule a "concise

general statement of their basis and purpose." *Id.* Rules issued without following with this process must be held "unlawful and set aside." *Id.* § 706(2)(E).

The Defendants did *none* of these things. They did not publish a Notice of Proposed Rule Making; they did not solicit comments on the Rules they were considering; and they did not wait until after they had considered all relevant comments to finalize the Rules with a concise general statement of their basis and purpose. Instead, the Defendants announced that the Rules were effective immediately – a full week before they could be published in the *Federal Register* –and invited comments only *after* they had gone into effect.

The Defendants justify their failure to follow the proper procedures by arguing that they had "good cause" under 5 U.S.C. § 553(b)(3)(B). Under that provision, notice-and-comment rulemaking is not required if the agency "for good cause" finds the otherwise required procedures are "impracticable, unnecessary, or contrary to the public interest" and it "incorporates its reasoning into the Rules." *Id.* That exception, however, "is to be 'narrowly construed and only reluctantly countenanced.'" *Util. Solid Waste Activities Grp. v. E.P.A.*, 236 F.3d 749, 754 (D.C. Cir. 2001) (citation omitted). It is not an "'escape clause[]' that may be arbitrarily utilized at the agency's whim," but instead "should be limited to emergency situations." *Am. Fed'n of Gov't Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981) (citing S. Rep. No. 79-752). Here, it was not.

The rationale that the Defendants offer in the Rules for engaging this emergency "escape clause" falls far short of the demanding standard that is required.[10] In both Rules, the Defendants

[10] The Departments also claim that they need not satisfy the good cause requirement "because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act," each of which authorizes, in general terms, the promulgation of Interim Final Rules or IFRs. *See* Religious Exemption, Exh. A at 88; *see also*

repeatedly claim that the "extensive litigation" surrounding the Contraceptive Care Mandate requires their refusal to follow proper procedures. *See* Religious Exemption, Exh. A at 7; Moral Exemption, Exh. B at 7. They allege, for example, that "[d]ozens of lawsuits over the Mandate have been pending for nearly 5 years," and that "Courts of Appeals have been asking the parties in those cases to submit status reports every 30 through 90 days." Religious Exemption, Exh. A at 80. According to the Defendants, some courts have issued even "more pressing deadlines" than one to three months. Defendants claim, for example, that they were twice unable to comply with an order of the Seventh Circuit to "set forth their specific position" on a pending case. *Id.* at 81. Therefore, Defendants assert, the Rules "provide a specific policy resolution that courts have been waiting to receive from the Departments for more than a year." *Id.* at 82.

Litigation over agency rules is a constant. The mere fact of "extensive litigation" is not "good cause" to jettison the APA's procedural requirements. If anything, the fact that courts have struggled for years to resolve disputes over the Contraceptive Care Mandate underscores the importance of *following* the APA's deliberative process in issuing such regulations. And, while the Defendants suggest they had to issue their Rules immediately to respond to pressure from the courts, they do not cite a single instance in which a court ordered them to do anything other than state their position in a lawsuit.[11] At most, Defendants have shown that improperly issuing the

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Moral Exemption, Exh. B at 60. This argument was squarely rejected in *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 18-19 (D.D.C. 2010). That court concluded that the three provisions relied on by the Defendants here do not neuter the APA's notice-and-comment requirements or their obligation to establish "good cause" to disregard them. Rather, the court held these provisions were merely "a factor" in determining whether an agency had established good cause. *See id.* at 20.

[11] The Defendants argue that certain earlier rules relating to the Contraceptive Care Mandate also were issued as IFRs and point to a decision by the D.C. Circuit upholding use of an IFR in one such instance. *See* Religious Exemption, Exh. A at 83-84 (discussing *Priests for Life v. U.S. Department of Health and Human Services*, 772 F.3d 229, 276 (D.C. Cir. 2014), *vacated*

Rules as IFRs lessens the burden on *them* by bringing some pending litigation to a quicker conclusion. But agencies cannot abandon the procedural requirements of the APA simply for their own convenience.

Equally dubious is Defendants' assertion that the Rules had to be issued as IFRs to resolve "uncertainty." *See* Religious Exemption, Exh. A at 84 ("Good cause is also supported by the effect of these interim final rules in bringing to a close the uncertainty caused by years of litigation and regulatory changes.") Indeed, the Third Circuit has squarely rejected this rationale, holding that it would write the APA's notice and comment requirements "out of the statute." *United States v. Reynolds*, 710 F.3d 498, 510 (3d Cir. 2013) ("The desire to eliminate uncertainty, by itself, cannot constitute good cause [under the APA]. To hold otherwise would have the effect of writing the notice and comment requirements out of the statute."). That court correctly observed that any claim that an IFR would "eliminate uncertainty" is undercut by the simultaneous request for comments in the same document. *Id.* That request, the court observed, "suggests that the rule will be reconsidered and possibly changed in light of these comments." *Id.*

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on other grounds, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016)). Unlike the Rules here, however, the IFR in *Priests for Life* ***was*** issued in response to a specific court ruling. In July 2013, following a 15-month notice-and-comment rulemaking process, the Departments issued a rule clarifying the scope of the Original Religious Exemption and creating the Accommodation that the Supreme Court subsequently expanded in *Hobby Lobby*. *See* Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39870 (2013); *see also Hobby Lobby*, 134 S. Ct. at 2751. The Court separately issued an order allowing a nonprofit religious college to opt out of the Accommodation process altogether by notifying HHS – rather than its insurance carrier – of its objection. *See Wheaton Coll. v. Burwell*, 134 S. Ct. 2806, 2807 (2014). This process, the Court concluded, would still allow HHS to arrange contraceptive care for Wheaton's students. *Id.* In response to *Hobby Lobby*, the Departments initiated a notice-and-comment rulemaking process, *see* 79 Fed. Reg. 51118, and in response to *Wheaton College*, they issued an IFR. They did this because the process mandated by the Court had to be implemented immediately. The Defendants cite *that IFR* as precedent for their actions here notwithstanding the fact that: it followed a lengthy notice-and-comment rulemaking process on the same issue; was required to carry out a decision of the Supreme Court; and did little more than allow employers to notify HHS, rather than their insurance carrier, of their objections. *See* 79 Fed. Reg. 51092.

Here, that contradiction is even more obvious. The Defendants argue that issuing their Rules as immediate IFRs will "bring[] to a close the uncertainty" surrounding the Contraceptive Care Mandate. But they admit, *in the very next sentence*, that issuing them "with a comment period provides the public with an opportunity to comment on *whether these regulations expanding the exemption should be made permanent or subject to modification* without delaying the effective date of the regulations." Religious Exemption, Exh. A at 84 (emphasis added). As the Third Circuit explained in *Reynolds*, 710 F.3d at 510, the "uncertainty" remains.

Because there is no adequate justification or "good cause" for Defendants' failure to comply with the APA's procedural requirements, the Rules must be held unlawful and set aside.[12]

2. The Rules Are "Not in Accordance with Law," Arbitrary, Capricious, and an Abuse of Discretion.

Not only was did the Defendants disregard the APA's procedural requirements, but the Rules themselves are substantively defective. Under the APA, a reviewing court "shall … hold unlawful and set aside" any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." See 5 U.S.C. § 706(2)(A). Here, the Defendants' Rules violate the Women's Health Amendment as well as two additional provisions of the ACA. And because these new exemptions from the Contraceptive Care Mandate are overly broad, completely unnecessary, and have nothing to do with women's health, the Rules are arbitrary and capricious and constitute an abuse of discretion.

For all of these reasons, the Rules should be enjoined.

[12] *See* 5 U.S.C. § 706(2)(D) (Rules that are issued "without observance of procedure required by law" shall be set aside.).

i. The Rules Violate the Women's Health Amendment.

The Women's Health Amendment to the ACA amended the Public Health Service Act to require that non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must "provide coverage" without "impos[ing] any cost sharing requirements" for "additional preventive care and screenings … provided for in comprehensive guidelines supported by the Health Resources and Services Administration [HRSA]." 42 U.S.C. § 300gg-13(a)(4). This requirement specifically applies to coverage "with respect to women." *Id.*

The HRSA's guidelines specifically include no-cost coverage for "[c]ontraceptive methods and counseling." *See* Guidelines, Exh. G. These guidelines, which were updated on December 20, 2016, continue to identify contraception as appropriate and covered preventive care for women. *See* 2016 Guidelines, Exh. H. And even the Rules do not challenge that contraceptive care is, in fact, preventive care for women. Nor could they: the determination that contraception constitutes appropriate preventive care for women was made after a rigorous review by the 16-member Institute of Medicine Committee and is consistent with the views of numerous health professional associations. *See* Report, Exh. C at 11.

The language of the Women's Health Amendment is mandatory – a covered plan "shall" provide coverage for preventive services, without cost-sharing requirements. Nothing in the language of the ACA suggests that employers may choose not to provide the preventive care services identified by the HRSA, and nothing in the ACA or its legislative history suggests that Congress intended to give Defendants or any agency blanket authority to permit employers to opt out. To the contrary, the lead sponsor argued that the Women's Health Amendment "leaves the decision of which preventive services a patient will use between the doctor and the patient." This cannot be reconciled with the effect of these new Rules that allow *employers* – not the doctor and

the patient – to decide what preventive services their insured employees may receive. *See* 155 Cong. Rec. S11979, S11988 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski).

The Defendants, nevertheless, claim that the broad exemptions of the Rules are justified because "Congress has a consistent history of supporting conscience protections for moral convictions alongside protections for religious beliefs, including as part of its efforts to promote access to health services." Moral Exemption, Exh. B at 5.[13] But whether Congress may have included "conscience protections" in *other* statutes is beside the point: it did *not* do so here. In fact, the Senate even *rejected* a later effort to add such conscience protections to the ACA. *See* S. Amdt. 1520, 112th Congress (2011-2012). In arguing that such an amendment was necessary, its sponsors fully acknowledged that the ACA did not, in fact, contain "conscience protections" to begin with. Rather, they admitted that the ACA "does not allow purchasers, plan sponsors, and other stakeholders with religious or moral objections to specific items or services to decline providing or obtaining coverage of such items or services." *Id.*

The Defendants do not dispute that the ACA, in fact, has no "conscience clause" that might authorize the broad exemptions they seek. That should be the end of the matter. No principle of law allows an agency to invent a statutory provision simply because similar provisions have been included in other statutes on the same topic.[14]

ii. The Rules Cannot Be Justified Under the Religious Freedom Restoration Act.

Just as the ACA does not authorize the Rules, neither does RFRA. That statute provides that government may not "substantially burden a person's exercise of religion" unless it

[13] *See also* Religious Exemption, Exh. A at 5.

[14] Further, most of the examples of "conscience clauses" identified in the Rules are nowhere near as sweeping as those created by the Rules, themselves. *See* Religious Exemption, Exh. A at 5 n.1.

demonstrates that the act undertaken "is in furtherance of a compelling governmental interest" and is the "least restrictive means" of furthering that interest. 42 U.S.C. § 2000bb–1(a) & (b).

Here, RFRA provides no justification for the Moral Exemption Rule, and the Defendants do not claim otherwise. The Defendants seem to claim that the Religious Exemption Rule is somewhat justified under RFRA, but they make clear that they believe that Rule is also justified independently of the statute. *Compare* Religious Exemption, Exh. A at 52 ("[W]e now believe that requiring [compliance with the mandate] led to the violation of RFRA in many instances.") *with id.* at 53 ("Even if RFRA does not compel the religious exemptions provided in these interim final rules, the Departments believe they are the most appropriate administrative response to the religious objections that have been raised.").

The Defendants' excessively broad application of RFRA cannot be squared with relevant Third Circuit or Supreme Court precedent. For instance, the Religious Exemption seems to rely on the premise that the prior Religious Non-Profit Accommodation process imposes a "substantial burden" on the exercise of religion. But the Third Circuit reached the opposite conclusion in *Geneva College v. Secretary United States Department of Health and Human Services*, 778 F.3d 422, 427 (3d Cir. 2015), *vacated and remanded sub nom. Zubik*, 136 S. Ct. at 1561. While *Zubik* subsequently vacated *Geneva College*, it did not address whether the accommodation process imposed such a substantial burden – it was silent. And following *Zubik*, the Third Circuit reaffirmed the conclusion it reached in *Geneva College*: that the accommodation process did *not* impose a "substantial burden." *See Real Alternatives*, 867 F.3d at 356 n.18 (reaffirming that "the regulation at issue [in *Geneva College*] did not impose a substantial burden"). In that same opinion, the Third Circuit also rejected the argument that

merely providing an insured with unwanted contraceptive coverage can impose a substantial burden on the insured's exercise of religion. *See id.* at 366.

The Religious Exemption Rule also claims that the "Government does not have a compelling interest in applying the Mandate to employers that object to contraceptive coverage on religious grounds." Religious Exemption, Exh. A at 55; *see also id.* at 33. This position cannot be squared with the Supreme Court's opinion in *Hobby Lobby*. In *Hobby Lobby*, the majority accepted, without argument, that the Contraceptive Care Mandate served a "compelling interest" under RFRA. 134 S. Ct. at 2780. The four dissenters went even further, clearly finding that it did. *Id.* at 2799 (Ginsburg, J., dissenting) ("[T]he contraceptive coverage for which the ACA provides furthers compelling interests in public health and women's well being."). Justice Kennedy, writing separately, agreed, stating that "[i]t is important to confirm that a premise of the Court's opinion is its assumption that the [Contraceptive Care Mandate] furthers a *legitimate and compelling interest in the health of female employees*." *Id.* at 2785-86 (emphasis added).[15] The Defendants' position that the Contraceptive Care Mandate does not serve a compelling governmental interest flies in the face of Supreme Court precedent.[16]

For these reasons, the following *cannot* be supported by RFRA: (a) the Moral Exemption; (b) abandonment of the accommodation process under the Original Religious Exemption;

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[15] *Hobby Lobby* at 2785-86 (Kennedy, J., concurring) (HHS "makes the case that the mandate serves the Government's compelling interest in providing insurance coverage that is necessary to protect the health of female employees, coverage that is significantly more costly than for a male employee. There are many medical conditions for which pregnancy is contraindicated. It is important to confirm that a premise of the Court's opinion is its assumption that the HHS regulation here at issue furthers a legitimate and compelling interest in the health of female employees.") (citations omitted).

[16] For this reason, the Defendants' assertion that the existence of grandfathered plans supports the conclusion that the Contraceptive Care Mandate does not serve a compelling governmental interest, *see id.* at 35, is beside the point.

(c) extension of the Rules to individuals enrolled in covered plans; and (d) the conclusion that the Contraceptive Care Mandate does not serve a compelling governmental interest. RFRA simply does not justify the broad exemptions contained in the Rules.

iii. The Rules Are Arbitrary, Capricious, and an Abuse of Discretion.

Even if the Defendants had the broad statutory discretion they claim (and, as set forth above, they do not), they cannot use it in a way that is arbitrary and capricious. But the Defendants did that here. They issued sweeping exemptions, with no relation to the purpose of the statute they purport to implement, that were based on dubious logic and unsound factual assertions. In so doing, the Defendants abused their discretion. Because the Rules are arbitrary, capricious, and an abuse of the Defendants' discretion, they should be struck down.

Agencies do not exercise their discretion in a vacuum. Rather, a "decision in a particular case must be exercised in a manner consistent with the policy, purpose, and goals set forth in the applicable statute." *Frisby v. U.S. Dep't of Hous. & Urban Dev. (HUD)*, 755 F.2d 1052, 1057 (3d Cir. 1985) (citation and internal quotation marks omitted). Here, that applicable statute is the Women's Health Amendment. The purpose of that law is to give women greater access to necessary preventive care and more control over their own health care decisions. Indeed, the ACA itself was enacted to expand health coverage while keeping costs under control.

Yet it is hard to imagine regulations more antithetical to these goals than the Rules. Contrary to the statute, the Defendants' Rules *reduce* access to preventive care, give *employers* control over health care decisions made by female insureds, *discourage* more cost-effective services, and *increase* the overall burden on the health care system. Because the Rules run counter to the purpose of the statute, they are arbitrary and capricious and must be struck down.

The sweeping nature of the Rules only further underscores this conclusion. The Religious Exemption Rule allows shareholders of a publicly traded company to vote to deny female

employees and beneficiaries access to contraception. *See* Religious Exemption, Exh. A at 68-69. That the Defendants see such a vote as "very unlikely," *id.* at 69, does not make the Rule any more acceptable under the APA; rather, it calls into question why the Defendants so radically expanded the Original Religious Exemption to include large publicly traded companies in the first place.

Similarly, the Moral Exemption Rule contains no limit on the type of belief that can justify an employer refusing to provide contraceptive care to its employees, provided that belief is "sincerely held." *See* Moral Exemption, Exh. B at 43. Nothing in the Moral Exemption Rule prohibits, for instance, an employer from refusing to provide contraceptive coverage to women based on his "sincerely held" moral conviction that society would be better off if women did not participate in the workforce.

The Rules are arbitrary, capricious, and an abuse of discretion under the APA. They should be struck down.

B. The Rules Violate Title VII of the Civil Rights Act and the Pregnancy Discrimination Act.

Title VII of the Civil Rights Act prohibits employers from discriminating on the basis of sex. *See* 42 U.S.C. § 2000e–2(a). And, under the Pregnancy Discrimination Act, discrimination "on the basis of pregnancy, childbirth, or related medical conditions" is prohibited sex discrimination under Title VII. Employers must treat women affected by pregnancy and "related medical conditions" the same as other employees "for all employment-related purposes, including receipt of benefits under fringe benefit programs." *Id.* § 2000e(k). Because the Rules permit employers to unilaterally opt out of the Contraceptive Care Mandate, and the Contraceptive Care Mandate affects only women affected by pregnancy and "related medical conditions," the Rules allow employers to discriminate on the basis of sex. The Rules, therefore,

violate Title VII and the Pregnancy Discrimination Act, are "not in accordance with law," and must be struck down under the APA. *See* 5 U.S.C. § 706(2)(A).

In 1978, Congress enacted the Pregnancy Discrimination Act. That Act amended Title VII to make clear that discrimination on the basis of "pregnancy, childbirth, or related medical conditions" is prohibited discrimination on the basis of sex, and violates Title VII. *See* 42 U.S.C. § 2000e(k).[17] The Pregnancy Discrimination Act was specifically intended to correct the Supreme Court's improper interpretation of Title VII in *General Electric Co. v. Gilbert*, 429 U.S. 125 (1976). And, in enacting the statute, Congress expressly embraced the logic of the dissent in that case. *See* H. Rep. No. 95–948, at 2 (1978) ("It is the Committee's view that the dissenting justices correctly interpreted the [Civil Rights] Act."); *see also Newport News Shipbuilding and Dry Dock Co. v. EEOC*, 462 U.S. 669, 676–82 & n.17 (1983).

General Electric involved a challenge to a company rule that provided all employees with disability benefits – but specifically *excluded* disabilities related to pregnancy. *See* 429 U.S. at 125. Justice Stevens dissented, observing that, "[b]y definition, such a rule discriminates on account of sex; for it is the capacity to become pregnant which primarily differentiates the female from the male." *Id.* at 161-62. Congress embraced this principle in enacting the Pregnancy Discrimination Act: *discrimination on the basis of sex-based characteristics* ***is*** *discrimination on the basis of sex*. *See* H. Rep. No. 95–948, at 2 (quoting Stevens dissent with

[17] 42 U.S.C. § 2000e(k) of the Pregnancy Discrimination Act provides, in relevant part:

> The terms "because of sex" or "on the basis of sex" include, but are not limited to, because of or on the basis of pregnancy, childbirth, or related medical conditions; and women affected by pregnancy, childbirth, or related medical conditions shall be treated the same for all employment-related purposes, including receipt of benefits under fringe benefit programs, as other persons not so affected but similar in their ability or inability to work, and nothing in section 2000e–2(h) of this title shall be interpreted to permit otherwise.

approval); *see also Newport News*, 462 U.S. at 676 ("Accordingly, we shall consider whether Congress, by enacting the Pregnancy Discrimination Act, not only overturned the specific holding in *General Electric v. Gilbert, supra,* but also rejected the test of discrimination employed by the Court in that case. We believe it did.").

Relying on this principle, the Supreme Court subsequently struck down an employer's policy that excluded women – except those determined to be infertile – from jobs involving exposure to lead. *See U.A.W. v. Johnson Controls, Inc.*, 499 U.S. 187, 199 (1991). The Court held that, by so targeting "women with childbearing capacity," the policy violated Title VII's prohibition on sex discrimination. *See id.* at 200. The Court noted that its conclusion was "bolstered by" the Pregnancy Discrimination Act, finding that by using "the words 'capable of bearing children' … as the criterion for exclusion, [the employer] explicitly classifies on the basis of potential for pregnancy." *Id.* at 199. The Court concluded that, "[u]nder the [Pregnancy Discrimination Act], such a classification must be regarded, for Title VII purposes, in the same light as explicit sex discrimination." *Id.*

The same logic applies here, and it prohibits employer policies from treating contraception, which is prescribed "on the basis of potential for pregnancy," differently from analogous categories of health care. For example, if an employer provides prescription drug coverage to its employees, it cannot exclude *contraceptive* prescriptions without violating Title VII. *See Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266, 1269 (W.D. Wash. 2001) ("In light of the fact that prescription contraceptives are used only by women, [defendant's] choice to exclude that particular benefit from its generally applicable benefit plan is discriminatory"); *but*

see In re Union Pac. R.R. Employment Practices Litigation, 479 F.3d 936, 942 (8th Cir. 2007).[18] As the court recognized in *Erickson*, "when an employer decides to offer a prescription plan covering everything except a few specifically excluded drugs and devices, it has a legal obligation to make sure that the resulting plan does not discriminate based on sex-based characteristics and that it provides equally comprehensive coverage for both sexes." *See id.* at 1272.

That court's finding is grounded both in Title VII's prohibition of discrimination on the basis of "sex-based characteristics," *see id.*, and Congress's expressed intent that the Pregnancy Discrimination Act's protections should "extend[] to the whole range of matters concerning the childbearing process." *See* H. Rep. No. 95–948, at 5.[19] Since the capacity to become pregnant – and, therefore, the need for contraception if one wishes to prevent pregnancy – is a sex-based characteristic, differential coverage *is* discrimination on the basis of sex. Contraceptive use is also part of "the whole range of matters concerning the childbearing process." *Id.* Put otherwise,

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[18] In *Union Pacific*, the Eighth Circuit concluded that contraception is not "related to pregnancy" because "contraception is a treatment that is only indicated prior to pregnancy." *See* 479 F.3d at 942. That conclusion is inconsistent with both the Supreme Court's holding in *Johnson Controls* that discrimination even on the "basis of *potential* for pregnancy" violates the Pregnancy Discrimination Act, *see* 499 U.S. at 199 (emphasis added), and the broader principle that Title VII's prohibition on sex discrimination precludes discrimination on the basis of sex-based characteristics. *See* H. Rep. No. 95–948, at 2 (adopting Justice Stevens' interpretation of Title VII as prohibiting pregnancy discrimination because capacity for pregnancy "primarily differentiates the female from the male"). *See Union Pacific*, 479 F.3d at 947-49 (Bye, J., dissenting) (arguing that policy excluding coverage for contraception violated Title VII because contraception is a "gender-specific, female issue because of the adverse health consequences of an unplanned pregnancy"); *see also Kocak v. Cmty. Health Partners of Ohio, Inc.*, 400 F.3d 466, 469–70 (6th Cir. 2005), *cert. denied*, 546 U.S. 1015 (2005) (holding, in light of *Johnson Controls*, that district court erred in concluding plaintiff was not protected by Pregnancy Discrimination Act because she was not pregnant when defendant refused to hire her).

[19] In fact, Congress believed that the broad plain language of the Pregnancy Discrimination Act also applied to "decisions by women who chose to terminate their pregnancies," H. Rep. No. 95–948, at 7. Wishing to carve out such decisions, it therefore included a specific exclusion for services related to abortion. *See* 42 U.S.C. § 2000e(k).

"differential treatment" of contraceptive care is unlawful discrimination that violates Title VII and the Pregnancy Discrimination Act.

Such differential, discriminatory treatment, however, is precisely what the Rules allow. An employer that refuses to provide preventive contraceptive care is still obligated to provide other preventive care as well as prescription benefits. *See* 42 U.S.C. § 300gg–13(a)(1); *id.* § 18022(b)(1)(F), § 18022(b)(1)(I). But the Rules permit such an employer to exclude a category of preventive benefits used exclusively by women. This violates the law. Because the Rules authorize this illegal conduct, they are "not in accordance with law," and they must be held unlawful and set aside. *See* 5 U.S.C. § 706(2)(A); *see also Farrington v. Johnson*, 206 F. Supp. 3d 634, 635, 644 (D.D.C. 2016) (refusing to dismiss APA claim arising under Title VII); *Pima Cty. Cmty. Coll. Dist. v. EEOC*, 1976 WL 548, at *2 (D. Ariz. 1976) (observing that Title VII is "certainly a relevant statute within the contemplation" of the APA).

C. The Rules Violate the Equal Protection Guarantee of the Fifth Amendment.

The Rules also violate the constitutional guarantee of equal protection under the law. The Fifth Amendment prohibits the federal government from depriving any person "of life, liberty, or property, without due process of law." U.S. Const. amend. V. Although it does not contain a specific Equal Protection Clause, the Supreme Court has long recognized that "discrimination may be so unjustifiable as to be violative of due process." *See Bolling v. Sharpe*, 347 U.S. 497, 499 (1954). As a result, "the Court has construed the Fifth Amendment to contain an equal protection guarantee." *Abdul-Akbar v. McKelvie*, 239 F.3d 307, 316 (3d Cir. 2001).

Under the Fifth Amendment, classifications based on gender are subject to heightened scrutiny. *See Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1689-90 (2017).[20] Successful defense of such a classification, therefore, "requires an 'exceedingly persuasive justification'" – the government must demonstrate "at least that the challenged classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives." *Id.* at 1690 (citations and internal quotation marks omitted). This burden "is demanding and it rests entirely on the State." *United States v. Virginia*, 518 U.S. 515, 533 (1996).

Here, the President's Executive Order directed the Departments to consider allowing for additional "conscience-based objections" to services mandated by the Women's Health Amendment. *See* Executive Order, Exh. J § 3. In so doing, the President directed his subordinates to consider allowing employers to refuse to provide otherwise mandated insurance coverage for health services that are used by women *only.* And the resulting Rules, in fact, apply solely to health care used exclusively by women. Only women were targeted. By authorizing employers to opt out of providing health coverage for women only – but not for men – the Executive Order and the Rules created a gender-based classification that must receive heightened scrutiny.

In performing the analysis under the Fifth Amendment, it is plain that the Rules fall far short of providing the "exceedingly persuasive justification" necessary to survive such scrutiny. The Religious Exemption asserts merely that it serves "the Government's interests, including as reflected throughout Federal law, to provide conscience protections for individuals and entities

[20] Although *Morales-Santana* involved a challenge to a federal statute, the same principle applies equally to challenges to federal regulations.

with sincerely held religious beliefs in certain health care contexts, and to minimize burdens in our regulation of the health insurance market." Religious Exemption, Exh. A at 8. The Moral Exemption Rule contains a similar milquetoast justification. *See* Moral Exemption, Exh. B at 8 (justifying "the Government's interests in providing conscience protections for individuals and entities with sincerely held moral convictions in certain health care contexts, and in minimizing burdens imposed by our regulation of the health insurance market").

Even if the Rules served important governmental objectives, their gender-based classification does not have an "exceedingly persuasive justification" and is not "substantially related to the achievement of those objectives." *Morales-Santana*, 137 S. Ct. 1678, 1690. In fact, the discriminatory classification of the Rules is not related to these governmental objectives at all. Simply put, there is no reason why the government's stated "interests in providing conscience protections … in certain health care contexts" require singling out one specific category of health care that is used only by women. The Executive Order does not explain why the President directed the Defendants to target the Women's Health Amendment, and the resulting Rules contain no medical or other justification for treating women's contraceptive care differently from any other type of health care.

The complete lack of any relationship between the government's asserted interest and the gender-based classification it used to advance that purported interest here is fatal. Because there is no "exceedingly persuasive justification" for the discriminatory action encouraged by the Rules, the Rules violate the equal protection guarantee of the Fifth Amendment. They should be struck down.

D. The Rules Violate the Establishment Clause.

The Rules also violate the Establishment Clause of the First Amendment, which requires that "Congress shall make no law respecting an establishment of religion." U.S. Const. amend. I.

"It is an elemental First Amendment principle that the state may not coerce its citizens 'to support or participate in any religion or its exercise.'" *Town of Greece, N.Y. v. Galloway*, 134 S. Ct. 1811, 1825 (2014) (plurality) (quoting *Cty. of Allegheny v. Am. Civil Liberties Union, Greater Pittsburgh Chapter*, 492 U.S. 573, 659 (1989) (Kennedy, J., concurring in judgment in part and dissenting in part)). In enacting policy, government "must not press religious observances upon their citizens." *Van Orden v. Perry*, 545 U.S. 677, 683 (2005) (plurality). Indeed, even action performed by a private actor can violate the Establishment Clause where it "bear[s] 'the imprint of the State.'" *Santa Fe Independent Sch. Dist. v. Doe*, 530 U.S. 290, 305 (2000).

Establishment Clause challenges traditionally follow the *Lemon* test: First, the statute must have a "secular legislative purpose"; second, its "principal or primary effect" must be one that "neither advances nor inhibits religion"; finally, it must not "foster an excessive government entanglement with religion." *Lemon v. Kurtzman*, 403 U.S. 602, 612-13 (1971) (internal citation and quotation marks omitted). Although the Supreme Court has not universally applied the *Lemon* test in recent years, it has remained consistent that the government violates the Establishment Clause when it "acts with the ostensible and predominant purpose of advancing religion." *McCreary Cty., Ky. v. Am. Civil Liberties Union of Ky.*, 545 U.S. 844, 860 (2005). Therefore, to survive constitutional scrutiny, a state action must have a secular purpose that is "genuine, not a sham, and not merely secondary to a religious objective." *Id.* at 864. Further, the state's "manifest objective may be dispositive of the constitutional enquiry" and, as such, it is proper for courts to consider the history and background of the state action at issue when determining its purpose. *Id.* at 850-51.

Here, the Rules have both the purpose and effect of advancing the religious beliefs of employers and other plan sponsors over those of their employees. This purpose is clear from the language of the Executive Order, which states that it is the policy of the Executive Branch to "vigorously enforce Federal law's robust protections for religious freedom." *See* Executive Order, Exh. J; *see also* Religious Exemption, Exh. A at 7 and Moral Exemption, Exh. B at 7. Similarly, the stated purpose of the Religious Exemption Rule is to "protect religious beliefs in the context of health care and human services" and "provide conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts."[21] *See* Religious Exemption, Exh. A at 5, 8.[22]

This stated purpose indicates that the Rules are unconstitutional. In *McCreary County,* the Supreme Court found unconstitutional two Kentucky courthouse displays of the Ten Commandments. *McCreary Cty.*, 545 U.S. at 851. But, that same day, the Court (by plurality opinion) *upheld* the constitutionality of a monument of the Ten Commandments on the Texas statehouse grounds. *Van Orden*, 545 U.S. at 681. The difference, made plain by their histories, was their respective purposes. *See Van Orden*, 545 U.S. at 703 (Breyer, J., concurring) ("[*Van Orden*] also differs from *McCreary County*, where the short (and stormy) history of the

[21] Any legal distinction between the purpose of the Religious Exemption Rule and the Moral Exemption Rule is meaningless because couching an obviously religious motive as secular morality cannot survive constitutional scrutiny. *See Am. Civil Liberties Union of Ohio Foundation, Inc. v. DeWeese*, 633 F.3d 424, 432-33 (6th Cir. 2011) (rejecting as a "sham" the contention that a Ten Commandments poster was hung for a secular moral purpose); *see also Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 534 (1993) ("Facial neutrality is not determinative" of a First Amendment challenge).

[22] The Establishment Clause issue here is not whether the government *must* require insurance companies to cover contraception or whether the Defendants could have declined to guarantee contraceptive coverage for other reasons. Rather, the issue is that the particular context and history behind the Rules clearly demonstrates that the primary, if not sole, purpose of the Rules is to advance a particular religious belief and foist it upon women who would otherwise take advantage of their no-cost preventive contraceptive coverage. This bell cannot be un-rung.

courthouse Commandments' displays demonstrates the substantially religious objectives of those who mounted them, and the effect of this readily apparent objective upon those who view them. That history there indicates a governmental effort substantially to promote religion, not simply an effort primarily to reflect, historically, the secular impact of a religiously inspired document.").

The Defendants' abrupt change in policy regarding contraceptive coverage demonstrates their clear religious objective. The Rules do not even bother to feign a non-religious purpose, like in *McCreary County*, such as "health" or "economic" concerns.[23] And any attempt to do so now would plainly be revisionist history as it was with McCreary County's futile attempt to repackage its Ten Commandments monument into a broader display of documents with "historical and legal significance." *See McCreary Cty.*, 545 U.S. 855-56; *see also id.* at 865 (courts need not accept a government's stated intent "where the claim was an apparent sham, or the secular purpose secondary").

While the government may, under certain circumstances, seek to alleviate a burden on religious exercise without running afoul of the Establishment Clause, *see Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005), it may not do so by imposing a substantial burden on others. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709 (1985). And here, the burden imposed on women goes well beyond anything that could be justified to alleviate a burden on plan sponsors' religious exercise. The government action here is similar to that in *Santa Fe*, 530 U.S. at 290 – but with far more substantial consequences. In *Santa Fe*, the Court held that prayer delivered

[23] Although the Rules make passing reference to "minimiz[ing] burdens in our regulation of the health insurance market," *see* Religious Exemption, Exh. A at 8, they provide no further analysis and cite no evidence that the initial regulations created any such burden on the health insurance market in the first place. In fact, it is acknowledged in the text of the Religious Exemption Rule that the Rules, themselves, may create ***new*** burdens on the market. *Id.* at 56.

over a public school's public address system before a football game violated the Establishment Clause even though it was delivered by a private individual. *Id*. at 302-10. Because of the overall *context* of the prayer – that it was sanctioned, facilitated, and magnified by the school – the Court held that it was impermissible state sponsorship of a religious message. *Id.* at 309-10. The Rules here similarly and explicitly sanction, facilitate, and magnify a religious belief about contraception. But, unlike in *Santa Fe*, where the only burden on football fans was listening to a religious prayer,[24] the effect of the Defendants' state-sponsored religious practice here is far more burdensome to those it reaches. Many women in Pennsylvania and around the Country will be denied access to necessary health care in deference to the religious beliefs of their employers.

Where, like here, the state gives companies the legal platform to impose their religious will on others, the Establishment Clause has been violated.

II. IF RELIEF IS NOT GRANTED, THE COMMONWEALTH WILL BE IRREPARABLY INJURED.

Unless the Rules are enjoined, the Commonwealth will suffer irreparable injury. Women across the Commonwealth who rely on contraception as necessary preventive medicine will no longer have insurance coverage to pay for it. They will either get contraceptives from another source or pay out of pocket; if they can do neither, they will go without.

Those who look for other options will turn to programs funded, in whole or part, by state governments. This will increase demand for the already limited resources of such programs and impose additional costs on the Commonwealth. Pennsylvania citizens who go without contraception will have more unintended pregnancies. Some will be unable to afford the children

[24] Even this comparatively minimal burden, the Court noted, was harmful because it told certain audience members that they were "outsiders [and] not full members of the political community." *See* 530 U.S. at 310.

they did not plan to have or the unintended medical consequences of going without contraceptive care. These extra costs, too, will frequently be borne by the Commonwealth.

In addition to the economic, medical and societal harm to Pennsylvania and its citizens, the Rules also frustrate the Commonwealth's goals of ensuring equal treatment of men and women and seeing that women can fully participate in the workforce. These injuries are real, they are serious, they are imminent, and they are irreparable.

A. Women Will Lose Contraceptive Care.

Under the Rules, women in Pennsylvania and other states will lose access to contraceptive coverage through their employer-provided insurance. Indeed, that is the purpose of the Rules: to allow employers to refuse to provide their employees with contraceptive coverage. Under the Rules, there are virtually no limits on the types of organizations that can claim the Religious Exemption, and few limits on the types of organizations that can claim the Moral Exemption. Nor are there any clear standards or certifications required to claim either. And since the Rules have rendered the Accommodation process optional, entities that opt out of the Contraceptive Care Mandate have no obligation to notify their insurer so that the insurer can provide coverage directly.

These women have limited choices. They can seek contraceptive care from state-funded programs such as Medical Assistance or Family Planning Services, or from clinics that receive state grant money; or they can pay the full cost of contraception, themselves – if they are able. If they can do neither, they can stop using contraception altogether. Some may be able to join the insurance plan of a spouse or other family member who has contraceptive coverage, although doing so will likely raise their premiums. But, regardless of the choices these women are forced to make, *someone* will bear additional costs when employers terminate contraceptive coverage.

In the Rules, the Defendants attempt to quantify the number of women who will lose access to contraceptive care.[25] Their own estimates, which rely on assumptions that seem calculated to underestimate the effect of the Rules, show that harm will be widespread. In trying to assess the impact of the Rules, the Defendants focus on two categories of women: (1) those whose coverage is paid directly by insurance companies because employers opted out under the Religious Non-Profit Accommodation; and (2) those who work for employers currently in litigation against the government on this issue.

These two categories, of course, ignore all of the women who work for publicly traded and other large companies that were not previously permitted to take advantage of the Religious Non-Profit Accommodation. It also ignores those who work for nonprofit and other entities that did not seek the Accommodation or bother suing the government but whose employers will now opt out with no cost, certification or oversight, and women who work for entities that will opt out under the new Moral Exemption. Defendants concede that they cannot estimate how many women will fall into these other categories but, nonetheless, assert that the number will be small. *See* Religious Exemption, Exh. A at 99 ("Overall, the Departments do not know how many entities will use the expanded exemption. We expect that some non-litigating entities will use it, but given the aforementioned considerations, we believe it might not be very many more.").

Defendants estimate that there are 1,027,000 individuals currently covered by plans that use the Religious Non-Profit Accommodation process. Religious Exemption, Exh. A at 1065. Under the Accommodation, the sponsors of these plans do not have to pay for contraception

[25] Their estimates are based on thin evidence, at best, and rest on a series of questionable assumptions. Given the rushed, improper manner in which they issued the Rules, it is unsurprising that Defendants were unable to quantify, with any degree of accuracy, the number of women who will be harmed. What is surprising is that they did not see their inability to produce reliable numbers as an invitation to slow down and follow the APA.

coverage, but the insurance companies or third-party administrators still do. *Id.* at 106. Relying on some questionable assumptions, the Defendants whittle this number down to just 23,000 women of childbearing age who use contraception. The Defendants admit these women will lose contraception coverage – their employers will drop the Accommodation altogether, opting out under the Rules, instead, so their employees will not get coverage even if the employers do not have to pay for it. *Id.*

Defendants also estimate that 8,700 women who work for entities currently litigating against the government will lose coverage, for a total of 31,700 women. *Id.* On a proportional basis by state, this equates to roughly 1,250 women in Pennsylvania of childbearing age who, Defendants admit, use contraception but will lose coverage as a result of their actions. And Pennsylvania may have a greater proportional share of objecting employers than other states, as many of the lawsuits challenging the Contraceptive Care Mandate have involved Pennsylvania entities. For instance, one of the two cases consolidated with *Hobby Lobby* before the Supreme Court was filed by a Pennsylvania corporation with *950* employees. *See Conestoga Wood Specialties Corp. v. Sec'y of U.S. Dep't of Health & Human Servs.*, 724 F.3d 377, 381 (3d Cir. 2013), *rev'd and remanded sub nom. Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). *Zubik* was also filed by Pennsylvania plaintiffs, along with three other cases initiated in the same district, all of which challenge the Contraceptive Care Mandate. *See Zubik et al. v. Sebelius et al.*, No. 2:13-cv-01459 (W.D.P.A); *Brandt et al. v. Sebelius et al.*, No. 2:14-cv-00681 (W.D.P.A.); *Persico et al. v. Sebelius et al.*, No. 1:13-cv-00303 (W.D.P.A.); *Geneva College et al. v. Sebelius et al.*, No. 2:12-cv-00207 (W.D.P.A.). These cases all involved multiple plaintiffs, some of which stated in pleadings that their health plans covered hundreds or thousands of

individuals. *See* Complaint ¶ 36, *Zubik* (Oct. 8, 2013); Complaint ¶ 39, *Brandt* (May 27, 2014); Complaint ¶¶ 38-39, *Geneva College* (Oct. 18, 2013).

These numbers, however, represent only a fraction of the women who will be harmed. And if Defendants' assumptions are wrong, as they likely are, these numbers could be much higher. For instance, Defendants assume that 75% of individuals covered by the insurer of an employer that opts out under the Religious Non-Profit Accommodation will continue to receive coverage through the insurer now that the Accommodation is optional. *Id.* at 106. This is arbitrary and makes no sense: the Defendants admit they "do not have specific data on which plans of which sizes will actually continue to opt into the accommodation." *Id.* But because some organizations – before passage of the Rules – "indicated that they do not object to the accommodation," the Defendants guessed that only 25% of women covered under the Accommodation will lose coverage. But if these employers truly object to contraception based on a sincerely held belief, why would they not opt out under the new Rules? That way their insurers will not have to pay for their employees' contraception coverage, either. The Defendants' assumption is too low; the number of women who will be harmed is significantly higher than they estimate.

Harm this widespread warrants injunctive relief. By way of comparison, in a case challenging an employer's decision to reduce health benefits and wages for only 90 employees in Pennsylvania and 415 elsewhere, this Court issued an injunction maintaining benefits. *See Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am., UAW v. Exide Corp.*, 688 F. Supp. 174, 176 (E.D. Pa.), *aff'd*, 857 F.2d 1464 (3d Cir. 1988). This Court found irreparable harm "as a result of the drastic reduction in health insurance benefits and the wholesale wage cuts implemented by the company." *Id.* at 188. In so doing, it specifically cited the "substantial

risk" that "workers will forego necessary medical treatment or diagnosis because of their inability to pay their share of the costs." *Id.* at 188. The Third Circuit affirmed. 857 F.2d at 1464.

Here, the risk that "workers will forego necessary treatment or diagnosis because of their inability to pay their fair share of the costs" is the same as in *Exide Corp.* But the scope of the "drastic reduction in health insurance benefits" here is far greater. Therefore, like in *Exide Corp.*, this Court should enjoin the Rules and maintain benefits.

B. The Commonwealth Will Suffer Direct, Irreparable Harm.

Defendants argue that women who lose employer-provided contraceptive care can always obtain contraception from somewhere else. They assert that "there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women." Religious Exemption, Exh. A at 42. The Commonwealth agrees with this last statement. But who do the Defendants think *pays* for these state and local programs? The many women who lose access to contraception will undoubtedly seek care from these programs. As a result, the costs to the Commonwealth and other states will increase.

In Pennsylvania, women denied contraceptive coverage by their employers can seek similar coverage from a state-sponsored program. Women who are citizens of Pennsylvania with incomes up to 138% of the federal poverty level ($16,642 for an individual and $33,948 for a family of four) can enroll in Medicaid which, in Pennsylvania, is known as "Medical Assistance." *See* Allen Decl, Exh. K ¶ 8. Those with incomes up to 215% of the poverty level ($25,929 for an individual and $52,890 for a family of four) can participate in the Commonwealth's Family Planning Services Program. *Id.* ¶ 9. Both programs provide contraceptive care and rely on a combination of federal and Commonwealth funding.

In addition, all women who lose contraceptive coverage can get some care from Pennsylvania's network of clinics funded under the Title X grant program. Under this program,

clinics located throughout the Commonwealth receive funding from different sources – including from programs funded by the Commonwealth. These Title X clinics provide services to all women who ask, and they charge on a sliding scale based on income. They also help women who are eligible for Commonwealth-funded health care (including Medical Assistance and Family Planning Services) enroll in these programs to offset their own costs. As a result, only a small portion of the revenue for these clinics actually comes from Title X funding. *See* Steinberg Decl., Exh. L ¶ 13.

For low income women who lose access to contraception, government-funded care is likely the only available option – unless they give up contraception entirely. Therefore, because of the Rules, the Commonwealth's cost to fund the Medical Assistance and Family Planning Services programs will increase. And women who lose access to contraceptive care will experience unplanned pregnancies and/or significant health problems as a result. They will turn to these same state-funded sources of care, imposing additional costs on the Commonwealth.

To be clear, all of these additional costs to the Commonwealth would not exist but for the Rules – and all are *unrecoverable*.[26] The APA does not permit suits against the federal

[26] These costs *would not exist* but for the Rules. Requiring employers to provide contraceptive coverage (or, in the case of entities that opted out under the Accommodation, their insurers) *does not increase costs to the employer or insurer* because "insurance coverage of contraceptive services and supplies … actually saves money." Sonfield, Adam, "The Case for Insurance Coverage of Contraceptive Services And Supplies Without Cost-Sharing," *Guttmacher Policy Review* (Winter 2011) at 7 (attached hereto as Exhibit N). Studies show that insurers who provide contraceptive coverage see their costs *decrease* because their insureds have fewer unplanned pregnancies. *Id.* This is why the Accommodation worked in the first place: insurers could be forced to provide contraceptive care directly to plan participants because that additional coverage caused them to have a net cost *savings*. *See Hobby Lobby*, 134 S. Ct. at 2759 (noting that HHS asserted that the Accommodation "imposes no net economic burden on the insurance companies that are required to provide or secure the coverage."). But by forcing women to get contraceptive care from someone *other than own their health insurance provider*, the Rules upend the incentive structure of the Contraceptive Care Mandate and impose additional costs. Those additional costs are borne, by the States – here, Pennsylvania.

government for money damages, so the Commonwealth and other states will have no way of recovering the additional funds they will be forced to spend. *See* 5 U.S.C. § 702. And where a plaintiff "cannot recover damages from the defendant due to the defendant's sovereign immunity" – as is the case here – "any loss of income suffered by a plaintiff is irreparable per se." *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (citing *Bowen v. Massachusetts*, 487 U.S. 879 (1988) and *United States v. State of New York*, 708 F.2d 92, 93–94 (2d Cir.1983).

The damage to the Commonwealth goes far beyond dollars and cents, even dollars and cents that are not recoverable. As of the date of this filing, the Commonwealth of Pennsylvania has a budget deficit of approximately $2.2 Billion.[27] On September 20, 2017, Pennsylvania's bond rating was lowered by Standard & Poor's.[28] No one can deny that the Commonwealth of Pennsylvania is in dire financial shape. The additional harm to the Commonwealth caused by the Defendants' Rules is not just significant – it is economically unsustainable. The Commonwealth will suffer direct and irreparable harm.

This injury is imminent. The Exemption Rules permit an entity to opt out of providing contraceptive coverage with no more notice than required under ERISA and the ACA. *See* Religious Exemption, Exh. A at 61 ("[T]hese interim final rules do not impose any new notice requirements on [entities wishing to opt out]."). As a result, employers can drop contraceptive coverage for their employees on only 60 days' notice. *See* 42 U.S.C. § 300gg–15(d)(4); *see also*

---

[27] Roper, Mark, *House vote closes Pennsylvania's budget gap*, Fox 43 News, Oct. 26, 2017, *available at* http://fox43.com/2017/10/26/house-vote-closes-pennsylvanias-budget-gap/.

[28] Couloumbis, Angela and Liz Navratil, *Pennsylvania takes credit ratings hit amid budget impasse*, Pittsburgh Post-Gazette, Sept. 20, 2017, *available at* http://www.post-gazette.com/news/politics-state/2017/09/20/Pennsylvania-budget-impasse-leads-to-credit-rating-downgrade/stories/201709200149.

26 C.F.R. § 54.9815-2715(b). And in some cases, they need only give 30 days' notice if they drop coverage at the start of a plan year. *See* Religious Exemption at 77 ("If contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the 1st day of the 1st plan year that begins on or after 30 days after the date of the revocation…."); *see also* 26 C.F.R. § 54.9815-2715(a)(1)(i)(C)(2).

As a result, employers, colleges and universities, and other plan sponsors that use the calendar year as their plan year can drop coverage on January 1, 2018.[29] And those that provided notice when the Exemption Rules were issued can revoke coverage even earlier.

C. The Commonwealth Will Be Harmed Because It Will Be Unable to Protect the Health, Safety, and Well-Being of Its Residents.

In addition to direct pecuniary harm, the Commonwealth will suffer injury to its *parens patriae* interest in protecting its own citizens. The Commonwealth, like all states, has "quasi-sovereign" interests that include "protecting the 'health and well-being – both physical and economic – of its residents in general.'" *In re Oxycontin Antitrust Litig.*, 821 F. Supp. 2d 591, 601 (S.D.N.Y. 2011) (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 607 (1982)); *see also Snapp*, 458 U.S. at 607 ("[A] State has a quasi-sovereign interest in the health and well-being – both physical and economic – of its residents in general."). This bedrock principle of law is as old as the founding of the Commonwealth – even older. *See Massachusetts v. E.P.A.*, 549 U.S. 497, 518-19 (2007); *Snapp*, 458 U.S. at 607. And "[i]t is unquestionable that a state, in its *parens patriae* capacity, does qualify as 'personally ... suffer[ing] some actual or threatened injury." *Maryland People's Counsel v. F.E.R.C.*, 760 F.2d 318, 321 (D.C. Cir. 1985) (Scalia, J.)

[29] As discussed above, *see supra note* 9, the University of Notre Dame recently informed participants in its plan that it would no longer provide cost-free contraceptive care. Its employees were told that they would lose their coverage on January 1, 2018. Fosmoe, Margaret, *Notre Dame to end no-cost contraceptive coverage for employees*, South Bend Tribune, Oct. 31, 2017.

(quoting *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) (alteration in original). Not only is this harm irreparable, but it is also unquantifiable and not subject to reparation in the form of money damages. An injunction is required to address this state harm.

The Commonwealth's interests are particularly relevant here, given its limited authority to regulate many of the plans covered by the Rules. The federal government, through ERISA, has taken over responsibility for regulating self-insured groups plans, which are used by the vast majority of large employers.[30] *See id.* 29 U.S.C. § 1144(a). Pennsylvania, like all other states, "surrender[ed] certain sovereign prerogatives" when it joined the Union. *Massachusetts v. E.P.A.*, 549 U.S. at 519. These prerogatives "are now lodged in the Federal Government," which, in this instance, has ordered the Defendants to enforce the provisions of the Women's Health Amendment to protect the interests of Pennsylvania and the other states. *See id.* at 519 ("These sovereign prerogatives are now lodged in the Federal Government, and Congress has ordered EPA to protect Massachusetts [from certain environmental harms]."); *see also See Texas v. United States*, 809 F.3d 134, 154 (5th Cir. 2015), *affirmed by an evenly divided Court*, 136 S. Ct. 2271 (2016) ("Both these plaintiff states and Massachusetts now rely on the federal government to protect their interests.").

III. THE PUBLIC INTEREST WEIGHS STRONGLY IN FAVOR OF AN INJUNCTION.

Finally, the public interest strongly favors issuing a preliminary injunction. The Third Circuit has stated that "[i]f a plaintiff proves 'both' a likelihood of success on the merits and

[30] As of 2010, approximately 80% of "large employers" (with over 1000 employees), and 50% of "mid-sized employers" (with 200-1000 employees), offered self-insured plans. See Rand Corp., "Employer Self-Insurance Decisions," at 17-18 (Mar. 2011) (prepared for United States Department of Labor and HHS).

irreparable injury, it 'almost always will be the case' that the public interest favors preliminary relief." *Issa v. Sch. Dist. of Lancaster*, 847 F.3d 121, 143 (3d Cir. 2017) (citing *Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1427 n.8 (3d Cir. 1994)). According to the Third Circuit, then, analyzing whether an injunction favors the public interest is "often fairly routine." *Id.* (citing *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 730 (3d Cir. 2004)).

So it is here. The public interest favors an injunction in this case because the lack of contraceptive care will cause irreparable injury, in the form of medical harm to women who rely on contraceptives for a wide range of medical reasons, increased unintended pregnancy, and widespread disruption in medical care. The public interest further favors an injunction because the Rules infringe on the sovereignty of the Commonwealth, and because direct financial and other harm will befall the Commonwealth and that harm, too, is irreparable. Finally, the public interest favors an injunction because the Rules are unconstitutional. *See Council of Alternative Political Parties v. Hooks*, 121 F.3d 876, 883–84 (3d Cir. 1997) ("In the absence of legitimate, countervailing concerns, the public interest clearly favors the protection of constitutional rights.").

CONCLUSION

For the reasons set forth above, the Commonwealth's Motion for a Preliminary Injunction should be granted.

Respectfully submitted,

JOSH SHAPIRO
Attorney General
Commonwealth of Pennsylvania

November 2, 2017

s/ Jonathan Scott Goldman
JONATHAN SCOTT GOLDMAN
Executive Deputy Attorney General
MICHAEL J. FISCHER
Chief Deputy Attorney General
NICOLE VAN ORDER
Senior Deputy Attorney General
NICOLE J. BOLAND
PATRICK GREENE
Deputy Attorneys General

Office of Attorney General
Strawberry Square
Harrisburg, PA 17120
(717) 787-3391
jgoldman@attorneygeneral.gov

EXHIBIT F

Clinical Preventive Services for Women

Closing the Gaps

Committee on Preventive Services for Women

Board on Population Health and Public Health Practice

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This study was supported by Contract HHSP23337013T between the National Academy of Sciences and the U.S. Department of Health and Human Services. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the authors and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

International Standard Book Number-13: 978-0-309-21538-1
International Standard Book Number-10: 0-309-21538-2

Additional copies of this report are available from the National Academies Press, 500 Fifth Street NW, Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, http://www.nap.edu.

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Printed in the United States of America

The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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Suggested citation: IOM (Institute of Medicine). 2011. *Clinical Preventive Services for Women: Closing the Gaps*. Washington, DC: The National Academies Press.

"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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www.national-academies.org

COMMITTEE ON PREVENTIVE SERVICES FOR WOMEN

Linda Rosenstock (*Chair*), Dean, School of Public Health, University of California, Los Angeles

Alfred O. Berg, Professor, Department of Family Medicine, University of Washington School of Medicine, Seattle

Claire D. Brindis, Professor of Pediatrics and Health Policy, Department of Pediatrics and Department of Obstetrics, Gynecology and Reproductive Health Services, and Director, Philip R. Lee Institute for Health Policy Studies, School of Medicine, University of California, San Francisco

Angela Diaz, Jean C. and James W. Crystal Professor of Adolescent Health, Department of Pediatrics and Community Preventative Medicine, Mount Sinai Medical Center, New York, New York

Francisco Garcia, Distinguished Outreach Professor of Public Health, Obstetrics and Gynecology; Director, University of Arizona Center of Excellence in Women's Health; and Codirector, Cancer Disparities Institute, University of Arizona, Tucson

Kimberly Gregory, Vice Chair, Women's Healthcare Quality and Performance Improvement, Department of Obstetrics and Gynecology, Cedars-Sinai Medical Center, Los Angeles, California

Paula A. Johnson, Executive Director, Connors Center for Women's Health and Gender Biology, and Chief, Division of Women's Health, Brigham and Women's Hospital, Boston, Massachusetts

Anthony Lo Sasso, Professor and Senior Research Scientist, Division of Health Policy and Administration, University of Illinois at Chicago School of Public Health

Jeanette H. Magnus, Cecile Usdin Professor in Women's Health and Chair, Department of Community Health Sciences, School of Public Health and Tropical Medicine, Tulane University, New Orleans, Louisiana

Heidi D. Nelson, Research Professor of Medical Informatics and Clinical Epidemiology and Medicine, Oregon Health and Science University, and Medical Director for Cancer Prevention and Screening, Providence Cancer Center, Providence Health & Services, Portland, Oregon

Roberta B. Ness, Dean and M. David Low Chair in Public Health, School of Public Health, University of Texas, Houston

Magda G. Peck, Professor of Public Health and Pediatrics and Associate Dean for Community Engagement and Public Health Practice, College of Public Health, University of Nebraska Medical Centers, Omaha, Nebraska

E. Albert Reece, Vice President for Medical Affairs, University of Maryland, and John Z. and Akiko K. Bowers Distinguished Professor and Dean, University of Maryland School of Medicine, Baltimore
Alina Salganicoff, Vice President and Director, Women's Health Policy, Henry J. Kaiser Family Foundation, Menlo Park, California
Sally W. Vernon, Division Director, Health Promotion and Behavioral Sciences, Blair Justice, Ph.D. Professorship in Mind-Body Medicine and Public Health, and Professor of Epidemiology and Behavioral Sciences, University of Texas School of Public Health, Houston
Carol S. Weisman, Distinguished Professor of Public Health Sciences and Obstetrics and Gynecology and Associate Dean for Faculty Affairs, Pennsylvania State University College of Medicine, Hershey

Study Staff

Karen Helsing, Study Director
Jesse Flynn, Associate Program Officer
Suzanne Landi, Research Assistant
Chelsea Frakes, Senior Program Assistant
Rebekah E. Gee, Institute of Medicine Anniversary Fellow
Amy Pryzbocki, Financial Associate
Rose Marie Martinez, Senior Director, Board on Population Health and Public Health Practice

Reviewers

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We thank the following for their review of this report:

Eli Y. Adashi, Professor of Medical Science, The Warren Alpert Medical School, Brown University
Wylie Burke, Professor and Chair, Department of Bioethics and Humanities, School of Medicine, University of Washington
Ned Calonge, President and Chief Executive Officer, The Colorado Trust
Carol A. Ford, Chief, Craig Dalsimer Division of Adolescent Medicine and Orton Jackson Endowed Chair in Adolescent Medicine, the Children's Hospital of Philadelphia
Paula M. Lantz, S.J. Axelrod Collegiate Professor of Health Management and Policy and Chair, Department of Health Management and Policy, School of Public Health, University of Michigan
JoAnn E. Manson, Chief, Division of Preventive Medicine, Brigham and Women's Hospital and Elizabeth F. Brigham Professor of Medicine and Women's Health, Harvard Medical School

Gary E. Raskob, Dean and Professor of Epidemiology and Medicine, College of Public Health, University of Oklahoma Health Sciences Center
Rita Redberg, Director, Women's Cardiovascular Services Medical Center, University of California, San Francisco
Sara Rosenbaum, Hirsh Professor and Chair, Department of Health Policy, School of Public Health and Health Services, The George Washington University Medical Center
Donna Strobino, Professor and Vice Chair of Education, Bloomberg School of Public Health, Johns Hopkins University
Nancy Fugate Woods, Dean Emeritus, School of Nursing, University of Washington

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by **Nancy E. Adler,** Professor of Medical Psychology, Departments of Psychiatry and Pediatrics, and Director, Center for Health and Community, University of California, San Francisco and **Susan J. Curry,** Dean, College of Public Health, University of Iowa. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the report rests entirely with the author committee and the institution.

Preface

As chair of the Committee on Preventive Services for Women, I want to personally thank my fellow committee members for their willingness to serve, for their hard work, and for contributing their remarkable expertise to this study. I have been honored to contribute to this effort. Each of us works in different domains relating to preventive health services, and although the short time frame provided to perform this study presented a challenge, my esteemed colleagues who comprised the committee worked as a team with great dedication and spirit to achieve consensus. It was a pleasure to work with each and every one of them.

The diverse committee involves an impressive array of researchers and practitioners, including two members who served on the United States Preventive Services Task Force (USPSTF) and one who leads USPSTF systematic evidence reviews. Although we could not conduct a USPSTF-style systematic review for any single preventable health condition or determinant of well-being, nor were we expected to do so, I believe that our end product is a study that has important, evidence-based recommendations that provide a road map to improved preventive services for women. Throughout the process we repeatedly asked ourselves whether the disease or condition that we were addressing was of significance to women and especially whether it was more common or more serious in women than in men or whether women experienced different outcomes or benefited from different interventions than men. I believe that the preventive services that we recommend for consideration in this report readily satisfy these questions.

The Patient Protection and Affordable Care Act of 2010 has afforded

us an historic occasion. For the first time, prevention plays a central role within the scope of new health insurance plans in the United States. Also, an ongoing focus on women's preventive services is expected to be included in these efforts. Given the history of inadequate attention to women's health research and preventive services noted by many (including previous Institute of Medicine [IOM] committees), I am truly optimistic that gains in women's health and well-being will ensue. With the multiple roles that women play in society, to invest in the health and well-being of women is to invest in progress for all.

I regret that we were unable to resolve to his satisfaction the issues raised by one committee member, Anthony Lo Sasso. In his statement of dissent, he identifies his main concerns, which are with the constraints of the study's charge and subsequent process. His statement, along with the committee's response, can be found in Appendix D of the report.

I thank the IOM staff, especially our senior project officer, Karen Helsing, and also Jesse Flynn, Suzanne Landi, Chelsea Frakes, and IOM Anniversary Fellow Rebekah Gee. All went above and beyond to support the committee throughout the process. We also are indebted to Rose Marie Martinez, senior director of the Board on Population Health and Public Health Practice, for her presence throughout and her invaluable guidance and support. I am grateful as well to those who presented and attended our committee's open sessions and those who submitted comments and informed our work with their research and opinion pieces. Without their dedicated work this report would not have been possible.

Linda Rosenstock, *Chair*
Committee on Preventive Services for Women

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Summary

BACKGROUND

The Patient Protection and Affordable Care Act of 2010 (ACA) holds much promise—beyond the expansion of health care coverage—for millions of Americans. The preventive health care services and screenings specified in the legislation will be fully covered without requiring a patient copayment. These include the services with Grade A and B recommendations made by the United States Preventive Services Task Force (USPSTF), the Bright Futures recommendations for adolescents from the American Academy of Pediatrics (AAP) in cooperation with the U.S. Department of Health and Human Services (HHS), and vaccinations specified by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP). These three sets of guidelines provide a list of preventive services, such as blood pressure measurement, diabetes and cholesterol tests, and mammography and colonoscopy screenings. As part of the ACA, the list of preventive services specific to women's health was requested to be reviewed.

CHARGE TO THE COMMITTEE

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) of HHS provided funds for the Institute of Medicine (IOM) to conduct a review of effective preventive services to ensure women's health and well-being. The charge to the committee for the project is presented in Box S-1.

BOX S-1
Statement of Task to the Committee on Preventive Services for Women

The Institute of Medicine will convene an expert committee to review what preventive services are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women. The committee will also provide guidance on a process for regularly updating the preventive screenings and services to be considered. In conducting its work, the committee will: conduct a series of meetings to examine existing prevention guidelines, obtain input from stakeholders, identify gaps that may exist in recommended preventive services for USPSTF Grade A and B preventive services guidelines for women and in Bright Futures and USPSTF Grade A and B guidelines for adolescents, and highlight specific services and screenings that could supplement currently recommended preventive services for women. Specifically, the committee will consider the following questions:

- What is the scope of preventive services for women not included in those graded A and B by the USPSTF?
- What additional screenings and preventive services have been shown to be effective for women? Consideration may be given to those services shown to be effective but not well utilized among women disproportionately affected by preventable chronic illnesses.
- What services and screenings are needed to fill gaps in recommended preventive services for women?
- What models could HHS and its agencies use to coordinate regular updates of the comprehensive guidelines for preventive services and screenings for women and adolescent girls?

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) on behalf of the U.S. Department of Health and Human Services (HHS) has been charged to examine recommendations for women's preventive services. ASPE will use the information and recommendations from the committee's report to guide policy and program development related to provisions in the Affordable Care Act addressing preventive services for women.

In response, the IOM convened a committee of 16 members—including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines—to develop a set of recommendations for consideration by the ASPE of HHS.

The committee sought clarification from ASPE on a number of issues regarding its charge. In summary:

- **Preventive services were specified to be applicable to females aged 10 to 65 years;**

- **The mammography screenings specified in the ACA legislation used USPSTF guidelines from 2002, which specify that such screenings be performed every one to two years for women aged 40 years and older;**
- **The cost-effectiveness of screenings or services could not be a factor for the committee to consider in its analyses leading to its recommendations;**
- **The committee was not intended to duplicate the processes used by the USPSTF and thus should look to other bodies of evidence beyond systematic evidence-based reviews; and**
- **Preventive services were specified for clinical settings, and thus community-based prevention activities were considered beyond the scope of committee consideration.**

COMMITTEE'S APPROACH TO ITS CHARGE

The committee met five times within six months. The committee held three open information-gathering sessions at which the members heard from a diverse group of stakeholders, researchers, members of advocacy organizations, and the public. Box S-2 provides the committee definition of preventive health services.

BOX S-2
Definition of Preventive Health Services

For the purposes of this study, the Committee on Preventive Services for Women defines preventive health services to be measures—including medications, procedures, devices, tests, education and counseling—shown to improve well-being, and/or decrease the likelihood or delay the onset of a targeted disease or condition.

COMMITTEE'S METHODOLOGY

The committee's methodology to identify preventive services necessary for women's health and well-being and to identify specific services that could supplement the current list of recommended preventive services for women under the ACA follows.

The committee's first step was to review and reach an understanding of existing guidelines. The second step was to assemble and assess additional evidence, including reviews of the literature, federal health priority goals

and objectives, federal reimbursement policies, and the clinical guidelines of health care professional organizations. The committee also considered the public comments that it received. Finally, the committee formulated a list of recommendations to be considered by the Secretary of HHS in developing a comprehensive package of preventive services for women to be included under the ACA.

USPSTF Recommendations

The USPSTF process for developing recommendations is a disease-focused one. The intent of its recommendations has been to provide guidance to primary care providers. The IOM committee's approach to identifying gaps in existing services accounts for contextual issues beyond traditional research evidence used by the USPSTF. The committee looked at women's preventive service needs more broadly to account for women's health and well-being. The committee found that its interpretation of the Grade A and B recommendations was important in those cases in which ambiguity was found regarding periodicity of screenings. Furthermore, the committee compared USPSTF guidelines with those of numerous health care professional organizations to identify potential gaps.

The committee recognized that USPSTF Grade C recommendations and I statements warranted further analysis because the USPSTF did not develop and has not used these grades as support to offer or deny coverage of a preventive service. The USPSTF Grade C recommendations are made when the balance of potential benefits and harms does not strongly favor the clinician recommending the preventive service to all patients, although it may be appropriate in some cases.

The USPSTF I statements identify services for which the evidence is insufficient to suggest the effectiveness of a service because evidence is lacking, of lower quality, or conflicting. The committee notes that from a coverage perspective, the evidence supporting many clinical interventions in common use, whether in prevention or in general medical practice, is insufficient or unclear, and coverage decisions may be or have been made on the basis of other factors.

For example, although physician knowledge of the evidence of the benefits associated with a counseling service will inform a physician's decision for each patient, in many instances, it is difficult for researchers to show or conclude that outcomes are positive. Many preventive interventions that are intended to be conducted early in the life span (e.g., skin cancer prevention) require decades to demonstrate effectiveness.

Thus, each of the USPSTF Grade C and I statement recommendations and the evidence supporting them were collected and reviewed. The committee's evaluation included reviewing relevant supporting USPSTF

publications, other peer-reviewed research and clinical articles, and clinician fact sheets. Additional literature searches were conducted to identify randomized control trials published after the USPSTF recommendation was released. Furthermore, the committee compared the Grade C and I statement guidelines with guidelines from other professional organizations. The committee did not reexamine the services with Grade D recommendations, because the USPSTF recommends against providing these services.

Bright Futures Recommendations

The committee reviewed all Bright Futures guidelines and compared them with the USPSTF guidelines for adolescents. The committee noted that the methodology that Bright Futures uses is quite different from that which the USPSTF uses. Bright Futures makes decisions through a consensus-driven process; thus, expert opinion is at the core of its development of recommendations.

The committee interpreted the sample questions and advice suggested in the anticipatory guidance section of the *Bright Futures* report (AAP, 2008) to describe topics to be covered as preventive services under the ACA and addressed in an annual health care visit of sufficient length to cover age- and sex-appropriate topics in the health domain. The committee assumes that physicians will identify priorities from this section of the *Bright Futures* report on the basis of the unique circumstances of each patient.

ACIP Recommendations

The committee reviewed ACIP General Recommendations on Immunizations, which include all of the Food and Drug Administration-approved immunizations recommended for the general population of adolescent and adult women. Although literature searches were conducted to identify areas where supplemental immunization recommendations might be warranted, the committee identified little evidence to clearly indicate deficiencies in existing ACIP recommendations.

Further Committee Considerations

The committee reviewed oral and written comments submitted throughout the course of the study. The committee also invited researchers and leaders of organizations to deliver presentations in areas in which the committee believed that it could benefit from their expertise. In addition, the committee reviewed HHS documents relating to prevention priorities and reimbursement policies. It also reviewed the existing coverage practices of national, state, and private health plans. In some cases, current practice

in clinical care was also identified. Finally, the committee used the 2011 IOM report *Leading Health Indicators for Healthy People 2020* as a tool to perform horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify potential gaps (IOM, 2011).

COMMITTEE ANALYSIS

The product of these reviews was an array of potential areas where supplemental preventive measures might be warranted. Some of these areas were identified on the basis of traditional indicators, such as morbidity and mortality, whereas others were identified as being more generally supportive of a woman's well-being. The committee focused on conditions unique to women or that affected women in some specific or disproportionate way. The committee moved forward using criteria adapted from the USPSTF that considered frequency, severity, morbidity, mortality, and quality of life to bring consistency to the analyses.

For each potential supplemental preventive measure considered, the committee conducted an extensive comparison of the guidelines of professional organizations to understand the development of the guidelines and the evidence that the organizations used to reach their conclusions. The committee also performed targeted literature searches. However, it should be noted that the committee did not have adequate time or resources to conduct its own meta-analyses or comprehensive systematic review of each preventive service.

Supplemental Preventive Measures

The committee attempted to identify preventive measures that were aimed at filling the gaps that it had identified. In most cases, the committee found that measures had already been proposed in the guidelines of other professional organizations. The committee also eliminated preventive measures that, even at this early stage in the analysis, were clearly not developed, tested, or known well enough to have a measurable impact. The resulting product of this step was a series of preventive service areas with gaps in coverage and the accompanying preventive measure or measures that could be considered by HHS. The core of the committee's task was to assemble the evidence that would allow it to recommend consideration of a preventive service.

Coverage Decisions

As noted above, the USPSTF, Bright Futures, and ACIP guidelines focus on guidance for primary care providers and patients. Coverage decisions

often consider a host of other issues, such as established practice; patient and clinician preferences; availability; ethical, legal, and social issues; and availability of alternatives. Further complicating matters, special population groups such as minority populations, disabled women, recent immigrants, lesbians, prisoners, and those employed in high-risk environments, may have different health needs or benefit from different preventive services. High-risk groups, population subsets, and special populations are unevenly identified and addressed to varying degrees in current guidelines. Finally, cost-effectiveness was explicitly excluded as a factor that the committee could use in developing recommendations, and so the committee process could not evaluate preventive services on this basis.

Committee Approach

The committee developed a hybrid approach that collected relevant evidence for each measure. Four categories of evidence—posed in the form of questions—to be examined for each potential preventive measure were developed. The committee did not formally rank or assign weights to the categories, nor did it stipulate that evidence in any one category would automatically result in a recommendation for a measure or service to be considered. Instead, the queries and categories were used to consider the range of evidence and to ensure consistency in the committee's analysis and deliberations. Many of the recommendations are supported by more than one category of evidence.

Category I. Are high-quality systematic evidence reviews available indicating that the service is effective in women?

Category II. Are quality peer-reviewed studies available demonstrating effectiveness of the service in women?

Category III. Has the measure been identified as a federal priority to address in women's preventive services?

Category IV. Are there existing federal, state, or international practices, professional guidelines, or federal reimbursement policies that support the use of the measure?

RECOMMENDATIONS

Subcommittees were formed, and each subcommittee reviewed the available evidence applicable to its identified potential preventive measure(s) and assigned the evidence to one or more of the above categories. Each subcommittee then brought its analysis of the range of evidence before the full committee for deliberation. The committee then combined the burden of the condition and its potential impact on health and well-being with the array of available evidence and support to reach a consensus regarding

whether to recommend a specific preventive measure for that condition. As is true in most analytical processes in decision making, evidence and expert judgment are inextricably linked; thus, the expert judgments of the committee members also played a role in decision making.

In general, the preventive measures recommended by the committee for consideration of coverage (see Table S-1) met the following criteria:

- **The condition to be prevented affects a broad population;**
- **The condition to be prevented has a large potential impact on health and well-being; and**
- **The quality and strength of the evidence is supportive.**

Ultimately, the decision to develop a recommendation for a preventive service to be considered was made after a thoughtful review and debate of each of the subcommittee reports and when the committee found the evidence to be compelling.

TABLE S-1 Summary of the Committee's Recommendations on Preventive Services for Women

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Screening for gestational diabetes	I	The evidence provided to support a recommendation for screening for gestational diabetes is based on current federal practice policy from the U.S. Indian Health Service, the U.S. Department of Veterans Affairs, as well as current practice and clinical professional guidelines such as those set forth by the American Academy of Family Physicians and the American Congress of Obstetricians and Gynecologists.	**Recommendation 5.1** The committee recommends for consideration as a preventive service for women: screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Human papillomavirus testing (HPV)	I	The evidence provided to support a recommendation to support testing for HPV is based on federal practice policy from the U.S. Department of Defense. Peer-reviewed studies demonstrate that improved testing technologies, particularly combined screening using both conventional cytology and high-risk HPV DNA testing, may significantly improve the rate of detection of cervical cancer precursors and facilitate the safe lengthening of the interval for screening.	**Recommendation 5.2** The committee recommends for consideration as a preventive service for women: the addition of high-risk human papillomavirus DNA testing in addition to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections (STIs)	I	The evidence provided to support a recommendation related to STI counseling is based on federal goals from the Centers for Disease Control and Prevention and *Healthy People 2020*, as well as recommendations from the American Medical Association and the American College of Obstetricians and Gynecologists.	**Recommendation 5.3** The committee recommends for consideration as a preventive service for women: annual counseling on sexually transmitted infections for sexually active women.

continued

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Counseling and screening for human immunodeficiency virus (HIV)	C	The evidence provided to support a recommendation for expanding screening for HIV is based on federal goals from the Centers for Disease Control and Prevention, as well as clinical professional guidelines, such as those from the American College of Physicians, the Infectious Diseases Society of America, the American Medical Association, and the American College of Obstetricians and Gynecologists.	**Recommendation 5.4** The committee recommends for consideration as a preventive service for women: counseling and screening for human immunodeficiency virus infection on an annual basis for sexually active women.
Contraceptive methods and counseling	Not Addressed	The evidence provided to support a recommendation related to unintended pregnancy is based on systematic evidence reviews and other peer-reviewed studies, which indicate that contraception and contraceptive counseling are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling, and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in *Healthy People 2010* and *Healthy People 2020*.	**Recommendation 5.5** The committee recommends for consideration as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Breastfeeding support, supplies, and counseling	B	The evidence provided to support a recommendation regarding the inclusion of breastfeeding services is based on systematic evidence reviews, federal and international goals (such as the U.S. Surgeon General, Health Resources and Services Administration [HRSA], *Healthy People 2020*, World Health Organization and UNICEF) and clinical professional guidelines such as those set forth by the American Academy of Family Physicians, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists.	**Recommendation 5.6** The committee recommends for consideration as a preventive service for women: comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)
Screening and counseling for interpersonal and domestic violence	I	The evidence provided to support a recommendation related to increasing detection of and counseling for domestic violence and abuse is based on peer-review studies and federal and international policies, in addition to clinical professional guidelines from organizations, such as the American Medical Association and the American College of Obstetricians and Gynecologists.	**Recommendation 5.7** The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.

continued

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Well-woman visits	Not Addressed	The evidence provided to support a recommendation for including well-woman visits is based on federal and state policies (such as included in Medicaid, Medicare and the state of Massachusetts), clinical professional guidelines (such as those of the American Medical Association and the American Academy of Family Practitioners), and private health plan policies (such as those of Kaiser Permanente).	**Recommendation 5.8** The committee recommends for consideration as a preventive service for women: at least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

UPDATING GUIDELINES

Developing and maintaining a comprehensive list of covered preventive services for women is not currently under the specific purview of any HHS entity. Thus, the committee believes that it will be necessary to develop structures, accountability, and processes to ensure that preventive services meeting evidence-based standards are considered in the context of the general approach taken to identify and update preventive services for women.

The committee recommends a process supported by guiding principles that separates evidence assessment and coverage decisions.

Recommendation 6.1: The committee recommends that the process for updating the preventive services for women be:

- **Independent;**
- **Free of conflict of interest;**
- **Evidence-based;**
- **Gender-specific;**
- **Life-course oriented;**
- **Transparent;**
- **Informed by systematic surveillance and monitoring;**

- **Cognizant of the need to integrate clinical preventive services with effective interventions in public health, the community, work place, and environment; and**
- **Appropriately resourced to meet its mandate.**

Recommendation 6.2: The committee recommends that the Secretary of HHS establish a commission to recommend coverage of new preventive services for women to be covered under the ACA.

In carrying out its work the commission should:

- **Be independent of bodies conducting evidence reviews, free of conflict of interest, and transparent;**
- **Set goals for prevention (it may use available HHS reports and products or commission its own at its discretion);**
- **Design and implement a coverage decision making methodology to consider information from evidence review bodies (and other clinical guideline bodies) and coverage factors (e.g., cost, cost-effectiveness, legal, ethical);**
- **Conduct horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify new information on significant health conditions, preventive interventions, new evidence regarding efficacy, effectiveness, periodicity, and safety;**
- **Focus on the general population, but also search for conditions that may differentially affect women and high-risk subpopulations of women;**
- **Assign evidence review topics and set review priorities for the bodies reviewing clinical effectiveness;**
- **Set timetables and processes for updating clinical practice guidelines and coverage recommendations; and**
- **Submit its coverage recommendations to the Secretary of HHS.**

Recommendation 6.3: The committee recommends that the Secretary of HHS identify existing bodies or appoint new ones as needed to review the evidence and develop clinical practice guidelines to be reviewed by a preventive services coverage commission.

Bringing clinical preventive services into rational alignment with the coverage for other health care services under the ACA will be a major task. The committee notes that many of the individual components for review of the evidence are already managed within HHS but currently lack effective coordination for the purposes outlined in the ACA and that some functions are entirely new. The structure might be effectively built over time by using

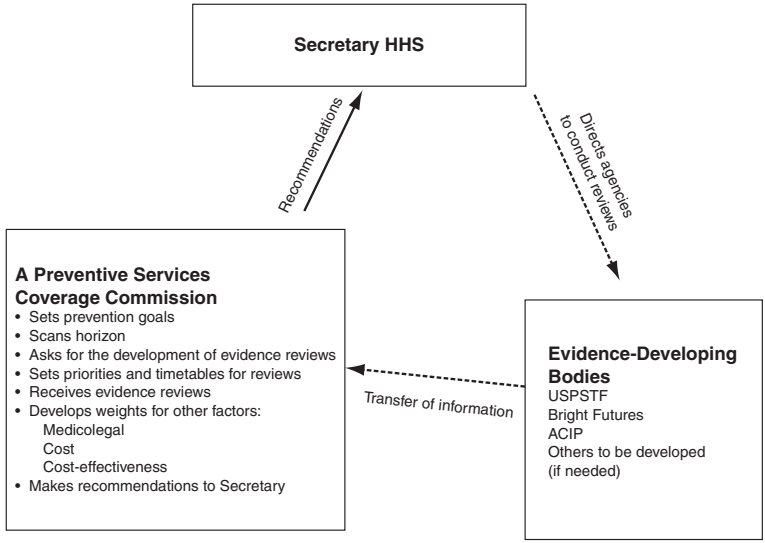

FIGURE S-1 Suggested structure for updating preventive services under the ACA.

some current bodies and adding new ones as resources permit. The committee does not believe that it has enough information to recommend which unit in HHS should implement the recommendations. Figure S-1 illustrates the committee's suggested structure.

In view of the critical importance of community-based preventive services in achieving clinical aims, the committee encourages the Secretary to consider widening the scope of authority to include public health efforts to more comprehensively address prevention. It will be critical for a preventive services coverage commission to coordinate with the new and existing committees that are charged with overseeing other elements of the ACA.

Finally, the committee notes that it would make the most sense to consider preventive services for women, men, children, and adolescents in the same way. Thus, although the committee's recommendations address women's preventive services, a parallel approach could be equally useful for determining covered preventive services for men, children, and male adolescents.

REFERENCES

AAP (American Academy of Pediatrics). 2008. *Bright Futures: Guidelines for health supervision of infants, children and adolescents*, 3rd ed. (J. F. Hagan, J. S. Shaw, and P. M. Duncan, eds.). Elk Grove Village, IL: American Academy of Pediatrics.

IOM (Institute of Medicine). 2011. *Leading health indicators for Healthy People 2020 Report*. Washington, DC: The National Academies Press.

1

Introduction

The passage of the Patient Protection and Affordable Care Act of 2010 (ACA) provides the United States with an opportunity to offer an unprecedented level of population health care coverage and dramatically reduce existing health disparities. The expansion of coverage to millions of uninsured Americans and the new standards for coverage of preventive services that are included in the ACA have the potential to increase the use of preventive health care services and screenings and in turn improve the health and well-being of individuals across the United States.

SPECIFICS OF THE LEGISLATION

The approaches to prevention and wellness offered within the Act are broad based and range from new coverage requirements and incentives to expand workplace wellness activities to new investments. Among these are prohibition of the imposition of cost-sharing requirements for recommended preventive services (an overview of the Act is provided in Box 1-1, and the preventive services are listed and described in detail in Chapter 2), the requirement to link health insurance premiums to participation in health promotion programs, public health workforce development (the ACA authorizes new training and placement programs for public health workers), and community-based prevention activities.

This report focuses on the preventive services for women specified in Section 2713 of the Public Health Service Act. These services were added by the ACA and are detailed in the last bulleted item in Box 1-1 (HHS, 2010; *Federal Register,* 2010).

BOX 1-1
Overview of Regulations in Section 2713 of the Public Health Service Act

Section 2713 of the Public Health Service Act, Coverage of Preventive Health Services, which was added by the Affordable Care Act, and the interim final regulations (26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, 45 CFR 147.130) require that group health plans and health insurance issuers offering health insurance coverage for groups or individuals provide benefits and prohibit the imposition of cost-sharing requirements for

- Medical devices or services that are evidence based and that have, in effect, a rating of Grade A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF) for the individual involved.
- Immunizations for routine use in children, adolescents, and adults that have, in effect, a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) for the individual involved. A recommended ACIP immunization is considered to be "in effect" after it has been adopted by the CDC director. A recommended immunization is considered to be for routine use if it appears on the immunization schedules of the Centers for Disease Control and Prevention.
- Preventive health care and screenings for infants, children, and adolescents informed by scientific evidence and provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- Preventive health care and screenings for women informed by scientific evidence and provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the USPSTF). The U.S. Department of Health and Human Services is developing these guidelines and expects to issue them no later than August 1, 2011.

The complete list of recommendations and guidelines that these interim final regulations are required to cover can be found at http://www.HealthCare.gov/center/regulations/prevention.html.

ROLE OF PREVENTION IN ADDRESSING HEALTH AND WELL-BEING

Prevention is a well-recognized, effective tool in improving health and well-being and has been shown to be cost-effective in addressing many conditions early (Maciosek et al., 2010). Prevention goes beyond the use of disease prevention measures. For example, interventions to prevent injuries and binge drinking can increase positive health outcomes and reduce harm.

Historically, the many disparate components of the U.S. health care system have relied more on responding to acute problems and the urgent

needs of patients than on prevention. Although these functions are appropriate for acute and episodic health problems, a notable disparity occurs when this model of care is applied to the prevention and management of chronic conditions. The provision of preventive health care services is thus inherently different from the treatment of acute problems, but the U.S. health care system has fallen short in the provision of such services. Compared with a system that prevents avoidable conditions early, a system that responds to the acute health care needs of patients can be inefficient and costly, and a focus on response instead of prevention is a major barrier to the achievement of optimal health and well-being by Americans.

Nearly half of all deaths in the United States are caused by modifiable health behaviors (McGinnis and Foege, 1993). Maciosek and colleagues found that an increase in the use of clinical preventive services in the United States could result in the saving of more than 2 million life-years annually (Maciosek et al., 2010). Because of the numbers of diseases and conditions that are preventable, inclusion of support for prevention has become more routine during clinical health care visits (Sussman et al., 2006). When patients are systematically provided with the tools and information that they need to reduce their health risks, the likelihood that they will take steps to, for example, reduce substance use, stop using tobacco products, practice safe sex, eat healthful foods, and engage in physical activity increases (WHO, 2002). Therefore, physicians who routinely educate patients on risk-reducing behaviors may reduce the long-term burden and health care demands of chronic conditions. Stimulating the commitment and action of patients, families, and health care teams is also necessary to promote prevention and improve overall population well-being.

Evidence-based testing, diagnosis, and relief of symptoms are also hallmarks of contemporary health care, but these services are often underutilized. A well-cited reason for this underutilization is, for example, the high cost of prescription copayments, with the result being that patients do not fill their prescribed medications, resulting in the loss of lives and dollars (Shrank et al., 2010). Moreover, a recent study by The Commonwealth Fund that analyzed the responses of U.S. adults to a questionnaire indicated that U.S. adults were significantly less likely than adults in all other countries studied to have confidence in their ability to afford health care (Schoen et al., 2009).

About 51 million Americans lacked health insurance in 2009 (DeNavas-Walt et al., 2010). This is in addition to the millions of underinsured Americans who lack access to the appropriate screenings and services needed to detect and address preventable health conditions and diseases. Furthermore, health care workers have often failed to seize patient interactions as opportunities to promote health and well-being and to inform patients about disease prevention strategies (WHO, 2002). This failure to

inform patients has been found to be due to time constraints in the clinical setting, a lack of reimbursement for provision of these services, and a lack of consensus and provider knowledge about what services to prioritize for their patients. The ACA intends to mitigate these issues.

WHY WOMEN?

The ACA has the potential to transform the way in which the U.S. health care system addresses women's health issues in many ways. It expands access to coverage to millions of uninsured women, ends discriminatory practices such as gender rating in the insurance market, eliminates exclusions for preexisting conditions, and improves women's access to affordable, necessary care. The Women's Health Amendment (*Federal Register,* 2010), which was introduced by Senator Barbara Mikulski and which was added to the ACA, expands on these improvements by requiring that all private health plans cover—with no cost-sharing requirements—a newly identified set of preventive health care services for women. Defining appropriate preventive services for women and ensuring that those services can be accessed without cost sharing are important strategies to improve women's health and well-being (Bernstein et al., 2010; Blustein, 1995).

Many reasons exist for expanding the list of preventive care and screening services for women beyond those included in the guidelines of the United States Preventive Services Task Force (USPSTF) Grade A and B guidelines, the Advisory Committee on Immunization Practices (ACIP), and Bright Futures (for adolescents) stipulated in the ACA (USPSTF, ACIP, and Bright Futures and their guidelines are described in detail in Chapter 2). Even though women have longer life expectancies than men, women suffer from chronic disease and disability at rates disproportionate to those of men, with consequences for their own health and the health of their families (Wood et al., 2010). Furthermore, mounting evidence suggests that women not only have different health care needs than men (because of reproductive differences) but also manifest different symptoms and responses to treatment modalities (IOM, 2010). Behavioral factors that are shown to contribute to morbidity and mortality in women, include smoking, eating habits, physical activity, sexual risk-taking, and alcohol use (IOM, 2010). Pregnancy and childbirth also carry risks to women's health including maternal mortality (CDC, 2008). Figure 1-1 illustrates preventable mortality in women.

Health outcomes occur because of multiple factors including biology, behavior, and the social, cultural, and environmental contexts in which women live. Smoking, eating habits, physical activity, and other health-related behaviors are shaped by cultural and social contexts, including factors associated with social disadvantage. The marked differences in

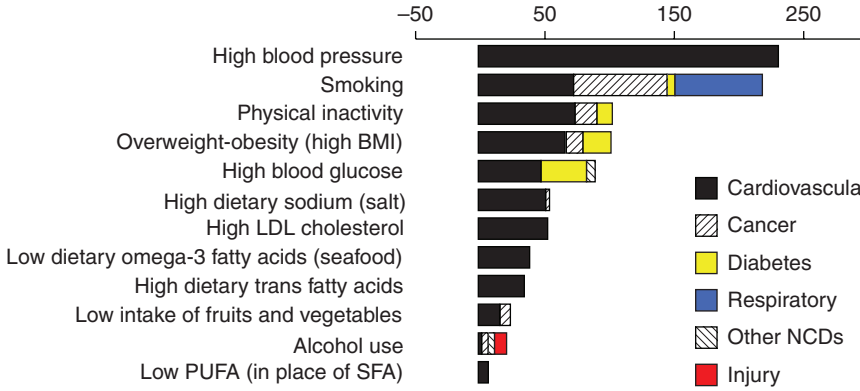

FIGURE 1-1 Deaths in women attributable to total effects of individual risk factors (in thousands), by disease.
ABBREVIATIONS: BMI, body-mass index; LDL, low-density lipoproteins; NCD, non-communicable disease; PUFA, polyunsaturated fatty acid; SFA, saturated fatty acid.
SOURCE: Danaei et al. (2009).

condition prevalence and mortality in women who experience social disadvantage are associated with minority race/ethnicity, lower education, low income, and differential exposure to stressors such as domestic violence. Such exposures are related to outcomes as varied as injury and trauma, depression, asthma, heart disease, human immunodeficiency virus (HIV) infection, and other sexually transmitted infections (Campbell et al., 2002; Coker et al., 2000; Ozer and Weinstein, 2004; Tjaden and Thoennes, 1998).

On average, women need to use more preventive care than men (Asch et al., 2006; HHS, 2001), owing to reproductive and gender-specific conditions, causing significant out-of-pocket expenditures for women (Bertakis et al., 2000; Kjerulff et al., 2007). This creates a particular challenge to women, who typically earn less than men and who disproportionately have low incomes. Indeed, women are consistently more likely than men to report a wide range of cost-related barriers to receiving or delaying medical tests and treatments and to filling prescriptions for themselves and their families (KFF, 2010). For example, women have been shown to be more likely than men to forgo preventive services such as cancer screenings and dental examinations because of cost (Rustgi et al., 2009). Studies have also shown that even moderate copayments for preventive services such as mammograms and Pap smears deter patients from receiving those services (Solanki et al., 2000; Trivedi et al., 2010). A 2010 Commonwealth Fund

survey found that 44 percent of adult women (compared with 35 percent of adult men) either reported that they had a problem paying medical bills or indicated that they were paying off medical debt over time, an increase from 38 percent in 2005 (Robertson and Collins, 2011). The same survey indicated that less than half of women are up to date with recommended preventive care screenings and services (Robertson and Collins, 2011).

Most women and men in the United States are covered by insurance obtained through the workplace. However, women with employer-based insurance are almost twice as likely as men to be covered as dependents, increasing their vulnerability to losing their insurance if they divorce, their partners lose their jobs, or they become widowed (KFF, 2010). Even though results of studies indicate that evidence-based preventive care services lower the burden of disease, are often cost-effective, increase the efficiency of health care spending, and contribute to the creation of a more productive and prosperous America, many financial barriers exist that prevent women from achieving health and well-being for themselves and their families.

PREVENTIVE SERVICES FOR WOMEN

Preventive services for women are services that prevent conditions harmful to women's health and well-being. "Conditions" are considered diseases, disabilities, injuries, behaviors, and functional states that have direct implications for women's health and well-being. These conditions may be specific to women, such as gynecologic infections and unintended pregnancy; they may be more common or more serious in women, such as autoimmune diseases and depression; they may have distinct causes or manifestations in women, such as alcohol abuse, obesity, and interpersonal violence-related posttraumatic stress disorder; or they may have different outcomes in women or different treatments, such as cardiovascular disease and diabetes (IOM, 2010). To "prevent" is to forestall the onset of a condition; detect a condition at an early stage, when it is more treatable; or slow the progress of a condition that may worsen or result in additional harm. Preventive services may therefore include the provision of immunizations, screening tests, counseling and education, Food and Drug Administration-approved medications and devices, procedures, and over-the-counter medications and devices.

COMMITTEE ON PREVENTIVE SERVICES FOR WOMEN

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services (HHS) asked the Institute of Medicine to convene a diverse committee of experts in disease prevention, women's health issues, adolescent health issues, and

evidence-based guidelines to review existing guidelines, identify existing coverage gaps, and recommend services and screenings for HHS to consider in order to fill those gaps (Box 1-2). A 16-member committee was selected to complete the statement of task.

In subsequent guidance to the committee, HHS sponsors at ASPE directed the committee to limit its focus to females between the ages of 10 and 65 years.

BOX 1-2
Statement of Task to the Committee on Preventive Services for Women

The Institute of Medicine will convene an expert committee to review what preventive services are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women. The committee will also provide guidance on a process for regularly updating the preventive screenings and services to be considered. In conducting its work, the committee will: conduct a series of meetings to examine existing prevention guidelines, obtain input from stakeholders, identify gaps that may exist in recommended preventive services for USPSTF Grade A and B preventive services guidelines for women and in Bright Futures and USPSTF Grade A and B guidelines for adolescents, and highlight specific services and screenings that could supplement currently recommended preventive services for women. Specifically, the committee will consider the following questions:

- What is the scope of preventive services for women not included in those graded A and B by the USPSTF?
- What additional screenings and preventive services have been shown to be effective for women? Consideration may be given to those services shown to be effective but not well utilized among women disproportionately affected by preventable chronic illnesses.
- What services and screenings are needed to fill gaps in recommended preventive services for women?
- What models could HHS and its agencies use to coordinate regular updates of the comprehensive guidelines for preventive services and screenings for women and adolescent girls?

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) on behalf of the U.S. Department of Health and Human Services (HHS) has been charged to examine recommendations for women's preventive services. ASPE will use the information and recommendations from the committee's report to guide policy and program development related to provisions in the Affordable Care Act addressing preventive services for women.

The ACA defines the current USPSTF recommendations regarding breast cancer screening, mammography, and breast cancer prevention to be "the most current other than those issued in or around November 2009." Thus, coverage for screening mammography is guided by the 2002 USPSTF guideline, which specifies that such screenings be performed every one to two years for women aged 40 years and older.

Furthermore, for consistency in approach with the other three guidelines used by the ACA and given the time limitations for this study, the committee was restricted from considering cost-effectiveness in its process for identifying gaps in current recommendations. Finally, despite the potential health and well-being benefits to some women, abortion services were considered to be outside of the project's scope, given the restrictions contained in the ACA.

The committee received clarification from ASPE that its work was not intended to duplicate the processes used by the USPSTF or Bright Futures. Thus, the committee interpreted this guidance to indicate that evidence ranging from systematic reviews of the evidence to other bodies of evidence could be considered. This appears to be consistent with the process that led to the current preventive services within the ACA.

The committee was also directed to limit its work to identifying clinical preventive service coverage gaps and not to make recommendations regarding community-based prevention activities.

The committee recognizes that many factors that shape the health and well-being of women fall outside the realm of clinical services. These include, for example, changes to the environment and the workplace to promote health, changes in women's concept of self-efficacy to promote health, and changes in women's self-empowerment to address their own health and wellness. These factors and determinants of health are elements of models such as the Whitehead and Dahlgren (1991) determinants-of-health model and encompass biological, behavioral, and social factors. Nevertheless, evaluation of these factors and determinants of health were outside of the committee's purview.

HHS will consider the committee's recommendations as it develops guidelines to support the delivery of effective preventive services for women. If they are enacted, the recommendations from this study, along with the other coverage requirements in the ACA, will provide a comprehensive package of clinical preventive services for women.

COMMITTEE PROCESS

To meet its charge, the committee held three information-gathering meetings on preventive services for women and reviewed the relevant literature. Before the first meeting and throughout the committee's delibera-

tions, the committee gathered extensive information on numerous topics related to health and health care services for women, including chronic and mental health conditions, cancers, sexually transmitted infections, bone diseases, breastfeeding, interpersonal violence, unintended pregnancy, and a variety of behavioral health issues. During the public forums, representatives from women's health organizations, national health interest groups, health coverage providers, employer interest groups, and other experts presented statements to the committee on the latest status and developments in their respective fields (see Appendix B for the meeting agendas). Committee members questioned the speakers to address additional concerns that they did not cover in their statements. The committee also invited comments (both written and oral) from the general public and representatives from numerous organizations with interest in women's preventive services.

The committee first met in November 2010 and held its last meeting in May 2011. Within that time frame, it should be noted that the committee did not have adequate time or resources to conduct its own meta-analyses or comprehensive systematic review for each preventive service or for every special population group that may have different health needs or benefit from different preventive services, such as minority populations, disabled women, recent immigrants, lesbians, prisoners, and those employed in high-risk environments.

Box 1-3 details the committee's definition of preventive health services, which was used as a starting point for the study.

This definition of preventive health services is primarily derived from a blend of definitions from multiple health care organizations and agencies, including the USPSTF and the World Health Organization, with the text regarding well-being possessing the most original phrasing by the committee and stems from the statement of task. In addition, other key definitions are included in Box 1-4. These definitions were adapted from the Five Major Steps to Intervention of the Agency for Healthcare Research

BOX 1-3
Definition of Preventive Health Services

For the purposes of this study, the Committee on Preventive Services for Women defines preventive health services to be measures—including medications, procedures, devices, tests, education, and counseling—shown to improve well-being and/or decrease the likelihood or delay the onset of a targeted disease or condition.

BOX 1-4
Key Definitions: Preventive Interventions

Preventive interventions come in several forms: screening, testing, counseling, immunization, preventive medication, and preventive treatment.

- **Screening** is best described as tests that assess the likelihood of the presence of a disease or condition in an apparently healthy individual. Screening methods use, for example, laboratory analyses and X rays and similar technologies. Screening also includes questions from clinicians. Screening may be targeted to people at increased risk because of age, gender, family or personal history, and other factors. Each screening tool is different in design and method, affecting the sensitivity (ability to correctly identify those with the disease), specificity (ability to correctly identify those without the disease), and positive and negative predictive values of the tool. Ideally, screening tests are rapid, simple, and safe. Screening is not a definitive diagnostic test, and a positive result on a screening test merely indicates that the screened individual has a higher likelihood of having the disease or condition for which the individual is being screened. Individuals who screen positive on such tests should have confirmatory diagnostic tests to ensure an accurate diagnosis.
- **Testing** refers to any process used to determine whether a condition is present or to assess the status of a condition. Testing may involve questioning patients (e.g., asking a patient about tobacco use), physical examination (e.g., mammography screening to detect potential breast cancers), or examining blood, body fluids, or tissues (e.g., to see if a cancer is present in a biopsy sample). Testing may also require the use of sophisticated technology, such as computed tomography and magnetic resonance imaging scans and other X rays, or invasive procedures, such as heart catheterization to detect blockage of coronary arteries. Tests may be used to

    1. Screen individuals who have risk factors but no indication of having the condition,
    2. Diagnose a disease or condition in individuals who have symptoms and signs but for whom a test will add certainty about the diagnosis, or
    3. Monitor the progress of an individual who is being treated or being considered for treatment, such as monitoring blood pressure over time.

- **Counseling** refers to a discussion between a clinician and patient about ways that changes in personal behavior can reduce the risk of illness or injury. The goal of counseling is for clinicians to educate patients about their health risks as well as to provide them with the skills, motivation, and knowledge that they need to address their risk behaviors (e.g., the "5 A" framework for tobacco cessation: **a**sk, **a**dvise, **a**ssess, **a**ssist, **a**rrange). A special kind of counseling, informed decision making, recognizes that different people will make different decisions, even though their situations may seem to be similar. Informed decision making is structured to give an individual all the information needed

BOX 1-4 Continued

to choose from among different clinical options, such as whether to undergo genetic testing.

- **Immunization** protects an individual from a specific communicable disease (e.g., hepatitis) by exposing the individual to an antigen or a trace amount of an inactivated disease-causing agent, spurring the development of natural immunity.
- **Preventive medications** are used to prevent the onset of a disease or a condition (e.g., aspirin therapy to prevent cardiovascular events).
- **Preventive treatment** involves a procedure intended to prevent the occurrence of a disease or condition or to prevent the progression of a disease from one stage to another. Preventive treatments usually refer to the use of prescription or nonprescription (over-the-counter) medications, but they may also involve the use of prescriptions for lifestyle changes (e.g., exercise or diet change) or other interventions. Some surgical procedures may be considered preventive treatment, such as removal of polyps in the colon identified during a screening colonoscopy to prevent their progression to cancer lesions.

SOURCES: AHRQ, 2011; NBGH, 2005.

and Quality (AHRQ, 2011) and the National Business Group on Health's *Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage* (NBGH, 2005).

The report that follows is organized into seven chapters, summarized below.

- In Chapter 2, the report reviews the three existing guidelines used in the ACA to determine coverage.
- Chapter 3 details the existing practices of national, state, and selected private health plans.
- In Chapter 4, the committee discusses its framework for identifying gaps in existing preventive services and its process for selecting how to fill those gaps.
- Chapter 5 provides a description of the gaps identified through the committee's work.
- The committee's recommendations for updating guidelines for preventive services are proposed in Chapter 6.
- Chapter 7 includes committee conclusions and summarizes committee recommendations while identifying the limitations under which the committee performed its work.

- Appendix A includes a review of the conditions that the committee considered as part of its deliberations. Although no new recommendations were developed, the committee made clarifying statements or suggestions of ways to use preventive services to address these conditions.
- Appendix B provides agendas for the committee's three public meetings.
- Appendix C includes condensed biographies of committee members.
- Appendix D contains one committee member's statement of dissent and a response from all other committee members.

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2

Preventive Services Defined by the ACA

The Patient Protection and Affordable Care Act of 2010 (ACA) defined covered preventive health services for all patient populations to be those with Grade A and B recommendations made by the United States Preventive Services Task Force (USPSTF or the Task Force); for adolescents, the Bright Futures recommendations from the American Academy of Pediatrics (AAP) in cooperation with the U.S. Department of Health and Human Services (HHS), and for all patient populations, recommendations from the Advisory Committee on Immunization Practices (ACIP). The USPSTF, AAP, and ACIP are national authorities on health with defined processes for generating clinical recommendations. A summary of the methods that these entities use to arrive at recommendations and the actual recommendations follows.

UNITED STATES PREVENTIVE SERVICES TASK FORCE

The Task Force is an independent panel composed of nonfederal primary care clinicians, health behavior specialists, and methodologists. Its mission is twofold: (1) assess the benefits and harms of preventive services for people asymptomatic for the target condition on the basis of age, gender, and risk factors for disease; and (2) make recommendations about which preventive services should be incorporated into routine primary care practice. The USPSTF is now entering its 27th year of existence, and the medical community considers its methodologies and resulting recommendations to be the "gold standard" for evidence-based clinical practice in preventive services (USPSTF, 2008b).

TABLE 2-1 USPSTF Grade Definitions

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate degree of certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting; and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

SOURCE: USPSTF, 2008a.

The charge of the Task Force is limited in scope: "its recommendations address primary or secondary preventive services targeting conditions that represent a substantial burden in the United States and that are provided in primary care settings or available through primary care referral" (USPSTF, 2008b). These recommendations are intended to inform primary care providers as they care for individual patients in primary care practice. They are not intended to determine which preventive health care services health insurers should be required to cover. The methodology used in developing Task Force clinical recommendations does not take into consideration many nonclinical issues related to health care coverage (USPSTF, 2011). USPSTF uses a grade system, which is described in Table 2-1.

USPSTF Methodology

Task Force recommendations and their accompanying evidence reports are produced through the collaborative efforts of the USPSTF, the Agency

for Healthcare Research and Quality (AHRQ), Evidence-based Practice Centers (EPCs), and partner organizations. AHRQ provides methodological, technical, scientific, and administrative support to the Task Force. EPCs aid the USPSTF by developing technical reports, evidence summaries and reports, and systematic reviews that target new topics under consideration by the Task Force or that update ones addressed previously. The USPSTF uses systematic evidence reviews produced primarily by the Oregon EPC (under contract by AHRQ) and occasionally uses reviews and other analyses conducted by other groups, depending on the topic under consideration. Partner organizations consist of federal partners (examples include the Centers for Disease Control and Prevention [CDC], the U.S. Department of Defense, Centers for Medicare and Medicaid Services, and the Food and Drug Administration [FDA]) and organizations representing primary care professionals (examples include the American Academy of Family Physicians [AAFP], the American College of Obstetricians and Gynecologists [ACOG], the American Medical Association [AMA], and AAP). They contribute expertise to the evaluation process and comment on preliminary drafts of Task Force recommendation statements and the accompanying evidence reports. A step-by-step overview of the process of recommendation development, from topic selection to recommendation dissemination, follows. The average amount of time required to complete this process is 21 months (USPSTF, 2011).

1. Topic Selection—USPSTF

EPCs, Task Force members, organizations, and individuals can nominate topics through a publicly accessible website, as well as through solicitations to partner organizations and the *Federal Register.* On the basis of these submissions, the Task Force Topic Prioritization Work Group periodically updates a prioritized list of topics to be addressed either for the first time or for updating during the year.

2. Work Plan Development—AHRQ, EPCs, USPSTF

Prioritized topics are appointed to "topic teams," consisting of USPSTF "leads," AHRQ staff (including a Medical Officer), and EPC members. The topic team develops preliminary work plans from the work assignment that AHRQ has issued to the team. The work plan includes the analytic framework, key questions, the literature search strategy, and a timeline for recommendation dissemination.

3. External Work Plan Peer Review—Outside Experts

Work plans for new topics are sent to a limited number of outside experts in appropriate fields for their comments and review.

4. Approval of Work Plan—USPSTF

The topic team presents work plans for new topics to the entire Task Force. The Task Force then evaluates and requests any revisions to the work plan that it deems necessary. The work plan is then edited by the EPC in accordance with the Task Force's requests and is finalized.

5. Draft Evidence Report—EPC

The EPC next conducts a systematic evidence review addressing the key questions posed by the Task Force in the work plan, and generates a draft evidence report.

6. Peer-Review of Draft Evidence Report—USPSTF, Content Area Experts, Federal Partners

Draft evidence reports are sent to Task Force leads, content area experts, federal partners, and other partner organizations for review and comment.

7. Development of Draft Recommendation Statement—USPSTF, AHRQ

Concomitant with the draft evidence report review process, Task Force leads collaborate with the AHRQ Medical Officer to discuss and draft a preliminary recommendation statement.

8. Vote on Draft Recommendation Statement—USPSTF

The Task Force is presented with the peer-reviewed evidence report findings by the EPC and the preliminary recommendation statement by the Task Force leads at one of three annual meetings that include the USPSTF, AHRQ, the EPC, and representatives from the partner organizations. The entire Task Force, including the leads, discusses the evidence and debates the language of the recommendation statement until a consensus is reached and the statement passes a vote. The revised recommendation statement is then sent to Task Force leads for completion and editing prior to external review.

9. Final Evidence Report—EPC

The EPC revises the evidence report in response to comments from the federal partners, content area experts, and Task Force leads. The EPC then sends a summary of the comments and how the comments were addressed to AHRQ. AHRQ staff then review, approve, and finalize the revised evidence report. The EPC then prepares the finalized evidence report for submission to a peer-reviewed journal for publication. The final technical report is also made available on the AHRQ website.

10. Review of Draft Recommendation Statement—Federal and Primary Care Professional Organization Partners and the Public

The newly revised and approved recommendation statement is sent to relevant federal and primary care professional organization partners for review and comment. The statement is also posted on the AHRQ website for one month for public comment.

11. Approval of Final Recommendation Statement—USPSTF

Task Force leads edit the recommendation statement on the basis of the comments received from the federal and primary care professional organization partners and the public after discussion with the AHRQ Medical Officer.

12. Release of Recommendation Statement and Evidence Report—Peer-Reviewed Journals

Recommendation statements and the accompanying EPC evidence report-derived manuscript are often published simultaneously in the professional journals *Annals of Internal Medicine* (adult topics) or *Pediatrics* (child/adolescent topics) and must go through the respective journal's peer-review process before publication. They are occasionally published in other journals (USPSTF, 2008b).

Preventive services relevant to women that have a grade of A or B from the USPSTF are listed in Table 2-2.

TABLE 2-2 USPSTF Preventive Services Relevant to Women That Have a Grade of A or B

Topic	Description	Grade
Alcohol misuse counseling	The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.	B
Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B
Aspirin to prevent cardiovascular disease (CVD): women	The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.	A
Bacteriuria screening: pregnant women	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A
Blood pressure screening	The USPSTF recommends screening for high blood pressure in adults aged 18 and older.	A
BRCA screening, counseling about	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.	B
Breast cancer preventive medication	The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention.	B
Breast cancer screening[a]	The USPSTF recommends screening mammography for women, with or without clinical breast examination, every 1–2 years for women aged 40 and older.	B
Breastfeeding counseling	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B

TABLE 2-2 Continued

Topic	Description	Grade
Cervical cancer screening	The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix.	A
Chlamydial infection screening: non-pregnant women	The USPSTF recommends screening for chlamydial infection for all sexually active non-pregnant young women aged 24 and younger and for older non-pregnant women who are at increased risk.	A
Chlamydial infection screening: pregnant women	The USPSTF recommends screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk.	B
Cholesterol abnormalities screening: women 45 and older	The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease.	A
Cholesterol abnormalities screening: women younger than 45	The USPSTF recommends screening women aged 20 to 45 for lipid disorders if they are at increased risk for coronary heart disease.	B
Colorectal cancer screening	The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.	A
Depression screening: adolescents	The USPSTF recommends screening of adolescents (12–18 years of age) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B
Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B
Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B

continued

TABLE 2-2 Continued

Topic	Description	Grade
Folic acid supplementation	The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.	A
Gonorrhea screening: women	The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors).	B
Healthy diet counseling	The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.	B
Hepatitis B screening: pregnant women	The USPSTF strongly recommends screening for hepatitis B virus infection in pregnant women at their first prenatal visit.	A
Human immunodeficiency virus (HIV) screening	The USPSTF strongly recommends that clinicians screen for HIV all adolescents and adults at increased risk for HIV infection.	A
Obesity screening and counseling: adults	The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.	B
Osteoporosis screening: women	The USPSTF recommends screening for osteoporosis in women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors.	B
Rh incompatibility screening: first pregnancy visit	The USPSTF strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	A

TABLE 2-2 Continued

Topic	Description	Grade
Rh incompatibility screening: 24–28 weeks gestation	The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24–28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	B
Sexually transmitted infections (STIs) counseling	The USPSTF recommends high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs.	B
Tobacco use counseling and interventions: non-pregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A
Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.	A
Syphilis screening: non-pregnant persons	The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A
Syphilis screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A

[a] HHS, in implementing ACA under the standard that it sets out in revised Section 2713(a)(5) of the Public Health Service Act, uses the 2002 recommendation on breast cancer screening of the USPSTF.
SOURCE: USPSTF, 2010b.

BRIGHT FUTURES—AMERICAN ACADEMY OF PEDIATRICS

The HHS Health Resources and Services Administration's Maternal and Child Health Bureau established the Bright Futures project in 1990 with the mission to "promote and improve the health, education, and well-being of infants, children, adolescents, families, and communities" (AAP, 2008). It is a "set of principles, strategies, and tools that are theory based and system oriented that can be used to improve the health and well-being of all children through culturally appropriate interventions that address the

current and emerging health promotion needs at the family, clinical practice, community, health system, and policy levels" (AAP, 2008). The most recent report, published in 2008, was developed through the collaborative efforts of four multidisciplinary panels consisting of experts in health during infancy, early childhood, middle childhood, and adolescence and was then reviewed by more than 1,000 educators, public health and health care professionals, child health advocates, and parents.

Bright Futures Methodology

The Bright Futures Steering Committee used three approaches to develop its guidance and recommendations and described these approaches as follows:

1. "Multidisciplinary Expert Panels were convened to write recommendations for Bright Futures visit priorities, the physical examination, anticipatory guidance, immunizations, and universal and selective screening topics for each age and stage of development. In carrying out this task, the Expert Panels were charged with examining the evidence for each recommendation, and evidence was an important consideration in the guidance they provided. However, lack of evidence was sometimes problematic for the physical examination (the elements of which can be considered screening interventions) and for counseling interventions. For these components, the Expert Panels relied on an indirect approach buttressed by their expertise and clinical experience" (AAP, 2008).
2. A Bright Futures Evidence Panel, composed of consultants who are experts in finding and evaluating evidence from clinical studies, was convened to examine studies and systematic evidence reviews and to develop a method of informing readers about the strength of the evidence.

> The Evidence Panel conducted literature searches for key questions using the MEDLINE® database of the National Library of Medicine. Key themes were searched in the Medical Subject Headings (MeSH) database to determine the most appropriate search terms. Searches were limited to clinical trials, meta-analyses, and randomized controlled trials. Other limits included English language and designations for age, when appropriate. Standardized terms were used for counseling (i.e., counseling, primary prevention, health promotion, health education, and patient education) and for screening (i.e., mass screening and risk assessment). The Evidence Panel also used the systematic

> evidence reviews performed for the USPSTF and the Cochrane Collaboration [the publisher of *Cochrane Reviews* of primary research in human health care and health policy]. This approach was by no means exhaustive, but it did provide an assessment of the most relevant literature. (AAP, 2008)

3. "Throughout the Guidelines development process, the Project Advisory Committee and Expert Panels consulted with individuals and organizations with expertise and experience in a wide range of topic areas. The entire Guidelines document also underwent public review twice in 2004 and once in 2006. More than 1,000 reviewers, representing national organizations concerned with infant, child, and adolescent health and welfare, provided nearly 3,500 comments. The contributions of these reviewers provided an opportunity to refine the guidelines and strengthen the scientific base for the guidance provided" (AAP, 2008).

Bright Futures describes its guidelines as "evidence informed rather than fully evidence driven" (AAP, 2008) and takes a broader view of prevention that is less focused on specific conditions and more on general health guidance (e.g., aggregating services into health supervision visits and extensive anticipatory guidance). Like the USPSTF, Bright Futures does not directly comment on insurance coverage, but unlike the USPSTF, Bright Futures does not have categories regarding services comparable to "C" or "I" grades that do not definitively recommend for or against a particular service. Bright Futures intends to leave no gaps in its recommendations, supplementing the evidence where needed with experience and expert opinion so that clinical guidance is always provided. Figures 2-1, 2-2, and 2-3 present the Bright Futures recommendations for adolescents and outline the preventive services that are covered for adolescent women in the ACA. In addition to the information in the tables shown in Figures 2-1 to 2-3, Bright Futures also provides extensive anticipatory guidance on a range of health matters in the context of discussing health issues with adolescents. These measures do not provide action steps and are not suitable for summary in a structured format.

Physical Examination

A complete physical examination is included as part of every health supervision visit.

When performing a physical examination, the health care professional's attention is directed to the following components of the exam that are important for 11- to 14-year-olds:

- **Measure:**
  - Blood pressure
- **Measure and plot:**
  - Height
  - Weight
- **Calculate and plot:**
  - BMI
- **Skin**
  - Inspect for acne, acanthosis nigricans, atypical nevi, tattoos, piercings, and signs of abuse or self-inflicted injury
- **Spine**
  - Examine back
- **Breast**

  Female
  - Assess sexual maturity rating

  Male
  - Observe for gynecomastia
- **Genitalia**

Female
- Perform visual inspection for sexual maturity rating and observation for signs of STIs (eg, warts, vesicles, vaginal discharge)
- Perform pelvic exam, if clinically warranted, based on sexual activity (eg, for Pap smear within 3 years of onset of sexual activity) and/or specific problems (eg, pubertal aberrancy, abnormal bleeding, abdominal or pelvic pain)

Male
- Perform visual inspection for sexual maturity rating and observations for signs of STIs (ie, warts, vesicles)
- Examine testicles for hydrocele, hernias, varicocele, or masses

Screening

UNIVERSAL SCREENING	ACTION	
Vision (once in early adolescence)	Snellen test	
SELECTIVE SCREENING	**RISK ASSESSMENT***	**ACTION IF RA +**
Vision at other ages	+ on risk screening questions	Snellen test
Hearing	+ on risk screening questions	Audiometry
Anemia	+ on risk screening questions	Hemoglobin or hematocrit
Tuberculosis	+ on risk screening questions	Tuberculin skin test
Dyslipidemia	+ on risk screening questions and not previously screened with normal results	Lipid screen
STIs	Sexually active	Screen for chlamydia and gonorrhea; use tests appropriate to the patient population and clinical setting
	Sexually active and + on risk questions	Syphilis blood test HIV†
Pregnancy	Sexually active without contraception, late menses, or amenorrhea	Urine hCG
Cervical dysplasia	Sexually active, within 3 years of onset of sexual activity	Pap smear, conventional slide or liquid-based
Alcohol or drug use	+ on risk screening questions	Administer alcohol and drug screening tool

*See Rationale and Evidence chapter for the criteria on which risk screening questions are based.

†The CDC has recently recommended universal voluntary HIV screening for all sexually active people, beginning at age 13. At the time of publication, the AAP and other groups had not yet commented on the CDC recommendation, nor recommended screening criteria or techniques. The health care professional's attention is drawn to the voluntary nature of screening and that the CDC allows an opt out in communities where the HIV rate is <0.1%. The management of positives and false positives must be considered before testing.

FIGURE 2-1 Adolescence 11–14 year visits.
ABBREVIATIONS: AAP = American Academy of Pediatrics; BMI = body mass index; CDC = Centers for Disease Control and Prevention; hCG = human chorionic gonadotropin; HIV = human immunodeficiency virus; RA = risk assessment; STI = sexually transmitted infection.
SOURCE: AAP, 2008. Used with permission of the American Academy of Pediatrics, Bright Futures—Guidelines for Health Supervision of Infants, Children, and Adolescents, Third Edition, American Academy of Pediatrics, 2008.

Physical Examination

A complete physical examination is included as part of every health supervision visit.

When performing a physical examination, the health care professional's attention is directed to the following components of the exam that are important for 15- to 17-year-olds:

- **Measure:**
  - Blood pressure
- **Measure and plot:**
  - Height
  - Weight
- **Calculate and plot:**
  - BMI
- **Skin**
  - Inspect for acne, acanthosis nigricans, atypical nevi, tattoos, piercings, and signs of abuse or self-inflicted injury
- **Spine**
  - Examine back
- **Breast**

  Female
  - Assess sexual maturity rating

  Male
  - Observe for gynecomastia
- **Genitalia**

Female
- Perform visual inspection for sexual maturity rating and observation for signs of STIs (eg, warts, vesicles, vaginal discharge)
- Perform pelvic exam, if clinically warranted, based on sexual activity (eg, for Pap smear within 3 years of onset of sexual activity) and/or specific problems (eg, pubertal aberrancy, abnormal bleeding, abdominal or pelvic pain)

Male
- Perform visual inspection for sexual maturity rating and observations for signs of STIs (ie, warts, vesicles)
- Examine testicles for hydrocele, hernias, varicocele, or masses

Screening

UNIVERSAL SCREENING	ACTION	
Vision (once in middle adolescence)	Snellen test	
SELECTIVE SCREENING	**RISK ASSESSMENT***	**ACTION IF RA +**
Vision at other ages	+ on risk screening questions	Snellen test
Hearing	+ on risk screening questions	Audiometry
Anemia	+ on risk screening questions	Hemoglobin or hematocrit
Tuberculosis	+ on risk screening questions	Tuberculin skin test
Dyslipidemia	+ on risk screening questions and not previously screened with normal results	Lipid screen
STIs	Sexually active	Screen for chlamydia and gonorrhea; use tests appropriate to the patient population and clinical setting
	Sexually active and + on risk questions	Syphilis blood test HIV†
Pregnancy	Sexually active without contraception, late menses, or amenorrhea	Urine hCG
Cervical dysplasia	Sexually active, within 3 years of onset of sexual activity	Pap smear, conventional slide or liquid-based
Alcohol or drug use	+ on risk screening questions	Administer alcohol and drug screening tool

*See Rationale and Evidence chapter for the criteria on which risk screening questions are based.

†The CDC has recently recommended universal voluntary HIV screening for all sexually active people, beginning at age 13. At the time of publication, the AAP and other groups had not yet commented on the CDC recommendation, nor recommended screening criteria or techniques. The health care professional's attention is drawn to the voluntary nature of screening and that the CDC allows an opt out in communities where the HIV rate is <0.1%. The management of positives and false positives must be considered before testing.

FIGURE 2-2 Adolescence 15–17 year visits.
ABBREVIATIONS: AAP = American Academy of Pediatrics; BMI = body mass index; CDC = Centers for Disease Control and Prevention; hCG = human chorionic gonadotropin; HIV = human immunodeficiency virus; RA = risk assessment; STI = sexually transmitted infection.
SOURCE: AAP, 2008. Used with permission of the American Academy of Pediatrics, Bright Futures—Guidelines for Health Supervision of Infants, Children, and Adolescents, Third Edition, American Academy of Pediatrics, 2008.

Physical Examination

A complete physical examination is included as part of every health supervision visit.

When performing a physical examination, the health care professional's attention is directed to the following components of the exam that are important for 18- to 21-year-olds:

- **Measure:**
  - Blood pressure
- **Measure and plot:**
  - Height
  - Weight
- **Calculate and plot:**
  - BMI
- **Skin**
  - Inspect for acne, acanthosis nigricans, atypical nevi, tattoos, piercings, and signs of abuse or self-inflicted injury
- **Breast**

Female
- Clinical Breast Examination is considered routine after age 20.

- **Genitalia**

Female
- Inspect for signs of STIs (eg, warts, vesicles, vaginal discharge)
- Perform pelvic exam by age 21 or if clinically warranted, based on sexual activity (eg, for Pap smear within 3 years of onset of sexual activity) and/or specific problems (eg, pubertal aberrancy, abnormal bleeding, abdominal or pelvic pain)

Male
- Perform visual inspection for sexual maturity rating and observations for signs of STIs (ie, warts, vesicles)
- Examine testicles for hydrocele, hernias, varicocele, or masses

Screening

UNIVERSAL SCREENING	ACTION	
Vision (once in late adolescence)	Snellen test	
Dyslipidemia (once in late adolescence)	A fasting lipoprotein profile (total cholesterol, LDL choesterol, high density lipoprotein (HCL), cholesterol, and triglyceride). If the testing opportunity is non-fasting, only total cholesterol and HDL cholesterol will be usable.	
SELECTIVE SCREENING	**RISK ASSESSMENT***	**ACTION IF RA +**
Vision at other ages	+ on risk screening questions	Snellen test
Hearing	+ on risk screening questions	Audiometry
Anemia	+ on risk screening questions	Hemoglobin or hematocrit
Tuberculosis	+ on risk screening questions	Tuberculin skin test
Dyslipidemia	If not age 20, + on risk screening questions and not previously screeened with normal resaults	Lipid screen
STIs	Sexually active	Screen for chlamydia and gonorrhea; use tests appropriate to the patient population and clinical setting
	Sexually active and + on risk questions	Syphilis blood test HIV†
Pregnancy	Sexually active without contraception, late or absent menses, or heavy or irregular bleeding	Urine hCG
Cervical dysplasia	Sexually active, within 3 years of onset of sexual activity	Pap smear, conventional slide or liquid-based
Alcohol or drug use	+ on risk screening questions	Administer alcohol and drug screening tool

*See Rationale and Evidence chapter for the criteria on which risk screening questions are based.

†The CDC has recently recommended universal voluntary HIV screening for all sexually active people, beginning at age 13. At the time of publication, the AAP and other groups had not yet commented on the CDC recommendation, nor recommended screening criteria or techniques. The health care professional's attention is drawn to the voluntary nature of screening and that the CDC allows an opt out in communities where the HIV rate is <0.1%. The management of positives and false positives must be considered before testing.

FIGURE 2-3 Adolescence 18–21 year visits.
ABBREVIATIONS: AAP = American Academy of Pediatrics; BMI = body mass index; CDC = Centers for Disease Control and Prevention; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; LDL = low-density lipoprotein; RA = risk assessment; STI = sexually transmitted infection.
SOURCE: AAP, 2008. Used with permission of the American Academy of Pediatrics, Bright Futures—Guidelines for Health Supervision of Infants, Children, and Adolescents, Third Edition, American Academy of Pediatrics, 2008.

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

ACIP is the sole federal government entity that provides written recommendations for delivering vaccines to children and adults in the general population. It provides guidance and recommendations to HHS and the CDC on matters regarding the approval, administration, and safety of vaccines. Its goal is to reduce the prevalence of vaccine-preventable diseases in the United States and bolster the safe use of vaccines and other related biological products. ACIP is comprised of 15 voting immunization-related experts and 34 other representatives from liaison organizations and federal agencies that oversee national immunizations programs (CDC, 2011a).

ACIP Methodology

The ACIP General Recommendations Work Group (GRWG) revises the *General Recommendations on Immunization* every 3 to 5 years. Relevant topics are those identified by ACIP to be topics that relate to all vaccines, including timing and spacing of doses, vaccine administration procedures, and vaccine storage and handling. New topics are often added when ACIP decides that previous ACIP statements on general issues, such as combination vaccines, adolescent vaccination, and adult vaccination, should be revised and combined with the *General Recommendations on Immunization* (CDC, 2011b).

The recommendations in the 2011 GRWG report are based not only on available scientific evidence but also on expertise that comes directly from a diverse group of health care providers and public health officials. GRWG includes "professionals from academic medicine (pediatrics, family practice, and pharmacy); international (Canada), federal, and state public health professionals; and a member of the nongovernmental Immunization Action Coalition" (CDC, 2011b).

ACIP committee work groups comprising an ACIP member chair, a CDC subject-matter expert, and at least two ACIP members meet during the year to perform analyses of vaccine-related data and generate potential policy recommendations to be presented to the committee. These analyses include review of the available scientific literature on the immunizing agent, morbidity and mortality from the disease in the U.S. population, recommendation statements issued by other professional organizations, results of clinical trials with the immunizing agent, cost-effectiveness projections, and the feasibility of incorporating the vaccine into preexisting U.S. immunization programs. Draft recommendations are then subjected to further review by the FDA, CDC, ACIP members, external expert consultants, and other relevant federal agencies. Work group findings and potential recommendations are presented to ACIP at one of three annual open meetings and

are deliberated upon by the committee. Public comments are heard at the meetings and taken into consideration during the deliberations. A majority vote is then conducted to pass a recommendation that includes guidance regarding the route of administration and dosing intervals, contraindications and precautions, and target groups for immunization. Recommendations are published on the ACIP website and in *Morbidity and Mortality Weekly Report* (Smith et al., 2009).

ACIP functions in a unique position because its recommendations are relevant to the general population and to some quite specific subpopulations, but its recommendations focus on efficacy and safety for intended populations. Some of its recommendations are not intended for general clinical use (e.g., recommendations for international travelers), are not intended for the entire population (e.g., recommendations for high-risk groups such as health care workers), or require specific guidance in footnotes for special circumstances (e.g., allergies and immunosuppression).

Table 2-3 lists the FDA-Licensed Combination Vaccines, and Table 2-4 lists ACIP-recommended vaccines that are covered without cost sharing as part of the ACA.

TABLE 2-3 FDA-Licensed Combination Vaccines

Vaccine	Trade Name (Year Licensed)	Age Range	Routinely Recommended Ages
HepA-HepB	Twinrix (2001)	≥18 years	Three doses on a schedule of 0, 1, and 6 months
MMRV	ProQuad (2005)	12 months–12 years	Two doses, the first at 12–15 months, the second at 4–6 years

ABBREVIATIONS: HepA = hepatitis A; HepB = hepatitis B; MMRV = measles, mumps, rubella, and varicella.
SOURCES: AAP, 2009; CDC, 2011.

TABLE 2-4 Recommended and Minimum Ages and Intervals Between Vaccine Doses

Vaccine and Dose Number	Recommended Age for This Dose	Minimum Age for This Dose	Recommended Interval to Next Dose	Minimum Interval to Next Dose
LAIV (intranasal)[a]	2–49 years	2 years	1 month	4 weeks
MCV4-1[b]	11–12 years	2 years	5 years	8 weeks
MCV4-2	16 years	11 years (+8 weeks)		
HPV-1[c]	11–12 years	9 years	2 months	4 weeks
HPV-2	11–12 years (+2 months)	9 years (+4 weeks)	4 months	12 weeks
HPV-3[d]	11–12 years (+6 months)	9 years (+24 weeks)		
Td	11–12 years	7 years	10 years	5 years
Tdap	11–12 years	7 years		

NOTE: Combination vaccines are available. Use of licensed combination vaccines is generally preferred to separate injections of their equivalent component vaccines. When combination vaccines, the minimum age for administration is the oldest age for any of the individual components; the minimum interval between doses is equal to the greatest interval of any of the individual components. Information on traveler vaccines, including typhoid, Japanese encephalitis, and yellow fever, is available at http://www.cdc.gov/travel. Information on other vaccines that are licensed in the United States but not distributed, including anthrax and smallpox, is available at http://www.bt.cdc.gov.

ABBREVIATIONS: LAIV = live, attenuated influenza vaccine; MCV4 = quadrivalent meningococcal conjugate vaccine; HPV-1 to HPV-3 = human papillomavirus doses 1 to 3, respectively; Td = adult tetanus and diphtheria toxoids; Tdap = tetanus and reduced diphtheria toxoids and acellular pertussis vaccine (for adolescents and adults).

[a] One dose of influenza vaccine per season is recommended for most persons. Children aged < 9 years who are receiving influenza vaccine for the first time or who received only one dose the previous season (if it was their first vaccination season) should receive two doses this season.

[b] Revaccination with meningococcal vaccine is recommended for previously vaccinated persons who remain at high risk for meningococcal disease (CDC, 2009).

[c] Bivalent HPV vaccine is approved for females aged 10–25 years. Quadrivalent HPV vaccine is approved for males and females aged 9–26 years.

[d] The minimum age for HPV-3 is based on the baseline minimum age for the first dose (i.e., 108 months) and the minimum interval of 24 weeks between the first and third doses. Dose 3 need not be repeated if it is administered at least 16 weeks after the first dose.

SOURCES: AAP, 2009; CDC, 2011b.

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3

Existing Coverage Practices of National, State, and Private Health Plans

Before passage of the Patient Protection and Affordable Care Act of 2010 (ACA), little standardization of the preventive services covered by both private and public payers existed. Historically, in the private sector, the extent of coverage for the preventive services that individuals receive and their exposure to out-of-pocket spending for these services have largely depended on the type of plan in which they are enrolled and the degree of cost sharing (including copayments and deductibles) that is part of the plan design. The passage of the ACA changed this variability by expanding federal requirements for plan benefits and limits on cost sharing for certain preventive services for private plans.

On September 23, 2010, the ACA preventive services requirements, detailed in Section 2713, went into effect. This section of the law adds to and amends the Public Health Services Act and the Employee Retirement Income Security Act and, as such, has jurisdiction over plans that are sold on the individual, small-group, and large-group markets by insurers as well as self-insured plans that are funded by employers.

These new rules require that private plans cover all United States Preventive Services Task Force (USPSTF) Grade A and B recommendations, all vaccinations recommended by the Advisory Committee for Immunization Practices (ACIP) of the Centers for Disease Control and Prevention, and Bright Futures recommendations for children from the American Academy of Pediatrics (see Chapter 2) and the preventive services for women that will be informed by the deliberations of this Institute of Medicine committee and subsequently identified by the U.S. Department of Health and Human Services (HHS).

Therefore, for the first time in U.S. history, federal rules stipulate the preventive services that private plans must cover and prohibit out-of-pocket payments for individuals who obtain these covered services from in-network providers (*Federal Register,* 2010a; HHS, 2010). Only new plans or those plans that change are affected by these new requirements.[1] Private plans that do not change their benefits or cost-sharing requirements are considered to be grandfathered and are not initially subject to the new requirements for the preventive services that must be covered.

HHS estimates that 78 million people enrolled in group plans and approximately 10 million people with individual policies will be subject to the prevention provisions in the ACA (HHS, 2010). These provisions will also apply to the plans that will be offered to consumers under the new state health insurance exchanges, although these exchanges and plans will not become operational until 2014.

This chapter reviews the policies and practices of private plans and publicly sponsored programs regarding the coverage before and after the enactment of the ACA of preventive services important to women. It describes the federal and state rules that are in effect today as well as identifies the types of plans or programs that will be affected by the new rules outlined in Section 2713 of the ACA.

RULES GOVERNING COVERAGE REQUIREMENTS BEFORE AND AFTER THE ACA

The coverage of preventive care provided under the individual and group markets and through self-funded employer health plans has been highly variable, differing by employer, insurer, and plan type. The Federal Employee Retirement and Income Security Act of 1974 regulates the coverage offered by self-insured or self-funded employer health plans as well as health insurance plans. An estimated 59 percent of covered workers are enrolled in self-insured group health plans (Claxton et al., 2010).

Federal Rules and Coverage Requirements

With few exceptions, federal rules do not specify what benefits plans must cover. The exceptions are that all self-funded employer health plans and health insurance issuers must offer coverage for a 48-hour hospital stay

[1] Plans will lose their "grandfather" status if, compared to March 23, 2010, they significantly cut or reduce benefits, raise co-insurance charges or significantly raise co-payment charges or deductibles, significantly reduce employer contributions, tighten annual limits on what insurers will pay, or change insurers. Plans that make any of these changes can be deemed to lose their grandfather status and will be required to follow the ACA preventive benefit coverage rules (*Federal Register*, 2010b).

after a vaginal delivery or a 96-hour stay after a delivery by cesarean section if they cover maternity care; mental health parity, which affects mental health care benefits and benefits for the treatment of substance use disorders; and benefits for breast reconstruction after a mastectomy and treatment of surgical complications for health plans that cover mastectomies.

In addition, the Pregnancy Discrimination Act of 1978 (P.L. 95-555), which amended Title VII of the Civil Rights Act of 1964, requires that employers with 15 or more employees treat women who are pregnant or affected by pregnancy-related conditions in the same manner that employers treat other workers or applicants. It requires that "any health insurance provided by an employer must cover expenses for pregnancy-related conditions on the same basis as costs for other medical conditions." An employer is "not required to provide health insurance for expenses arising from abortion, except where the life of the mother is endangered" (95th U.S. Congress, 1978). These payments must be paid for exactly like other medical conditions; and no additional, increased, or larger deductible can be imposed. Moreover, employers must provide the same level of health benefits for spouses of male employees as they do for spouses of female employees (95th U.S. Congress, 1978).

In 2000, a ruling by Equal Employment Opportunity Commission (EEOC) found that employers that offered plans that provided coverage for drugs, devices, and preventive care but that did not include coverage for preventive contraceptives to be in violation of the Pregnancy Discrimination Act (EEOC, 2000). Although this ruling was upheld by a federal district court in the state of Washington (*Erickson v. Bartell Drug Co.*), the U.S. Court of Appeals for the 8th Circuit (No. 06-1706, 2007 WL 763842) ruled in a 2-to-1 decision that an employer may exclude contraception coverage from its health plan without violating the Pregnancy Discrimination Act because the employer also failed to cover condoms and vasectomies that affect men (2007). Despite this ruling, the EEOC finding still stands, and the vast majority of health plans cover contraceptives, and in 2002, more than 89 percent of insurance plans covered contraceptive methods (Sonfield et al., 2004). A more recent (2010) survey of employers found that 85 percent of large employers and 62 percent of small employers covered Food and Drug Administration-approved contraceptives (Claxton et al., 2010).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 permits individuals enrolled in high-deductible health plans to make tax-favored contributions to health savings accounts (HSAs). These plans may provide preventive care benefits without a deductible or with a separate deductible below the minimum plan deductible. In 2010, 93 percent of high-deductible health plans with HSAs covered preventive services without having to meet the deductible (Claxton et al., 2010). In 2004, the Internal Revenue Service (IRS) issued a bulletin that identified certain

TABLE 3-1 IRS-Defined Preventive Care Screening Services

Preventive Care Screening Service
Cancer
Breast cancer (e.g., mammogram)
Cervical cancer (e.g., Pap smear)
Colorectal cancer
Prostate cancer (e.g., prostate-specific antigen test)
Skin cancer
Oral cancer
Ovarian cancer
Testicular cancer
Thyroid cancer
Heart and Vascular Diseases
Abdominal aortic aneurysm
Carotid artery stenosis
Coronary heart disease
Hemoglobinopathies
Hypertension
Lipid disorders
Infectious Diseases
Bacteriuria
Chlamydial infection
Gonorrhea
Hepatitis B virus infection
Hepatitis C
Human immunodeficiency virus (HIV) infection
Syphilis
Tuberculosis
Mental Health Conditions and Substance Abuse
Dementia
Depression
Drug abuse
Problem drinking
Suicide risk
Family violence
Metabolic, Nutritional, and Endocrine Conditions
Anemia, iron deficiency
Dental and periodontal disease
Diabetes mellitus
Obesity in adults
Thyroid disease
Musculoskeletal Disorders
Osteoporosis
Obstetric and Gynecologic Conditions
Bacterial vaginosis in pregnancy
Gestational diabetes mellitus
Home uterine activity monitoring
Neural tube defects
Preeclampsia
Rh incompatibility
Rubella
Ultrasonography in pregnancy
Pediatric Conditions
Child developmental delay
Congenital hypothyroidism
Lead levels in childhood and pregnancy
Phenylketonuria
Scoliosis, adolescent idiopathic
Vision and hearing disorders
Glaucoma
Hearing impairment in older adults
Newborn hearing

NOTE: Services that are important to women as well as those that disproportionately or differentially affect women are indicated by boldface italic type.
SOURCE: IRS, 2004.

preventive services that are allowed to be included in these plans, which include, but are not limited to, the services listed in Table 3-1.

State Coverage Requirements

The business of insurance is regulated at the state level, and state requirements for the preventive services that health plans must cover vary

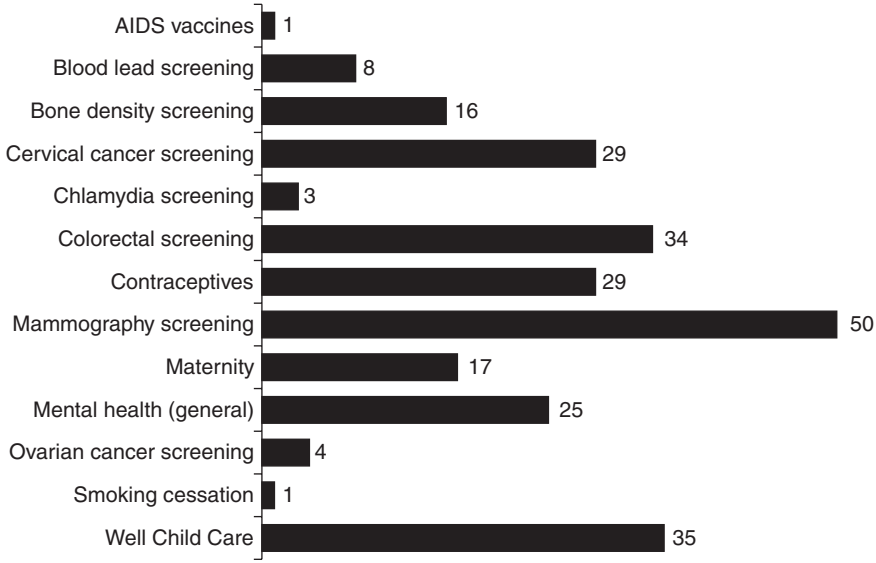

FIGURE 3-1 State-mandated preventive benefits of importance to adult women, 2010.
SOURCE: BlueCross BlueShield Association, 2010.

considerably (Figure 3-1).[2] In recent years, state lawmakers have enacted a wide range of mandates for different types of health care services. The reach of these benefit mandates is limited, however, as they apply only to insurance plans that are sold to employers and individuals in the state and do not apply to self-funded employer health plans, which are plans that provide coverage for the majority of the employer's workers and their dependents.

All states, with the exception of Utah, require plans to cover mammography screening, 29 states require coverage of cervical cancer, and 29 require coverage of contraception (Bluecross Blueshield Association, 2010). Far fewer states require bone density screening (16 states), maternity care (17 states in the case of the individual market), and screening for chlamydia infection (3 states). It also worth noting that some states require coverage for preventive services that do not yet exist, such as an AIDS vaccine and ovarian cancer screening.

[2] Many different organizations collect this information, including the BlueCross BlueShield Association, the National Association of Health Commissioners, the Council for Affordable Health Insurance, and the National Conference of State Legislatures. Figure 3-1 is presented to show the variability in coverage by state rather than an exact count of the laws that states currently have in place.

How these mandates are structured also differ substantially. For example, they can be legislated to affect the benefits that different types of insurance markets (small- or large-group plans or the individual market) must cover, what they must offer to sell (but not necessarily cover), the type of plan that is included (e.g., health maintenance organizations [HMOs]), the target populations for the service, and the periodicity of the service. Many, but not all, of these benefits are now covered under the new ACA preventive coverage rules without any cost sharing. Nevertheless, the ACA preventive care rules do not supersede state requirements. This means that for states that have coverage mandates for preventive services that are broader than the list of services required to be covered by Section 2713 of the ACA, insurance plans that sell policies in those states must still offer coverage for those services, in addition to the services required by the ACA.[3]

Although many states have coverage mandates or specific benefit requirements, 12 states have also required plans that sell on the individual and small-group markets to offer standardized benefit packages (KFF, 2009b). These standardized policies generally include a class of services and outline cost-sharing requirements. They were intended to facilitate the comparison of different plans for consumers and to make it harder for insurers to design benefit packages that are attractive to healthy individuals and avoid drawing those with health problems. In most states, insurers must offer the standardized plans but can also sell other types of plans (KFF, 2009b).

The benefit package that the commonwealth of Massachusetts requires, however, is a notable exception and does provide detailed coverage information. In 2006, the commonwealth of Massachusetts passed Chapter 58, the health reform law. This law combines the concept of individual responsibility through an individual mandate, which requires that individuals purchase health insurance that meets minimum standards developed by the state (creditable coverage). To ensure affordability, however, government subsidies are provided. This law created multiple public and private health insurance pathways and initiated a system of shared responsibility among the stakeholders in health care provision. Chapter 58 also created a health insurance exchange, known as the Commonwealth Connector, to make health coverage available to residents and to regulate the insurance products offered through the exchange to ensure that individuals have minimum creditable coverage. The reforms enacted by the commonwealth of Massachusetts served as a model for the ACA.

[3] When the federal subsidies for individuals to purchase coverage through the insurance exchanges become available, the costs of any benefits mandated by the states that exceed those specified in federal law will have to be funded by the states for those receiving subsidies. Given this new cost, it is possible that some states will eliminate these mandated benefits, at least in the individual market.

Although the overall rate of insurance coverage in Massachusetts before passage of the legislation exceeded 90 percent, since enactment, numerous subgroups of women have experienced substantial gains in coverage. In particularly, ethnic and racial minorities, low-income women, women without dependent children, and nonelderly women aged 50 to 64 years have experienced substantial gains in coverage, such that coverage is nearly universal for these subgroups of women (Long et al., 2010).

The preventive services benefits for women that plans must offer to be considered to have minimum creditable coverage are based on the recommendations for adults issued by the Massachusetts Health Quality Partners (MHQP) and other nationally recognized guidelines (Hyams and Cohen, 2010; MHQP, 2007). MHQP recommendations closely mirror those of the USPSTF but also include the coverage of preventive services such as counseling for preconception and menopause management and treatment for menopause.

According to the ACA, the new coverage rules for private plans in Massachusetts will be subject to the requirements of Section 2713, although the coverage may be broader than that included in the state law.[4] In addition, the Chapter 58 rules state that plans must cover at least three preventive visits without applying the costs for those visits to the deductible (but copayments may exist) and require that contraceptive services and supplies be covered as preventive services without cost sharing.

Private Insurance Coverage Practices

Detailed information on the coverage and benefits provided by private insurance plans and employers and on the scope of the preventive benefits that they cover is often proprietary and difficult to obtain. This information is enormously complex, and details about the coverage provided differ considerably from plan to plan and employer to employer. Although periodic surveys of employers of the health care benefits that they cover and reviews of documents that summarize the plans are performed, most surveys and reviews look at classes of services rather than the actual specific benefits provided.

In addition, research on this topic suffers from other limitations. The research is often conducted by researchers who are either funded by or who are employees of health plans or employer groups; the response rates for these surveys are usually low; and the respondents, who are typically employers, may not know the specific details about benefit coverage included

[4] Grandfathered plans, including those sold through the Commonwealth Connector, will not be subject to the new requirements unless and until they lose the grandfathered status discussed earlier.

in the plans that they have purchased. The following section highlights some of this research to provide some insights into the level of coverage and services provided by the private insurance sector but does not provide information on how plans and employers address cost sharing, copayments, and coinsurance for these specific services.

Employer-Based Health Plans

The Bureau of Labor Statistics' ongoing National Compensation Survey (DOL, 2011) surveyed approximately 3,900 employers with the aim of providing comprehensive data on employment-based health care benefits. A supplemental analysis of approximately 3,200 plan documents, including summary descriptions of the plans and other short summaries or comparison charts, was conducted to look at the extent of coverage of certain health benefits. When coverage or exclusion of a specific benefit by a plan is specifically mentioned, it is noted. For many of the benefits reviewed, coverage for particular services was mentioned one way or the other, but it is possible that the services would be covered for the workers.

The data on preventive care are limited but indicate that 56 percent of participants were in plans that identified coverage for adult immunizations and inoculations, 80 percent were in plans that covered adult physical examinations, and 77 percent were in plans that covered well-baby care. Gynecological examinations and services, such as pelvic examinations and Pap smears were covered for 60 percent of participants of employer-based health plans, usually under headings such as "well-woman exams." However, these services were often subject to plan or separate limits, and copayments were commonly required. Plans often limited the number of examinations per year and the dollar amount on the services covered during examinations.

Sterilization was not mentioned in the coverage documents for the employer-based health plans of more than 70 percent of participants. However, when it was mentioned, approximately 90 percent of participants were in plans that cover sterilization. Coverage for maternity care was also not uniformly identified by the plans. Sixty-six percent of workers were in plans that explicitly covered maternity care, and only 6 percent of the workers in those plans had these benefits in full (virtually all of the remaining third of workers were in plans that did not specifically mention coverage for maternity care).

In 2001, Mercer Human Resource Consulting Inc. conducted the National Survey of Employer-Sponsored Health Plans, which had a special supplement on preventive care. More than 2,000 employers providing benefits to their employees completed the survey. The response rate was 21 percent. The survey uncovered significant differences in the preventive services covered. These differences were related to employer size, incentives, and extent of coverage (Bondi et al., 2006). Because only one-fifth of

employers offered their workers a choice of more than one plan, examination of the rates of coverage of clinical preventive services in the employer's primary plans provides the best summary of the ranges of rates of coverage for different services: 75 percent covered physical examinations, 74 percent covered gynecological examinations, 57 percent covered cholesterol screenings, and only 37 percent covered screening for *Chlamydia* infection.

For women, primary employer-based health plans covered breast cancer and cervical cancer screening at rates of 80 and 79 percent, respectively. Lifestyle modification services were covered at much lower rates, with nutritional counseling covered by 17 percent of primary plans, weight loss and management counseling was covered by 15 percent, physical activity counseling was covered by 13 percent, alcohol problem prevention was covered by 18 percent, and any kind of tobacco cessation service was covered by 20 percent.

Approximately half of all large employers required that their plans cover clinical preventive services, whereas only 17 percent of small employers had the same requirement. Small employers were also less likely to offer coverage of clinical preventive services and lifestyle modification services, although the differences were not large.

Large employers were far more likely than small employers to offer financial incentives to employees to use clinical preventive services. However, small employers offered flexible scheduling or time off to access preventive services much more often than large employers did. Lifestyle modification services, such as physical activity counseling and weight loss management, were covered the least often, regardless of employer size.

The National Business Group on Health conducted a comprehensive analysis and synthesis of a wide range of clinical preventive services and their impacts on disease prevention and early detection of health conditions and disease according to both health and economic measures (NBGH, 2009). On the basis of their analyses, they compiled a purchaser's guide that recommends 46 clinical preventive services that should be included in employer health benefit plans. Benefits directly relevant to women are summarized in Box 3-1.

Individual Insurance Plans

As with the small- and large-group insurance markets, the individual insurance market appears to have considerable variability in coverage of preventive services. In a 2006–2007 survey of individual insurance plans conducted by American's Health Insurance Plans, the trade association for health insurers in the United States (AHIP, 2007), coverage levels were found to vary considerably by type of plan, with all HMO plans responding to the survey indicating that they covered physical examinations for adults, annual visits to an obstetrician-gynecologist, and cancer screening; but far

BOX 3-1
National Business Group on Health's Recommended Benefits Directly Relevant to Women

Breast Cancer: Breast cancer screening should include clinical breast examination and an annual mammography (for women from ages 40 to 80 years and for younger women, if it was deemed medically indicated), assessment of a woman's genetic risk for breast cancer and testing for mutations in the *BRCA* breast cancer-associated gene for women at high risk, counseling, and preventive medication and treatment (i.e., tamoxifen) for women with a high risk of breast cancer or surgical removal of the breasts or ovaries.

Cervical Cancer: The purchaser's guide recommends coverage of conventional Pap smears. Plans are to use their own discretion on coverage for newer screening methods, including liquid-based, thin-layer preparations, computer-assisted screening, and tests for human papillomavirus infection for women beginning at age 21 years or within 3 years of onset of sexual activity through age 65 years and beyond for high-risk women. The guidelines recommends coverage for screening services at least once every three years and not more than once a year.

Contraceptive Use: The guidelines recommend coverage for counseling on contraceptive use at least once a year and when emergency contraception is provided for all beneficiaries aged 13 to 55 years. They also recommend coverage of the full range of Food and Drug Administration-approved contraceptives, including all hormonal medications, contraceptive devices, and voluntary sterilization.

Osteoporosis: The guidelines recommend screening and treatment for osteoporosis starting at age 65 years for women with a normal risk. High-risk women are eligible at age 60 years or earlier, if it is medically indicated, and not more than once every two calendar years. The screening tools recommended for coverage include the Osteoporosis Risk Assessment Instrument and the Simple Calculated Osteoporosis Risk Estimation tool, dual-energy X-ray absorptiometry, peripheral dual-energy X-ray absorptiometry, peripheral quantitative computed tomography, radiographic absorptiometry, single-energy absorptiometry, and ultrasound. All Food and Drug Administration-approved treatments for osteoporosis are covered for beneficiaries age 60 years and older who meet medical necessity criteria.

Pregnancy: Pregnant women should receive screening and counseling (up to eight interventions per calendar year) for alcohol misuse during pregnancy; urine culture for asymptomatic bacteriuria at between 12 and 16 weeks of gestation and subsequently as medically indicated; structured breastfeeding education and behavioral counseling for all pregnant and lactating women (in office, in the hospital, or at home after birth), without a limit on the number of sessions, provided that care is medically necessary; folic acid counseling and supplements; screening and medication for group B streptococcal disease; screening for hepatitis B virus infection and immunizations against hepatitis B virus; screening, counseling, and preventive medication for human immunodeficiency virus; influenza immuniza-

BOX 3-1 Continued

tions; screening for preeclampsia; prenatal screening and testing for neural tube defects (for all women at elevated risk) and chromosomal abnormalities (for all women aged 35 years and older), including, but not limited to amniocentesis, chorionic villus sampling, and ultrasound; Rh (D) blood typing and antibody and immunoglobulin testing; screening for rubella and syphilis; tetanus immunization; screening and treatment (counseling) for tobacco use; and screening, counseling, and treatment for hypertension.

Sexually Transmitted Infections: The guidelines recommend coverage for counseling to prevent sexually transmitted infections for all adolescents and adults. They also recommend screening for chlamydia infection and gonorrhea for all women aged 25 years and younger (and for older women, if it is medically indicated); screening and counseling for human immunodeficiency virus infection for all people aged 13 to 64 years; and an annual screening (and screening more frequently, if needed) for syphilis for all beneficiaries at risk of infection.

SOURCE: NBGH, 2009.

fewer HMOs covered contraceptives (39 percent for HMO plans for single individuals and 59 percent for HMO plans for families).

Coverage rates were lower for preferred provider organizations (PPOs) and point-of-service (POS) plans as well as high-deductible plans with HSAs or medical savings accounts (MSAs). The rate of coverage for physical examinations for adults ranged from 66 percent for PPO or POS plans for single individuals to 75 percent of plans with HSAs or MSAs for families. The rate of coverage for annual visits to an obstetrician-gynecologist was higher, ranging from a low of 82 percent for plans with HSAs and MSAs for families to a high of 96 percent for PPOs and POS plans for single individuals. Rates of coverage for cancer screenings ranged from 81 percent for HSAs and MSAs for families to 94 percent for PPOs and POS plans for single individuals. Coverage rates for oral contraceptives were also lower, ranging from 39 percent for HMOs for single individuals to 79 percent for PPOs and POS plans for single individuals.

Federal Employees Health Benefits Program

Millions of federal workers and their dependents receive their health insurance coverage through the Federal Employee Health Benefits (FEHB) program. The FEHB program purchases health insurance coverage through private plans for federal workers and their dependents. The preventive ser-

vices covered, provider networks, and out-of-pocket spending responsibilities for these private plans vary by state. According to the ACA, plans that are offered under the FEHB program either are or will be required to offer coverage of all services that are recommended by the USPSTF, the ACIP, and Bright Futures. The plans offered under the FEHB program either are or will be required to offer coverage for preventive services for women without cost sharing if the services are obtained from an in-network provider. In addition, since 1999, almost all FEHB program plans are required to cover all Food and Drug Administration-approved contraceptive supplies and devices (OPM, 1998).

Public-Sector Programs

The federal and state governments provide health coverage to a sizable share of the U.S. population through a wide range of programs. Nearly all seniors have primary coverage through Medicare, the federal program for those aged 65 years and over and individuals with permanent disabilities. In 2010, more than 66 million low-income individuals were covered by Medicaid, the federal-state program for low-income parents, children, seniors, and people with disabilities (MACPAC, 2011). The U.S. Department of Veterans Affairs (VA) provided health care services to 5.3 million veterans and their families in 2008 (VA, 2011a); and TRICARE, the health care plan for the U.S. military, serves millions of individuals in active-duty military service and their dependents, military retirees and their families, and other beneficiaries from any of the seven services. The Indian Health Service (IHS) covers nearly 2 million American Indians and Alaska Natives (IHS, 2011).

Although the ACA contains new rules for Medicare coverage of preventive services for beneficiaries and incentives for Medicaid to cover preventive services without cost sharing, the preventive services requirements that are promulgated under Section 2713 affect only private plans. The rules in Section 2713 only amend and add to the Public Health Services Act and the Federal Employee Retirement and Income Security Act and therefore do not affect the coverage offered by military health care programs, such as TRICARE and VA program, or the IHS. It is useful, however, to understand how these different programs have handled policies for coverage of preventive services important to women. These policies are detailed in the following sections.

Medicare

Medicare provides health care coverage for about 39 million seniors and 8 million people under age 65 years with permanent disabilities (KFF, 2010). About 56 percent of Medicare beneficiaries are women (KFF, 2009a).

Sections of the ACA other than those related to Medicare make many changes to the covered preventive services that are important to female Medicare beneficiaries. Before passage of the ACA, many preventive benefits important to women's health, such as mammography, clinical breast examinations, bone density tests, Pap smears, and pelvic examinations, were covered but required a 20 percent copayment; that is, Medicare covered only 80 percent of the full cost of these tests. The ACA requires that all Medicare beneficiaries receive coverage without copayments for those services that receive Grade A or B recommendations from the USPSTF, as well as coverage for all vaccines recommended by ACIP (111th U.S. Congress, 2010). This rule became effective on January 1, 2011.

All new Medicare beneficiaries have been eligible to receive a "welcome to Medicare" visit that is similar in scope to a wellness visit. The ACA broadened this benefit for beneficiaries to include a new annual wellness examination for all beneficiaries with no copayment (111th U.S. Congress, 2010). At this visit, the medical and family health histories are reviewed, basic health measurements are taken, a screening for the preventive services required is performed, and risk factors and treatment options are identified.

Although Medicare is typically considered a program for seniors, a sizable share of Medicare beneficiaries are nonelderly and qualify on the basis of a permanent disability. In 2009, about 850,000 disabled women under age 45 years were enrolled in Medicare (CMS, 2010). Women Medicare beneficiaries in this age group have reproductive health care needs but do not get coverage for contraceptive services or devices through Medicare Part A or B. They may get coverage, however, for oral contraceptive pills through their Medicare Part D prescription drug coverage. The extent of their out-of-pocket costs and the scope of coverage for prescriptions are largely dependent on the type of Part D drug plan that they select.

A growing share of Medicare beneficiaries are enrolled in managed care arrangements through Medicare Advantage plans. These plans can be more flexible in the types of benefits that they cover. Some cover services that are not part of the traditional Medicare benefit package, such as contraceptives, although the federal government has no requirement to cover such things. Medicare does not cover sterilization when it is not part of a necessary treatment for an illness or injury, nor would any payment be made for sterilization as a preventive measure. This includes the case when a primary care provider believes that pregnancy would cause overall endangerment to a woman's health or psychological well-being (CMS, 2011).

Medicaid

Medicaid, a program for certain low-income Americans jointly financed and operated by state and federal governments, offers coverage for many preventive services. Approximately 66 million individuals were covered by

Medicaid in 2010 (MACPAC, 2011). An estimated 30 million children in the United States are insured by Medicaid (KFF, 2011b), and it provides coverage for 40 percent of all births in the United States (Wier et al., 2010). With the exception of mandatory coverage for smoking cessation with no cost sharing for pregnant women (Section 4107), the ACA does not require that Medicaid cover preventive services with or without cost sharing. Rather, it includes an incentive for states to cover the services in the form of an increased 1 percent matching federal payment for these services to states that provide the recommended preventive services without cost sharing to their beneficiaries (Section 4106) (111th U.S. Congress, 2010). Figure 3-2 shows the numbers of states offering coverage for preventive services through Medicaid.

Today, Medicaid coverage of preventive services depends on the enrollees' age and state of residence. For children under age 21 years, the scope of coverage is comprehensive as a result of the Early Periodic Screening, Diagnostic, and Treatment Program. This mandatory program requires that

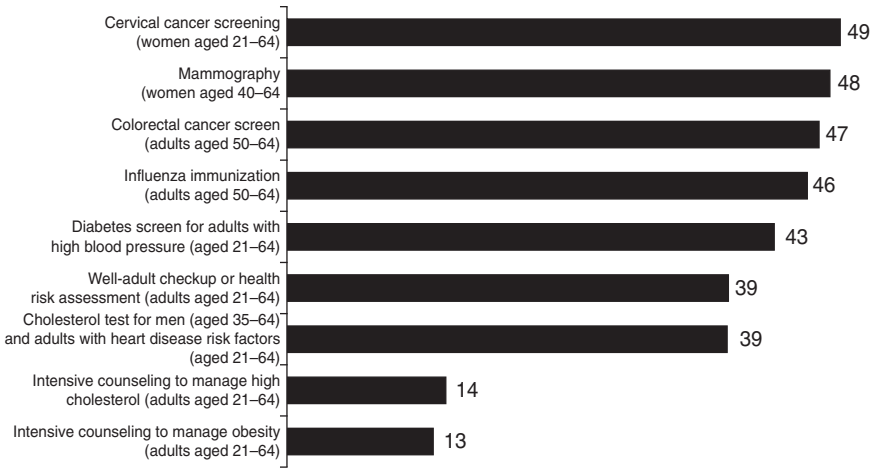

FIGURE 3-2 Number of state Medicaid programs that reported covering certain recommended preventive services for adults and health risk assessments or well-adult checkups. Although the USPSTF does not explicitly recommend well-adult checkups or health risk assessments for adults, such health care visits provide an opportunity to deliver recommended preventive services, such as blood pressure tests and obesity screenings. The data do not include the numbers for states that reported that a service is covered under the managed care program but not under the fee-for-service program.
SOURCE: Government Accountability Office analysis of survey of state Medicaid directors conducted between October 2008 and February 2009.

state Medicaid programs cover screening and diagnostic services, as well as the treatments needed to correct or improve the problems identified by the screening and diagnostic services. For children, the screening and preventive services typically include well-child visits, vision and dental screenings, and immunizations (CMS, 2005). State Medicaid programs are not permitted to charge cost sharing for services provided to children and pregnant women but may charge other eligible populations a nominal fee (SSA, 2011c).

For adults participating in Medicaid, preventive services are generally covered according to the recommendations of each state, but the preventive services for adults that the states cover vary considerably (GAO, 2009). For example, services such as cervical cancer screening and mammography were covered by nearly all state Medicaid programs, but far fewer states covered well-adult checkups or cholesterol tests (GAO, 2009). Coverage of screening and treatment for sexually transmitted infections is also typically included in almost all state Medicaid programs (Ranji et al., 2009a).

Family planning services, in contrast, are federally required for all states that participate in Medicaid. Since 1972, state Medicaid programs have been required to cover "family planning services and supplies furnished (directly or under arrangements with others) to individuals of childbearing age (including minors who can be considered to be sexually active), who are eligible under the State plan, and who desire such services and supplies" (SSA, 2011a). These services must be provided without cost sharing. In return, states receive a 90 percent federal match on the funds that they spend on these services (SSA, 2011b). All states provide coverage for family planning services and prescription contraceptive supplies, although coverage of nonprescription contraceptives, such as condoms and emergency contraceptives, and sterilization varies considerably from state to state (Ranji et al., 2009a).

Coverage of preconception counseling and other elements of preconception care are optional for state Medicaid programs and, as a result, are not as universally covered as contraceptives. Of the 44 states that responded to a 2008 Henry J. Kaiser Family Foundation survey, only 26 covered preconception counseling for women enrolled in Medicaid (Ranji et al., 2009a).

Medicaid is the largest payer of maternity services in the nation and provides coverage of a comprehensive range of pregnancy-related services for low-income women who qualify. These services, however, vary considerably from state to state. For example, in 2008, 24 out of 44 states responding to a national survey covered genetic counseling and 39 covered nutrition counseling and psychosocial counseling (Ranji et al., 2009b). Similarly, coverage of breastfeeding support services is also an optional Medicaid benefit and is more limited. Twenty-five of the 44 surveyed states covered breastfeeding education services, 15 states covered lactation con-

sultations, and 31 states covered breast pump rentals. Eight states did not cover any breastfeeding support services for women enrolled in Medicaid (Ranji et al., 2009b).

Children's Health Insurance Program

For low-income children whose family incomes exceed Medicaid eligibility levels, the Children's Health Insurance Program (CHIP) provides insurance coverage at generally affordable costs. Established in 1997, this federal block grant program to states provides state and federal funds to extend insurance coverage to low-income children. Each state may expand coverage by raising Medicaid income eligibility levels for families with children, establishing a separate state program, or designing a combination of the two approaches. In 2010, an estimated 7.7 million children and 347,000 parents and pregnant women who did not qualify for Medicaid were enrolled in CHIP at some point during the year (MACPAC, 2011).

CHIPs are prohibited from imposing cost sharing for well-baby and well-child care, including immunizations. Children who are covered through a CHIP Medicaid expansion option receive the same benefits as children who are covered through Medicaid. However, considerable variation in the scope of covered preventive services exists among the states, which operate separate programs. A 2001 review of CHIP coverage of reproductive health services conducted by the Guttmacher Institute found that of the 29 states that operated separate state programs, 16 specifically identified that family planning services and supplies were covered and most of the remaining plans covered these services through the general category "prenatal care and prepregnancy family planning services" (Gold and Sonfield, 2001). Most states also covered screening and treatment for sexually transmitted infections.

The 2008 CHIP Reauthorization Act made it easier for states to extend CHIP to cover pregnancy-related services through CHIP, and 18 states have done this either through extending eligibility to pregnant women or through a new option to extend eligibility to "unborn children" (KFF, 2011a). Like Medicaid, coverage for pregnant women under CHIP typically ends at 60 days postpartum. States that cover this group of women through the Medicaid expansion use Medicaid benefit rules.

U.S. Department of Veterans Affairs Health Care Services

The rising enlistment of women in active-duty military services has led to the growth in the numbers of women receiving care through VA. According to VA, women make up approximately 1.8 million of the nation's

23 million veterans and account for nearly 5.5 percent of veterans who use VA health care services (VA, 2011b).

The scope of care offered to women veterans is broad and includes the following preventive services important to women: health evaluation and counseling, disease prevention, nutrition counseling, weight control, smoking cessation, and substance abuse counseling and treatment, as well as gender-specific primary care, including Pap smears, mammogram, birth control, preconception counseling, human papillomavirus vaccine, and menopausal support (hormone replacement therapy). In addition, women receive coverage for "mental health, including evaluation and assistance for issues such as depression, mood, and anxiety disorders; intimate partner and domestic violence; sexual trauma; elder abuse or neglect; parenting and anger management; marital, caregiver, or family-related stress; and post-deployment adjustment or post-traumatic stress disorder (PTSD)" (VA, 2011b).

TRICARE

The U.S. Department of Defense operates TRICARE, a managed health care program for active-duty members of the military, families of active-duty service members, retirees and their families, and other beneficiaries from any of the seven services (TRICARE, 2011). Depending on their level of service, enrollees can choose from different coverage plans that have the same benefits but different provider networks and out-of-pocket spending requirements. TRICARE covers a broad range of preventive services for women enrollees, including contraceptive supplies, services, and sterilization; mammograms and physical breast examinations; counseling; maternity care; Pap smears (including human papillomavirus testing); and genetic testing.

Indian Health Service

American Indians and Alaska Natives who are members of federally recognized tribes are eligible to receive health care services without cost sharing though the IHS, which operates health care facilities on or near Indian reservations. Although a wide range of "health promotion and disease prevention services" (LII, 2010) are specified, the availability of the actual services for those using IHS services varies tremendously from region to region. Health promotion services whose provision is defined by Title 25 of the U.S. Code include smoking cessation, reduction in alcohol and drug misuse, improvement in nutrition, improvement in physical fitness, family planning, stress control, and pregnancy and infant care (including fetal alcohol syndrome prevention). The disease prevention services covered

under Title 25 include immunizations, control of high blood pressure, control of sexually transmitted diseases, prevention and control of diabetes, control of toxic agents, occupational safety and health, accident prevention, fluoridation of water, and control of infectious agents (LII, 2010). Screening mammography is also included as a covered benefit for women.

DISCUSSION

Growing attention to the importance of preventive care in both federal- and state-supported and private-sector plans has been seen in recent years. Despite this attention, coverage of preventive services in both the private and public sectors is uneven at best. Heavy reliance has been placed on the clinical guidance promulgated by the USPTSF, but adoption of the full range of services is still not the norm. Some programs and plans have provided more limited coverage, whereas others are broader in scope, providing coverage for preventive services like preconception counseling, contraceptive services and supplies, and well-woman visits, despite their absence from these recommendations. The ACA requirements will make important strides in ensuring that most Americans have coverage for the full range of recommended preventive services.

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4

Committee Methodology

This chapter outlines the methodology that the Institute of Medicine Committee on Preventive Services for Women used to identify preventive services necessary for women's health and well-being that are not included in the United States Preventive Services Task Force (USPSTF) Grade A and B recommendations, Bright Futures' recommendations, or the Advisory Committee on Immunization Practices (ACIP) guidelines and to identify specific services that could supplement the current list of preventive services recommended for women under the Patient Protection and Affordable Care Act of 2010 (ACA). The committee's first step in this process was to review and reach an understanding of the guidelines of these analytic bodies. The second step was to assemble and assess additional evidence, including reviews of the literature, federal health priority goals and objectives, federal reimbursement policies, and professional clinical guidelines. The committee also considered comments submitted by the public. Finally, the committee recommended preventive services that the Secretary of the U.S. Department of Health and Human Services (HHS) should consider in developing a comprehensive package of preventive services for women to be included under the ACA.[1]

REVIEW OF USPSTF RECOMMENDATIONS

The USPSTF process was developed to provide guidance to primary care providers. The committee's approach to identifying gaps in existing

[1] One committee member's dissenting comments regarding much of the study process are included in Appendix D.

services accounts for contextual issues beyond traditional research evidence used by the USPSTF. The committee looked at women's preventive service needs more broadly to account for women's health and well-being.

The committee found that the USPSTF Grade A and B recommendations required close examination. The specificity of several recommendations is not clear in some cases, including such details as the periodicity of screenings or how the service is to be delivered. For example, the Grade B recommendation for screening for depression could be interpreted to be universal screening, under the assumption that the primary care provider offices offering the service have adequate staff in place to support the correct delivery of the service, or the USPSTF's recommendation could be interpreted narrowly to include screening only in those practices that have a certified depression screening quality assurance program in place. Thus, after a review of the supporting evidence that led to their recommendations, the committee decided that it was important to note its interpretation of the Grade A and B recommendations in those cases in which specific aspects of the recommendation were found to be ambiguous (see Table 5-1). The committee also compared the USPSTF guidelines with the guidelines of other professional organizations to identify potential gaps.

The USPSTF Grade C and I statements (Table 4-1) also required further analysis by the committee because in neither case had the USPSTF intended its conclusions to limit or preclude consideration for coverage. The USPSTF informally refers to Grade C recommendations as close calls in which the balance of potential benefits and harms does not strongly favor the clinician recommending the preventive service to all patients, although it may be appropriate in some cases. The USPSTF makes the point that either choosing or not choosing the service with a Grade C recommendation would be within the standard of care and assumes that the service would be covered if clinically appropriate (USPSTF, 2008). The USPSTF also considers decision making to be a shared activity of the patient and the provider based on the individual circumstances of the patient.

The Grade I statement is a conclusion that the evidence is "insufficient to conclude whether the service is effective or not because evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined" (USPSTF, 2008). The I statement simply means that important outcomes have not yet been adequately evaluated by current research. The committee notes that from a coverage perspective, the evidence supporting many clinical interventions in common use, whether in prevention or in general medical practice, is insufficient or unclear, and that coverage decisions may be made or have been made on the basis of other factors. For example, although knowledge of the evidence for the benefits and harms of services and screenings informs a primary care provider's

TABLE 4-1 USPSTF Grade C Recommendations and I Statements

Topic	Description	Grade
Additional risk factors for intermediate coronary heart disease (CHD) risk: screening	The U.S. Preventive Services Task Force (USPSTF) concludes that the evidence is insufficient to assess the balance of benefits and harms of using the nontraditional risk factors discussed in this statement to screen asymptomatic men and women with no history of CHD to prevent CHD events (select "Clinical Considerations" for suggestions for practice when evidence is insufficient).	I
Avoidance of alcohol use counseling	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of routine counseling of all patients in the primary care setting to reduce driving while under the influence of alcohol or riding with drivers who are alcohol-impaired.	I
Back pain: counseling	The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of interventions to prevent low back pain in adults in primary care settings.	I
Bacterial vaginosis screening: pregnant women	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for bacterial vaginosis in asymptomatic pregnant women at high risk for preterm delivery.	I
Breast cancer screening	The USPSTF concludes that the evidence is insufficient to recommend for or against routine clinical breast examination alone to screen for breast cancer.	I
Cervical cancer screening	The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of new technologies to screen for cervical cancer.	I
Cervical cancer screening	The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of human papillomavirus (HPV) testing as a primary screening test for cervical cancer.	I
CHD risk assessment	The USPSTF concludes that the evidence is insufficient to assess the balance of benefits and harms of using the nontraditional risk factors discussed in this statement to screen asymptomatic men and women with no history of CHD to prevent CHD events	I
CHD screening	The USPSTF found insufficient evidence to recommend for or against routine screening with resting electrocardiography (ECG), exercise treadmill test (ETT), or electron-beam computerized tomography (EBCT) scanning for coronary calcium for either the presence of severe coronary artery stenosis (CAS) or the prediction of CHD events in adults at increased risk for CHD events.	I
Chlamydial infection screening: non-pregnant women	The USPSTF recommends against routinely providing screening for chlamydial infection for women aged 25 and older, whether or not they are pregnant, if they are not at increased risk.	C

continued

TABLE 4-1 Continued

Topic	Description	Grade
Cholesterol abnormalities screening	The USPSTF makes no recommendation for or against routine screening for lipid disorders in men aged 20 to 35, or in women aged 20 and older who are not at increased risk for coronary heart disease.	C
Colorectal cancer screening	The USPSTF concludes that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing as screening modalities for colorectal cancer.	I
Depression screening: adults	The USPTF recommends against routinely screening adults for depression when staff-assisted depression care supports are not in place. There may be considerations that support screening for depression in an individual patient.	C
Diabetes screening	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for type 2 diabetes in asymptomatic adults with blood pressure of 135/80 mm Hg or lower.	I
Diet counseling	The USPSTF concludes that the evidence is insufficient to recommend for or against routine behavioral counseling to promote a healthy diet in unselected patients in primary care settings.	I
Drug use screening	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening adolescents, adults, and pregnant women for illicit drug use.	I
Family violence screening	The USPSTF found insufficient evidence to recommend for or against routine screening of parents or guardians for the physical abuse or neglect of children, of women for intimate partner violence, or of older adults or their caregivers for elder abuse.	I
Gestational diabetes screening	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for gestational diabetes.	I
Glaucoma screening	The USPSTF found insufficient evidence to recommend for or against screening adults for glaucoma.	I
Gonorrhea screening: pregnant women	The USPSTF found insufficient evidence to recommend for or against routine screening for gonorrhea infection in pregnant women who are not at increased risk for infection.	I
Hepatitis B screening	The USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection.	I
Hepatitis C screening	The USPSTF found insufficient evidence to recommend for or against routine screening for HCV infection in adults at high risk for infection.	I

TABLE 4-1 Continued

Topic	Description	Grade
Human immunodeficiency virus (HIV) screening	The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection	C
Lung cancer screening	The USPSTF concludes that the evidence is insufficient to recommend for or against screening asymptomatic persons for lung cancer with either low dose computerized tomography (LDCT), chest X-ray (CXR), sputum cytology, or a combination of these tests.	I
Motor vehicle restraint counseling	The USPSTF concludes that the current evidence is insufficient to assess the incremental benefit, beyond the efficacy of legislation and community-based interventions, of counseling in the primary care setting, in improving rates of proper use of motor vehicle occupant restraints (child safety seats, booster seats, and lap-and-shoulder belts).	I
Obesity screening and counseling	The USPSTF concludes that the evidence is insufficient to recommend for or against the use of moderate- or low-intensity counseling together with behavioral interventions to promote sustained weight loss in obese adults.	I
Obesity screening and counseling	The USPSTF concludes that the evidence is insufficient to recommend for or against the use of counseling of any intensity and behavioral interventions to promote sustained weight loss in overweight adults.	I
Oral cancer screening	The USPSTF concludes that the evidence is insufficient to recommend for or against routinely screening adults for oral cancer.	I
Physical activity counseling	The USPSTF concludes that the evidence is insufficient to recommend for or against behavioral counseling in primary care settings to promote physical activity.	I
Sexually transmitted infections (STIs) counseling	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of behavioral counseling to prevent STIs in nonsexually-active adolescents and in adults not at increased risk for STIs.	I
Skin cancer counseling	The USPSTF concludes that the evidence is insufficient to recommend for or against routine counseling by primary care clinicians to prevent skin cancer.	I
Skin cancer screening	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of using a whole-body skin examination by a primary care clinician or patient skin self-examination for the early detection of cutaneous melanoma, basal cell cancer, or squamous cell skin cancer in the adult general population.	I
Suicide risk screening	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening by primary care clinicians to detect suicide risk in the general population.	I

continued

TABLE 4-1 Continued

Topic	Description	Grade
Thyroid disease screening	The USPSTF concludes the evidence is insufficient to recommend for or against routine screening for thyroid disease in adults.	I
Vitamin supplementation for disease prevention	The USPSTF concludes that the evidence is insufficient to recommend for or against the use of supplements of vitamins A, C, or E; multivitamins with folic acid; or antioxidant combinations for the prevention of cancer or cardiovascular disease	I

SOURCE: USPSTF, 2011.

decision for each patient, in many instances, research either is inconclusive or has not been conducted.

The Institute of Medicine (IOM) report on women's health research identified many areas in which research is needed (IOM, 2010). For example, the report indicated a lack of large-scale studies identifying effective gender- and age-specific interventions involving modification of lifestyle and other behaviors that affect health, such as alcohol abuse and obesity. Furthermore, determining the evidence for the value of certain services is challenging, because it is difficult to prove the effectiveness of an intervention across the life span. For example, prevention interventions that should be conducted early in the life span (e.g., skin cancer prevention) require decades to demonstrate effectiveness.

Each of the Grade C and I recommendation statements and the evidence supporting them were collected and reviewed. The committee's evaluation included reviewing relevant supporting USPSTF publications, other peer-reviewed research and clinical articles, and clinician fact sheets. The committee did not reassess the Grade D recommendations, given the evidence base driving the USPSTF to recommend against providing these services. Additional literature searches were conducted to identify randomized control trials that were conducted after the USPSTF recommendation was released for each of the Grade C and I recommendations. Furthermore, the committee compared the Grade C and I guidelines with guidelines from other professional groups.

REVIEW OF BRIGHT FUTURES RECOMMENDATIONS

The committee reviewed all Bright Futures guidelines and compared them with the USPSTF guidelines for adolescents. The committee noted that the methodology that Bright Futures uses to develop recommendations is considered "evidence informed" and includes expert opinion. Bright

Futures also uses a more comprehensive focus on health promotion and disease prevention, on the basis of its criteria for the burden of the condition (AAP, 2008).

For the committee, the principal challenge in identifying preventive services to supplement the guidance from Bright Futures was to disaggregate the health supervision visits recommended by Bright Futures and some of its anticipatory guidance into conditions and preventive measures fitting the committee's overall approach. The committee considered the sample questions and advice suggested in the anticipatory guidance section of the *Bright Futures* report to be preventive services to be covered under the ACA. According to the guidelines, these preventive services should be addressed in an annual visit of sufficient length to cover age- and sex-appropriate topics in the health domain. Thus, the topics of physical growth and development, social and academic competence, emotional well-being, risk reduction, and violence and injury prevention, as well as the sample questions and suggested guidance for both the parents and the adolescent, are expected to be addressed at each and every annual visit. The task of addressing each and every one of the suggested topics during a yearly visit seemed daunting to the committee. However, the committee assumes that primary care providers will identify priorities from this section on the basis of the unique circumstances of each patient.

REVIEW OF ACIP RECOMMENDATIONS

The committee reviewed ACIP General Recommendations on Immunization, which include all Food and Drug Administration-approved immunizations recommended for the general population of adolescent and adult women (CDC, 2011; Smith et al., 2009). In addition, to assess potential supplemental immunizations, the committee reviewed the immunizations recommended for high-risk groups and for individuals in special circumstances to determine whether some substantial subpopulation of women, clearly defined, might warrant further attention. Although literature searches were conducted to identify areas where supplemental immunization recommendations might be warranted, the committee identified little evidence to indicate clear deficiencies in existing ACIP recommendations.

FURTHER COMMITTEE CONSIDERATIONS

The committee reviewed both oral and written public comments submitted throughout the course of the study. Some of these comments were from experts, individuals expressing personal experiences with preventable conditions, and members of the U.S. Congress. All of these comments contained recommendations for the committee's consideration. Additionally,

several nongovernmental organizations submitted research studies, public statements, and recommended guidelines for preventive services for women. The committee reviewed all of this information.

The committee also invited researchers and leaders of organizations to deliver presentations in areas where the committee believed that it could benefit from their expertise. These included, for example, presentations on mental health, oral health, occupational health, and the perspectives of employers and health insurers. The committee invited speakers who requested the opportunity in addition to inviting individuals with expertise in potential gap areas or individuals identified as having a perspective that the committee should consider. Furthermore, the committee reviewed HHS documents relating to prevention priorities and reimbursement policies. It also reviewed the existing coverage practices of national, state, and private health plans (these are detailed in Chapter 3). In some cases, committee members also identified current practice in clinical care by using sources such as the British Medical Journal Best Evidence and UpToDate (BMJ Clinical Evidence, 2011; UpToDate Inc., 2011). Finally, the committee also used the 2011 IOM report *Leading Health Indicators for Healthy People 2020* as a tool to perform horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify potential gaps (IOM, 2011).

Committee Analysis

The product of these reviews was an array of areas in which supplemental preventive measures might be warranted. Some of these areas were identified on the basis of traditional indicators such as morbidity and mortality, whereas others were more generally identified to be supportive of a woman's well-being. Adhering to the definitions described in Chapter 1, the committee focused on conditions unique to women or that affect women in some specific or disproportionate way. In general, the committee used criteria adapted from the USPSTF that consider frequency, severity, morbidity, mortality, and quality of life to bring consistency to the analyses.

For each potential supplemental preventive measure considered, an extensive comparison with the guidelines of professional organizations (e.g., American Academy of Family Physicians, American College of Physicians, American College of Obstetricians and Gynecologists, American Cancer Society, American Medical Association) was conducted to understand these guidelines development processes and the evidence that the organizations use to reach their conclusions. Many of these guidelines are posted in the Agency for Healthcare Research and Quality's National Guidelines Clearinghouse. The committee also performed targeted literature searches.

Identifying Potential Supplemental Preventive Measures

The committee then attempted to identify preventive measures that were aimed at filling the gaps that it had identified. In most cases, the committee found that measures had already been proposed by the other organizations mentioned above. The committee also eliminated preventive measures that, even at this early stage in the analysis, were clearly not developed, tested, or known well enough to have a measurable impact. The resulting product of this step was a series of areas with gaps, with the accompanying preventive measure or measures that could be considered by the Secretary for HHS for inclusion in guiding policy and program development relating to the ACA.

Identifying Gap Areas and Measures with Adequate Evidence

The core of the committee's task was to assemble the evidence that would allow it to recommend consideration of a preventive service. The committee found that systematic reviews of clinical effectiveness were not available to address all the potential gaps and that a standard methodology addressing coverage of preventive services does not exist. These two issues are discussed below.

Reviews of Clinical Effectiveness

Assessment of the efficacy and effectiveness of preventive measures to provide clinical guidance was one of the topics of clinical focus that, more than 30 years ago, launched the change in the approach to health care delivery that is now called evidence-based medicine. The USPSTF and its Canadian sister organization, the Canadian Taskforce on Preventive Health Care, were active at the beginning of this movement, with a major focus being on developing the methodology. Since the 1980s, the standards for judging the effectiveness of preventive measures have matured, and the bar for determining the effectiveness of preventive measures has been set very high. Furthermore, for a number of reasons, including ethical constraints, the evidence bar is usually set higher for preventive services than for the services offered in many other areas of conventional medical care. It is generally assumed that a preventive service intended for the general population should have proven benefits and minimal harms, with the benefits clearly outweighing the harms. As noted below, the committee had neither the time and resources nor a charge to conduct its own systematic reviews, which, using the USPSTF as an example, often take 12 to 18 months for a single topic.

Methodologies with a Coverage Decision as the Goal

The USPSTF, Bright Futures, and ACIP focus on the provision of guidance to clinicians and patients, not on insurance coverage. Decision making about covering a preventive service may consider a host of other issues, such as established practice; patient and clinician preferences; availability; ethical, legal, and social issues; and availability of alternatives. Further complicating matters, special population groups, such as minority populations, recent immigrants, lesbians, prisoners, and those employed in high-risk environments, may have different health needs or benefit from different preventive services. In addition, high-risk groups, population subsets, and special populations are unevenly identified and are addressed at varying degrees in current guidelines. Finally, because cost was explicitly excluded as a factor that the committee could use in forming recommendations, the committee process could not evaluate preventive services on the basis of cost.

Against this background, the committee selected a hybrid approach that collected relevant evidence for each measure, and it determined that the question of a methodology to fully address insurance coverage was beyond its scope. Four categories of evidence—posed in the form of questions—were developed to systematically query support for each potential preventive measure. The committee neither formally ranked or assigned weights to the categories, nor did it stipulate that evidence in any one category would automatically result in a recommendation for a measure or service to be considered. Instead, the queries and categories were used to consider the range of evidence and to ensure consistency in the committee's analysis and deliberations. Many of the recommendations are supported by more than one category of evidence.

Category I. Are high-quality systematic evidence reviews available indicating that the service is effective in women?
Category II. Are quality peer-reviewed studies available demonstrating effectiveness of the service in women?
Category III. Has the measure been identified as a federal priority to address in women's preventive services?
Category IV. Are there existing federal, state, or international practices, professional guidelines, or federal reimbursement policies that support the use of the measure?

RECOMMENDATIONS ON PREVENTIVE SERVICES TO BE CONSIDERED IN DEVELOPMENT OF COMPREHENSIVE GUIDELINES

Subcommittees queried the available evidence applicable to potential preventive measures and assigned the evidence to one or more of the categories listed above. Each subcommittee then brought its analysis of the range of evidence before the full committee for deliberation. The committee combined the burden of the condition and its potential impact on health and well-being with the array of available evidence and support noted above to come to a consensus over whether to recommend that a specific preventive measure be considered by the Secretary. As is true in most analytical processes in decision making, evidence and expert judgment are inextricably linked; thus, the expert judgments of the committee members also played a role in decision making.

In general, preventive measures recommended by the committee met the following criteria:

- The condition to be prevented affects a broad population;
- The condition to be prevented has a large potential impact on health and well-being; and
- The quality and strength of the evidence is supportive.

Ultimately, the decision to develop a recommendation for a preventive measure or service was made after a thoughtful review and debate of each of the subcommittee's reports. Recommendations were made when the evidence was found compelling based on the committee's interpretation of the strength of the evidence. In Chapters 5, the committee describes the evidence that factored into its decision making for each supplemental preventive measure recommendation.

In some instances, a subcommittee's analysis resulted in the development of a clarifying statement (added to Table 5-1) on the committee's interpretation of current USPSTF guidelines. In other cases, the subcommittee's analysis suggested a service that could be considered part of a well-woman visit (Table 5-6). These are addressed in Appendix A of this report.

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5

Recommendations

This chapter describes the committee's recommendations for preventive services necessary for women's health and well-being that are not included in the United States Preventive Services Task Force (USPSTF) Grade A and B recommendations, Bright Futures, and Advisory Committee on Immunization Practices (ACIP) guidelines, and that could supplement the current list of preventive services for women recommended under the Patient Protection and Affordable Care Act of 2010 (ACA). The committee's recommendations regarding chronic diseases, sexual and reproductive health conditions, interpersonal and domestic violence, and well-woman visits follow.

The committee also provided interpretations for unclear USPSTF Grade A and B recommendations as described in Chapter 4; these are annotated in Table 5-1. Clarifying statements for osteoporosis screening and tobacco use have also been added. The rationale for including these two statements is presented in Appendix A.

DIABETES AND GESTATIONAL DIABETES

Diabetes mellitus (DM) is a syndrome characterized by either an absolute or a relative deficiency of insulin in various organ systems of the body. The inability of these organ systems to utilize glucose thus exposes all tissues of the body to chronic excess glucose in the bloodstream, or hyperglycemia (ADA, 2011a). DM has three main types: type 1, type 2, and gestational DM. Only about 5 percent of people with diabetes in the United States have type 1 diabetes, which results from the body's failure to produce insulin (ADA, 2011a). Type 2 diabetes, which accounts for about

TABLE 5-1 Grade A and B Recommendations with Committee Interpretations and Clarification Statements

Topic	USPSTF Recommendation	USPSTF Grade	IOM Committee Interpretation
Alcohol misuse counseling	The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.	B	Annual screening with approved screening instrument.
Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B	Screening in each trimester.
Blood pressure screening	The USPSTF recommends screening for high blood pressure in adults aged 18 and older.	A	Annual screening.
BRCA screening, counseling about	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.	B	Referral for genetic counseling and testing, if appropriate.
Breast cancer preventive medication	The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention.	B	Medication provided if indicated.
Depression screening: adolescents	The USPSTF recommends screening of adolescents (12–18 years of age) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B	Annual depression screening.
Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B	Annual depression screening.
Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B	Annual screening.

TABLE 5-1 Continued

Topic	USPSTF Recommendation	USPSTF Grade	IOM Committee Interpretation
Human immunodeficiency virus HIV screening	The USPSTF strongly recommends that clinicians screen for HIV all adolescents and adults at increased risk for HIV infection.	A	Annual screening.
Obesity screening and counseling: adults	The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.	B	Annual screening.
Osteoporosis screening: women	The USPSTF recommends that women aged 65 and older be screened routinely for osteoporosis and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has not additional risk.	B	Women with previous fractures and women with secondary causes of osteoporosis are suggested to be included (see Appendix A).
Tobacco use counseling and interventions: nonpregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A	Annual screening. Counseling and Food and Drug Administration (FDA)-approved and over-the-counter medications are suggested (see Appendix A).
Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.	A	Discussion at each prenatal visit. It is appropriate for pregnant women who smoke to receive counseling that is tailored to their needs.
Syphilis screening: nonpregnant persons	The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A	Annual screening.
Syphilis screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A	Screening at first prenatal visit, and as indicated if at high risk.

90 to 95 percent of the cases of diabetes in the United States, results from the body's inability to produce sufficient amounts of insulin as well as its resistance to insulin, which means that the body does not use insulin effectively (NIDDK, 2008).

Gestational diabetes mellitus (GDM) is diabetes that arises or is diagnosed in pregnancy, typically during the second and third trimesters of pregnancy. It accounts for about 135,000 diabetic patients annually in the United States and occurs in approximately 2 to 10 percent of pregnant women (NIDDK, 2011). Although most women recover from GDM after giving birth, they have an increased risk of developing type 2 diabetes in the future (Turok et al., 2003). Furthermore, their offspring are at significantly increased risk of being overweight and insulin resistant throughout childhood (Boerschmann et al., 2010).

Prevalence/Burden

Almost 25.8 million Americans, or 8.3 percent of the population, have diabetes, which is widely recognized as one of the leading causes of death and disability in the United States (CDC, 2011c). By 2050, it is estimated that the rate of adult diabetes in the United States will triple, from 1 in 10 now to 1 in 3 (Boyle et al., 2010).

No striking gender difference in the rates of diabetes exist between men and women in the United States (ADA, 2011b). However, a gender difference in the burden of this disease does appear to exist. Narayan and colleagues (2003) found that women have a significantly higher estimated lifetime risk of developing diabetes than men (38.5 percent for females versus 32.8 percent for males born in 2000). The authors further estimated that women diagnosed with diabetes at age 40 years will lose 14.3 life-years and 22 quality-adjusted life years, whereas the length of life lost for men diagnosed with diabetes at the same age are 11.6 life-years and 18.6 quality-adjusted life-years, respectively.

The consequences of diabetes appear to be more severe for women as well. In a study to assess whether trends in mortality rates among adults with diabetes had changed, Gregg and colleagues found that between the 1971 to 1986 and 1988 to 2000 survey periods for the National Health and Nutrition Examination Survey, the all-cause mortality rate for men with diabetes decreased by 18.2 deaths per 1,000 persons annually (from 42.6 to 24.4 deaths per 1,000 persons annually), whereas for diabetic women, the all-cause mortality rate more than doubled (from 8.3 to 18.2 deaths per 1,000 persons annually) (Gregg et al., 2007).

Furthermore, recent data indicate that women with diabetes are at high risk for developing cardiovascular disease. Women with diabetes were found to be four to six times more likely to develop cardiovascular disease

than women who do not have diabetes (Rivellese et al., 2010). Women with diabetes are more than three times more likely to have a stroke as women without diabetes but no prior history of a cardiovascular event. In fact, women with diabetes have a stroke risk profile similar to that of non-diabetic women who have had a prior stroke (Ho et al., 2003).

In addition to having one of the highest diabetes rates in the world (8.3 percent), the United States has the highest rates of GDM in the world, with as many as 2 to 10 percent of pregnancies being complicated by GDM each year (Danaei et al., 2011; NIDDK, 2011). This may be in part due to increased screening conducted in the United States. Although the incidence of preexisting diabetes in pregnancy has increased over the past decade, the incidence of GDM has remained relatively stable since the late 1990s because of better recognition of the disease and more aggressive intervention, according to a Southern California Kaiser Permanente study (Lawrence et al., 2008). This suggests that the complications of GDM for both mother and infant can be reduced even further by better detection and prevention and more aggressive management of this condition (Crowther et al., 2005; Langer et al., 2005).

Many women who are first diagnosed with diabetes during pregnancy are classified as having GDM. However, it is possible that many had pre-existing or pregestational type 2 diabetes. Indeed, the majority of women with GDM seem to have β-cell dysfunction that appears on a background of chronic insulin resistance already present before pregnancy (Buchanan, 2001).

If a woman who has had GDM is not tested after delivery, the diabetes may have persisted and her next pregnancy may be incorrectly classified as recurrent GDM instead of preexisting diabetes. This distinction is important, because preexisting diabetes could be associated with more serious consequences for the fetus, including cardiac, neurological, and vascular anomalies, than diabetes that arises in the second and third trimesters of pregnancy (Jenkins et al., 2007; Ornoy, 2005; Sivan et al., 2004).

Cases of GDM increase with maternal age and occur 7 to 10 times more often among pregnant women age 24 and older than among women younger than 24 years old (Reece, 2010), suggesting that universal screening may be the most effective in the latter group (Marquette et al., 1985). GDM is itself a risk factor for type 2 diabetes. Women who have GDM during pregnancy have a seven-fold increased risk for the development of type 2 diabetes after delivery, which persists for their lifetime (Reece et al., 2009). One large, population-based study of 659,000 women found that 20 percent of women with GDM progressed to type 2 diabetes within nine years of pregnancy (Feig et al., 2008). Furthermore, the children of women with a history of GDM are at an increased risk for obesity and diabetes compared to other children (Reece, 2010).

Diabetes care costs the United States an estimated $174 billion annually, including both indirect and direct costs (ADA, 2011a). The United States spends more than half (54 percent) of the global expenditure on diabetes care and is expected to still be doing so by 2030, when it will spend an estimated $264 billion annually (Zhang et al., 2010).

Risk Factors for Diabetes

The primary risk factors for type 1 diabetes are genetics and family history (ADA, 2011a), diseases of the pancreas (Buxbaum and Eloubeidi, 2010), and infections or illnesses (Hober and Sane, 2010). The number one risk factor for type 2 diabetes is obesity (Chan et al., 1994; Colditz et al., 1995). Besides obesity, other risk factors for developing type 2 diabetes include impaired glucose tolerance or impaired fasting glucose, insulin resistance, ethnic background, high blood pressure, a history of gestational diabetes, a sedentary lifestyle, family history, polycystic ovary syndrome, and older age (ADA, 2011a).

A number of risk factors have been consistently linked to the development of GDM during pregnancy, including a history of GDM in a prior pregnancy, previously having had a large for gestational age (LGA) infant, obesity, a strong immediate family history of type 2 diabetes or GDM and a history of unexplained fetal death (Mayo Clinic, 2011).

Obesity

Obesity is an excess amount of subcutaneous body fat in proportion to lean body mass. (CDC, 2010d). The most common measure of obesity is the body mass index (BMI). If BMI is 25 to 29.9, an individual is considered overweight; a person is considered obese when his/her BMI, is greater than 30.

The rapid increase in diabetes in recent decades has closely paralleled the increase in obesity and overweight in the general population (Wang et al., 2008). The United States currently has the highest obesity rate in the world, with more than 30 percent of adults, or 77 million, considered obese. By 2030, if the secular rate of increase continues, it is estimated that nearly 90 percent of Americans will be overweight and 51 percent will be obese (Wang et al., 2008). Obesity recently passed smoking as America's greatest health threat, at least as measured by quality-adjusted life-years (QALYs) lost (Jia and Lubetkin, 2010). Obesity-related diseases account for nearly 10 percent of all medical spending in the United States (Finkelstein et al., 2009). Greater weight means a higher risk of insulin resistance, because fat interferes with the body's ability to use insulin.

Overall there are a variety of factors that play a role in obesity. This makes it a complex health issue to address. The risk factors for obesity include overeating; lack of exercise; genetics; environment; and some diseases and drugs. However, experts have concluded that the two chief causes of obesity are a sedentary lifestyle and the overconsumption of high-calorie foods (Vainio and Bianchini, 2002). Thus, most obesity interventions are directed toward modifying these two lifestyle factors.

The USPSTF recommends screening for type 2 diabetes only in asymptomatic adults with a sustained blood pressure of greater than 135/80 mm Hg and found insufficient evidence to support screening in asymptomatic adults with lower blood pressure levels. Bright Futures does not specifically address screening for diabetes.

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg. Grade B Recommendation (USPSTF, 2008b).

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for type 2 diabetes in asymptomatic adults with blood pressure of 135/80 mm Hg or lower. Grade I Statement (USPSTF, 2008b).

The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for gestational diabetes. Grade I Statement (USPSTF, 2008a).

The USPSTF recommends that all clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. Grade B Recommendation (USPSTF, 2003).

The U.S. Department of Veterans Affairs (VA) and the U.S. Department of Defense (DOD) Clinical Practice Guidelines recommend that physicians consider screening for diabetes and encourage aerobic exercise and diet to achieve weight loss and prevent the progression of pre-diabetes to diabetes (VA, 2010). Numerous health professional associations and other organizations recommend screening for diabetes as part of preventive care for women. The American Diabetes Association, for example, recommends

that physicians consider testing for diabetes in all adults who are overweight and who have additional risk factors and all adults 45 years and older not exhibiting these conditions (Zinman et al., 2010).

Guidelines for GDM Screening

Little evidence indicates that screening for GDM improves health outcomes. For this reason, the USPSTF concluded that the evidence is insufficient to recommend for or against routine screening for gestational diabetes. However, according to the USPSTF, "clinicians should discuss screening for GDM with their patients and make case-by-case decisions. Discussions should include information about the uncertainty of benefits and harms as well as the frequency of positive screening test results." Women at increased risk include women who are obese, older than 25 years of age, have a family history of diabetes, have a history of previous GDM, or are of certain ethnic groups (Hispanic, American Indian, Asian, or African-American). There are no existing interventions to prevent GDM from occurring in pregnancy. However, some bodies have considered it important to screen pregnant women for GDM because these women are at increased risk for having infants with excessive birth weight and require operative delivery or infants with increased neonatal morbidity.

The U.S. Indian Health Service (IHS), VA, and the DOD Clinical Management Guideline for the Management of Pregnancy, for example, recommend routine screening of all pregnant women for GDM at 24 to 28 weeks of gestation (VA, 2009). While the American Academy of Family Physicians (AAFP) recognizes that more studies are needed to unequivocally support the benefit of universal screening for GDM, it also identifies that universal screening for GDM at 24 to 28 weeks of gestation is recommended by many experts. The recommendation is based on consensus, disease-oriented evidence, expert opinion, and case series (Serlin and Lash, 2009). In support of the recommendation, AAFP also notes that most obstetric practices employ this strategy. The American Congress of Obstetricians and Gynecologists (ACOG), in its Clinical Management Guidelines for Obstetrician-Gynecologists on gestational diabetes (ACOG, 2001), recommends screening for GDM at 24 to 28 weeks of gestation. Its recommendation is based on limited or inconsistent scientific evidence. Other organizations with guidelines include the National Collaborating Centre for Women's and Children's Health, the American Heart Association, the Endocrine Society, and the National Kidney Foundation.

Effective Interventions

The value of early detection of diabetes, other than type 1 diabetes, remains controversial because of the lack of an established evidence base. Randomized trials have established the benefits of interventions to prevent or delay diabetes (Knowler et al., 2002; Tuomilehto et al., 2001) and to reduce diabetes-related complications (UKPDS, 1998). However, no randomized control trial has established the benefits of early detection of diabetes. Several major studies have demonstrated that delaying and/or aggressively managing diabetes can ameliorate many of its negative consequences for women and their children.

The Diabetes Control and Complications Trial (DCCT), an almost 10-year study sponsored by the National Institutes of Health found that maintaining blood glucose levels as close to normal as possible slowed the development and progression of the eye, kidney, and nerve damage caused by diabetes (Genuth, 2006). It also found that any sustained lowering of blood glucose was beneficial. The most significant side effect of intensive treatment in the DCCT was an increase in the risk for hypoglycemia, or low blood glucose, including episodes severe enough to require additional medical assistance (Genuth, 2006).

The Diabetes Prevention Program (DPP), another intervention study, was designed to assess whether modest weight reduction through dietary changes and increased physical activity or treatment with oral diabetes medication could prevent or delay the onset of type 2 diabetes. Results from this study showed that participants who were pre-diabetic could sharply reduce their risk of developing diabetes with a modest loss of weight through dietary changes and increased physical activity (The Diabetes Prevention Program Research Group, 2000). Taking oral diabetes medication could also reduce risk, although less dramatically.

Since the conclusion of the DPP study, additional data analyses continue to provide important insights into the value of lifestyle changes in helping people prevent type 2 diabetes and its complications. One analysis found that DPP participants with specific genetic profiles had a significantly increased risk of developing diabetes and selective responses to specific interventions (Florez et al., 2007). It is possible that subgroups of individuals will not respond well to standard interventions or that some responders may respond very well to a particular treatment on the basis of their genetic profile.

Nutritional support and exercise also can have a significant impact on the incidence and severity of diabetes. The DPP found that just 30 minutes of moderate physical activity a day, coupled with a 5 to 10 percent reduction in body weight, produced a 58 percent reduction in the incidence of diabetes (Knowler et al., 2002).

The current evidence of the efficacy of obesity prevention and interven-

tions is based on a very small number of studies (Lemmens et al., 2008). Some studies showed a positive impact of the intervention on BMI or weight status, but there is too much heterogeneity in terms of study design, theoretical underpinning, and target population to be able to draw firm conclusions about which intervention approaches are more effective than others (Lemmens et al., 2008). More research is urgently needed to extend the body of evidence in this area of prevention.

The only intervention for obesity that has been shown to have great benefit for preventing other complications of obesity is surgery (Valezi et al., 2010). Gastric bypass surgery has been shown to ameliorate diabetes (Gill et al., 2011) and cardiovascular morbidity and mortality (Pontiroli and Morabito, 2011). However, this is an invasive surgical intervention, and an estimated 5 percent or more of people have serious or life-threatening complications after gastric bypass surgery (Picot et al., 2009).

Identified Gaps

The primary gaps in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) were screening for diabetes in all women and screening for gestational diabetes among pregnant women, especially those identified to be at high risk for developing gestational diabetes. The committee found insufficient evidence to support screening for diabetes in all women.

The evidence provided to support a recommendation for gestational diabetes is based on current federal practice policy from IHS and the VA as well as current practice and clinical professional guidelines such as those set forth by AAFP and ACOG.

Recommendation 5.1: The committee recommends for consideration as a preventive service for women: screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.

CERVICAL CANCER

Invasive cervical neoplasia is a low-prevalence cancer with a lengthy pre-invasive phase that is amenable to screening and early detection. Current USPSTF screening recommendations do not yet address the potential role of high-risk (oncogenic) human papillomavirus (HPV) DNA testing within practice of screening for invasive cervical neoplasia (USPSTF, 2003a). High-risk HPV DNA testing detects the viral types most commonly associated with the development of cancer.

Persistent infection with 1 of 20 high-risk HPV types is the necessary precursor for the development of squamous cell carcinoma and adenocarcinoma of the uterine cervix (Plummer et al., 2007; Walboomers et al., 1999; WHO, 2005). HPV infection is highly prevalent and is sexually acquired with the onset of sexual intercourse, typically resolving within 24 months (Insinga et al., 2007; Khan et al., 2005). Progression from persistent infection to precursor lesion (high-grade squamous intraepithelial lesion or cervical intraepithelial neoplasia [CIN] grade 2 [CIN2] or CIN3) can be a lengthy process, with the 10-year risk for the development of these lesions (even for the highest-risk viral types) being approximately 17 percent (Khan et al., 2005). Even after precursor lesions, the risk of progression to invasive disease is about 31 percent in 30 years (McCredie et al., 2008). On the basis of the current understanding of the natural history or HPV infection and cervical carcinogenesis, it is recommended that adult women with a history of sexual activity undergo periodic screening as part of their routine preventive care.

Prevalence/Burden

In 2010, 12,200 cases of invasive cervical cancer were diagnosed and 4,210 deaths were estimated to have occurred in the United States (CDC, 2007a), and the incidence of cervical cancer has been steadily decreasing in the United States and Western Europe since the introduction of formal and informal cytological screening programs in the 1950s. By 2007, the rate of mortality in the United States has decreased from 10.2 and 18 per 100,000 among White and non-White women, respectively, to 2.2 and 4.3 per 100,000 for White and African-American women, respectively (CDC, 1953; NCI, 2011a). Despite these tremendous gains, women with poor access to health care services and specifically women from communities of color have lagged significantly behind and currently represent a disproportionate share of cervical cancer incidence and mortality (NCI, 2011b; Saslow et al., 2002).

Although the annual incidence of death from cervical cancer is less than that of other cancers (ACS, 2010), the fact that these deaths are almost entirely preventable through primary prevention, screening and early detection, treatment of precancerous lesions, and effective therapies for invasive disease, makes cervical cancer a high-impact public health priority. Because sexually acquired persistent high-risk HPV infection is the primary causal factor associated with the development of cervical cancer, regular screening of all adult women with a history of sexual activity has been the mainstay of prevention efforts (USPSTF, 2003a). Periodic exfoliative cervical cytology-based screening (with or without high-risk HPV DNA testing) detects pre-invasive and early-stage disease, contributing to reductions in

the rate of mortality from cervical cancer. This type of screening, in combination with prophylactic (bivalent or quadrivalent) HPV vaccination of young women and girls, has made the prevention of mortality from cervical cancer an attainable public health goal.

Healthy People 2020, which sets health goals for the United States, contains specific objectives for increasing the proportion of women who receive screening for cervical cancer (HHS, 2011a). The specific targets set for this objective are increasing the rate of screening among women aged 21 to 65 years who receive a cervical cancer screen (based on the most recent guidelines) by 10 percent so that 93 percent of women are screened.

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix. Grade A Recommendation (USPSTF, 2003a).

The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of new technologies to screen for cervical cancer. Grade I Statement (USPSTF, 2003a).

The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of human papillomavirus (HPV) testing as a primary screening test for cervical cancer. Grade I recommendation (USPSTF, 2003a).

Broad consensus exists about the need for periodic screening of adult women with a history of sexual activity. The American Cancer Society (ACS) and ACOG recommend the periodic screening of women beginning at 21 years of age (or three years after the onset of intercourse) (ACOG, 2005a, 2008, 2009; Saslow et al., 2002, 2007). Both entities also recommend the combined use of cytology with testing for high-risk HPV to improve detection and lengthen screening intervals in women 30 years of age and older. The discontinuation of cervical cancer screening in later life is also addressed by these recommendations, with ACS suggesting 70 years of age as the upper limit and ACOG mentioning 65 or 70 years as the upper limit. Both entities caution that discontinuation of screening should occur only when a woman has a documented history of negative screenings. Discontinuation is also recommended by both entities when a woman has had

a hysterectomy for benign disease. The DOD recently added the high-risk HPV DNA test to its list of covered preventive services (TRICARE, 2011).

The ACS and ACOG recommendations also largely agree with the 2003 recommendations of the USPSTF (USPSTF, 2003a). These call for the screening of all sexually active women with cervical cytology beginning at age 21 years or within years of the onset of sexual activity and at least every three years thereafter (Grade A). Like ACS and ACOG, the USPSTF recommends against the screening of women who have undergone hysterectomy for benign disease (Grade D), as well as women age 65 years and older in the setting of prior normal screening examinations (Grade D). In 2003, the USPSTF concluded that there was insufficient evidence to recommend for or against HPV testing in a routine screening setting.

Effective Interventions

On the basis of the summary of observational data, it can be concluded that the use of cytology for cervical cancer screening has contributed significantly to the reduction in the incidence of and rate of mortality from invasive cervical cancer. This has been accomplished on the basis of the substantial uptake of screening for cervical cancer. In 2008, more than 80 percent of women, aged 18–44, reported that they had undergone cytological screening during the previous three years (CDC, 2011a). The rate of screening utilization, however, varies substantially by race and ethnicity, level of educational attainment, and age, with significantly lower rates of screening being seen for Asian and American Indian/Alaska Native women, those with a high-school education or less, and those older than 64 years of age (CDC, 2011a). These considerations are critical, because more than half of all invasive cervical cancers occur among un- and underscreened women, while nearly a third occur among women with screening failures and the remainder are due to inadequate postscreening follow-up or misreadings (Janerich et al., 1995; Kinney et al., 1998; Leyden et al., 2005; Sung et al., 2000).

Cytology has also evolved with liquid-based cytology platforms now largely replacing conventional dry slide cytology in the United States (Irwin et al., 2006). The quality of liquid-based cytology has arguably been proposed to be superior to that of conventional dry slide cytology on the basis of lower rates of unsatisfactory results (Ronco et al., 2007; Siebers et al., 2009), although they are otherwise comparable on the basis of test performance characteristics (Arbyn et al., 2008; Davey et al., 2006). The shift to liquid-based cytology has been driven by practical considerations, including the advent of automated high-throughput processing, an aging cytotechnology workforce, and the advent of molecular testing. It is, however, the ability to perform high-risk HPV DNA testing and cytology on a

single patient specimen that may represent the most important contribution of this technology to overall cancer prevention.

The identification of HPV infection as the requisite etiologic precursor to cervical carcinoma has led to the development of clinically useful assays. The high-risk HPV DNA hybrid capture (HC2) assay (de Cremoux et al., 2003) is the most widely used assay for HPV detection. The HC2 assay is a pooled probe assay that detects 13 different high-risk HPV types and is approved by the Food and Drug Administration (FDA) for use for the triage of a cytology result indicating an atypical squamous cell of undetermined significance as well as for primary screening in combination with cytology for primary screening in women 30 years of age and older (FDA, 2009b,c). More recently, another pooled test (Cervista; Hologic, Bedford, MA) was approved for the same indication as the HC2 assay, as was a related type-specific probe for the detection of HPV types 16 and 18 (FDA, 2009a; Ronco et al., 2010). Although they are not FDA approved, a variety of commercially available and laboratory-specific molecular assays are currently in use under laboratory-specific internal validation standards.

Changing Screening Paradigms

A number of European trials have examined the usefulness of primary screening using high-risk HPV DNA testing compared with that of cervical cytology for the detection of cervical cancer and its precursors. A large randomized controlled trial conducted within the Italian national screening program compared the performance of the HC2 assay to that of conventional cytology among 35,471 women 35 years of age or older (Ronco et al., 2007). After 3.5 years of follow-up, the cumulative rates of detection of CIN3 and above (CIN3+) were 55 and 35 percent for cervical intraepithelial neoplasm grade 2 (HC2 assay) and cytology, respectively (relative risk [RR] = 1.57, 95 percent confidence interval [CI] = 1.03 to 2.4), although no differences in the number of invasive cancers detected in the two groups were detected (four in the HC2 assay arm compared with five in the cytology arm). In another large population-based European trial of 7,908 women aged 30 years and older, the HC2 assay was significantly more sensitive than cytology for the detection of CIN3+: 97 percent (95 percent CI = 83 to 99 percent) and 46 percent (95 percent CI = 31 to 62 percent), respectively (Petry et al., 2003). The magnitude of these findings is even greater at the lower, yet still clinically relevant, treatment threshold of CIN2 or greater (Bigras and de Marval, 2005; Cardenas-Turanzas et al., 2008; Cochand-Priollet et al., 2001; de Cremoux et al., 2003; Mayrand et al., 2006, 2007; Petry et al., 2003).

Taking a slightly different approach, a large Finnish randomized controlled trial compared the HC2 assay (with cytology triage of abnormal)

with cytology alone among 61,149 women in the national screening program (Kotaniemi-Talonen et al., 2008). On extended follow-up at 3.3 years, the rates of detection of CIN3+ and cancer in the HC2 testing arm (59 cases of CIN3+ and 11 invasive cancers) were significantly increased (RR = 1.77, 95 percent CI = 1.16 to 2.74) compared with those for the arm that used cytology only (33 cases of CIN3+ and 6 invasive cancers) (Anttila et al., 2010).

The impressive negative predictive value of the combination of cytology and screening for high-risk HPV was first noted in large cross-sectional studies (Cuzick et al., 2006; Kjaer et al., 2006). The combination has also subsequently been assessed in various European trials, although none used methods that reflect the current practice in the United States. In general, these trials of the combination of cytology and screening for high-risk HPV have consistently demonstrated the improved detection of cervical cancer precursors (CIN2+) over that by cytology by itself, as well as extremely high negative predictive values (Mayrand et al., 2006, 2007; Petry et al., 2003). It is this impressive predictive value of the combination of a negative cytology result and a negative result for HPV, first identified in cross-sectional studies that may permit further safe lengthening of screening intervals.

A recent U.S. study examined data from 331,818 women aged 30 and older who received care in a Kaiser Permanente Northern California from 2003 to 2005. The authors found 7.5 cervical cancers per 100,000 women/year for all women with a normal conventional cytology test, while the rate of cervical cancer was 3.8 per 100,000 woman/years for all women who were HPV-negative. The rate was lowest among women who were HPV-negative and had a normal conventional cytology result, at 3.2 per 100,000 women/year. The study also found that HPV-positive women had a 7.6 percent risk of developing a cancerous or pre-cancerous lesion over five years, while women with an abnormal conventional test result had a 4.7 percent risk. Women with a negative HPV had a lower cancer risk than women who had a normal conventional cytology test. When both cytology and HPV were positive, women had twice the risk for cancer compared to women with a positive HPV test and a normal conventional cytology test (Katki et al., 2011).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that currently there is an absence of coverage for co-testing with cytology and high-risk HPV DNA testing among women 30 years of age and older as a strategy to increase screening intervals to every three years. Cervical cancer is

almost entirely preventable through early screening, detection, and treatment. Evidence to support high-risk HPV DNA testing is based on federal practice policy from the DOD. Peer-reviewed studies demonstrate that improved testing technologies, particularly combined screening using both conventional cytology and high-risk HPV DNA screening, may significantly improve the rate of detection of cervical cancer precursors and facilitate the safe lengthening of the interval for screening.

Recommendation 5.2: The committee recommends for consideration as a preventive service for women: the addition of high-risk HPV DNA testing to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.

SEXUALLY TRANSMITTED INFECTIONS

Sexually transmitted infections (STIs), or sexually transmitted diseases (STDs), are diseases transmitted primarily by sexual activity. In 1997, the Institute of Medicine (IOM) labeled STDs a hidden epidemic, reflecting the knowledge that this largely unrecognized public health threat had considerable scope (IOM, 1997). The discussion that follows focuses primarily on chlamydia, gonorrhea, and syphilis.

Prevalence/Burden

For all STIs generally and for chlamydia, gonorrhea, and syphilis more specifically, the prevalence and number of reported cases are high among certain age groups, racial and ethnic groups and in certain geographic areas. Nevertheless, many STIs are asymptomatic and go undiagnosed; thus, current surveillance systems tend to underestimate the actual burden of disease. Significant short- and long-term morbidities are associated with these conditions, as is the risk for perinatal transmission, with its disease-specific attendant consequences. The services under consideration here include screening and counseling.

Women who contract STIs suffer from adverse reproductive health outcomes (Friedel and Lavoie, 2008). Infections in women, which are usually asymptomatic, can result in pelvic inflammatory disease, a major cause of infertility, ectopic pregnancy, and chronic pelvic pain. As with human immunodeficiency virus (HIV), women at risk for STIs often do not appreciate that they are at risk if they consider themselves in a monogamous relationship (Hodder et al., 2010).

In 2009, the overall rate of reported chlamydia infection among women (592 cases per 100,000 women) was almost three times higher than the

rate among men. Although the rates of reported chlamydia infections have been rising for several years, this could be due at least in part to increased screening and improvements in detection methods. The highest age-specific rates of reported cases in 2009 were among those aged 15 to 19 years.

In 2009, the rates of gonorrhea were 105.5 cases per 100,000 women and 91.9 per 100,000 men. Rates continue to be the highest among adolescents and young adults (CDC, 2009b; Workowski and Berman, 2010). In addition, epidemiological and biological studies provide strong evidence that gonococcal infections facilitate the transmission of HIV infection (Fleming and Wasserheit, 1999).

Syphilis is a genital ulcerative disease that causes significant complications if it is left untreated, including perinatal death in up to 40 percent of pregnant women, and can lead to infection of the fetus in 80 percent of cases, even if the infection is acquired during the four years before pregnancy (CDC, 2009b). Syphilis is also shown to facilitate the transmission of HIV infection (Fleming and Wasserheit, 1999). In 2009, the rate of syphilis was 7.8 cases per 100,000 men and 1.4 cases per 100,000 women. Consistent with other STIs, the rates are the highest for women aged 20 to 24 years (5.6 cases per 100,000) (Workowski and Berman, 2010).

Although the absolute risk factors for each disease may vary, in general, populations at increased risk for one STI are at increased risk for all STIs. The prevalence of gonorrhea and syphilis is highly dependent on the geographic area and sociodemographic factors, with increased rates occurring among Hispanics, African Americans, and lower socioeconomic groups. However, in general, in addition to sexual activity and age, other risk factors for STIs include a history of a prior STI; new, bisexual, or multiple sexual partners; inconsistent condom use; exchanging sex for money or drugs; and incarceration in adult correctional facilities. Sexually active adolescents are at higher risk of acquiring STIs, for a combination of developmental, behavioral, and biological reasons (Friedel and Lavoie, 2008). The risk factors for pregnant women are the same as those for nonpregnant women.

A 2008 Henry J. Kaiser Family Foundation survey found that only 38 percent of women, aged 18 to 44 years reported that they had discussed their sexual history with a doctor or nurse within the past three years. Furthermore, only 28 percent reported that they had discussed STIs with a doctor or nurse. Nevertheless, many women assume that they are tested routinely for STIs (Ranji and Salganicoff, 2011).

Existing Guidelines and Recommendations

The USPSTF recommends screening and counseling for STIs on the basis of the following risk factors listed in Table 5-2.

TABLE 5-2 Indicators of Increased Risk for STIs from USPSTF and Populations Excluded by the Guidelines

Condition/ Intervention	Indicators of Increased Risk Defined by the USPSTF	Populations Excluded
Chlamydia	Sexually active women aged 24 and younger History of STIs New or multiple sexual partners Inconsistent condom use Exchanging sex for money or drugs Incarcerated persons Military recruits Patients at public STI clinics African-American women Hispanic women	"Average risk" women older than 25
Gonorrhea	Women aged younger than 25 History of previous gonorrhea infection Other STIs New or multiple sexual partners Inconsistent condom use Commercial sex workers Drug use African-American women Individual risk depends on local epidemiology of disease	Sexually active and pregnant women not at increased risk
Syphilis	Commercial sex workers Exchanging sex for drugs Incarcerated persons	Sexually active women not at increased risk
STI counseling	Sexually active adolescents Adults/married adolescents with current STIs or infections within the past year Adults/married adolescents with multiple current sexual partners Sexually active patients in nonmonogamous relationships in a location with a high rate of STIs	Nonsexually active adolescents Sexually active women not at increased risk

SOURCES: USPSTF, 2004b, 2005a, 2007, 2008a.

The USPSTF 2008 Clinical Guidelines for counseling to prevent STIs indicate that "clinicians should also consider the communities they serve. If the practice's population has a high rate of STIs, all sexually active patients in non-monogamous relationships may be considered to be at increased risk" (Calonge et al., 2008).

The National Institute for Health and Clinical Excellence in the United Kingdom recommends identifying individuals at high risk for STIs by obtaining a sexual history and conducting one-on-one structured discussions with those at high risk of STIs. Those at risk include people who come from or who have visited areas with a high prevalence of HIV infection. Other

risk factors are misuse of alcohol or other substances, early onset of sexual activity, and unprotected sex or multiple sex partners (NICE, 2007).

The Centers for Disease Control and Prevention (CDC) recommends that all providers obtain a sexual history from each patient and engage in risk-reduction counseling. Evaluation of patients for the Five P's (partners, prevention of pregnancy, protection from STDs, practices, and past STDs) is considered an effective strategy for this purpose (Workowski and Berman, 2010). *Healthy People 2020* outlines a series of objectives for reducing STIs and STI complications, as well as addressing sexual risk behaviors (HHS, 2011a). The National Business Group on Health's (NBGH's) 2006 Evidence Statement also addresses the need for STI education and counseling (Campbell and Lantine, 2006). Furthermore, the Michigan Quality Improvement Consortium recommends that health maintenance exams include risk evaluation and counseling for STI prevention for all individuals aged 18 to 49 years (Michigan Quality Improvement Consortium, 2008). ACOG recommends counseling on STIs, including discussion of partner selection, barrier protection, and high-risk behaviors, as part of their recommended periodic assessments for women aged 13 and older (ACOG, 2007c). The American Medical Association (AMA) encourages physicians to educate their patients about STIs and condom use (AMA, 2003).

Bright Futures recommends that sexually active adolescents receive annual screenings for gonorrhea and chlamydia. In addition, Bright Futures provides anticipatory guidance for physicians to encourage adolescents to protect themselves from STIs and risky behaviors. Counseling on methods of safe sex and contraceptive use is recommended for sexually active adolescents (AAP, 2008).

Effective Interventions

Although many studies have focused primarily on behavioral interventions for prevention of HIV infection, interventions for prevention of STI and HIV infection are interdependent, because the risk-taking behaviors that result in an STI or HIV infection are similar. Short counseling interventions were shown to reduce risky behavior in patients at risk for HIV infection. Project RESPECT, a multicenter randomized control trial of 5,758 heterosexual individuals with STIs, showed that brief, individualized counseling increased the frequency of self-reported condom use through six months and reduced the rate of STI acquisition by 30 percent through six months and 20 percent through 12 months. It was also shown that counseling for those who had ever used drugs was effective and could be effective for current drug users (Kamb et al., 1998). Drug use, past and present, is a risk factor for HIV infection, gonorrhea, and potentially syphilis (Semaan et al., 2010). A study by Kelly et al. provides

some of the strongest evidence for the success of behavioral interventions in heterosexual women (Kelly et al., 1994). Rates of condom use increased from 26 to 56 percent after a cognitive behavioral intervention aimed at high-risk women.

The USPSTF currently recommends that physicians offer high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and adults at increased risk, defined by current STI status and multiple sexual partners. High-intensity interventions that were found to be effective were delivered in multiple sessions, most often in groups, with total durations being three to nine hours (USPSTF, 2008a).

In addition to a client-centered approach, the CDC recommends that comprehensive counseling includes addressing abstinence and condom use, reducing sex partners, and types of sex practiced (Friedel and Lavoie, 2008).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA is that STI counseling is limited to adults who currently have STIs or who identify themselves as having multiple sex partners. Additionally, screening for chlamydia for women aged 25 years and older is not defined by geographic risk factors.

The evidence provided to support a recommendation related to STI counseling is based on federal goals from CDC and *Healthy People 2020* (CDC, 2010e; HHS, 2011a), as well as recommendations from AMA and ACOG. The committee found insufficient evidence to support a new recommendation related to screening for chlamydia or gonorrhea; instead, the evidence supported by federal priorities and clinical professional guidelines led to a suggestion for those screenings to be addressed during a well-woman visit.

Recommendation 5.3: The committee recommends for consideration as a preventive service for women: annual counseling on sexually transmitted infections for sexually active women.

HUMAN IMMUNODEFICIENCY VIRUS INFECTION

HIV was addressed above in the section on STIs, as HIV infection frequently coexists with other STIs and the risk factors for HIV infection and STIs are much the same. HIV is a sexually transmitted virus that causes damage to an infected person's CD4+ T cells, which are crucial for helping

the body defend itself against diseases. HIV is the virus that causes AIDS, a condition in humans in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive. HIV can develop into AIDS within just a few years if it is left untreated (CDC, 2010a). Currently, no vaccine for HIV infection/AIDS is available (Flexner, 2007). However, to date more than 30 anti-HIV drugs have been developed and licensed. In combinations of three or more, these medications have proved extremely effective in slowing the progression of HIV if it is detected and treated early (Fauci, 2011). New HIV infections in women are found at the highest rates between ages 13 and 39 years (KFF, 2011).

Prevalence/Burden

Although HIV infection/AIDS is more prevalent in men, the rate of HIV infection/AIDS in women is increasing (IOM, 2010b). From 1999 to 2003, the CDC reported a 15 percent increase in AIDS cases among women but only a 1 percent increase in men (CDC, 2006). In 1985, women accounted for 8 percent of new AIDS cases, a proportion that grew to 25 percent in 2009 (CDC, 2011b; KFF, 2011). In 2009, 9,973 women were diagnosed with HIV infection.

The majority of HIV infection and AIDS cases in women are a result of high-risk heterosexual sex (CDC, 2010b; KFF, 2011). However, many women are unknowingly infected because of the risk behavior of their partners (Hader et al., 2001; IOM, 2010b; Varghese et al., 2002). In addition, an estimated 6,000 to 7,000 HIV-positive women in the United States give birth each year (Bulterys et al., 2002; CDC, 2007c; Lee and Fleming, 2001).

Women with HIV infection often have lower socioeconomic status. Family responsibilities and a lack of access to care have been identified as barriers to women managing their HIV infection and pursuing appropriate care (Bozzette et al., 1998; Cunningham et al., 1999; Fleishman et al., 2005; Shapiro et al., 1999). Although women share with men the complication of the progression of HIV infection to AIDS, they also experience gender-specific comorbidities, such as recurrent vaginal yeast infections, severe pelvic inflammatory disease, and increased risk of precancerous changes in the cervix (NIAID, 2008). In 2007, HIV infection was the fifth leading cause of death for women (aged 25 to 44 years), but it was the third leading cause of death for black women (CDC, 2011b; KFF, 2011). HIV infection was the number one cause of death for black women aged 25 to 34 years (CDC, 2008).

Women at risk for acquisition of HIV frequently do not appreciate that they are at risk (Hodder et al., 2010). Black women, in particular, report

not knowing their sexual partner's risks, such as injection drug use, having other current sex partners, or unknown HIV status (DeCarlo and Reznick, 2009). In 2005, 80 percent of HIV-positive black woman were infected through heterosexual sex (Rose et al., 2008).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection. Grade A Recommendation (USPSTF, 2005b).

The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection. Grade C Recommendation (USPSTF, 2005b).

Increased risk for HIV is defined by the following factors:

- Receives health care in a high-prevalence or high-risk clinical setting;
- Women having unprotected sex with multiple partners;
- Past or present injection drug users;
- Women who exchange sex for money or drugs or have sex partners who do;
- Individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users;
- Persons being treated for STDs;
- Persons with a history of blood transfusion between 1978 and 1985; and
- Persons who request an HIV test (USPSTF, 2005b).

The USPSTF also recommends that all pregnant women receive screening for HIV infection as part of prenatal care. Screening of adults and adolescent women who are not pregnant or who are not considered to be at increased risk for HIV infection is a USPSTF Grade C recommendation, implying that screening should not be routinely done but, rather, should be done on an individualized case-specific basis. Bright Futures recommends that all sexually active and at risk adolescents aged 11 to 21 years be screened for HIV infection annually (AAP, 2008).

The CDC, the American College of Physicians (ACP), the Infectious

Diseases Society of America (IDSA), AMA, ACOG, the American College of Nurse-Midwives, as well as the IOM recommend broader screening for HIV infection to include adolescents and sexually active adults to age 65 years (CDC, 2006; IOM, 2010a). The CDC qualifies its recommendation, stating that screening may not be warranted if the prevalence rate is <0.1 percent or the diagnostic yield is <1/1,000 screened. The CDC recommends opt-out screening and instructs physicians to offer counseling on HIV infection and test results before the patient is tested if the patient does not decline the screening. Preventive counseling regarding HIV infection is still recommended by the CDC, but the revised guidelines recommend separation of testing from screening for high-risk individuals as a way to eliminate one potential barrier to testing. For patients with a positive test result, the CDC recommends the provision of access to care, prevention counseling, and support services.

Effective Interventions

Risk-based screening has been shown in large health care networks to be an ineffective means of identifying individuals with HIV infection. Identified risk factors such as a current sexually transmitted disease or substance abuse have not been shown to be reliably used by physicians as reasons to screen, even within a health care system in which access to care is not a barrier (Gandhi et al., 2007; Owens et al., 2007). A review of Medicaid claims from 1998 revealed that of all cohort patients diagnosed with a non-blood-borne STI (gonorrhea, chlamydia, or pelvic inflammatory disease, strong risk factors for co-infection with HIV), only 10 percent were subsequently screened for HIV infection, despite the evidence that these are known risk factors for HIV infection (Rust et al., 2003). Additionally, among people who tested positive for HIV, approximately 25 percent did not report high-risk behaviors that would have led a physician to perform risk-based screening (Chou et al., 2005). As referenced earlier, many women do not believe themselves to be at risk, so it is unlikely that they will ask to be tested.

Opt-out screening was shown to be very effective in prenatal screening for HIV. In a retrospective cohort study of 12,221 pregnancies resulting in delivery, only 221 women declined the screening (Breese et al., 2004). This type of screening has been accepted by women and is now widely implemented (Schuman et al., 2004).

Early screening for HIV infection is crucial to afford patients effective treatment and also for the benefit of the patients' sexual partners. In a recent worldwide clinical trial, researchers found that HIV-infected men and women who were able to start oral antiretroviral medicines early in

the stage of HIV progression actually reduced their risk of transmitting the virus to their partners by 96 percent (NIAID, 2011).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that current screening recommendations by the USPSTF are limited in scope; that is, they are limited to pregnant women and high-risk adolescents and adults.

The evidence provided to support a recommendation for expanding screening is based on federal goals from the CDC, as well as clinical professional guidelines, such as those from the ACP, IDSA, AMA, and ACOG.

Recommendation 5.4: The committee recommends for consideration as a preventive service for women: counseling and screening for HIV infection on an annual basis for sexually active women.

PREVENTING UNINTENDED PREGNANCY AND PROMOTING HEALTHY BIRTH SPACING

Unintended pregnancy is defined as a pregnancy that is either unwanted or mistimed at the time of conception (Finer and Henshaw, 2006) and affects women with reproductive capacity, that is, from the time of menarche to menopause. Family planning services that are provided to prevent unintended pregnancies include contraception (i.e., all FDA-approved contraceptive drugs and devices, sterilization procedures) as well as patient education and counseling.

Prevalence/Burden

Unintended pregnancy is highly prevalent in the United States. In 2001, an estimated 49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time of conception—according to the National Survey of Family Growth (Finer and Henshaw, 2006). The unintended pregnancy rate is much lower in other developed countries (Trussell and Wynn, 2008). In 2001, 42 percent of U.S. unintended pregnancies ended in abortion (Finer and Henshaw, 2006). Although 1 in 20 American women has an unintended pregnancy each year, unintended pregnancy is more likely among women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group (Finer and Henshaw, 2006).

The consequences of an unintended pregnancy for the mother and the baby have been documented, although for some outcomes, research is limited. Because women experiencing an unintended pregnancy may not immediately be aware that they are pregnant; their entry into prenatal care may be delayed, they may not be motivated to discontinue behaviors that present risks for the developing fetus; and they may experience depression, anxiety, or other conditions. According to the IOM Committee on Unintended Pregnancy, women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy (IOM, 1995).

A more recent literature review found that U.S. children born as the result of unintended pregnancies are less likely to be breastfed or are breastfed for a shorter duration than children born as the result of intended pregnancies and that mothers who have experienced any unwanted birth report higher levels of depression and lower levels of happiness (Gipson et al., 2008). Finally, a recent systematic literature review found significantly increased odds of preterm birth and low birth weight among unintended pregnancies ending in live births compared with pregnancies that were intended (Shah et al., 2008).

The risk factors for unintended pregnancy are female gender and reproductive capacity. Although certain subgroups of women are at greater risk for unintended pregnancy than others (e.g., women aged 18 to 24 years, unmarried women, women with low incomes, women who are not high school graduates, and women who are members of a racial or ethnic minority group), all sexually active women with reproductive capacity are at risk for unintended pregnancy. In 2008, approximately 36 million U.S. women of reproductive age (usually defined as ages 15 to 44 years) were estimated to be in need of family planning services because they were sexually active, able to get pregnant, and not trying to get pregnant (Frost et al., 2010). More than 99 percent of U.S. women aged 15 to 44 years who have ever had sexual intercourse with a male have used at least one contraceptive method (Mosher and Jones, 2010).

Pregnancy spacing is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy). Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small for gestational age births (Conde-Agudelo et al., 2006; Fuentes-Afflick and Hessol, 2000; Zhu, 2005). In addition, women with certain chronic medical conditions (e.g., diabetes and obesity) may need to postpone pregnancy until appropriate weight loss or glycemic control has been achieved (ADA, 2004; Johnson et al., 2006). Finally, pregnancy may be contraindicated for women with serious medical conditions such as pulmonary hyper-

tension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and for women with the Marfan Syndrome (Meijboom et al., 2005; Regitz-Zagrosek et al., 2008; Warnes, 2004).

Existing Guidelines and Recommendations

Numerous health care professional associations and other organizations recommend the use of family planning services as part of preventive care for women, including ACOG, AAFP, the American Academy of Pediatrics (AAP), the Society of Adolescent Medicine, the AMA, the American Public Health Association, the Association of Women's Health, Obstetric and Neonatal Nurses, and the March of Dimes. In addition, the CDC recommends family planning services as part of preventive visits for preconception health (Johnson et al., 2006).

The USPSTF does not address prevention of unintended pregnancy. Bright Futures recommends that information about contraception be offered to all sexually active adolescents and those who plan to become sexually active (AAP, 2008).

The IOM Committee on Women's Health Research recently identified unintended pregnancy to be a health condition of women for which little progress in prevention has been made, despite the availability of safe and effective preventive methods (IOM, 2010b). This report also found that progress in reducing the rate of unintended pregnancy would be possible by "making contraceptives more available, accessible, and acceptable through improved services (IOM, 2010b). Another IOM report on unintended pregnancy recommended that "all pregnancies should be intended" at the time of conception and set a goal to increase access to contraception in the United States (IOM, 1995). *Healthy People 2020* (HHS, 2011a), which sets health goals for the United States, includes a national objective of increasing the proportion of pregnancies that are intended from 51 to 56 percent. In addition, *Healthy People 2020* sets goals to increase the number of insurance plans that offer contraceptive supplies and services, to reduce the proportion of pregnancies conceived within 18 months of a previous birth, and to increase the proportion of females or their partners at risk of unintended pregnancy who used contraception during the most recent sexual intercourse (HHS, 2011a).

Effective Interventions

Family planning services are preventive services that enable women and couples to avoid an unwanted pregnancy and to space their pregnancies to promote optimal birth outcomes. A wide array of safe and highly

effective FDA-approved methods of contraception is available, including barrier methods, hormonal methods, emergency contraception, and implanted devices; sterilization is also available for women and for men (FDA, 2010). This range of methods provides options for women depending upon their life stage, sexual practices, and health status. Some methods, such as condoms, spermicides, and emergency contraceptives, are available without a prescription, whereas the more effective hormonal and long-acting reversible methods, such as oral contraceptives and intrauterine devices, are available by prescription or require insertion by a medical professional. Sterilization is a surgical procedure. For women with certain medical conditions or risk factors, some contraceptive methods may be contraindicated. These can be assessed clinically so that an appropriate method can be selected for the individual (CDC, 2010; Dragoman et al., 2010).

The effectiveness of contraceptives is determined by studying the rate of failure (i.e., having an unintended pregnancy) in the first year of use (Table 5-3). The failure rates of all FDA-approved methods in both U.S. and international populations have been well documented and are negligible with proper use (Amy and Tripathi, 2009; Hatcher et al., 2007; Kost et al., 2008; Mansour et al., 2010). Female sterilization, the intrauterine device, and the contraceptive implant have failure rates of 1 percent or less in the first 12 months of use (Fu et al., 1999; Hatcher et al., 2007). Injectable and oral contraceptives have use failure rates of seven and 9 percent, respectively, because some women miss or delay an injection or pill (Kost et al., 2008). Failure rates for both male and female condoms and other barrier methods are higher (e.g., 15 percent for the male condom) (Amy and Tripathi, 2009). These rates compare with an 85 percent chance of an unintended pregnancy within 12 months among couples using no method of contraception (Hatcher et al., 2007; Trussell and Kost, 1987).

In addition to this evidence of method effectiveness, evidence exists that greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally. Studies show that as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined (Boonstra et al., 2006). Other studies show that increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use (Santelli and Melnikas, 2010).

As with all pharmaceuticals and medical procedures, contraceptive methods have both risks and benefits. Side effects are generally considered minimal (ACOG, 2011a,b,c; Burkman et al., 2004). Death rates associated with contraceptive use are low and, except for oral contraceptive users who

TABLE 5-3 Percentage of U.S. Women Experiencing an Unintended Pregnancy During First Year of Typical Use and First Year of Perfect Use, by Contraceptive Method

Method	% Experiencing Unintended Pregnancy in First Year of	
	Typical Use[a]	Perfect Use[b]
None	85	85
Spermicides (foams, creams, gels, vaginal suppositories, and vaginal film)	29	18
Withdrawal	27	4
Fertility awareness-based methods[c]	25	
Standard days method		5
Two-day method		4
Ovulation method		3
Sponge		
Parous women	32	20
Nulliparous women	16	9
Diaphragm (with spermicidal cream or jelly)	16	6
Condom (without spermicides)		
Female	21	5
Male	15	2
Combined pill and progestin-only pill	8	0.30
Evra patch	8	0.30
NuvaRing	8	0.30
Depro-Provera	3	0.30
Intrauterine Device		
ParaGard (copper T)	0.80	0.60
Mirena (LNG-IUS)	0.20	0.20
Implanon	0.05	0.05
Female sterilization	0.50	0.50
Male sterilization	0.15	0.10

[a] Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
[b] Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.
[c] The ovulation and 2-day methods are based on evaluation of cervical mucus. The standard day method avoids intercourse on cycle days 8 through 19.
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smoke, lower than the U.S. maternal mortality rate (Hatcher et al., 1998). For example, the oral contraceptive death rate per 100,000 users under the age of 35 years who are nonsmokers was 1.5 per 100,000 live births (Hatcher et al., 1998), compared with 11.2 maternal deaths per 100,000 live births in 2006 (age adjusted) (CDC, 2010c).

Contraceptive methods often have benefits separate from the ability to plan one's family and attain optimal birth spacing. For example, the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain (ACOG, 2010a). Long-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011).

Education and counseling are important components of family planning services because they provide information about the availability of contraceptive options, elucidate method-specific risks and benefits for the individual woman, and provide instruction in effective use of the chosen method (NBGH, 2005; Shulman, 2006). Research on the effectiveness of structured contraceptive counseling is limited (Halpern et al., 2006; Lopez et al., 2010b; Moos et al., 2003). However, studies show that postpartum contraceptive counseling increases contraceptive use and decreases unplanned pregnancy (Lopez et al., 2010a), that counseling increases method use among adolescents in family planning clinics (Kirby, 2007), that counseling decreases nonuse of contraception in older women of reproductive age (35 to 44 years) who do not want a future baby (Upson et al., 2010), and that counseling of adult women in primary care settings is associated with greater contraceptive use and the use of more effective methods (Lee et al., 2011; Weisman et al., 2002).

Although it is beyond the scope of the committee's consideration, it should be noted that contraception is highly cost-effective. The direct medical cost of unintended pregnancy in the United States was estimated to be nearly $5 billion in 2002, with the cost savings due to contraceptive use estimated to be $19.3 billion (Trussell, 2007). The cost-effectiveness of family planning is also documented in an evaluation of FamilyPact, California's 1115 Medicaid Family Planning Waiver Program. The unintended pregnancies averted in this program in 2002 would have cost the state $1.1 billion within two years, and $2.2 billion within five years, for public-sector health and social services that otherwise would have been needed (Amaral et al., 2007).

In a study of the cost-effectiveness of specific contraceptive methods, all contraceptive methods were found to be more cost-effective than no

method, and the most cost-effective methods were long-acting contraceptives that do not rely on user compliance (Trussell et al., 2009). The most common contraceptive methods used in the United States are the oral contraceptive pill and female sterilization. It is thought that greater use of long-acting, reversible contraceptive methods—including intrauterine devices and contraceptive implants that require less action by the woman and therefore have lower use failure rates—might help further reduce unintended pregnancy rates (Blumenthal et al., 2011). Cost barriers to use of the most effective contraceptive methods are important because long-acting, reversible contraceptive methods and sterilization have high up-front costs (Trussell et al., 2009).

Contraceptive coverage has become standard practice for most private insurance and federally funded insurance programs. For example, contraceptive services are covered for all federal employees and individuals who obtain their care through federally financed programs, such as VA, TRICARE for active-duty military and their dependents, and IHS. Federal programs provide funding for family planning services in community health centers through the Public Health Service Act, in family planning centers through Title X [Population Research and Voluntary Family Planning Programs (P.L. 91-572)], through the Maternal and Child Health Block Grant, and through the Medicaid program.

Since 1972, Medicaid, the state-federal program for certain low-income individuals, has required coverage for family planning in all state programs and has exempted family planning services and supplies from cost-sharing requirements. In addition, 26 states currently operate special Medicaid-funded family planning programs for low-income women who either no longer qualify for Medicaid or do not meet the program's categorical requirements. In Massachusetts, family planning services with no copayments will be included as part of the preventive benefits offered to members of Commonwealth Care, a program of subsidized health insurance for low- and moderate-income people (Personal communication, Stephanie Chrobak and Nancy Turnbull, Massachusetts Health Connector, May 10, 2011).

Private employers have also expanded their coverage of contraceptives as part of the basic benefits packages of most policies. This expansion has occurred in response to state and federal policies. Twenty-eight states now have regulations requiring private insurers to cover contraceptives, and 17 of these states also require that insurance cover the associated outpatient visit costs (Guttmacher Institute, 2011) (see Chapter 3). A federal court ruling issued in 2000 by the Equal Employment Opportunity Commission found an employer's failure to cover prescription contraceptive drugs and devices in a health plan that covers other drugs, devices, and preventive care to be discrimination against women in violation of Title VII of the Civil Rights Act (EEOC, 2000).

In 2007, NBGH recommended that employer-sponsored health plans include coverage of family planning services, without cost sharing, as part of a minimum set of benefits for preventive care. The Guttmacher Institute also calls comprehensive coverage of contraceptive services and supplies "the current insurance industry standard," with more than 89 percent of insurance plans covering contraceptive methods in 2002 (Camp, 2011). A more recent 2010 survey of employers found that 85 percent of large employers and 62 of small employers offered coverage of FDA-approved contraceptives (Claxton et al., 2010).

Despite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years. In fact, a review of the research on the impact of cost sharing on the use of health care services found that cost-sharing requirements, such as deductibles and copayments, can pose barriers to care and result in reduced use of preventive and primary care services, particularly for low-income populations (Hudman and O'Malley, 2003). Even small increments in cost sharing have been shown to reduce the use of preventive services, such as mammograms (Trivedi et al., 2008). The elimination of cost sharing for contraception therefore could greatly increase its use, including use of the more effective and longer-acting methods, especially among poor and low-income women most at risk for unintended pregnancy. A recent study conducted by Kaiser Permanente found that when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods (Postlethwaite et al., 2007).

Identified Gaps

Contraception and contraceptive counseling are not currently in the array of preventive services available to women under the ACA.

Systematic evidence reviews and other peer-reviewed studies provide evidence that contraception and contraceptive counseling are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in *Healthy People 2010* and *Healthy People 2020* (HHS, 2000, 2011a).

Recommendation 5.5: The committee recommends for consideration as a preventive service for women: the full range of Food and Drug

Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

BREASTFEEDING

Breastfeeding benefits the mother, the child, and society. The challenge is to ensure that the majority of mothers initiate breastfeeding and exclusively breastfeed their children during the first six months, with breastfeeding continuing to a year or beyond for every child (Gartner et al., 1997).

Prevalence/Burden

An AHRQ report from 2007 includes a summary of systematic reviews and meta-analyses on breastfeeding and maternal and infant health outcomes (Ip et al., 2007). The evidence is clear that breastfeeding reduces Sudden Infant Death Syndrome, gastrointestinal infections, upper and lower respiratory diseases, childhood leukemia, asthma, ear infections, childhood obesity, and diabetes mellitus type 2 risk for children, as well as rates of hospitalization (Table 5-4). They also concluded that sufficient results are available to be able to state that breastfeeding significantly lowers the maternal risk of breast and ovarian cancers (Table 5-4). Breastfeeding soon after birth may reduce the risk of maternal blood loss and enhance maternal-infant bonding (ACNM, 2004). A recent study concluded that if 90 percent of all children were exclusively breastfeed during the first six months of life, the United States would save $13 billion per year and prevent an excess of 911 deaths (Bartick and Reinhold, 2010). If only 80 percent of U.S. families complied, $10.5 billion would be saved and 741 deaths would be prevented each year.

In the United States, the majority of pregnant women plan to breastfeed (DiGirolamo et al., 2005), and yet there is a clear gap between the proportion of women who prenatally intend to breastfeed and those who actually do so by the time they are discharged after a brief hospital stay (California WIC Association and U.C. Davis Human Lactation Center, 2008; CDC, 2007b). The National Immunization Survey found that among the mothers of children born in 2007, 75 percent of mothers initiated breastfeeding, 43 percent were breastfeeding at six months, and 22 percent were breastfeeding at 12 months (CDC, 2007b). Although considerable progress has been made through overall promotion of breastfeeding in the United States, gains in breastfeeding rates have not been made equally across geographic, racial, and socioeconomic groups (Table 5-5).

Contrary to popular conception, breastfeeding appears to be a learned skill and the mother must be supported to be successful. Nevertheless,

TABLE 5-4 Impact of Breastfeeding on Infant and Maternal Health Outcomes from the Surgeon General's Call to Action to Support Breastfeeding

Outcome	Excess Risk (%) (95% CI)	Comparison Groups
Among full-term infants		
Acute ear infections (otitis media)	100 (56, 233)	EFF vs. EBF for 3 or 6 mos
Eczema (atopic dermatitis)	47 (14, 92)	EBF <3 mos vs. EBF ≥3 mos
Diarrhea and vomiting (gastrointestinal infection)	178 (144, 213)	Never BF vs. ever BF
Hospitalization for lower respiratory tract diseases in the first year	257 (85, 614)	Never BF vs. EBF ≥4 mos
Asthma, with family history	67 (22, 133)	BF <3 mos vs. ≥3 mos
Asthma, no family history	35 (9, 67)	BF <3 mos vs. ≥3 mos
Childhood obesity	32 (16, 49)	Never BF vs. ever BF
Type 2 diabetes mellitus	64 (18, 127)	Never BF vs. ever BF
Acute lymphocytic leukemia	23 (10, 41)	Never BF vs. >6 mos
Acute myelogenous leukemia	18 (2, 37)	Never BF vs. >6 mos
Sudden infant death syndrome	56 (23, 96)	Never BF vs. ever BF
Among preterm infants		
Necrotizing enterocolitis	138 (22, 2400)	Never BF vs. ever BF
Among mothers		
Breast cancer	4 (3, 6)	Never BF vs. ever BF (per year of breastfeeding)
Ovarian cancer	27 (10, 47)	Never BF vs. ever BF

ABBREVIATIONS: BF = breastfeeding; CI = confidence interval; EBF = exclusive breastfeeding; EFF = exclusive formula feeding.
SOURCE: HHS, 2011b.

a large gap exists in the area of providers discussing breastfeeding with patients prenatally and assisting with breastfeeding issues postnatally. Mothers' experiences as they receive this care have an influence on their intention to breastfeed (Howard et al., 1997), the establishment of breastfeeding (Dewey et al., 2003), and the duration of breastfeeding (DiGirolamo et al., 2003). The duration of breastfeeding is dependent on several factors. Two of these are confidence and commitment. Blyth et al. (2002) identified confidence to be a modifiable variable that may be "amenable to supportive interventions," rather than nonmodifiable demographic risk factors that are associated with feeding choices. Another review concluded that mothers often wean their babies before six months of age because of perceived difficulties with breastfeeding rather than because of choice, thus suggesting that a mother's lack of confidence in her ability to breastfeed may have a

TABLE 5-5 Provisional Breastfeeding Rates Among Children Born in 2007[a]

Sociodemographic Factor	Ever Breastfed (%)	Breastfeeding at 6 Months (%)	Breastfeeding at 12 Months (%)
United States	**75.0**	**43.0**	**22.4**
Race/ethnicity			
American Indian or Alaska Native	73.8	42.4	20.7
Asian or Pacific Islander	83.0	56.4	32.8
Hispanic or Latino	80.6	46.0	24.7
Non-Hispanic Black or African American	58.1	27.5	12.5
Non-Hispanic White	76.2	44.7	23.3
Receiving WIC			
Yes	67.5	33.7	17.5
No, but eligible	77.5	48.2	30.7
Ineligible	84.6	54.2	27.6
Maternal education			
Not a high school graduate	67.0	37.0	21.9
High school graduate	66.1	31.4	15.1
Some college	76.5	41.0	20.5
College graduate	88.3	59.9	31.1

[a] Survey limited to children aged 19–35 months at the time of data collection. The lag between birth and collection of data allows for tracking of breastfeeding initiation as well as calculating the duration of breastfeeding.

ABBREVIATION: WIC = Special Supplemental Nutrition Program for Women, Infants, and Children; U.S. Department of Agriculture.

SOURCE: From the Surgeon General's Call to Action to Support Breastfeeding (HHS, 2011b).

greater impact on breastfeeding success than her intent or desire to breastfeed (Dennis, 2002).

Mothers' experiences as patients during the maternity stay influence future feeding behaviors (Taveras et al., 2004); however, the quality of prenatal, postpartum, and pediatric medical care in the United States is inconsistent (DiGirolamo et al., 2008; Stark and Lannon, 2009). The CDC survey of Maternity Practices in Infant Nutrition and Care biannually assesses breastfeeding-related maternity practices in hospitals and birth centers across the United States. This survey discloses that policies and practices in U.S. maternity care facilities that are unsupportive and even harmful to breastfeeding, are pervasive throughout labor, delivery, and postpartum care, as well as in hospital discharge planning (CDC, 2011d).

Examples of these unsupportive policies and practices include placement of the stable, healthy, full-term newborn on an infant warmer immediately upon delivery rather than skin to skin with the mother, provision of infant formula or water to breastfed newborns without a medical indica-

tion, removal of the newborn from the mother's room at night, inadequate assurance of postdischarge follow-up for lactation support, and provision of promotional samples of infant formula from manufacturers (Bystrova et al., 2007; Chung et al., 2008; Moore et al., 2007; Rosenberg et al., 2008; Wight et al., 2009). Studies have shown that practices such as these are associated with a shorter duration of breastfeeding (DiGirolamo et al., 2008; Fairbank et al., 2000).

After being discharged from the hospital, mothers may have no means of identifying or obtaining the skilled support needed to address their concerns about lactation and breastfeeding; furthermore, barriers to reimbursement for needed lactation support and services may exist (Salem-Schatz et al., 2004). In addition, limited communication between providers across health care settings (Cherouny et al., 2005) and between providers and mothers may also make mothers less likely to comply with recommended postpartum health care visits than they were during the prenatal period (Stark and Lannon, 2009).

Several studies have found gaps between providers' intentions surrounding breastfeeding counseling and their training, experience, and practice in supporting patients with breastfeeding. Taveras and colleagues (2004) found that clinicians' perceptions of the counseling they provided on breastfeeding did not match their patients' perceptions of the counseling received. When clinicians' and patients' reports on the counseling were linked, it was found that among mothers whose prenatal clinicians stated that they always or usually discussed breastfeeding with their patients, only 16 percent of mothers indicated that breastfeeding had been discussed during their prenatal visits.

Another factor affecting the duration of breastfeeding is whether the mother works. The percentage of women in the U.S. workforce has increased dramatically over the past century, particularly in the past 50 years. One outcome of this is that working mothers, particularly those who work full time, breastfeed for a shorter duration, but it has been found that longer maternity leave and part-time work increase the rates of breastfeeding initiation and duration. A breastfeeding support program in the workplace is also important in helping to increase the breastfeeding duration. By 2009, 15 U.S. states required that employers support breastfeeding employees when they return to work (CDC, 2009a). For the continuation of breastfeeding, it is important that mothers have access to breast pumps to maintain their milk supply (Meek, 2001). Buying or renting a pump without insurance coverage is out of the economic reach of many low-income women, leaving them with few options for maintaining breastfeeding. Further, Chamberlain and colleagues (Chamberlain et al., 2006) found that providing access to breast pumps increases overall breastfeeding rates. Despite the recognition of the importance of breastfeeding in improving

women's and infant's health, coverage of breastfeeding support services differs significantly across the United States. In an analysis of state Medicaid provisions, the Henry J. Kaiser Family Foundation found that 25 states cover breastfeeding education services, 15 states cover individual lactation consultations, and 31 states cover equipment rentals, such as breast pumps (Ranji and Salganicoff, 2009).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding. Grade B recommendation (USPSTF, 2008b).

The USPSTF gives a Grade B to promoting and supporting breastfeeding, and a systematic review of the published literature on the effectiveness of primary care-based interventions encouraging breastfeeding concluded that breastfeeding interventions are more effective than usual care in increasing short- and long-term breastfeeding rates. Specifically, combined pre- and postnatal interventions and inclusion of lay support (such as peer counseling) in a multicomponent intervention are most likely to be effective (Chung et al., 2010).

The USPSTF concluded that promotion and support of breastfeeding are effective when they are integrated into systems of care that include training of clinicians and other health care team members and policy development. The Task Force noted that breastfeeding interventions should be designed and implemented in ways that do not make women feel guilty when they make an informed choice not to breastfeed (Chung et al., 2010).

The AAP Bright Futures program provides a framework for breastfeeding support that covers topics from counseling to prevention of breastfeeding problems (AAP, 2008). In January 2011, the U.S. Surgeon General, Dr. Regina Benjamin, released *The Surgeon General's Call to Action to Support Breastfeeding*, a comprehensive report that identifies specific steps that can be taken at the micro- and macrolevels to support breastfeeding mothers (HHS, 2011b). Included among these steps are ensuring that maternity care practices throughout the United States are fully supportive of breastfeeding and including basic support for breastfeeding as a standard of care for obstetricians, family physicians, and pediatricians. The steps also include accelerating the implementation of the Baby-Friendly Hospital

Initiative (WHO and UNICEF, 1999), which was established by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) in 1991 and which includes the use of evidence-based maternity practices, which are summarized in the Ten Steps to Successful Breastfeeding (Box 5-1).

The Joint Commission, the major accrediting organization for health care organizations in the United States, has identified the concept of bundles of care, such as those in the Ten Steps to Successful Breastfeeding (Box 5-1), as a promising strategy to improve the care provided to patients (Joint Commission on Accrediation of Healthcare Organizations, 2006). Researchers in California have found that hospitals that have attained a Baby-Friendly Hospital designation of Baby-Friendly Hospital Initiative do not have the disparities in the rates of exclusive breastfeeding that other hospitals in the same geographic region show (California WIC Association and U.C. Davis Human Lacation Center, 2008). Despite evidence of improved rates of breastfeeding, as of May 2011 only 110 hospitals in the United States were designated Baby-Friendly Hospitals (Kramer et al., 2001).

The Health Resources and Services Administration (HRSA) recently developed a model for implementing support for lactation and direct breastfeeding in the workplace, which is described in *The Business Case for*

BOX 5-1
Baby-Friendly Hospital Initiative Ten Steps

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within a half hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breast milk, unless medically indicated.
7. Practice "rooming in"—allow mothers and infants to remain together 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

SOURCE: WHO and UNICEF, 1989.

Breastfeeding: Steps for Creating a Breastfeeding Friendly Worksite (HHS, 2008). The program components outlined in the model include flexible breaks and work schedules, a sanitary and private place to express milk, education for pregnant and lactating women, and support from supervisors and coworkers. In addition, Section 4207 of the ACA amends the Fair Labor Standards Act of 1938 by requiring employers with more than 50 employees to provide reasonable break time for a mother to express milk and to provide a place, other than a restroom, that is private and clean where she can express her milk (111th U.S. Congress, 2010).

Healthy People 2020 contains specific objectives for improving maternal, infant, and child health (HHS, 2011a). Among these objectives is increasing the proportion of infants who are breastfed. The specific targets set for this objective are increasing the proportions of infants ever breastfed to 81.9 percent, the proportions of infants breastfed at six months to 60.6 percent, and the proportions of infants breastfed at one year to 34.1 percent. It also sets targets for increasing the proportion of infants exclusively breastfed through three months to 46.2 percent and exclusively breastfed through six months to 25.5 percent (HHS, 2011a). One of the recommendations from the National Prevention Council's (NPC's) June 2011 National Prevention Strategy report includes the support of policies and programs that promote breastfeeding (National Prevention Council, 2011).

A number of professional organizations have guidance or supportive statements indicating that they find breastfeeding to be the preferred method of feeding newborns and infants. AAFP (2005) and AAP (2005) have developed guidelines and recommendations that mothers breastfeed their infants. In 2007, ACOG issued a committee opinion stating strong support for breastfeeding and urging obstetricians and gynecologists, other health care professionals, hospitals, and employers to support women in choosing to breastfeed their infants (ACOG, 2007a).

Identified Gaps

Although the ACA ensures that counseling on breastfeeding is included, the committee recognizes that interpretation of this varies. The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that comprehensive prenatal and postnatal lactation support, counseling, and supplies are not currently included.

The evidence provided to support the inclusion of these services is based on systematic evidence reviews, federal and international goals (such as the U.S. Surgeon General, HRSA, *Healthy People 2020* [HHS, 2011a], WHO and UNICEF), and clinical professional guidelines such as those set forth by AAFP, AAP, and ACOG.

Recommendation 5.6: The committee recommends for consideration as a preventive service for women: comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)

INTERPERSONAL AND DOMESTIC VIOLENCE

Interpersonal and domestic violence, including intimate partner violence and childhood abuse, is a pattern of coercive behaviors that may include progressive social isolation, deprivation, intimidation, psychological abuse, childhood physical abuse, childhood sexual abuse, sexual assault, and repeated battering and injury. These behaviors are perpetrated by someone who is or was involved in a familial or intimate relationship with the victim. Women and adolescent girls of all ages experience interpersonal and domestic violence.

Prevalence/Burden

The CDC recognizes four categories of violence: physical violence, sexual violence, threat of physical or sexual violence, and psychological or emotional abuse (CDC, 2010c). Each year, as many as 1 million to 5 million women are physically, sexually, or emotionally abused by their intimate partners in the United States (Black and Breiding, 2008; The Commonwealth Fund, 1993; National Center for Injury Prevention and Control, 2003; Tjaden and Thoennes, 1998, 2000), and 39 percent of all women report intimate partner violence in their lifetimes (The Commonwealth Fund, 1999).

Prevalence rates of abuse measured in health care settings range from 4 to 44 percent within the year prior to being asked about abuse and from 21 to 55 percent over a lifetime (Abbott, 1995; Dearwater et al., 1998; Gin et al., 1991; Hamberger et al., 1992; Martins et al., 1992; Mccauley et al., 1995; Richardson et al., 2002). Approximately 20 percent of female public high school students in Massachusetts reported that they had been physically or sexually abused by a dating partner (Silverman et al., 2001). In the United States, approximately 35 percent of emergency room visits, 50 percent of all acute injuries, and 21 percent of all injuries in women requiring urgent surgery were the result of partner violence (Guth and Pachter, 2000).

The CDC estimates that intimate partner rape, stalking, and assault cost the United States more than $5.8 billion yearly, of which $4.1 billion goes to direct medical and mental health care services (National Center for Injury Prevention and Control, 2003). Women experiencing intimate partner violence have medical care costs 60 percent higher than women not experiencing abuse (Ulrich et al., 2003).

The prevalence of childhood physical and sexual abuse is not known. Prevalence estimates from population-based studies of women reporting histories of childhood physical and sexual abuse range between 20 and 38 percent (Finkelhor, 1994; Schoen et al., 1997, 1998). For adolescents, an analysis of self-reported abuse and neglect from the National Longitudinal Study of Adolescent Health indicated that 28 percent of 15,197 respondents experienced physical assault, 12 percent experienced physical neglect, 5 percent experienced contact sexual abuse, and 42 percent experienced supervision neglect (Hussey et al., 2006). Variations in estimates across studies are due to differences in the methodologies used to assess prevalence, a lack of standardized and accepted research instruments, and gaps in knowledge about how abuse victims frame and define their experiences (Hulme, 2004).

Interpersonal and domestic violence committed against adolescent girls may also meet definitions of child abuse. The 2003 Keeping Children and Families Safe Act amendment to the 1996 Federal Child Abuse Prevention and Treatment Act (CAPTA; 42 U.S.C.A. §5106g) defines "child abuse and neglect" as any recent act or failure to act on the part of a parent or caretaker which results in death, serious physical or emotional harm, sexual abuse or exploitation; or an act or failure to act which presents an imminent risk of serious harm (104th U.S. Congress, 1996; HHS, 2003, 2010). Individual states are required to define child abuse and neglect using the minimum standards in the federal law according to CAPTA; however, state definitions vary (HHS, 2009).

The immediate health consequences of interpersonal and domestic violence include injuries (Corrigan et al., 2003) and death from sexual assault (Broch, 2003), as well as sexually transmitted infections, including HIV infection (Wingood et al., 2001), pelvic inflammatory disease (Letourneau et al., 1999), pregnancy (Hathaway et al., 2000), and adverse psychological responses. Several chronic mental health conditions are related to interpersonal and domestic violence (Campbell, 2002), including posttraumatic stress disorder, depression, anxiety disorders, substance abuse, and suicide (Campbell and Lewandowski, 1997; Golding, 1999; Lehmann, 2000). Long-term physical conditions include chronic pain; neurological disorders resulting from injuries; gastrointestinal disorders, such as irritable bowel syndrome; migraine headaches; and various disabilities (Campbell and Lewandowski, 1997; Coker et al., 2000, 2002).

Although childhood sexual abuse is predominantly a prepubertal phenomenon (Finkelhor et al., 2009), the impact and consequences of this form of abuse are usually expressed in adolescence and persist into adulthood (Trickett et al., 2005). These include disability, suffering, and limitations in the quality of life that can be serious and often severe (Sickel et al., 2002). Women with childhood sexual abuse histories report more problems during pregnancy (Lukasse et al., 2009). Physical and sexual abuse in adolescence and young adulthood have been associated with poor self-esteem, alcohol and drug abuse, eating disorders, obesity, risky sexual behaviors, teen pregnancy, depression, trauma, anxiety, suicidality, and other conditions (Sickel et al., 2002; Trickett et al., 2005).

Asking women and adolescent girls about their interpersonal and domestic violence experiences could identify abuse not otherwise detected, help prevent future abuse, lessen disability, and improve future functioning and success in life (Battaglia et al., 2003; Coker et al., 2009; Martin et al., 2008; National Center for Injury Prevention, 2003; Svavarsdottir and Orlygsdottir, 2009). Women may not disclose abuse unless directly questioned under safe and respectful conditions (Dienemann et al., 2005), although there is no consensus about the most acceptable approach (Feder et al., 2009). Surveys indicate that 43 to 85 percent of female respondents consider screening for abuse acceptable, although only one-third of physicians and approximately half of emergency department nurses favored screening (Ramsay et al., 2002). Most women who have been screened for abuse report no adverse effects from the screening process (MacMillan et al., 2009; Spangaro et al., 2010).

Victims of abuse have frequent encounters with clinicians and health care services because adult victims of childhood abuse have poorer health than nonvictims and higher rates of health services utilization (Felitti, 1991; Fillingim et al., 1999; Valente, 2005). Physicians are in a unique position to identify women and adolescents experiencing abuse or neglect, and many physicians consider screening for abuse to be one of their important roles (Flaherty and Stirling, 2010). In practice, however, physicians rarely screen their patients or screen only selected patients, such as patients who have physical injuries (Bair-Merritt et al., 2004; Borowsky and Ireland, 2002; Chamberlain and Perhma-Hester, 2000, 2002; Erickson et al., 2000; Glass et al., 2001; Lapidus et al., 2002; Rodriguez et al., 2001). Barriers to screening include a lack of experience, training, time, and confidence in handling abuse cases (Bair-Merritt et al., 2004; Flaherty et al., 2006; Lane and Dubowitz, 2009; Starling et al., 2009).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF found insufficient evidence to recommend for or against routine screening of parents or guardians for the physical abuse or neglect of children, of women for intimate partner violence, or of older adults or their caregivers for elder abuse. Grade I Statement (USPSTF, 2004b).

The USPSTF recommendation applies to women without apparent injuries or symptoms of abuse and is based on the lack of evidence that screening for intimate partner violence in primary care settings reduces adverse health outcomes, including premature death (USPSTF, 2004). The Canadian Task Force on Preventive Health Care also found insufficient evidence to recommend for or against screening women for intimate partner violence (Wathen and MacMillan, 2003). A report by the Health Technology Assessment Program in the United Kingdom also concluded that evidence is insufficient to implement a screening program for partner violence against women either in health services generally or in specific clinical settings (Feder et al., 2009).

WHO states that better awareness among health workers of violence and its consequences and wider knowledge of available resources for abused women can lessen the consequences of violence (WHO, 2010). AMA recommends that physicians regularly inquire about sexual, physical, and psychological abuse when taking a medical history. Furthermore, as interpersonal abuse or violence may adversely affect a patient's health status, physicians are advised to consider abuse to be a factor in the presentation of medical complaints (AMA, 2008). ACOG recommends that physicians screen all patients for intimate partner violence and that screening should occur during routine visits and over the course of pregnancy (ACOG, 2010b). AAP also recommends screening, stating that pediatricians are in a position to recognize abused women in pediatric settings (Thackeray et al., 2010). Other groups, such as the American Nurses Association (ANA, 2000) and the Futures Without Violence (formerly the Family Violence Prevention Fund) (Family Violence Prevention Fund, 2004), also recommend that health care providers screen patients for intimate partner violence. Finally, VA covers women for health services related to intimate partner violence.

Bright Futures guidelines for adolescents include the provision of anticipatory guidance through discussions about developing healthy dating

relationships, managing conflict nonviolently, avoiding risky situations and people, and seeking help when in danger (AAP, 2008). Recommendations of other groups relevant to adolescents fall under more broadly defined statements about child abuse and neglect.

AAP advocates a prominent role for pediatricians in preventing child abuse and neglect and provides specific guidelines and information on specific risk factors and protective factors (Flaherty and Sterling, 2010). AMA recommends routine inquiry about child abuse or neglect (AMA, 2008). Other organizations do not specifically recommend universal screening but recommend that pediatricians and family practice clinicians remain alert for indications of abuse or neglect (AAFP, 2009; ENA, 2006).

All U.S. states have laws that require physicians and other health care workers, as well as other professionals who interact with children, to report suspected child abuse and neglect to Child Protective Services (CPS) (HHS, 2010b). In 2009, teachers, law enforcement and legal personnel, and social services staff made three-fifths of the reports to CPS, whereas anonymous sources, family members, friends, and neighbors made the remaining reports (HHS, 2010a). It is not clear how many reports originated from health care clinicians specifically. Some states also require physicians to report cases of adult intimate partner violence to legal authorities, and most states require reporting of injuries resulting from firearms, knives, or other weapons.

Effective Interventions

Although numerous community-based programs to safeguard victims of interpersonal and domestic violence exist, including counseling, hotlines, shelters, and advocacy groups, they are usually not directly associated with health care delivery systems. Few studies have evaluated the effectiveness of screening for abuse in health care settings by demonstrating subsequent reductions in abuse or improvement in health as a result of screening (Feder et al., 2009; Ramsay et al., 2009; Trabold, 2007; Wathen and MacMillan, 2003). Existing research has been limited by many factors, including the lack of integration of screening with services such as counseling, inadequate definitions and measurement of outcomes, loss to follow-up, insufficient study designs, patient privacy, stigma and repercussions of disclosure, and variability of individual cases, among others (Feder, 2009; MacMillan, 2006, 2009; Nelson, 2004; Rabin, 2009; Ramsay et al., 2004 Wathen and MacMillan, 2003). The 2004 IOM study *Advancing the Federal Research Agenda on Violence Against Women* reiterated the importance of strengthening the data and research infrastructure, especially the need for better prevalence and longitudinal data to determine the causes of violent victimization of women and the impact of interventions (IOM, 2004).

In the context of these issues, new research on screening and interventions for women identified with abuse in health care settings has been published since the previous 2004 USPSTF recommendation. These include evaluations of methods of identifying women who have been abused (Basile, et al. 2007; Feder et al., 2009; Rabin et al., 2009). Standardized questions and scales designed for screening purposes generally include from one to five items that may be scored in various ways to determine if abuse is present. The diagnostic accuracy of these questions varies, but five different sets of questions have been found to be suitably accurate (i.e., sensitivity and specificity >80 percent) (Chen et al., 2005 et al.; Ernst, 2004; Sohal, 2007; Thombs et al., 2007; Wathen et al., 2008; Weiss et al., 2003).

A large randomized trial compared women who were screened for abuse versus not screened in primary care and acute care settings in Canada. Results indicated improvements in rates of abuse and quality of life several months later, but there were no significant differences between screened and unscreened women (MacMillan et al., 2009). However, for ethical reasons, women randomized to the unscreened comparison group were also asked questions about abuse, received information about intimate partner violence, and were offered services if needed, reducing measureable differences between screened and unscreened women. This study also collected information on the potential harms of screening and reported no harms.

A randomized trial of counseling that included intimate partner violence as well as other health risks during pregnancy and postpartum reported less violence and better infant outcomes among women receiving counseling compared to those who did not (Kiely et al., 2010). Women in the counseling group had significantly fewer very preterm (<33 weeks) and very low birth weight (<1,500 grams) newborns, and increased gestational age (38.2 versus 36.9 weeks) (Kiely et al., 2010). Randomized trials of home visitation for new mothers at risk for abuse showed reduced measures of abuse compared to women not receiving these services (Bair-Merritt et al., 2010; Taft et al., 2011). In other trials, women reporting abuse who were randomized to counseling adopted more safety behaviors than women not receiving counseling (Gillum et al., 2009; McFarlane et al., 2002). Many additional observational and descriptive studies supporting screening and intervention have also been published, but the designs of these studies limit conclusions regarding their effectiveness.

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that interpersonal and domestic violence detection and counseling are not included.

The evidence provided to support a recommendation related to increasing detection of and counseling for interpersonal and domestic violence is based on peer-reviewed studies and federal and international policies, in addition to clinical professional guidelines from organizations, such as the AMA and ACOG.

Recommendation 5.7: The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.

WELL-WOMAN PREVENTIVE VISITS

Provision of Preventive Services

The committee examined existing guidelines, available evidence, and current clinical best practices to identify effective provision of services that, when provided to women through dedicated clinical encounters, have been shown to promote optimal well-being. Primary care office visits that are dedicated to preventive care may facilitate increased access to health care services that are shown to identify chronic disease risk factors, promote well-being, and/or decrease the likelihood or delay the onset of a targeted disease or condition. Box 5-2 contains examples of terms that are commonly used to label the prevention-oriented clinical encounter; this report

BOX 5-2
Common Terms Used for Well Visits

Preventive pediatric health care visit (AAP/Bright Futures)
Well-child checkup (Early Periodic Screening, Diagnosis, and Treatment program and Medicaid)
Well-adult checkup (Medicaid)
Health risk assessment (Medicaid)
"Welcome to Medicare" visit (Medicare)
Annual wellness examination (Medicare)
Health maintenance visit (MHQP)

uses the term "well-woman preventive visit" to describe the provision of prevention services in an office visit or clinical encounter.

Target Populations

Well-woman preventive care visits apply to women of all ages (and according to the committee's charge, women from 10 through 64 years) and stages of life. Stages of womanhood are defined by age groupings, which are in general alignment with published frameworks and practice guidelines (AAP, 2008). These include adolescence (subdivided into two subgroups ages 10 to 14 years and 15 to 19 years), early adulthood (ages 20 to 24 years), middle adulthood (ages 25 to 49 years), and later adulthood (after age 50 years).

Justification of Well-Woman Visits for Provision of Preventive Services

Women's Preventive Care Is Fragmented

Although "well" visits for adults are not explicitly recommended by the USPSTF, they provide an opportunity for delivering prevention services recommended by a number of government and nongovernment health care agencies (GAO, 2009). In the U.S. health care system, for women, the tendency is to separate reproductive health care services from other components of primary care (Weisman, 1998). Because many preventive services for women are for reproductive health (e.g., screening for cervical cancer and sexually transmitted infections and contraception services), many women may see obstetrician-gynecologists for those services and a generalist physician (a family physician or a general internist) for other components of their routine health care. For example, a national survey of the U.S. female population in 1998 showed that 29 to 49 percent of women, depending of type of health plan, see both a generalist and an obstetrician-gynecologist for their regular health care (Weisman and Henderson, 2001). In another study of women aged 18 to 64 years, 58 percent of women in all stages of life saw an obstetrician-gynecologist in addition to a generalist physician (Henderson et al., 2002). In the 2008 Kaiser Women's Health Survey, 44 percent of women aged 18 to 64 years reported seeing two or more regular providers (Ranji and Salganicoff, 2011). Given these patterns of physician use, it is likely that women make more than one visit and use more than a single provider to attain needed preventive services in a given year. Thus, no single type of provider can be identified as the sole primary care provider for women.

Women have greater health care needs than men and require a broader array of health services, but not all providers are equipped or able to

provide the full range of preventive services for women. A consequence of women obtaining preventive health care from more than one provider is that women's primary care is often fragmented.

Cost as a Major Barrier to Services and Visits

Although the preventive services detailed in Table 5-6 will be covered with no cost sharing under the ACA, insurance plans are permitted to require copayments for office visits (*Federal Register,* 2010). Increased health care costs, combined with the fact that most Americans have seen too little or no gains in income in recent years, can be seen as a threat to the health and financial status of women across the country (Collins et al., 2011). Furthermore, evidence suggests that these issues are adversely affecting women disproportionately compared to men. In 2010, for example, 44 percent of women but only 35 percent of men indicated that they were experiencing difficulty paying medical bills or were paying off medical debt. Furthermore, almost a third of women stated that they did not visit a doctor or clinic when they were faced with a medical problem because of cost, whereas less than a quarter of men reported the same experience (Robertson and Collins, 2011).

Gaps in Well Visits for Women

Clinical guidelines and mandated coverage for well visits exist for children and adolescents (until age 21 years), for some adults, and into maturity (for individuals aged 65 years and older) in public-sector health plans (Medicaid and Medicare) as well as some private-sector health plans (see below and Chapter 3). However, public programs may be incomplete in providing coverage in early, middle, and later adulthood. According to a Government Accountability Office analysis of responses to a survey of state Medicaid directors conducted between October 2008 and February 2009, only 39 states cover health maintenance visits to adults under their Medicaid programs (GAO, 2009). This significant gap in coverage places a disproportionate burden on women of childbearing age, putting them at a greater risk for disease and illness in their most active reproductive years.

Existing Guidelines and Recommendations

Adolescence

Clinical preventive services guidelines for adolescents issued by governmental agencies and nonprofit medical organizations (e.g., HRSA, the Maternal and Child Health Bureau, AAP, AMA, and AAFP) have long

TABLE 5-6 List of Preventive Services to Be Obtained During Well-Woman Preventive Visits Under Recommendation 8

Topic	Description	Grade
USPSTF Grade A and B Recommended Services		
Alcohol misuse counseling	The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.	B
Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B
Bacteriuria screening: pregnant women	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A
Blood pressure screening	The USPSTF recommends screening for high blood pressure in adults aged 18 and older.	A
BRCA screening, counseling about	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.	B
Breast cancer preventive medication	The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention.	B
Breast cancer screening	The USPSTF recommends screening mammography for women, with or without clinical breast examination, every 1–2 years for women aged 40 and older.	B
Breastfeeding counseling	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B
Cervical cancer screening	The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix.	A
Chlamydial infection screening: non-pregnant women	The USPSTF recommends screening for chlamydial infection for all sexually active nonpregnant young women aged 24 and younger and for older nonpregnant women who are at increased risk.	A
Chlamydial infection screening: pregnant women	The USPSTF recommends screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk.	B
Cholesterol abnormalities screening: women 45 and older	The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease.	A

TABLE 5-6 Continued

Topic	Description	Grade
Cholesterol abnormalities screening: women younger than 45	The USPSTF recommends screening women aged 20 to 45 for lipid disorders if they are at increased risk for coronary heart disease.	B
Colorectal cancer screening	The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.	A
Depression screening: adolescents	The USPSTF recommends screening of adolescents (12–18 years of age) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B
Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B
Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B
Folic acid supplementation	The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 μg) of folic acid.	A
Gonorrhea screening: women	The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors).	B
Healthy diet counseling	The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.	B
Hepatitis B screening: pregnant women	The USPSTF strongly recommends screening for hepatitis B virus infection in pregnant women at their first prenatal visit.	A
Human immunodeficiency virus (HIV) screening	The USPSTF strongly recommends that clinicians screen for HIV all adolescents and adults at increased risk for HIV infection.	A

continued

TABLE 5-6 Continued

Topic	Description	Grade
Obesity screening and counseling: adults	The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.	B
Osteoporosis screening: women	The USPSTF recommends that women aged 65 and older be screened routinely for osteoporosis. The USPSTF recommends that routine screening begin at age 60 for women at increased risk for osteoporotic fractures.	B
Rh incompatibility screening: first pregnancy visit	The USPSTF strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	A
Rh incompatibility screening: 24–28 weeks gestation	The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24–28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	B
Sexually transmitted infections (STIs) counseling	The USPSTF recommends high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs.	B
Syphilis screening: non-pregnant persons	The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A
Syphilis screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A
Tobacco use counseling and interventions: non-pregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A
Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.	A
Services Suggested by the Institute of Medicine[a]		
Diet and physical activity	Determine current levels of physical activity and eating behaviors in all adolescent and adult women and make referrals to appropriate services.	
Establishing pregnancy history of CVD-related conditions	Obtain a history of pregnancy complications, including preeclampsia, gestational hypertension, and gestational diabetes mellitus, from all women who have had at least one pregnancy.	
Mental health	Screen for suicide ideation and postpartum depression in women who are pregnant or who have recently given birth.	
Metabolic syndrome	Obtain a waist circumference as an essential component of screening for metabolic syndrome.	

TABLE 5-6 Continued

Topic	Description	Grade
Preconception care	Provide evidence-based tests, procedures, and screening for nonpregnant women to optimize reproductive outcomes and prevent or optimize treatment for chronic conditions, as well as topics for counseling and guidance for preconception health.	
Prenatal care	Provide evidence-based tests, procedures, and screening for pregnant women to optimize birth outcomes and future chronic conditions, as well as topics for counseling and guidance for prenatal care.	
STIs	Screen for chlamydia and gonorrhea for women above age 25 years with risk factors outlined by the USPSTF or if local rates of infections are high. High-prevalence settings are defined by the Centers for Disease Control and Prevention as those known to have a one percent or greater prevalence of infection among the patient population being served.	

[a] As suggested in Chapter 5 and Appendix A.

recommended annual well-child visits as part of a unified package of preventive health care services for children and adolescents (AAP, 1995; Elster, 1998; Elster and Kuznets, 1994).

Most recently, the Bright Futures Health Initiative, which was launched by HRSA's Maternal and Child Health Bureau in 1990, recommended a schedule of preventive services beginning in the prenatal period (for an initial history and anticipatory guidance) and running through 21 years of age for "children who are receiving competent parenting, have no manifestations of any important health problems, and are growing and developing in satisfactory fashion" (AAP, 1995, 2008). Bright Futures recommends preventive pediatric health care visits for children annually from ages 3 through age 21 years, including initial/interval medical histories, measurements, sensory screening, developmental/behavioral assessments, physical examination, age-appropriate procedures, oral health, and anticipatory guidance. Although the content of well care is tailored by gender to females and males, the recommended frequency or timing of well-care visits for girls and young women does not vary.

Under federal law, state Medicaid programs generally must cover a package of prevention services for children under age 21 years through the Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program (GAO, 2009). A key component of the EPSDT services is that it entitles

children to coverage of well-child checkups, which include a comprehensive health and developmental history, a comprehensive unclothed physical examination, appropriate immunizations and laboratory tests, and health education. The EPSDT program also covers other preventive services for children, such as height and weight measurement, nutritional assessment and counseling, immunizations, blood pressure screening, and cholesterol and other appropriate laboratory tests. State Medicaid programs must provide EPSDT program services at intervals that meet reasonable standards of medical and dental practice, as determined by the state and as medically necessary to determine the existence of a suspected illness or condition. Accordingly, either states must develop their own periodicity schedules (i.e., age-specific timetables that identify when EPSDT well-child checkups and other EPSDT services should occur), or they may adopt a nationally recognized schedule, such as that of AAP, which recommends well-child checkups once each year or more frequently, depending on age. The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) required the Secretary of HHS to set annual goals for children's receipt of EPSDT services, and the Centers for Medicare and Medicaid Services (CMS) established a yearly goal that each state must provide EPSDT well-child checkups to at least 80 percent of the children enrolled in the Medicaid program in their state.

Adulthood

For adults, the USPSTF clinical preventive services recommendations do not address how, when, where, or by whom prevention services are to be provided. For adolescents and adults, ACIP recommends age-specific timing of a full array of immunizations but does not explicitly mention their preferred provision in the context of the well-care office visit. As noted in Chapter 3, states and health insurance plans in the public and private sectors vary widely in the preventive services that they cover, including the payment for designated office visits and extended coverage for specific prevention services.

For persons 65 years and older, well visits are generally covered. All new Medicare beneficiaries have been eligible to receive a welcome to Medicare visit that is similar in scope to a wellness visit (GAO, 2009). The ACA broadens this benefit for beneficiaries to include a new annual wellness examination for all beneficiaries with no copayment. At this visit, medical and family health histories are reviewed, along with the collection of basic health measurements, screening for preventive services, and the identification of risk factors and treatment options.

State Health Plan Example

In recent years, the Commonwealth of Massachusetts has been at the forefront in establishing a core set of clinical guidelines for the well care of average-risk adults 18 years of age and older from the general population (MHQP, 2007). These guidelines include health maintenance visits that were recommended annually for people age 18 to 21 years; every one to three years, depending on risk factors, from ages 22 to 49 years; and then annually for all adults 50 years of age and older. The health maintenance visit includes an individual and family history, an age-appropriate physical examination, indicated preventive screenings and counseling, and ACIP-based immunization updates. General counseling and guidance at every age include screening for alcohol and substance abuse, depression, physical activity, tobacco use, and violence or abuse in the home, as well as safety and injury and violence prevention

Statewide health care reform in Massachusetts established minimum creditable coverage regulations, which apply for purposes of the individual mandate and to all Commonwealth Care policies. These require that health plans cover at least three preventive care visits per year for an individual (six visits under a family policy) before any deductible is applied. However, preventive care visits require the normal copayment. After the enactment of the ACA, as of July 1, 2011, no copayments for preventive services, including both preventive service visits and the well office visit (Current Procedural Terminology Codes 99381 to 99397), will be charged for any patient (Personal communication, Stephanie Chrobak and Nancy Turnbull, Massachusetts Health Connector, May 10, 2011).

Private-Sector Coverage of Well-Visits

Private health maintenance plans, such as Kaiser Permanente, cover and encourage the utilization of a wide array of prevention services in the context of ongoing primary care for beneficiaries of all ages. They do not, however, promote a specific periodicity of prevention visits (Kaiser Permanente, 2011). Although detailed coverage and benefit information about the scope of preventive services covered by insurance plans is difficult to obtain, Chapter 3 addresses more examples of current private insurance practices.

Special Considerations for Reproductive Health Care

Provision of Preconception Health Care

The preconception period (before the first pregnancy) and the interconception period (between all subsequent pregnancies) have been identi-

fied as opportune times for the provision of focused well-woman preventive care visits to identify and modify biomedical, behavioral, and social risks to a woman's health and/or pregnancy outcomes. In 2006, the CDC developed recommendations for preconception care on the basis of a review of published research and the opinions of specialists from the CDC Agency for Toxic Substances and Disease Registry Preconception Care Work Group and the Select Panel on Preconception Care. The recommendations of the CDC were aimed at achieving four primary goals:

> 1) improving the knowledge and attitudes and behaviors of men and women related to preconception health; 2) assuring that all women of childbearing age in the United States receive preconception care services (i.e., evidence-based risk screening, health promotion, and interventions) that will enable them to enter pregnancy in optimal health; 3) reducing risks indicated by a previous adverse pregnancy outcome through interventions during the interconception period; and 4) reducing the racial disparities in adverse pregnancy outcomes. (Johnson et al., 2006)

However, the report did not recommend a specific suite of interventions to be included in routine preconception care. Strong evidence suggests that a number of components of preconception care are effective in improving health outcomes for women and children, in particular, screening of women who are seeking family planning services to identify and treat preconception risk conditions, the provision of nutrition services for women affected by particular metabolic conditions such as hyperphenylalanemia and diabetes, the use of dietary folate supplements by women of reproductive age who are sexually active (Korenbrot et al., 2002), and screening for depression. Furthermore, better pregnancy outcomes have been demonstrated as the result of preconception interventions for alcohol and smoking cessation (Lumley et al., 2004).

The CDC Select Panel on Preconception Care considers all women of reproductive age and potential presenting to primary care as candidates for preconception care. Its 2006 recommendations include the provision of a prepregnancy visit for couples and individuals planning a pregnancy and, as part of primary care preventive care visits, risk assessment and educational and health counseling for all women of childbearing age for improving reproductive outcomes and reducing the sequelae of future chronic diseases among women and their offspring. In 2011 the NPC issued the National Prevention Strategy. Recommendations include increasing use of preconception and prenatal care (National Prevention Council, 2011).

Prenatal Care for the Provision of Preventive Services

Another type of well-woman preventive care visit is the routine prenatal care visit for pregnant women. AAP and ACOG currently recommend

the following visit schedule for women with an uncomplicated pregnancy: a visit every 4 weeks for the first 28 weeks of pregnancy, a visit every 2 weeks until 36 weeks of pregnancy, and weekly visits thereafter (ACOG, 2007c). Women with high-risk pregnancies may need more frequent visits. The recommended content of the visit includes specific tests and procedures (e.g., blood pressure, weight, urine test, uterine size and fetal heart rate assessment, glucose tolerance testing, and screening for specific sexually transmitted infections and genetic or developmental conditions), as well as topics for counseling and guidance (e.g., tobacco avoidance and nutrition). The U.S. Public Health Service Expert Panel on the Content of Prenatal Care (USPHS, 1989) recommends less frequent visits, and some studies have supported the safety and efficacy of visits at a reduced frequency for multiparous and low-risk women. Regardless of the periodicity, pregnant women are likely to make more well-woman preventive care visits than nonpregnant women.

Additional Considerations to Assure Access to Well-Visits

Adolescence and Early Adulthood

Although an array of clinical guidelines recommend an annual well-child visit through age 21 years for the provision of preventive services, evidence on the rates of compliance with the recommendations are mixed. Only 38 percent of adolescents received a preventive care visit in the previous year, and black, Hispanic, and lower-income adolescents were the least likely to have had a preventive care visit (Irwin, 2009). Evidence of the efficacy of preventive services delivered to adolescents is stronger for increasing knowledge and awareness than for changing risky behaviors (Ozer et al., 2004).

As the ACA expands access to private and public health insurance for adolescents and young adults, it may also raise challenges for ensuring that confidential care is delivered to a newly insured segment of the adolescent and young adult population. Adolescents and young adults are likely to forgo health care when they feel that they lack access to confidential care. Time alone with the provider can enhance the client's sense of confidentiality, and it has been shown that adolescents attending a preventive care visit are more likely to have time alone with their provider than with those with a non-preventive care visit (40 and 28 percent, respectively) (Edman et al., 2010). However, the overall proportion of young people accessing confidential care remains relatively low, particularly for adolescents from low-income and ethnically diverse populations.

Other Barriers

Children enrolled in Medicaid are generally eligible for a well-child check up at least once every one to two years, but according to Medical Expenditure Panel Survey data from 2003 to 2006, an estimated 41 percent of children in Medicaid aged 2 through 20 years had not received a well-child checkup during the previous 2-year period. The estimated proportions of privately insured children who had received a well-child checkup were generally similar. CMS collects data and reports from states on the provision of EPSDT services, and reports from fiscal years 2000 through 2007 show that most states are not achieving the yearly goal of CMS that each state provide EPSDT well-child visits to at least 80 percent of the children enrolled in Medicaid in their state who should receive such care. State reports for 2007 showed that, on average, 58 percent of children enrolled in Medicaid received at least one EPSDT well-child visit for which they were eligible; the rates in individual states varied from 25 to 79 percent (GAO, 2009). As noted earlier for adults, only 39 states cover health maintenance visits to adults under Medicaid (GAO, 2009). Additional outreach to foster optimal utilization of preventive services may be necessary to overcome nonclinical barriers (e.g., transportation, literacy, and translation services).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is lack of inclusion of well-woman preventive visits for women 21 to 64 years of age, which are used for providing recommended preventive services.

The evidence provided to support the inclusion of this service is based on federal and state policies (such as included in Medicaid, Medicare, and the Commonwealth of Massachusetts), clinical professional guidelines (such as those of AMA and AAFP), and private health plan policies (such as those of Kaiser Permanente).

Recommendation 5.8: The committee recommends for consideration as a preventive service for women: at least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

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6

Process for Regularly Updating the Recommendations

In this report, the Committee on Preventive Services for Women identifies a supplemental set of preventive health care services for women that should be considered by the U.S. Department of Health and Human Services (HHS). This task meets the first portion of the committee's charge, which was to identify services and screenings that could fill the identified gaps in women's preventive care not otherwise included in existing preventive services covered under the Patient Protection and Affordable Care Act of 2010 (ACA).

The second part of the committee's charge was to provide guidance on a process for updating the preventive services and screenings to be considered. Developing and maintaining a comprehensive list of covered preventive services for women is not currently under the specific purview of any advisory group, task force, committee, or agency within HHS. Thus, the committee believes that it will be necessary to develop structures, accountability, and processes to ensure that preventive services meeting evidence standards are considered for coverage in the context of the general approach taken to identify and update preventive services for women. Here, the committee recommends a process supported by guiding principles that separates assessment and coverage decisions. The co-mingling of evidence reviews and coverage decision making in one body could result in skewing scientific results and a decrease in transparency in the rationale for the coverage decision. Components for a comprehensive structure are discussed below.

GUIDING PRINCIPLES AND RECOMMENDATIONS

Recommendation 6.1: The committee recommends that the process for updating the preventive services for women covered under the ACA be:

- **Independent;**
- **Free of conflict of interest;**
- **Evidence-based;**
- **Gender specific;**
- **Life-course oriented;**
- **Transparent;**
- **Informed by systematic surveillance and monitoring;**
- **Cognizant of the need to integrate clinical preventive services with effective interventions in public health, the community, the workplace, and the environment; and**
- **Appropriately resourced to meet its mandate.**

A PREVENTIVE SERVICES COVERAGE COMMISSION

The committee notes that coverage decisions must take into consideration a more extensive list of factors—including medicolegal considerations, ethical considerations, patient and provider preferences, cost, and cost-effectiveness—and that these decisions must be made in the context of the coverage decisions made in other clinical domains. Existing evidence review bodies (such as the United States Preventive Services Task Force [USPSTF]) focus on clinical evidence; and other bodies that develop clinical guidelines (professional organizations) do not have the methods, the expertise, or the independence to make coverage recommendations. The committee believes that the review of the evidence and decision making about coverage are two separate activities and that there is value in preserving the separation. Thus, the committee does not recommend adding coverage decision making to the scope of work of existing evidence review bodies or bodies that develop clinical guidelines.

Recommendation 6.2: The committee recommends that the Secretary of HHS establish a commission to recommend coverage of new preventive services for women to be covered under the ACA.

In carrying out its work, the commission should:

- **Be independent from bodies conducting evidence reviews, free of conflict of interest, and transparent;**
- **Set goals for prevention (it may use available HHS reports and products or commission its own at its discretion);**

- **Design and implement a methodology for making coverage decisions that considers information from bodies that review the available clinical evidence (and other bodies that establish clinical guidelines) and coverage factors (e.g., cost, cost-effectiveness, and legal and ethical factors);**
- **Conduct horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify new information on significant health conditions; preventive interventions; and new evidence on efficacy, effectiveness, periodicity, and safety;**
- **Focus on the general population but also search for conditions that may differentially affect women and high-risk subpopulations of women;**
- **Assign topics and set priorities for evidence-based reviews for the bodies reviewing clinical effectiveness;**
- **Set timetables and processes for updating clinical practice guidelines and coverage recommendations; and**
- **Submit its coverage recommendations to the Secretary of HHS.**

As noted in the guiding principles, suggested priorities are systematic surveillance and monitoring, as well as horizon scanning for new information on significant health conditions, preventive interventions, and new evidence on efficacy, effectiveness, periodicity, and safety. Similarly, setting agendas, timetables, and resources for developing the evidence reviews and guidelines will need to be recommended to the Secretary of HHS. A commission would not conduct its own systematic reviews of clinical effectiveness, relying instead on reviews completed by evidence review bodies under its direction. Recommendations will also need to be made by the commission regarding updates of evidence reviews and coverage decisions. Five years is a common benchmark for reevaluation of clinical practice guidelines and is the benchmark used by the National Guidelines Clearinghouse, but the committee notes that the process of scanning for new developments often uncovers issues that may require updates at other times.

ROLE OF EVIDENCE-BASED REVIEW BODIES

The committee believes that bodies that review the evidence, such as USPSTF, Bright Futures, and the Advisory Committee on Immunization Practices (ACIP), should continue to focus on evidence of efficacy and effectiveness. These bodies have an important role to perform and to contribute to this process in responding to direction from the Secretary of HHS and addressing topics requested. If necessary, systematic reviews will be commissioned, meeting established standards (e.g., the standards outlined in

Finding What Works in Health Care: Standards for Systematic Reviews [IOM, 2011b]). The evidence-review bodies should review the evidence with a primary focus on efficacy and effectiveness and develop clinical practice guidelines meeting established standards (e.g., the standards outlined in *Clinical Practice Guidelines We Can Trust* [IOM, 2011a]).

If the Secretary of HHS determines that existing evidence-review bodies cannot support these activities, new bodies that review the evidence should be created. Such bodies would best be populated with experts from within and outside government who are free of conflicts of interest and who represent a wide range of health and related disciplines. These experts should use standard, transparent, and accountable approaches to identify, assess, and synthesize the relevant evidence.

Recommendation 6.3. The committee recommends that the Secretary of HHS identify existing bodies or appoint new ones as needed to review the evidence and develop clinical practice guidelines to be reviewed by a preventive services coverage commission.

DISCUSSION

Bringing coverage for clinical preventive health care services into rational alignment with coverage for other health care services provided under the ACA will be a major task. The committee notes that many of the individual components are already managed within HHS but currently lack effective coordination for the purposes outlined in the ACA and that some functions are entirely new. The structure might be effectively built over time by using some current bodies and adding new ones as resources permit. The committee does not believe that it has enough information to specifically recommend which unit in HHS should implement the recommendations. Figure 6-1 illustrates the committee's suggested structure for updating preventive services under the ACA.

Additionally, the 2011 Institute of Medicine (IOM) study *Finding What Works in Health Care: Standards for Systematic Reviews* examines different grading systems in use. One review mentioned in the study found that there were more than 50 evidence-grading systems and 230 quality assessment instruments in current use. The variation, complexity, and lack of transparency in existing systems were identified (IOM, 2011b). In light of this, the Preventive Services for Women Committee chose not to identify a recommendation for HHS to consider for use in grading evidence. However, many of these models may warrant consideration.

The committee is aware that the IOM Determination of Essential Health Benefits Committee is developing recommendations regarding the criteria and methods for determining and updating the essential health

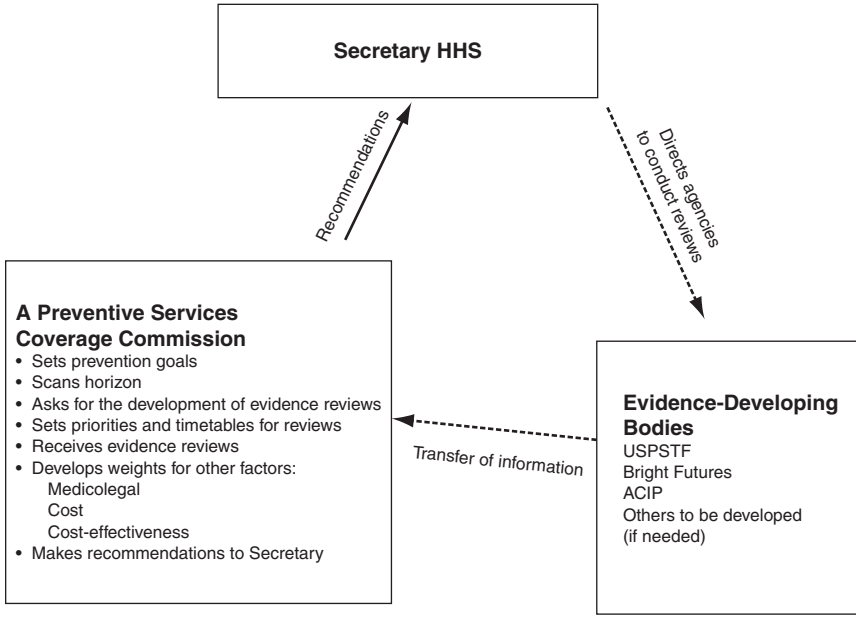

FIGURE 6-1 Suggested structure for updating preventive services under the ACA.

benefits package. That committee is reviewing how insurers determine covered benefits and medical necessity and will provide guidance on the policy principles and criteria for the Secretary to take into account when examining qualified health plans for appropriate balance among categories of care and limits on patient cost sharing. The committee's recommendations are forthcoming.

Although the ACA's preventive coverage rules are clearly directed at clinical services, the committee recognizes that in view of the critical importance of community-based preventive services and the public health system in achieving clinical aims, the committee thus encourages the Secretary to consider widening the scope of authority to include public health efforts to more comprehensively address prevention (e.g., as discussed in *Healthy People 2020: Topics & Objectives* [HHS, 2011]). It will be critical for the proposed preventive services coverage commission to coordinate with the new and existing bodies that are involved with other elements of the ACA.

Finally, the committee notes that it would make the most sense to consider preventive services for women, men, children, and adolescents in the same way. Thus, although the committee's recommendations presented here address women's preventive services, the process could be equally useful for

determining preventive services for men, children, and male adolescents that should be covered by the ACA.

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7

Findings and Recommendations for Addressing Identified Gaps in Preventive Services for Women

The Committee on Preventive Services for Women reviewed a large body of evidence on conditions that are important to women's health and well-being (see Chapters 1 and 4), including health conditions that may be specific to women, are more common or more serious in women, have distinct causes or manifestations in women, or have different outcomes or treatments in women (IOM, 2010). The committee also reviewed evidence on effective preventive measures used to address those diseases and conditions. The committee developed a list of potential preventive measures for the Secretary of the U.S. Department of Health and Human Services (HHS) to consider for coverage without cost sharing as it develops policies and programs as part of the requirements of the Patient Protection and Affordable Care Act of 2010 (ACA). Finally, Chapter 6 outlined the committee's suggested process for updating the review of preventive services for making decisions about coverage with no cost sharing by health plans governed by the ACA.

Table 7-1 summarizes the committee's recommendations for preventive services that could supplement currently recommended preventive services.

CONCLUDING OBSERVATIONS FROM THE COMMITTEE

The committee noted that a number of women's health-related research needs identified throughout the study process have been addressed more comprehensively in other Institute of Medicine (IOM) reports. Most recently, the IOM reports *Women's Health Research: Progress, Pitfalls, and Promise*, *Weight Gain During Pregnancy: Reexamining the Guidelines*,

TABLE 7-1 Summary of the Committee's Recommendations on Preventive Services for Women

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Screening for gestational diabetes	I	The evidence provided to support a recommendation for screening for gestational diabetes is based on current federal practice policy from the U.S. Indian Health Service, the U.S. Department of Veterans Affairs, as well as current practice and clinical professional guidelines such as those set forth by the American Academy of Family Physicians and the American Congress of Obstetricians and Gynecologists.	**Recommendation 5.1** The committee recommends for consideration as a preventive service for women: screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.
Human papillomavirus testing (HPV)	I	The evidence provided to support a recommendation to support testing for HPV is based on federal practice policy from the U.S. Department of Defense. Peer-reviewed studies demonstrate that improved testing technologies, particularly combined screening using both conventional cytology and high-risk HPV DNA testing, may significantly improve the rate of detection of cervical cancer precursors and facilitate the safe lengthening of the interval for screening.	**Recommendation 5.2** The committee recommends for consideration as a preventive service for women: the addition of high-risk human papillomavirus DNA testing in addition to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections (STI)	I	The evidence provided to support a recommendation related to STI counseling is based on federal goals from the Centers for Disease Control and Prevention and *Healthy People 2020*, as well as recommendations from the American Medical Association and the American College of Obstetricians and Gynecologists.	**Recommendation 5.3** The committee recommends for consideration as a preventive service for women: annual counseling on sexually transmitted infections for sexually active women.

TABLE 7-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Counseling and screening for human immunodeficiency virus (HIV)	C	The evidence provided to support a recommendation for expanding screening for HIV is based on federal goals from the Centers for Disease Control and Prevention, as well as clinical professional guidelines, such as those from the American College of Physicians, the Infectious Diseases Society of America, the American Medical Association, and the American College of Obstetricians and Gynecologists.	**Recommendation 5.4** The committee recommends for consideration as a preventive service for women: counseling and screening for human immunodeficiency virus infection on an annual basis for sexually active women.
Contraceptive methods and counseling	Not Addressed	The evidence provided to support a recommendation related to unintended pregnancy is based on systematic evidence reviews and other peer-reviewed studies, which indicate that contraception and contraceptive counseling, are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in *Healthy People 2010* and *Healthy People 2020*.	**Recommendation 5.5** The committee recommends for consideration as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

continued

TABLE 7-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Breastfeeding support, supplies, and counseling	B	The evidence provided to support a recommendation regarding the inclusion of breastfeeding services is based on systematic evidence reviews, federal and international goals (such as the U.S. Surgeon General, Health Resources and Services [HRSA], *Healthy People 2020*, World Health Organization and UNICEF), and clinical professional guidelines such as those set forth by the American Academy of Family Physicians, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists.	**Recommendation 5.6** The committee recommends for consideration as a preventive service for women: comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)
Screening and counseling for interpersonal and domestic violence	I	The evidence provided to support a recommendation related to increasing detection of and counseling for domestic violence and abuse is based on peer-review studies and federal and international policies, in addition to clinical professional guidelines from organizations, such as the American Medical Association and the American College of Obstetricians and Gynecologists.	**Recommendation 5.7** The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.

TABLE 7-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Well-woman visits	Not Addressed	The evidence provided to support a recommendation for including well-woman visits is based on federal and state policies (such as included in Medicaid, Medicare, and the commonwealth of Massachusetts), clinical professional guidelines (such as those of the American Medical Association and the American Academy of Family Practitioners), and private health plan policies (such as those of Kaiser Permanente).	**Recommendation 5.8** The committee recommends for consideration as a preventive service for women: at least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

and *Preterm Birth: Causes, Consequences, and Prevention* identified research priorities (IOM, 2007, 2009b, 2010). Additionally, the conditions described in Appendix A serve as examples for where additional high-quality research is needed to understand and better address preventive services specific to women.

The committee noted in its final deliberations that the United States Preventive Services Task Force (USPSTF) deserves much credit for identifying a nearly complete list of recommended preventive services for women. The USPSTF systematic evidence reviews were of great benefit during the committee's initial and follow-up examinations of the evidence. Additionally, the *Bright Futures* report (AAP, 2008) and the guidelines of the Advisory Committee on Immunization Practices filled several gaps not reviewed by the USPSTF. Although the committee started with an expansive look at a large number of diseases and conditions, the final recommendations summarized in this chapter are few.

Of note, during the course of the study process, the committee faced a number of difficult decisions. The committee decided that a strong case needed to be made regarding a disease or condition having a disproportionate effect on women. Although the committee upheld this standard, some of the recommendations made by the committee could also be considered for male populations.

Another factor that was difficult for the committee to fully ignore was the cost implications of the recommended services on the insurance market. Costs and cost-effectiveness are not easy to define or measure and differ depending upon priority perspectives—private insurer, government payer, patient, or society. The 2009 IOM study *Initial National Priorities for Comparative Effectiveness Research* examines priorities for considering cost-effectiveness in developing policy decisions (IOM, 2009a). Although the cost-effectiveness of services and examination of what the impact of new preventive health care services will have on health insurers were specifically excluded from committee's consideration, the committee notes that this sometimes made its task more difficult.

In addition, the committee deliberated on a number of interventions for reducing the incidence of diseases and conditions that were deemed effective but that were considered to be tertiary prevention, or interventions where a disease or condition had already been diagnosed. The committee determined that tertiary interventions involved treatment (and, potentially, prevention) decisions, which were outside of its scope.

Finally, questions rose as to what is common sense practice for a physician to discuss with patients. Does encouraging wearing a seat belt fall into this category? Is it the physician's responsibility to counsel patients with no clinical risk factors about healthful eating? To what extent should adolescents be afforded confidentiality? The gaps in gender analysis made this task even more difficult.

The ACA offers much promise in promoting prevention as an effective tool to improve health and well-being. When patients have health insurance coverage, a clear understanding of recommended services and screenings, and a usual source of care, it is the committee's belief that positive health outcomes will ensue. The ACA provides hope in efforts to eliminate health disparities and improve the health and well-being of women, children, and men across the United States.

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Appendixes

Appendix A

Clarifications

This appendix describes several conditions that the Committee on Preventive Services for Women examined to determine if there may be gaps in preventive services necessary for women's health and well-being that are not included in the United States Preventive Services Task Force (USPSTF) Grade A and B recommendations, Bright Futures, and Advisory Committee on Immunization Practices (ACIP) guidelines. The committee conducted a full review of the following conditions and risk factors, including those relating to cardiovascular disease, osteoporosis, breast cancer, mental health, tobacco use, and diet and physical activity. For these conditions, the committee concluded that there was insufficient evidence to develop new recommendations. At the same time, evidence supported by peer-reviewed studies, federal goals, professional clinical guidelines, and existing federal practices led the committee to suggest a clarifying statement to existing USPSTF recommendations, or led to a suggestion that specific services should be addressed within the context of the well-woman preventive care visit recommended by the committee. Several of the committee descriptions that follow serve as examples of areas in which further high-quality research is needed to understand and better address preventive services for women.

CARDIOVASCULAR DISEASE

Cardiovascular disease (CVD) is the class of diseases that involve the heart or blood vessels and includes high blood pressure, coronary heart disease (CHD), stroke, and heart failure (Bonow et al., 2011). Addressing cardiovascular disease across the life span in women, including during

adolescence, the reproductive years, and maturity, is important. It has been shown that risk factors experienced during pregnancy, such as hypertension of pregnancy, gestational diabetes, and preeclampsia, place women at risk for the development of cardiovascular disease as they age.

Prevalence/Burden

More women die annually from heart disease than men, but overall, men have a higher burden of CVD (Roger et al., 2011). Likely because of the obesity epidemic in the United States, rates of mortality from CHD (CVD affecting the coronary arteries) in women aged 35 to 54 years have increased in recent years.

CVD rates for American black females are significantly higher than those for their white counterparts (286.1/100,000 population and 205.7/100,000 population, respectively) (Mosca et al., 2011; Roger et al., 2011). The black female population also has a lower rate of awareness of heart disease than white women (Ferris et al., 2005; Kleindorfer et al., 2009; Mosca et al., 2010; Roger et al., 2011). More women die each year of stroke and stroke constitutes a higher proportion of CVD events in women, compared with a higher proportion of coronary heart disease in men. The majority of the research from which preventive care recommendations are derived is based on CHD and not stroke (Mosca et al., 2011).

Evidence shows differences in the pathology of CHD by sex, with women having a higher prevalence of disease of the small coronary vessels than men (Bairey Merz et al., 2006; Jacobs, 2006). Symptoms of CHD are more likely to be atypical, including dyspnea and epigastric discomfort (Canto et al., 2007). Lastly, premenopausal women who suffer sudden death are more likely to have pathologic findings of plaque erosion than plaque rupture, which is more common in men and postmenopausal women (Burke et al., 1998; Oparil, 1998). Older women who suffer a myocardial infarction are more likely than men to have plaque rupture with thrombus (Kruk et al., 2007). The relevance of these findings is unclear but points to biological differences in CHD in women, the full extent of which remains unknown.

Risk Factors for CVD

Most modifiable risk factors for the primary prevention of CVD, such as hypertension, hyperlipidemia, diabetes mellitus, smoking, obesity, metabolic syndrome, and physical inactivity, are similar in women and men; but the prevalence and impact of certain risk factors may differ by sex. Risk factors in which there are sex differences in prevalence and impact or in

which there are different criteria by sex are outlined below. Diabetes mellitus, obesity, smoking, and physical activity are addressed in other sections of this document.

Lipids: Elevated levels of low-density lipoprotein (LDL) present equivalent risks to women and men but a high-density lipoprotein (HDL) level of <50 mg/dL is considered a risk in women and an HDL level of <40 mg/dL is considered a risk in men (National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2002; Mosca et al., 2011). Currently, interventions to improve HDL mainly focus on lifestyle and control of traditional risk factors. No sex-specific interventions for increasing HDL levels currently exist.

Metabolic Syndrome: Metabolic syndrome is a constellation of risk factors that are associated with the development of CVD and type 2 diabetes mellitus. The diagnosis is made when three of the following five findings are present: (1) elevated waist circumference (≥40 in. [102 cm] in men and ≥35 in. [88 cm] in women), (2) elevated triglyceride levels (≥150 mg/dL [1.7 mmol/L]) or drug treatment for elevated triglyceride levels, (3) reduced HDL cholesterol levels (<40 mg/dL [1.03 mmol/L] in men and <50 mg/dL [1.3 mmol/L] in women or drug treatment for reduced HDL cholesterol levels, (4) elevated blood pressure (≥130 mm Hg systolic blood pressure or ≥85 mm Hg diastolic blood pressure) or antihypertensive drug treatment, and (5) elevated fasting glucose level of ≥100 mg/dL or drug treatment for elevated glucose levels (Grundy et al., 2005).

The prevalence of the metabolic syndrome is increasing and varies by age in women and men, with the prevalence being higher in men up to the age of 60 years, after which the rates are higher in women (51.5 percent in men versus 54.4 percent in women) (Ervin, 2009). Importantly, the rates of metabolic syndrome are significantly higher in non-Hispanic black and Mexican American women than in their male counterparts (38.8 and 25.3 percent, respectively, for non-Hispanic black women versus men and 40.6 and 33.2 percent, respectively, for Mexican American women versus men) (Ervin, 2009).

Meta-analyses of studies evaluating the metabolic syndrome showed an association of metabolic syndrome with an increased risk of developing CVD and death from CVD (relative risk = 1.78; 95 percent confidence interval = 1.58 to 2.00), with the association between metabolic syndrome and an increased risk of CVD being stronger in women than in men in the smaller number of studies that provide data by sex (relative risk = 2.63 versus 1.98, P = 0.09) (Gami et al., 2007).

Women with metabolic syndrome have a three times higher risk of dying from a heart attack or stroke than women who do not have it

(Cleveland Clinic, 2011), and they have a significantly elevated risk for developing type 2 diabetes (Lorenzo et al., 2007). Furthermore, women diagnosed with metabolic syndrome in early pregnancy have a significantly greater risk of developing gestational diabetes mellitus. An accurate measurement of the waist circumference must be obtained to make a diagnosis of metabolic syndrome.

Pregnancy-Related Risk Factors: Pregnancy-related risk factors such as preeclampsia, gestational hypertension, and gestational diabetes mellitus are specific to women and are risk factors for the development of CVD and CVD events in women as they age. These pregnancy-related disorders are highly prevalent, with approximately 5 percent of pregnancies complicated by preeclampsia. Gestational diabetes, which complicates 5 percent of pregnancies, is often seen in women who also have gestational hypertension.

Women who experience preeclampsia have twice the risk of heart disease, stroke, and venous thromboembolism as they age and are twice as likely to die of cardiovascular disease (Bellamy et al., 2007; McDonald et al., 2008; Rich-Edwards et al., 2010). In a Canadian population, women who have preeclampsia and preterm birth (<37 weeks of gestation) have been found to have an eight-fold higher risk of mortality from CVD than women who do not have preeclampsia and who give birth at term (Irgens et al., 2001).

Approximately 50 percent of the women who experience gestational diabetes mellitus will go on to develop type 2 diabetes mellitus and also experience a 70 percent increase in the risk of CVD, much of which can be attributed to the development of type 2 diabetes mellitus (Shah et al., 2008). Black women experience significantly higher rates of these pregnancy complications (Rich-Edwards et al., 2010).

Little is currently understood about the possible vascular abnormalities caused by these disorders or the time course of the increase in risk. Similarly, research on the etiology of these disorders and how best to prevent them before pregnancy, during pregnancy, or between pregnancies is lacking. Given the association of preeclampsia, gestational hypertension, and gestational diabetes with an increased risk of CVD in women as they age, the 2011 American Heart Association (AHA) guidelines for prevention of CVD in women recommends that a history of pregnancy complications be obtained as part of the evaluation of CVD risk in women (Mosca et al., 2011).

Depression: Depression is more common in women than men and disproportionately affects the outcomes of women who have experienced a myocardial infarction. Screening for depression is recommended for women with CVD, but no evidence suggests that screening affects the outcomes for these women. Research to understand the role of depression on the development of CVD and how sex and gender influence this relationship is emerging (Mosca et al., 2011).

Social Determinants of Health: Evidence shows that the risk for CVD is influenced by social determinants of health, such as socioeconomic status, geographic location, chronic stress, poverty, and racism. The intersection of race/ethnicity, gender, and economic status complicates the understanding of who is at risk for metabolic syndrome, but understanding this social patterning is important for the development of targeted interventions. In an analysis of data from the National Health and Nutrition Examination Survey III, economic status was found to have an impact on the incidence of metabolic syndrome for women but not for men. Women in the lowest economic group were more likely to be at risk than women in the highest economic group (Salsberry et al., 2007). Results such as these underscore the potential clinical significance of socioeconomic position, particularly for women (Loucks et al., 2007). Black women are at greater risk for CVD than white women of comparable socioeconomic status, and the age-adjusted rates of death from CVD for black women exceed those for white women (Hayes et al., 2006). Black women in the southern rural United States have among the highest rates of mortality from CVD, especially stroke (Casper et al., 2011).

These studies demonstrate that social determinants may have disproportionate impacts on the development of CVD in women, but more high-quality evidence is needed in this area.

High-Sensitivity C-Reactive Protein: High-sensitivity C-reactive protein is a nonspecific biomarker of increased risk for CVD. The role of the high-sensitivity C-reactive protein levels in the assessment of risk and in defining preventive strategies remains unclear. The Jupiter study, which is often cited as the rationale to use high-sensitivity C-reactive protein for screening, did not include women with low high-sensitivity C-reactive protein levels, and therefore, no definitive statement about the use of this biomarker to screen women in the general population can be made (Mosca et al., 2011; Ridker et al., 2010).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends the use of aspirin for women aged 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage. Grade A recommendation (USPSTF, 2009a).

The USPSTF recommends screening for high blood pressure in adults aged 18 and older. Grade A recommendation (USPSTF, 2007a).

The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease. Grade A recommendation (USPSTF, 2008).

The USPSTF recommends screening women aged 20 to 45 for lipid disorders if they are at increased risk for coronary heart disease. Grade B recommendation (USPSTF, 2008).

The USPSTF makes no recommendation for or against routine screening for lipid disorders in men aged 20 to 35 or in women aged 20 and older who are not at increased risk for CHD. Grade C recommendation (USPSTF, 2008).

The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for lipid disorders in infants, children, adolescents, or young adults (up to age 20). Grade I statement (USPSTF, 2007b).

The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Grade A recommendation (USPSTF, 2009b).

The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children or adolescents. Grade I statement (USPSTF, 2003c).

Bright Futures recommends screening for high blood pressure throughout adolescence and annual screening for dyslipidemia. Otherwise, Bright Futures provides only anticipatory guidance on this subject (AAP, 2008).

Numerous organizations such as the AHA provide a wealth of expansive and specific guidelines for preventing CVD in women. The AHA alone recently published an updated list of more than 20 guidelines. These recommendations are commonly in agreement with those of the USPSTF.

The Adult Treatment Panel III from the National Cholesterol Education Program recommends that lipids be treated according to the risk stratification obtained by use of the Framingham risk score. This system stratifies patients into three basic categories by 10-year risk (the percentage probability of experiencing an event in the next 10 years): >20 percent, 10 to 20 percent, and <10 percent. However, these recommendations do not differ by sex.

Effective Interventions

A large body of evidence has been amassed to support prevention strategies for CVD in women and men. Even though CVD-related conditions are often grouped together, most evidence is based on trials that do not include stroke as the primary outcome, which is particularly important, given that stroke is more prevalent in women than men (Mosca et al., 2011). CVD is primarily prevented through adequate treatment of modifiable risk factors, including hypertension, diabetes mellitus, hyperlipidemia, and obesity, and achievement of a healthy lifestyle, including smoking cessation, physical activity, a healthy diet, and maintaining a healthy weight.

Metabolic syndrome is a significant risk factor for CVD in women, and the major focus is on preventing or treating the underlying modifiable risk factors, such as central obesity, hypertension, increased LDL and triglyceride levels, and diabetes mellitus. Lifestyle modification, including weight loss, physical activity, and a healthy diet, decreases all of the metabolic risk factors (Grundy et al., 2005). Although good data that link the modification of each risk factor that comprises metabolic syndrome to a decrease in cardiovascular risk are available, the data on preventing or treating metabolic syndrome are lacking. No data directly link screening for metabolic syndrome and prevention of CVD, although the syndrome must be recognized to accurately define women's risk.

Few data are available on effective interventions to prevent the complications of pregnancy, such as gestational hypertension and preeclampsia, which are risk factors for CVD. Achieving a healthy weight before pregnancy has been linked with decreased rates of these complications (IOM, 2009). Much remains to be learned about the mechanisms underlying these disorders, in particular, preeclampsia. Knowledge of these mechanisms might lead to effective preventive strategies (Rich-Edwards et al., 2010). Finally, identification of these disorders when a woman's medical history is obtained is important and will help to more accurately define overall risk for CVD.

Identified Gaps

The primary gaps in preventive services not already addressed by the provisions set forth in the ACA are (1) there is no comprehensive mechanism for the prevention or screening of metabolic syndrome in all women, and (2) there is no comprehensive mechanism in place to collect pregnancy complication histories to better predict the risk level of a woman for developing cardiovascular disease in the future.

The committee found insufficient evidence to support a new recommendation; instead, evidence supported by professional clinical guidelines led to committee support for the reasonableness of including screening for metabolic syndrome in women and obtaining a history of pregnancy complications within the context of the well-woman preventive visit.

BONE/SKELETAL DISEASE

The USPSTF recommends screening for osteoporosis using bone densitometry testing for women aged 65 years and older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors (USPSTF Grade B recommendation). This recommendation was based on the age and personal risk factors of average-risk women with no previous fragility fractures and does not explicitly address women with secondary causes of osteoporosis or previous fractures (USPSTF, 2011d).

Osteoporosis is a systemic skeletal condition associated with aging that is characterized by low bone density and deterioration of bone tissue that weakens bones and leads to fractures (USDHS, 2004). Osteoporosis-related fragility fractures result from forces that would not normally cause fractures, such as hip or wrist fractures from falling from standing height or a spine fracture resulting from compression of the vertebra from gravity alone. Although some types of fractures are more commonly related to osteoporosis (e.g., spine, hip, and wrist fractures), osteoporotic fractures can occur at nearly all sites.

In the absence of a fracture, osteoporosis can also be diagnosed by measuring bone density, or the thickness of bone. Results are expressed as the T-score, which is the difference between an individual's bone density measurement and normal values. The World Health Organization developed definitions for levels of bone density based on T-scores (Kanis, 1994). T-scores identify only one aspect of the condition, however. Other important components, such as rate of bone loss and quality of bone, are not currently measured in clinical practice.

Women with previous osteoporosis-related fractures are at high risk

for subsequent fractures. Although most women can accurately recall having had a previous fracture that required medical attention and fractures are usually well documented in medical records, tracking of women for follow-up care is usually difficult. As a result, evaluations for osteoporosis are often missed, drug treatments are not prescribed, and rates of subsequent fractures are high. Fractures that do not require immediate medical attention are often not recognized, such as spine fractures with mild or no symptoms. Nonetheless, asymptomatic spine fractures are also important in establishing the diagnosis of osteoporosis and determining needs for drug therapy.

Osteoporosis may occur without a known cause (primary osteoporosis) or occur as the result of another condition (secondary osteoporosis). Common secondary causes include dietary deficiencies in calcium or vitamin D; use of certain medications (aluminum antacids, anticoagulants, anticonvulsants, aromatize inhibitors, barbiturates, cancer chemotherapeutic drugs, depo-medroxyprogesterone, glucocorticoids, gonadotropin-releasing hormone agonists, lithium, and others); and the presence of health conditions (rheumatoid arthritis, diabetes, hyperparathyroidism, gastric bypass and other gastrointestinal surgery, malabsorption, inflammatory bowel disease, hemophilia, lupus, rheumatoid arthritis, kidney disease, depression, multiple sclerosis, emphysema, and others).

Several additional risk factors for osteoporosis and fractures have been determined from large population studies. Risk factors that cannot be modified include age, menopause, low body mass index, and a family history of osteoporosis and fractures. Modifiable risk factors include immobility, falls, tobacco use, and excessive alcohol intake (three or more drinks daily).

Prevalence/Burden

Low bone density, osteoporosis, and related fragility fractures are common in older adults. Estimates indicate that as many as 50 percent of Americans over age 50 years, or 14 million individuals by 2020, will be at risk for osteoporotic fractures during their lifetimes (USDHS, 2004). Fracture rates are higher and ages of incidence are younger for women than for men. Rates are highest in whites than in other racial groups, although osteoporosis is common in all groups (George et al., 2003; Looker et al., 1997; Nelson et al., 1995). Older individuals have much higher fracture rates than younger individuals with the same bone density because of increasing risks from other important contributors, such as falling (Heaney, 1998). All types of fractures are associated with higher rates of death (Bliuc et al., 2009; Center et al., 1999; Leibson et al., 2002). Nonfatal fractures at any site can impair function and quality of life, cause chronic pain and

disability, and result in high costs for health care and lost productivity (HHS, 2004).

Bone densitometry measures the mass of bone and can be used to predict the risk of future fractures, although it is an imperfect measure. Among bone measurement tests at various sites, the result of dual-energy X-ray absorptiometry (DXA) of the hip is the strongest predictor of hip fracture (Marshall et al., 1996). Several peripheral bone measurement tests have also been developed, including quantitative ultrasound (QUS) of the calcaneus (heel), which can predict fractures, as well as DXA, although variation exists across studies (Nelson et al., 2010b). QUS measures bone qualities differently from DXA, and correlates only modestly. Therefore, it is not clear how the results of QUS can be used clinically to select individuals who should receive drug therapies that were proven effective in clinical trials on the basis of DXA criteria.

Measurement of the bone density of appropriate candidates is essential before initiation of drug therapy because all of the drugs approved by the Food and Drug Administration (FDA) to treat low bone density and osteoporosis work by increasing bone density. Obtaining a bone density measure before therapy also provides an opportunity to monitor a response to the drug, if needed.

Identification of secondary causes and modifiable risk factors can lead to decisions to treat the underlying cause or risk factor specifically; to monitor bone density and treat osteoporosis if bone density is low or a fracture occurs; or to treat osteoporosis, in addition to the secondary cause or risk factor. Actual management depends on the secondary cause or risk factor, the severity of osteoporosis, additional health considerations, and patient preferences.

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends screening for osteoporosis in women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors. Grade B recommendation (USPSTF, 2011c).

Clinical guidelines from the National Osteoporosis Foundation recommend bone density testing for individuals with osteoporosis-related fractures

or secondary causes of osteoporosis, all women aged 65 years and older, and younger postmenopausal women with key risk factors (NOF, 2010).

Despite the increased awareness of osteoporosis and recommendations for screening and treatment from multiple groups, osteoporosis is underdetected and inappropriately treated in the United States (Kiebzak, 2002; Wilkins and Goldfeder, 2004). The reasons for this are unclear, although the different recommendations for identifying candidates for testing and treatment and confusion in interpreting the results of testing may be contributors (Morris et al., 2004). In addition, current medical practice in the United States is commonly fragmented for individuals experiencing osteoporosis-related fractures. The fracture itself is usually treated by an acute care team in hospital emergency departments and orthopedic services, whereas screening, prevention, and treatment are addressed in other contexts.

Effective Interventions

Primary prevention of osteoporosis and fractures begins early in life, while bone undergoes development. Attainment of peak bone mass and its maintenance require optimal nutrition and physical activity throughout the life span and avoidance of tobacco, alcohol, and other exposures that contribute to osteoporosis. All women require adequate calcium (1,200 mg daily) and vitamin D (800 to 1,000 international units daily) intake to avoid deficiencies and prevent osteoporosis and fractures (Standing Committee, 1997). Those with secondary causes of osteoporosis may require treatment of their specific underlying conditions to reduce their risks for osteoporosis and fractures. Women using medications causing osteoporosis may require adjustments in their medications and serial measures of bone densitometry to monitor effects on their bones.

The FDA has approved several drugs for prevention or treatment of osteoporosis (FDA, 2011) that reduce the risk for osteoporosis-related fractures by increasing bone density. Women with the lowest levels of bone density or with previous osteoporosis-related fractures are the most likely to benefit (Cummings et al., 1998). These drugs differ by their mechanisms of action, effectiveness in reducing fractures, routes of administration, and adverse effects.

Drugs for prevention are intended for individuals who have no previous fractures and whose bone density levels are not in the osteoporotic range (i.e., T-score ≥–2.5). For women, these include four bisphosphonate drugs, alendronate (Fosamax), ibandronate (Boniva), risedronate (Actonel, Actonel with calcium), and zoledronic acid (Reclast); several forms of estrogen with or without a progestin hormone; and raloxifene (Evista). For

some of the drugs, such as alendronate, prevention doses are smaller than treatment doses. Alendronate, raloxifene, and estrogen significantly reduced the incidence of spine fractures in clinical trials of women without previous fractures (Nelson et al., 2010a,b).

Drugs approved for treatment purposes are intended for individuals who have had previous osteoporosis-related fractures or whose T-scores are low (≤–2.5). For women, these include four bisphosphonate drugs, alendronate (Fosamax, Fosamax Plus D), ibandronate (Boniva), risedronate (Actonel, Actonel with calcium), and zoledronic acid (Reclast); calcitonin (Fortical, Miacalcin); denosumab (Prolia); raloxifene (Evista); and teriparatide (Forteo). In clinical trials of women with previous fractures, all of these drugs significantly reduced spine fractures, and all except calcitonin and raloxifene reduced fractures at other sites (MacLean et al., 2008; Nelson et al., 2010b). Trials evaluating the effectiveness of non-drug interventions alone and in combination with drugs would be clinically useful but are lacking. These interventions include functional assessment and improvement, safety evaluations, vision examinations, and nutritional analyses, among others.

Identified Gap

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is the lack of bone densitometry testing explicitly for women below the age of 65 at high risk for osteoporosis, such as those with previous fractures and secondary causes of osteoporosis. Evidence supported by systematic evidence reviews and the National Osteoporosis Foundation guidelines support a clarification statement to the USPSTF recommendation.

Clarification Statement

The committee interprets the current USPSTF recommendation regarding osteoporosis screening for women to include screening women with previous fractures and with secondary causes of osteoporosis.

BREAST CANCER

Women at high risk for breast cancer may require additional screening and surveillance services that are not included in the USPSTF screening recommendations and current legislation intended for average-risk women (*Federal Register*, 2010; USPSTF, 2009f). Issues surrounding the prevention of breast cancer in high-risk women are technical in nature because of the complexity of the condition.

Although several factors are associated with increased risk for breast cancer, few increase a woman's risk to levels that are clinically significant for screening purposes. Women at high risk include those with known mutations in breast cancer susceptibility genes one and two (*BRCA1* and *BRCA2*), with unknown mutation status but have a first-degree relative (parent, brother, sister, or child) with a *BRCA1* or *BRCA2* gene mutation, or have a family history of breast and related cancers regardless of mutation status. Also at increased risk are women who received radiation therapy to the chest, such as for treatment of Hodgkin's disease (Wahner-Roedler et al., 2003); have abnormal pathology results on a previous breast biopsy (Arpino et al., 2005); or have extremely dense breasts when viewed on mammography (Kerlikowske et al., 2010).

Prevalence/Burden

Breast cancer is the most frequently diagnosed cancer after skin cancer and the second leading cause of cancer deaths after lung cancer among women in the United States (ACS, 2010). In 2010, an estimated 207,090 cases of invasive breast cancer and 54,010 cases of noninvasive breast cancer were diagnosed, and an estimated 39,840 women died of breast cancer (ACS, 2010). Periodic mammography screening detects early stages of breast cancer and reduces the rate of mortality from breast cancer in clinical trials, although the extent of these benefits varies by age (Nelson et al., 2009a). Because most women with breast cancer have no major risk factors and are considered to be at average risk, mammography screening is recommended for women at all levels of risk (Smith et al., 2003a; USPSTF, 2009f). However, several individual characteristics are associated with an increased risk for breast cancer in epidemiological studies. Identifying women with risk factors most strongly associated with breast cancer can lead to the use of additional screening measures to improve early breast cancer detection and reduce the burden of disease for these women.

Clinically significant *BRCA* mutations are associated with an approximately 60 percent lifetime risk of breast cancer and a 15–40 percent lifetime risk of ovarian cancer. The prevalence of deleterious *BRCA* mutations is estimated to be between 1 in 400 to 1 in 800 in the general population (Anglian Breast Cancer Study Group, 2000; Ford and Easton, 1995; Whittemore et al., 2004), although specific *BRCA* mutations are clustered among certain ethnic groups such as Ashkenazi Jews (1 in 40) (Struewing et al., 1997). Rare disease syndromes related to deleterious mutations located on different genes also increase breast cancer risk to high levels (Garber and Offit, 2005).

Women with high risk for breast cancer can also be identified by risk

assessment instruments used in genetic counseling that are based mainly on family history information (Amir et al., 2003; Claus et al., 1994; Domchek et al., 2003; Gail et al., 1989; Tyrer et al., 2004). Approximately 10 percent of women have a first-degree relative (i.e., mother, sister, or daughter) with breast cancer, which doubles their risk of having breast cancer themselves (Collaborative Group, 2001; Pharoah et al., 1997). Risks are higher if more than one relative is affected and if breast cancer in relatives was diagnosed at younger ages, especially below age 50 years (Collaborative Group, 2001; Pharoah et al., 1997). Risk assessment considers all of these factors to provide an estimate of an individual's breast cancer risk.

Most women previously treated for breast cancer are closely monitored after treatment, and this type of surveillance generally falls outside of screening recommendations. Women who had previous biopsies that indicated abnormal lesions that were not cancer often re-enter screening programs after their biopsies. Some of these abnormal lesions can increase the breast cancer risk 4 to 10 times above average, depending on the type of lesion (Arpino et al., 2005). Approximately 16 biopsies are obtained for every 1,000 women undergoing mammography screening in the United States (Weaver et al., 2006). Of these biopsies, approximately 1 of the 16 has an abnormal lesion that increases the risk for breast cancer.

Women with extremely dense breasts when viewed by mammography have twice the five-year risk for breast cancer than women with normal breast density (Kerlikowske et al., 2010). Women with unevenly dense breasts also have elevated risks, but to a lesser degree (Kerlikowske et al., 2010). High breast density compromises the accuracy of mammography and increases susceptibility to breast cancer (Boyd et al., 2007; Kerlikowske et al., 1996; van Gils et al., 1998a,b). Women with extremely dense breasts, particularly younger women, are more likely to be diagnosed with advanced-stage disease than women with average breast density (Kerlikowske et al., 2010). A national study of mammography screening found that approximately 9 percent of women have extremely dense breasts and 37 percent have unevenly dense breasts, with the highest rates among younger women (Kerlikowske et al., 2010). The use of breast density as a risk factor in screening is currently limited, however, because it is not routinely provided with mammography results and interpretations vary widely in practice (Kerlikowske et al., 1998).

Determination of a woman's risk of breast cancer provides important clinical information to guide appropriate screening and prevention decisions. Women with family history information indicating high risk could adopt more intensive screening regimens that begin at younger ages that are more frequent and include additional clinical examinations and imaging technologies than women at average risk (Burke et al., 1997; Kriege et

al., 2004; Lee et al., 2010; Saslow et al., 2007; Warner et al., 2004). Those with family histories suspicious for deleterious *BRCA* mutations could undergo genetic testing and inform their relatives of their status to benefit them as well. Women at high risk of breast cancer could consider the use of medications (i.e., tamoxifen or raloxifene) or surgeries (i.e., mastectomy or oophorectomy, or both) to reduce their risks (Nelson et al., 2005, 2009b). Conversely, women often overestimate their risk of breast cancer (Bowen et al., 1998; Lerman et al., 1991, 1996). Women initially suspected to be at high risk but determined to be at average risk after further evaluation could be spared unnecessary evaluations, procedures, and worry if they had that information available.

Screening recommendations target primary care practice as the appropriate context for initial identification of women at high risk for breast cancer; however, methods for accurately stratifying women into high-risk and average-risk groups in this setting have not been adequately demonstrated (Nelson et al., 2005, 2009c). The accuracy of family cancer history information is variable, although a report of breast cancer in a first-degree relative was reasonably accurate in one study (sensitivity = 82 percent, specificity = 91 percent) (Murff et al., 2004). The accuracy of information for a first-degree relative was better than for a second-degree relative.

Health maintenance organizations, professional organizations, cancer programs, and state and national health programs have developed referral guidelines to assist primary care clinicians with identifying women at potentially increased risk (Nelson et al., 2005). Although specific items vary, most include questions about personal and family histories of *BRCA* mutations and breast and ovarian cancer, age of diagnosis, bilateral breast cancer, and Ashkenazi Jewish heritage. Most guidelines are intended to lead to a referral for more extensive genetic evaluation and counseling. No consensus or gold standard about the use of guidelines currently exists, and the effectiveness of this approach has not been evaluated. Concerns about inappropriate referrals in current practice include not only too few referrals of high-risk women but also too many referrals of average-risk women (White et al., 2008).

Genetic counseling provides an assessment of risk using established risk calculation instruments and is an essential step in determining if a woman is at increased risk and requires enhanced screening and prevention services. Genetic counseling to determine cancer risk status for women without breast cancer is a new concept in practice. No study has yet determined how genetic counseling modifies cancer screening behaviors or if doing so improves early detection and mortality. Information to guide effective integration of shared decision making into this process is also lacking. Although enhanced screening is recommended by expert groups (Burke et al.,

1997) and is based on favorable results of programs designed for women with familial risk (Brekelmans et al., 2001; Burke et al., 1997; Gui et al., 2001; Kollias et al., 1998; Warner et al., 2004), no trials of its effectiveness have been conducted.

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. Grade B recommendation (USPSTF, 2009e).

The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms. Grade C recommendation (USPSTF, 2009e).

The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older. Grade I Statement (USPSTF, 2009e).

The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older. Grade I statement (USPSTF, 2009e).

The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer. Grade I statement (USPSTF, 2009e).

The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing. Grade B recommendation (USPSTF, 2005a).

The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention. Grade B recommendation (USPSTF, 2002b).

The American Cancer Society recommends yearly magnetic resonance imaging (MRI) screening, in addition to mammography screening, and that clinicians consider starting screening at age 30 years for women with lifetime risks for breast cancer of >20 percent (ACS, 2011; Saslow et al., 2007). Expert groups also advise that women with *BRCA* mutations or with

strong family histories of early age of breast cancer onset begin screening at younger ages (e.g., five years younger than the age of diagnosis) (Burke et al., 1997). The Society of Breast Imaging and the American College of Radiology recently published guidelines on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer, recommending for women at high risk earlier screening and additional technologies that vary depending on the risk factor (Lee et al., 2010).

Assessment of breast cancer risk status and use of enhanced screening services are highly variable in practice. Ideally, an initial risk assessment based on personal characteristics and family cancer history would occur for all women as part of routine prevention in primary care. Currently, referrals to risk and genetic counseling for women without existing breast cancer are most commonly offered to relatives of women diagnosed with cancer and with strong family histories. As a result, enhanced screening is being provided to only some women who have been appropriately identified to be at high risk, as well as to others whose risk status may have been inadequately determined.

Effective Interventions

The efficacy of MRI in detecting breast cancer for screening purposes was demonstrated in a study of women with either deleterious *BRCA* mutations or a family history of breast cancer indicting a lifetime risk of 15 percent or greater (Kriege et al., 2004). Women were screened every six months by clinical breast examination and yearly by mammography and MRI. The sensitivity and specificity for detecting invasive breast cancer were 18 and 98 percent, respectively, for clinical breast examination; 33 and 95 percent, respectively, for mammography; and 79.5 and 90 percent, respectively, for MRI. The results were compared with those for two age-matched control groups undergoing usual screening (yearly mammography and clinical breast examination). One control group had a lifetime risk of 15 percent or greater, and the other had average risk. Women screened with clinical breast examination, mammography, and MRI had significantly smaller tumors at diagnosis and fewer cases of cancer spreading beyond the breast than women in either control group. Use of MRI also led to twice as many unneeded additional examinations as mammography and three times as many unneeded biopsies.

A comparison of four intensive screening approaches in *BRCA* mutation carriers included yearly MRI, mammography, and ultrasound and clinical breast examinations provided every 6 months (Warner et al., 2004). MRI was more sensitive in detecting breast cancers (sensitivity = 77 percent, specificity = 95 percent) than mammography (sensitivity = 36 percent, specificity = 99.8 percent), ultrasound (sensitivity = 33 percent, specificity = 96 percent), or clinical breast examination alone (sensitivity = 9 percent, speci-

ficity = 99 percent). Use of MRI, ultrasound, clinical breast examination, and mammography together had a sensitivity of 95 percent. In this study, 14 percent of women had a biopsy that proved to be benign. Additional clinical outcomes, including mortality, were not reported in either study.

Identified Gap

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is the lack of enhanced breast cancer screening services for high-risk women who may require earlier and/or more frequent examinations and imaging, as well as additional imaging technologies beyond mammography.

The committee believes that the evidence is insufficient to recommend coverage for additional breast cancer screening services for high-risk women at this time. The committee recognizes the complexity of appropriately identifying women with high levels of breast cancer risk to determine eligibility for services and the limitations of research on the potential benefits of the services. Considerations for increasing use of screening services are coupled with the acknowledgment of the harms that can also occur, including increasing the rates of false-positive results and benign biopsies and the adverse impact these experiences have on women. Nonetheless, the committee feels that with rapidly evolving scientific inquiry, such consideration should be reevaluated given evidence that may alter this assessment.

MENTAL HEALTH

Depression is a widespread mental disorder that affects approximately 121 million people worldwide and has been identified to be one of the top 10 leading causes of disease burden (Lopez et al., 2006; WHO, 2011). Symptoms include depressed mood, loss of interest or pleasure, feelings of guilt or low self-worth, fatigue, insomnia, and disturbed appetite. Depression may also lead to suicidal ideation and actions (NIMH, 2011b; WHO, 2011). In addition, postpartum depression is a condition specific to new mothers. Depression can occur throughout the life course, from childhood to late in life.

Prevalence/Burden

Adolescence is perhaps the most critical time period for recognizing mental health issues. Half of all mental disorders diagnosed in adulthood develop in puberty, by age 14 years (Merikangas et al., 2010). Data from the Behavioral Risk Factor Surveillance System (BRFSS) survey from 2008 revealed that young adults aged 18 to 24 years experienced the highest rates of current depression at 10.9 percent. The 45- to 64-year-old adult age

group experienced the next highest rates at 10 percent (CDC, 2010a). Adolescents and young adults also have high rates of suicide, which accounts for 12.2 percent of deaths among 15- to 24-year-olds annually (CDC, 2010b). In 2009, one in seven U.S. high school students reported that he/she had seriously considered attempting suicide over the past 12 months, and 6.3 percent reported that they had made at least one attempt during this time period. Suicide rates in women are highest over the age range of 45 to 54 years (CDC, 2010b). Across the life course, women may develop depression more often or more prominently around the time of certain reproductive events, such as menstruation, pregnancy, loss of a baby, birth of a baby, infertility, and menopause (ACOG, 2008).

Women are consistently rated as a high-risk group for depression (Kessler, 2003; Kessler et al., 2003) because depression is significantly more prevalent in women than in men at almost twice the rate. According to data from the BRFSS survey from 2008, 4 percent of women currently fit the criteria for major depression, whereas the rate was 2.7 percent among the surveyed men (CDC, 2010a). This disproportionate ratio emerges in adolescence, between ages 10 and 15 years (Angold et al., 1998). A lifetime experience of abuse, which women experience at higher rates, contributes to the development of depression, as well as suicide ideation and suicide (NIMH, 2011a,b; Tjaden and Thoennes, 1998).

Although death rates by suicide are higher among men, women attempt suicide two to three times more often (WHO, 2002). Existing mental disorders, particularly mood disorders like depression, are often seen as a precursor to a suicide attempt (Bertolote et al., 2003; Henriksson et al., 1993; Mann et al., 2005; Robins et al., 1959). Data from psychological autopsy studies have revealed that diagnoses of clinical mental disorders were found in nearly all suicide victims. The most prevalent disorders were depression and alcohol dependence or abuse. A diagnosis of major depression was documented in 46 percent of female suicide victims (of 26 percent of male suicide victims) (Henriksson et al., 1993). Minority sexual orientation and disclosure of sexuality are associated with various rates of suicidal ideation in women. In a U.S. survey of women, lesbians and bisexual women who were not "out" were more likely to have attempted suicide than heterosexual women (Koh and Ross, 2006).

Between 10 and 20 percent of mothers experience postpartum depression within the first year after giving birth, which has significant consequences for both the child's development and the mother's well-being (Chaudron et al., 2004; Freeman et al., 2005; Mishina and Takayama, 2009). Although it is common for new mothers to experience feelings of sadness, anxiety, and mood swings after giving birth, these "baby blues" last for a short period of time and are not severe. Postpartum depression symptoms are markedly more severe, last longer than two weeks, and require treatment from a trained professional (womenshealth.gov). Women

with postpartum depression are at risk for future depression, including recurrent postpartum depression. Like other instances of depression, postpartum depression can lead to suicidal ideation. One in five postpartum maternal deaths is a result of suicide (Lindahl et al., 2005). Mothers with postpartum depression may have difficulty with mother-infant bonding or have thoughts of harming their infant. They may also have impaired attention to pediatric preventive practices, like the use of care safety seats and pediatric health care utilization (Chaudron et al., 2004).

Diagnosis of postpartum depression is challenging for a number of reasons. Women who did not receive their pregnancy care from a family physician may be confused about who to turn to, if they are not scheduled to visit their obstetrician-gynecologist until a year later or if they view their pediatrician as purely their child's doctor. Symptoms of postpartum depression such as sleep disturbance, loss of energy, weight loss, and diminished concentration may be seen as normal sequelae of childbirth and not recognized as a marker of illness (Epperson, 1999).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up. Grade B recommendation (USPSTF, 2009g).

The USPSTF recommends against routinely screening adults for depression when staff-assisted depression care supports are not in place. There may be considerations that support screening for depression in an individual patient. Grade C recommendation (USPSTF, 2009g).

The USPSTF recommends screening of adolescents (12–18 years of age) for major depressive disorder (MDD) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up. Grade B recommendation (USPSTF, 2009d).

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening of children (7–11 years of age). Grade I statement (USPSTF, 2009d).

The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening by primary care clinicians to detect suicide risk in the general population. Grade I Statement (USPSTF, 2004).

Bright Futures identifies emotional well-being and mental health to be priority screening areas for adolescents from ages 11 to 21 years and directs physicians to screen for depression and suicidal thoughts through the use of sample questions and anticipatory guidance. Bright Futures also recommends that mothers be screened for postpartum depression during the first- and second-month infant visits (AAP, 2008).

To help bring awareness to and combat the high rates of depression, the Institute of Medicine's (IOM's) report *Leading Health Indicators* recommended that *Healthy People 2020* (HHS, 2011) adopt a reduction in the proportion of people who experience major depressive episodes as one of its objectives (IOM, 2011). *Healthy People 2020* has already set a goal of increasing rates of screening for depression in primary care (HHS, 2011). In 1999, the U.S. Surgeon General identified suicide to be a major public health issue in the report *Call to Action to Prevent Suicide,* and current *Healthy People 2020* goals are to reduce the suicide rate overall, particularly for adolescents (HHS, 1999, 2011).

Professional organizations have also published guidelines on screening for suicide and postpartum depression, in addition to the depression screening that is already recommended by the USPSTF. The American College of Obstetricians and Gynecologists (ACOG) recommends a psychosocial evaluation that includes asking about suicide and depressive symptoms in patients aged 13 through 18 years (ACOG, 2007b). The American Medical Association (AMA) advises physicians with adolescent patients to ask about behaviors or emotions that indicate severe depression or suicidal thoughts on an annual basis (AMA, 1997). ACOG recommends that women be counseled about postpartum depression during the third trimester of pregnancy and that obstetricians-gynecologists consult with their patients about their risk of psychiatric illness during the postpartum period (ACOG, 2007a). ACOG also recommends that postpartum counseling take place as part of preconception care (ACOG, 2007b). In recognition of the underdiagnosis of postpartum depression, the U.S. Department of Veterans Affairs (VA) Clinical Practice Guideline for the Management of Major Depressive Disorder states that women receiving care through the VA be screened for depression at first contact with health care services in the antenatal and postnatal periods, separate from its guidelines on screening for depression in the general patient population (VA, 2009).

Effective Interventions

Depression is a condition commonly encountered in primary care because people with major depression utilize health care at high rates. A review of the evidence of rates of primary care and mental health specialist contact rates in select developed countries revealed that 45 percent

of suicide victims visit their primary care provider within one month of the suicide (Luoma et al., 2002). Moreover, increased rates of physician education and recognition of depression in primary care are associated with a reduction in the accompanying suicide rates (Mann et al., 2005). This evidence points to the utility of screening for depression in a primary care setting as a method of suicide prevention. However, the most recent systematic review of the evidence by the USPSTF, which was in 2004, found insufficient evidence to routinely screen for suicide risk in the general population (Gaynes et al., 2004).

Postpartum depression can be screened for and detected in the context of a well-child visit, as Bright Futures already recommends (AAP, 2008; Chaudron et al., 2004; Freeman et al., 2005; Mishina and Takayama, 2009). Six states (Illinois, Iowa, Kentucky, Pennsylvania, Louisiana, and Massachusetts) have implemented projects funded by the Health Resources and Services Administration to increase rates of screening for postpartum depression by increasing awareness, assessment, and treatment and joining the maternal and infant health care systems (Shade et al., 2011). The USPSTF recommendation for screening for depression does not address postpartum depression or denotes new mothers to be a high-risk group.

Mental health issues are increasingly becoming a part of primary care, in part because of increased physician education (Kessler et al., 2007). Although the numbers of patients who receive outpatient treatment for depression have increased, most individuals with depression receive inadequate care for their symptoms (Olfson et al., 2002). Among those receiving mental health services, more than one-fifth of patients received their treatment from a general medical provider (Wang et al., 2005). Psychotherapy treatment has decreased, whereas prescriptions for antidepressants have increased, including in children and adolescents, in part because of managed care plan support of pharmaceuticals over specialty care and also the challenges of providing psychotherapy in a physician's office, including but not limited to time constraints (Ma et al., 2005; Olfson et al., 2002; Pignone et al., 2002). Under the Mental Health Parity and Addiction Equity Act of 2008, group health plans and health insurance issuers must not place dollar limits on mental health benefits that are any lower than limits for medical and surgical benefits (DOL, 2011). Mental health benefits for depression would include ongoing psychotherapy and pharmacotherapy treatments.

Identified Gap

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that the current

recommendation for depression screening and follow-up does not address suicide and postpartum depression as related conditions to be evaluated. The committee found insufficient evidence to support a new recommendation; instead, evidence supported by systematic reviews, federal agendas from *Healthy People 2020* (HHS, 2011), and the U.S. Surgeon General, as well as clinical professional guidelines and federal practice guidelines support the reasonableness of including screening for suicide ideation and postpartum depression in women who are pregnant and/or who have recently given birth during the context of a well-woman visit.

TOBACCO USE

Tobacco use in the form of cigarette smoking is the leading cause of preventable morbidity and mortality in the United States. Quitting smoking with the help of cessation aids such as counseling and pharmacotherapy greatly improves a woman's health and well-being. Women of all ages should be encouraged and aided in their efforts to quit smoking, although pharmacotherapy is currently approved only for those over 18 years.

Prevalence/Burden

From 2000 to 2004, there were approximately 270,000 smoking-attributable deaths annually among males and approximately 174,000 smoking-attributable deaths annually among females (CDC, 2008a). Approximately 90 percent of lung cancer deaths are due to smoking (Stewart et al., 2008). Almost all tobacco use in women consists of cigarette smoking (SAMHSA, 2004). Although trends in the prevalence of smoking show that it is lower among women than men, between 1955 and 1995 the prevalence of smoking decreased more rapidly among men (Chilcoat, 2009). After 1995, a gradual decrease in the incidence of cigarette smoking occurred for both men and women. Data from the 2009 National Health Interview Survey show that in 1997, 27.6 percent of men and 22.1 percent of women reported being current smokers (CDC, 1999), whereas in 2009, 23.5 percent of men and 17.9 percent of women reported being current smokers (CDC, 2010c). Although the gap in smoking prevalence between men and women has narrowed considerably over time, these trends differ across levels of educational attainment. Women with less education appear to be a group at particularly high risk (Chilcoat, 2009).

In addition to lung cancer, smoking increases women's risk of developing uterine, cervix, and other cancers, including cancers of the head and neck, pancreas, kidney, and bladder. Smoking doubles a woman's risk of developing coronary heart disease (HHS, 2001). Women who smoke and

concurrently use oral contraceptives are at a 30-fold increased risk for myocardial infarction and a 3-fold increased risk of stroke compared with nonsmokers (Burkman et al., 2004). Postmenopausal women who smoke have lower bone density than women who never smoked, and they have an increased risk for hip fracture than woman who never smoked (HHS, 2001; Law et al., 1997). Cigarette smoking also increases the risk for infertility, and smoking during pregnancy may result in negative reproductive and developmental effects, including premature birth, stillbirth, low birth weight, intrauterine growth retardation, and sudden infant death syndrome (Ashford et al., 2010; Behm et al., 2011; IOM, 2011; Khader et al., 2011; Ye et al., 2010).

Smoking cessation may be more difficult for women for a number of reasons. Women metabolize nicotine faster than men, and oral contraceptives lead to an even faster rate of metabolization of nicotine (Benowitz, 2008; Benowitz et al., 2006). The faster rate of metabolism found in women may contribute to a higher level of nicotine addiction. In addition, smoking and depression are strongly linked, and women suffer higher rates of depression, which may make quitting smoking more difficult (Smith et al., 2003b). Women may be motivated to quit for different reasons than men, such as improving fertility and reproductive health, pregnancy outcomes, physical appearance, and health problems that occur predominantly in women, such as osteoporosis (Smith et al., 2003b).

Most cases of tobacco dependence begin during childhood and adolescence (Fiore et al., 2008). The younger that a person is when he or she starts smoking, the more likely it is that the person will become dependent on nicotine and the more difficult it will be to quit (IOM, 1994). Only about 4 percent of young smokers are successful in quitting each year. Between 1991 and 2009, the prevalence rates of current cigarette smoking in high school students were similar in males and females and have shown a gradual decline over the past decade (Latimer and Zur, 2010). During this period, the prevalence of smoking decreased from 27.3 to 19.1 percent in females and from 27.6 to 19.8 percent in males (Garrett et al., 2011). Among adolescents 12 to 17 years of age, the prevalence of tobacco use is 11.4 percent (CDC, 2010e), and it has been found that tobacco use during adolescence is associated with risky sexual behavior and use of alcohol and other drugs (Latimer and Zur, 2010).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Grade A recommendation (USPSTF, 2009b).

The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke. Grade A recommendation (USPSTF, 2009b).

The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children or adolescents. Grade I statement (USPSTF, 2003c).

The 2008 Public Health Service Guideline Update Panel (Fiore et al., 2008) made 10 recommendations regarding effective interventions delivered in health care settings. The updated guidelines were sponsored by eight federal government and private nonprofit organizations, including the Adolescent Health Research Program, the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Drug Abuse (NIDA), the American Legacy Foundation, the Robert Wood Johnson Foundation, and the University of Wisconsin Center for Tobacco Research and Intervention. These recommendations go beyond those of the USPSTF, in that they provide in detail the specific types of behavioral interventions and pharmacological treatments that clinicians can recommend to patients. The guideline panel noted that providing coverage for these treatments increased quit rates, and it recommended that all insurance plans include coverage for the strategies that it identified to be effective. The Partnership for Prevention supports the more detailed recommendations of the panel on the tobacco cessation services that should be covered by health insurance, including recognition that quitting often requires multiple or repeated interventions (Richland, 2011).

The panel emphasized that tobacco cessation interventions be interpreted to include both counseling and FDA-approved and over-the-counter medications. These recommendations have been echoed by numerous federal agencies and national medical and health associations and are consistent with the mandates of the Affordable Care Act (ACA) and the Centers

for Medicare and Medicaid Services to provide expanded coverage for tobacco screening and cessation services delivered in health care settings (Morris et al., 2011).

A number of organizations have made recommendations regarding screening for and counseling about tobacco use in adolescents (ACOG, 2010; Binns et al., 2009; Fiore et al., 2008; Gostin et al., 1997; Marwick, 1997). The 2008 guideline panel made specific recommendations for children and adolescents. It recommended that clinicians (1) ask their pediatric and adolescent patients about tobacco use and provide a strong message about abstaining from tobacco use (strength of evidence C); (2) provide counseling interventions to facilitate cessation (strength of evidence B); and (3) ask parents about tobacco use and offer cessation advice and assistance to quit (strength of evidence B).

Effective Interventions

A number of intervention strategies, including behavioral counseling and pharmacotherapies, have been shown to be effective for tobacco cessation when they are delivered in a primary care setting to nonpregnant adults aged 18 years and over (USPSTF, 2009c). The USPSTF concluded that a dose-response relation between quit rates and the intensity of counseling exists. Providing more sessions or increasing the length of sessions increased quit rates. Components of counseling strategies that were effective included instruction in problem solving and coping techniques, goal setting, developing a plan for quitting, motivational interviewing, telephone quit lines, and referrals. Combining counseling with pharmacotherapy was more effective than either approach alone. Although women appear to benefit from the same interventions as men, the data are inconsistent as to whether they benefit as much and what types of interventions are the most effective for women (Fiore et al., 2008; Munafo et al., 2004; Perkins and Scott, 2008). One meta-analysis found that the efficacy of nicotine replacement therapy was less effective in women than in men (Perkins and Scott, 2008); however, other meta-analyses have shown equivalent benefits in men and women (Baker et al., 2011; Killen et al., 2002). Behavioral interventions, such as tailored educational messages and self-help materials, were found to increase abstinence from smoking during pregnancy, but the USPSTF found inadequate evidence to evaluate the safety or efficacy of pharmacotherapy during pregnancy (USPSTF, 2009c).

In a systematic review conducted by the National Commission on Prevention Priorities for the Partnership for Prevention, screening for tobacco use and brief intervention counseling with an offer of pharmacotherapy ranked third of 25 clinical preventive services in terms of the most beneficial services to offer patients (Maciosek et al., 2009, 2010). The percent-

age of adult smokers who visited a clinician within the past year and who reported that they received advice to quit was about 68 percent, but only about 35 percent of smokers received brief counseling in which medication and cessation strategies recommended by the USPSTF were discussed (CDC, 2003; NCQA, 2005). Likewise, identifying and counseling adolescent smokers are estimated to occur in only 33 to 42 percent of physician visits and about 20 percent of dental visits (Alfano et al., 2002; Shelley et al., 2005).

Most behavior change intervention studies of smoking cessation and prevention in youth and adolescents have been conducted in school or community settings. Scant data on intervention strategies delivered in clinical settings are available, and the existing data are inconsistent (Fiore et al., 2008; Grimshaw and Stanton, 2006). In an analysis of seven studies comparing counseling with usual care or no treatment, the long-term abstinence rate doubled for the groups receiving counseling; however, the absolute abstinence rate was low (Fiore et al., 2008). Effective strategies varied in content, format, and intensity and included brief advice, educational pamphlets, self-help materials, and/or referrals. No data were available on whether these strategies were equally effective in boys and girls when they were offered in clinical settings. An update of the Surgeon General's report on preventing tobacco use among young people is expected to be released by December 2011 (in press).

Identified Gap

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that while tobacco cessation aids and counseling are recommended, the potential need for multiple interventions defined by the Public Health Service Guidelines, which include pharmacotherapy, in helping women to quit smoking are not addressed. The committee found insufficient evidence to develop a new recommendation; instead, the evidence supported by high-quality systematic reviews, supportive systematic reviews, federal agendas from the CDC, NCI, NHLBI, and NIDA, as well as clinical professional guidelines, led to a clarifying statement, which was added to the USPSTF recommendation.

Clarification Statement

In recognizing that women may need more than one type of intervention for successful tobacco cessation, the committee interprets the current USPSTF recommendation regarding tobacco use screening and cessation to consider including both counseling and FDA-approved and over-the-

counter medications. Additionally, it is appropriate for pregnant women who smoke to receive counseling that is tailored to their needs.

DIET/PHYSICAL ACTIVITY

An unhealthy diet and physical inactivity are associated with the leading causes of morbidity and mortality among women in the United States. Counseling patients in a clinical setting offers an opportunity to motivate women to adopt healthy dietary and physical activity behaviors. The target populations for diet and physical activity counseling are adult women 18 years of age and older, pregnant women of any age, and adolescent females.

Prevalence/Burden

Physical inactivity is associated with increased risk of all-cause mortality, coronary heart disease, high blood pressure, stroke, type 2 diabetes, metabolic syndrome, colon cancer, breast cancer, osteoporotic fractures, falls, and depression. Regular physical activity during pregnancy may reduce the risk of preterm birth, low birth weight, early pregnancy loss, and chronic health problems in the offspring; and moderate-intensity physical activity may increase cardiorespiratory and metabolic fitness (Physical Activity Guidelines Advisory Committee, 2008).

The benefits of physical activity in children and adolescents have been less studied; however, data support the findings that important health and fitness benefits accrue to children and adolescents who participate in 60 or more minutes of moderate to vigorous physical activity daily. Regular exercise helps control weight and build and maintain strong bones and confers positive psychological benefits (CDC, 2008b; Physical Activity Guidelines Advisory Committee, 2008).

Data from the 2008 National Health Interview Survey show that women are less likely than men to be highly active and are more likely to be insufficiently active and inactive (Carlson et al., 2010). Every year from 1998 through 2008, women were less likely to be aerobically active, according to *Healthy People 2010* criteria (Carlson et al., 2010; HHS, 2011). In 2008, 33 percent of men but only 24 percent of women were highly active. Data from the BRFSS also show that women are less active than men for every measure of physical activity (e.g., recommended physical activity, insufficient physical activity, inactivity, and no leisure-time physical activity), and this pattern was consistent from 2001 through 2008 (CDC, 2008c).

As the prevalence of physical activity has decreased, the prevalence of

unhealthy eating behaviors has increased, contributing to an epidemic of obesity in the United States. Men and women appear to be equally at risk for obesity. In the 2009 BRFSS survey, 27.4 percent of men and 26 percent of women were obese, as measured from the body mass index (CDC, 2010d). Data from the first National Health and Nutrition Examination Survey (NHANES I) for the period from 1971 to 1975 compared with data from the 2005 and 2006 NHANES show that the percentage of overweight and obese men and women has increased substantially. For women, the proportion who were overweight or obese increased from 40.7 to 61.5 percent; for men, the increase was from 52.9 to 73.6 percent (Austin et al., 2011).

In contrast to the male-female differences in physical activity, women are more likely than men to report that they eat a healthier diet. In the 2009 BRFSS survey, 36.1 percent of women and 28.7 percent of men reported eating fruit two or more times a day (2010). Women were also more likely than men to report eating vegetables three or more times a day: 30.9 and 21.4 percent for women and men, respectively. This pattern has been consistent since 1996 (CDC, 1996; Serdula et al., 2004). Despite these differences, the average intake of carbohydrates, protein, total fat, and saturated fat as a percentage of total kilocalories was similar for men and women (Wright and Wang, 2010).

Healthy diet and physical activity during pregnancy have health benefits for the woman and her child (Physical Activity Guidelines Advisory Committee, 2008). Moreover, 20 percent of women are obese when they become pregnant (Van Horn, 2010), indicating that they may not be receiving appropriate nutrients or maintaining a healthy diet. Many women put on excess weight during pregnancy and have difficulty losing it afterwards, but during the postpartum period, physical activity alone will not produce weight loss unless it is coupled with dietary changes. The importance of proper nutritional intake and proper eating behavior during pregnancy was underscored by the 2010 Dietary Guidelines Advisory Committee, which recommended that future reports include dietary recommendations from birth (Van Horn, 2010).

Similar to the pattern for adult females, data from the Youth Risk Behavioral Surveillance System show that the self-reported prevalence of physical activity is substantially lower in girls than in boys and remained so from 1993 to 2009 (CDC, 2011). During that period, there was a marked decrease in the percentage of adolescents who met the recommended physical activity levels. In 1993, 75 percent of boys and 56 percent of girls met the recommended levels. In 2009, only 46 percent of boys and 28 percent of girls met the recommended activity levels (CDC, 2011).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF concludes that the evidence is insufficient to recommend for or against routine behavioral counseling to promote a healthy diet in unselected patients in primary care settings. Grade I statement (USPSTF, 2003a).

The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians. Grade B recommendation (USPSTF, 2003a).

The USPSTF concludes that the evidence is insufficient to recommend for or against behavioral counseling in primary care settings to promote physical activity. Grade I statement (USPSTF, 2002a).

The USPSTF is in the process of updating its 2002 recommendation on behavioral counseling to promote physical activity (Berg et al., 2002) and its 2003 recommendation on behavioral counseling to promote a healthy diet in adults (USPSTF, 2003b). The earlier systematic reviews found insufficient evidence to recommend for or against behavioral counseling in primary care settings to promote either physical activity or healthy dietary behaviors in adults without preexisting cardiovascular disease or its risk factors (2003; Berg et al., 2002). An updated draft recommendation statement was available for comment from February 22 to March 22, 2011 (USPSTF, 2011b). This recommendation (Lin et al., 2010) will replace the USPSTF's previous separate recommendations on behavioral counseling to promote a healthful diet (USPSTF, 2003b) and physical activity (Berg et al., 2002).

Although the 2003 recommendation on dietary counseling included a positive recommendation for counseling adults with risk factors for cardiovascular disease (Grade B recommendation) (USPSTF, 2003b), the updated statement does not include a recommendation for this subgroup (Lin et al., 2010). On the basis of the updated systematic review, the USPSTF concluded that "the average benefit of primary care behavioral counseling interventions to promote a healthful diet and/or physical activity for cardiovascular disease prevention is small. Clinicians may consider selectively providing or referring individual patients for medium- or high-intensity behavioral counseling interventions" (Grade C recommendation) (USPSTF, 2011b).

Bright Futures recommends that physicians calculate the body mass

index for patients ages 10 to 21 years and discuss healthy diet and physical activity through the provision of anticipatory guidance (AAP, 2008). The AMA also advises physicians to provide adolescents with annual guidance about healthy dietary habits and the benefits of engaging in physical activity on a regular basis (Copperman, 1997).

Effective Interventions

Counseling about diet and physical activity in the primary care setting provides an opportunity to mitigate the negative health outcomes associated with poor dietary behaviors and physical inactivity. The systematic review conducted for the USPSTF (Lin et al., 2010) identified 66 trials of counseling to promote physical activity, a healthy diet, or both. The outcomes measured in these trials included morbidity and mortality related to cardiovascular disease, risk factors for cardiovascular disease, and self-reported dietary and physical activity behaviors. High-intensity counseling about a healthy diet with or without counseling about physical activity resulted in positive changes in body mass index (adiposity), systolic and diastolic blood pressure, and total and low-density lipoprotein cholesterol levels. Medium- and high-intensity physical activity counseling interventions resulted in small increases in physical activity levels, although data for low-intensity interventions were inconsistent. Reductions in self-reported fat intake were observed at all levels of intervention intensity, but high-intensity interventions resulted in larger reductions. Increased fruit and vegetable consumption was observed at all levels of intervention intensity. Very few trials had periods of follow-up beyond 12 months, thus the long-term effects of the counseling interventions about dietary patterns is unknown.

Although all of the trials were conducted in health care settings or recruited participants from health care settings, the role of the primary care provider was minimal in some of the studies.

Virtually all of the trials included women; however, very few provided gender-specific comparisons of the impact of the interventions on health-related outcomes, and very few studies included women during pregnancy or the postpartum period (Lin et al., 2010). An earlier review examined diet and physical activity interventions delivered in health care settings only to women (Wilcox et al., 2001). Findings from these earlier studies were consistent with the positive results of the USPSTF review for body mass index; systolic and diastolic blood pressure; and total cholesterol, low-density lipoprotein cholesterol, dietary fat, and physical activity levels. Although effect size estimates, as measured by the mean correlation coefficient, were small, they were statistically significant. Results for dietary fiber, energy in-

take, general dietary factors, and high-density lipoprotein cholesterol were not statistically significant (Wilcox et al., 2001).

The AHA recently reviewed interventions to promote physical activity and dietary changes and issued recommendations for counseling people to increase their levels of physical activity and make healthy dietary changes. Although the review was not limited to interventions delivered in a clinical setting, the group made recommendations about strategies that clinicians could use in primary care settings to assist adults in adopting and maintaining health dietary and physical activity behaviors, including the use of cognitive-behavioral strategies and modifying interventions to be appropriate to the patient's social and cultural context (Artinian et al., 2010).

Most intervention studies to promote a healthy diet or physical activity in children and adolescents have been conducted in school or community settings. Interventions conducted in clinical settings have targeted overweight and obese children (Summerbell et al., 2003; Whitlock et al., 2010). A 2006 report of the USPSTF on screening and interventions that targeted overweight children and adolescents found insufficient evidence for the effectiveness of behavioral counseling or other preventive interventions that could be conducted in primary care settings or to which primary care clinicians could make referrals. However, some reviews of interventions for preventing obesity in children and adolescents have been conducted (Summerbell et al., 2003; Whitlock et al., 2010).

Identified Gaps

The primary gaps in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) are the lack of interventions in primary care practice that address healthy diet and physical activity. The committee found insufficient evidence to develop a new recommendation; instead, the evidence supported by high-quality systematic evidence reviews and clinical practice guidelines, as well as the draft recommendation statement from the USPSTF (indicating that medium- to high-intensity interventions for diet and physical activity led to small benefits toward prevention of cardiovascular disease), led to support for the reasonableness of including diet and physical activity counseling during a well-woman visit.

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Appendix B

Agendas of Public Meetings Held by the Committee on Preventive Services for Women

FIRST MEETING
November 16, 2010
The Dupont Circle Hotel
Washington, DC

Welcome and Overview
Linda Rosenstock, M.D., M.P.H.
Committee Chair

Presentation of the Charge
Mona Shah, J.D., M.P.H.
Professional Staff Member
Office of Senator Barbara Mikulski (MD)
Senate Committee on Health, Education, Labor, and Pensions

Sherry Glied, Ph.D.
Assistant Secretary for Planning and Evaluation
Department of Health and Human Services

Mary Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration

Committee Discussion

Groups Interested in Women's Issues

Judy Waxman, J.D.
Vice President of Health and Reproductive Rights
National Women's Law Center

Cynthia Pearson
National Women's Health Network
Women's Voices Are Raising Women's Voices for the Health Care We Need

Carolyn Westhoff, M.D., M.Sc.
Planned Parenthood Federation of America
Board Member and Immediate Past Chair of the National Medical Advisory Committee

Eleanor Hinton Hoytt
Women of Color United for Health Reform

Esta Soler
President and Founder of the Family Violence Prevention Fund

Adolescent Issues

Sarah S. Brown
Cofounder and Chief Executive Officer
The National Campaign to Prevent Teen and Unplanned Pregnancy

John Santelli, M.D., M.P.H.
Mailman School of Public Health
Columbia University
and Society for Adolescent Medicine

Methodological Approaches

Mary Barton, M.D., M.P.P.
Scientific Director of the United States Preventive Services Task Force (USPSTF).
Agency for Healthcare Research and Quality

Ned Calonge, M.D., M.P.H. (via phone)
Chair, USPSTF

Joseph Hagan, M.D.
Paula Duncan, M.D. (via phone)
Authors
Bright Futures for Infants, Children, and Adolescents

Sarah Scholle, Dr.P.H., M.P.H.
Assistant Vice President of Research and Analysis
National Committee on Quality Assurance
Quality for Well-Woman Care

Committee Discussion

Opportunity for Attendees to Comment

SECOND MEETING
January 12, 2011
National Academies Keck Center
Washington, DC

Welcome and Overview
Linda Rosenstock, M.D., M.P.H.
Committee Chair

Women's Health Organizations
Sharon Camp, M.A., Ph.D.
President and Chief Executive Officer
The Guttmacher Institute

Hal Lawrence, M.D., F.A.C.O.G.
Incoming Executive Vice President
Vice President of Practice Activities
American Congress of Obstetricians and Gynecologists

Catherine Ruhl, C.N.M., M.S.
The Association of Women's Health, Obstetric and Neonatal Nurses

National Health Interest Groups
Sharon Moffatt, R.N., B.S.N., M.S.
Chief of Health Promotion and Disease Prevention
Association of State and Territorial Health Officials

Jud Richland, M.P.H.
President and Chief Executive Officer
Partnership for Prevention

Margaret Blythe, M.D. F.A.A.P.
Chair, Committee on Adolescence
American Academy of Pediatrics

Provider and Employer Perspectives
George Isham, M.D., M.S.
Medical Director and Chief Health Officer
HealthPartners

Joanne Armstrong, M.D., M.P.H. (via phone)
Senior Medical Director and Head of Women's Health
Aetna

Helen Darling, M.A.
President
National Business Group on Health

Wayne Burton, M.D.
Global Corporate Medical Director
American Express Corporation

Opportunity for Attendees to Comment

THIRD MEETING
March 9, 2011
National Academy of Public Administration
Washington, DC

Welcome and Overview
Linda Rosenstock, M.D., M.P.H.
Committee Chair

Guidelines Development and Use
Doug Campos-Outcalt, M.D., M.P.A.
AAFP Liaison to United States Preventive Services Task Force and Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention

Melissa Starkey, Ph.D.
Clinical Guidelines Administrator
American College of Physicians

David Rind, M.D. (via phone)
Co-Executive Editor
UpToDate
GRADE Working Group

Coverage Design and Decision Making

Sara Rosenbaum, J.D.
Hirsh Professor and Chair
Department of Health Policy
School of Public Health and Health Services
The George Washington University Medical Center

Other Preventive Health Issues

Gwen Keita, Ph.D.
Director, Women's Programs Office
and Associate Executive Director
Public Interest Directorate
American Psychological Association

Lauren Patton, D.D.S.
Professor and Chair
Department of Dental Ecology
and Program Director
General Practice Residency
School of Dentistry
University of North Carolina, Chapel Hill

Melissa A. McDiarmid, M.D., M.P.H., D.A.B.T.
Professor
Departments of Medicine and Epidemiology and Public Health
and Director
Occupational Health Program
University of Maryland School of Medicine

Opportunity for Attendees to Comment

Appendix C

Committee Biographies

Linda Rosenstock, M.D., M.P.H. (elected to the Institute of Medicine [IOM] in 1995), is dean of the School of Public Health, University of California at Los Angeles (UCLA). She is a recognized authority in occupational and environmental health as well as global public health and science policy. Prior to going to UCLA in 2000, Dr. Rosenstock served for seven years as the director of the National Institute for Occupational Safety and Health, where she led a staff of 1,500 at the only federal agency mandated to undertake research and prevention activities in occupational safety and health. In recognition of her efforts, Dr. Rosenstock received the Presidential Distinguished Executive Rank Award, the highest executive service award in the federal government. In 2003 she cochaired the IOM committee addressing public health workforce needs that authored the report *Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century*. Dr. Rosenstock is immediate past chair of the Association of Schools of Public Health and immediate past president of the Society of Medical Administrators.

Alfred O. Berg, M.D., M.P.H., is professor in the Department of Family Medicine at the University of Washington School of Medicine, Seattle. Dr. Berg received his professional education in family medicine and in general preventive medicine and public health at Washington University in St. Louis, Missouri; the University of Missouri; and the University of Washington and is a member of the Institute of Medicine. Dr. Berg's research has focused on clinical epidemiology in primary care settings. He has been active on many expert panels using evidence-based methods to develop

clinical guidelines, including chair of the United States Preventive Services Task Force, cochair of the otitis media panel convened by the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality), chair and moderator of the STD Treatment Guidelines panel of the Centers for Disease Control and Prevention (CDC), member of the American Medical Association-CDC panel producing Guidelines for Adolescent Preventive Services, and chair of the CDC's Evaluation of Genetic Applications in Practice and Prevention working group. He has served on the Institute of Medicine's Immunization Safety Review Committee (member), the Committee on the Treatment of Post Traumatic Stress Disorder (chair), and the Committee on Standards for Systematic Reviews of Clinical Effectiveness Research (chair).

Claire D. Brindis, Dr.P.H., M.P.H., is professor of pediatrics and health policy in the Department of Pediatrics and Department of Obstetrics, Gynecology, and Reproductive Health Sciences at the University of California, San Francisco. Dr. Brindis is director of the Philip R. Lee Institute for Health Policy Studies, executive director of National Adolescent Health Information and Innovation Center, and director of the Bixby Center for Global Reproductive Health. Dr. Brindis's research interests are in the area of developing and evaluating innovative, community-based, comprehensive, integrated services for children, youth, and women and in combining qualitative and quantitative approaches to program evaluation. Her research focuses on child and adolescent health policy and women's health, with a special focus on Latina health. Dr. Brindis's educational background includes a doctoral degree in public health and behavioral sciences from the University of California at Berkeley and a master's degree in public health from the University of California at Los Angeles.

Angela Diaz, M.D., M.P.H., is the Jean C. and James W. Crystal Professor of Pediatrics and Community Medicine at Mount Sinai School of Medicine. After earning her medical degree in 1981 at the Columbia University College of Physicians and Surgeons, she completed her postdoctoral training at the Mount Sinai School of Medicine in 1985 and subsequently received a master's in public health from Harvard University. Dr. Diaz is the director of the Mount Sinai Adolescent Health Center, a unique program that provides comprehensive, integrated, interdisciplinary primary care, sexual and reproductive health, mental health, and health education services to teens. She has been a White House Fellow, a member of the Food and Drug Administration Pediatric Advisory Committee, and a member of the National Institutes of Health State of the Science Conference on Preventing Violence and Related Health Risk Social Behaviors in Adolescents. She serves on an advisory panel for the National Institutes of Health Reproductive Sciences

Branch. She is a frequent speaker at conferences throughout the country and around the world.

Francisco Garcia, M.D., M.P.H., is the director of the University of Arizona Center of Excellence in Women's Health. Dr. Garcia is the Distinguished Professor of Public Health, Obstetrics and Gynecology, Pharmacy and Mexican-American Studies at the University of Arizona and Chair of Family and Child Health of the Mel and Enid Zuckerman College of Public Health. He also serves as the codirector of the Cancer Disparities Institute of the Arizona Cancer Center. He is the past director of the Arizona Hispanic Center of Excellence (until 2007), as well as former director of the Division of Gynecology (until 2006). Dr. Garcia has served as a consultant to and collaborator on a variety of domestic and international agencies and nongovernmental organizations concerned with cervical cancer prevention, including the Department of Health of the State of Sonora, Population Council, the Pan-American Health Organization, the Instituto Nacional de Enfermedades Neoplasicas (Peruvian National Cancer Institute), IMSS-Solidaridad, Programa de Salud Reproductiva (the Mexican Social Security Institute-Reproductive Health Program), JHPIEGO, and PATH.

Kimberly Gregory, M.D., M.P.H., is vice chair of Women's Healthcare Quality and Performance Improvement, Department of Obstetrics and Gynecology at Cedars-Sinai Medical Center. She also serves as professor at the David Geffen School of Medicine at the University of California at Los Angeles (UCLA) and the UCLA School of Public Health. Dr. Gregory is board certified in obstetrics and gynecology and maternal-fetal medicine. Her research interests include obstetrical health care utilization, rates of delivery by cesarean section, and the management of complications of labor and delivery as it relates to patient safety and health care quality. Dr. Gregory served on the U.S. Public Health Service's Prevention Task Force (2006 to 2010). Dr. Gregory received her bachelor's degree from UCLA and her medical degree from the Charles Drew University School of Medicine and Science. She completed her internship and residency in obstetrics and gynecology at Beth Israel Hospital in Boston and her fellowship in maternal-fetal medicine at Los Angeles County, University of Southern California Medical Center. Dr. Gregory received her master's of public health from the Harvard University School of Public Health in 1991.

Paula A. Johnson, M.D., M.P.H., an internationally recognized cardiologist, is the executive director of the Connors Center for Women's Health and Gender Biology and chief of the Division of Women's Health at Brigham and Women's Hospital, and associate professor of Medicine at Harvard Medical School. Dr. Johnson brings a broad range of experience as a phy-

sician, researcher, and expert in public health and health policy to bear in the effort to transform the health of women. Central to the Connors Center's mission is discovering how disease is expressed differently in women and men, integrating leading-edge research about women's health into the delivery of care, influencing health policy, addressing the health of women globally, and training the next generation of leadership in the field. Dr. Johnson is a graduate of Harvard and Radcliffe Colleges, and received her M.D. and M.P.H. from Harvard. Dr. Johnson has been recognized with many awards for her contributions in women's and minority health and public health and is featured as a national leader in medicine by the National Library of Medicine.

Anthony Lo Sasso, Ph.D., is a professor and senior research scientist in the Division of Health Policy and Administration at the University of Illinois at Chicago School of Public Health and the Institute of Government and Public Affairs at the University of Illinois. He joined the University of Illinois at Chicago faculty in 2004. Dr. Lo Sasso is an economist whose research spans several dimensions of health economics and health services research. Dr. Lo Sasso is keenly interested in how government policies affect private-sector decisions. Dr. Lo Sasso has studied the impact of the State Children's Health Insurance Program on uninsurance among children and the extent to which public coverage crowded out private coverage. In addition, he has examined how community rating provisions affected non-group health insurance coverage and uninsurance. Dr. Lo Sasso also studies the effects of health savings accounts and other high-deductible health insurance products on service use and spending. He is currently working with the Upstate Health Research Network in New York to calculate usual and customary reimbursement rates for the health insurance industry. Dr. Lo Sasso received his doctorate in economics in 1996 from Indiana University, Bloomington.

Jeanette H. Magnus, M.D., Ph.D., is Cecile Usdin Professor in Women's Health; professor of public health and chair of the Department of Community Health Sciences at the Tulane University School of Public Health and Tropical Medicine; and a clinical professor in the Department of Medicine, Tulane University School of Medicine. She is also the director of the Tulane Xavier National Center of Excellence in Women's Health and the Mary Amelia Douglas-Whited Community Women's Health Education Center. Dr. Magnus's work bridges clinical medicine and science, epidemiology, public health, and community research. She has extensive experience in rheumatology and internal medicine. She developed and established the Tulane University Total Woman Health Care Clinic in 2000, providing primary and specialty care to women across the life span. Her research interests are in gender and race disparity in health and disease;

the association between health behaviors, self-evaluated health or mental health, and chronic disease; cardiovascular disease; and osteoporosis. Dr. Magnus has more than 130 publications and extensive experience in network building and coordination of projects that involve research scientists and practitioners with different backgrounds. She is the associate editor for the Epidemiology and Population Health Section for *Gender Medicine* and a member of the editorial boards of the B*iology of Sex Differences* and the *Journal of Women's Health*. Dr. Magnus earned both her M.D. and Ph.D. from University of Tromsø in Norway.

Heidi D. Nelson M.D., M.P.H., is a research professor of medical informatics and clinical epidemiology and medicine at the Oregon Health & Science University and medical director for cancer prevention and screening at Providence Health and Services, Portland, Oregon. Dr. Nelson received her M.D. and M.P.H. at the University of Minnesota and completed her internal medicine residency at the Oregon Health & Science University and fellowship in clinical epidemiology at the University of California, San Francisco. Since 1998, Dr. Nelson has conducted systematic evidence reviews and comparative effectiveness reviews for the United States Preventive Services Task Force, National Institutes of Health, Agency for Healthcare Research and Quality Effective Healthcare Program, and Drug Effectiveness Review Project, among others, at the Oregon Evidence-Based Practice Center. Her work has been used in developing clinical recommendations, practice guidelines, and consensus statements primarily in areas of women's health. At Providence, a not-for-profit, community-based, integrated health system in the western United States, she has developed patient data registries for quality improvement and research purposes, including a breast cancer screening and treatment registry. She has also led planning, implementation, and evaluation of health care programs and practices across the state to improve health care for women.

Roberta B. Ness, M.D., M.P.H., is dean, M. David Low Chair in Public Health, and professor in epidemiology at The University of Texas School of Public Health. Dr. Ness was formerly chair of the Department of Epidemiology at the University of Pittsburgh Graduate School of Public Health and served as interim dean in 2005 and 2006. Dr. Ness received her M.D. from Cornell University and her M.P.H. from Columbia University. Dr. Ness was one of the first to propose the research paradigm now termed "gender-based biology" in her book titled *Health and Disease Among Women* (1999). Dr. Ness is also known for her work on teaching innovation. She recently authored *Innovation Generation*, an instructional program for innovative thinking (to be published in 2012 by Oxford University Press). Dr. Ness is a fellow of the American College of Physicians; member of the Academy

of Medicine, Engineering, and Science of Texas; and member of the Institute of Medicine of the National Academies. She is president-elect of the American Epidemiologic Society and past president of the American College of Epidemiology. She is an elected member of the prestigious American Society for Clinical Investigation, Delta Omega Honorary Society, and the American Epidemiologic Society. She was selected by the Society for General Internal Medicine to be the 2008 Distinguished Professor of Women's Health. In 2011 she was named a U.S. presidential appointee to the Mickey Leland Center for Environmental Air Toxicant Research.

Magda G. Peck, Sc.D., professor of public health and pediatric at the University of Nebraska Medical Center (UNMC), in Omaha, is a national leader in maternal and child health. Dr. Peck's specific areas of expertise include prevention and public health for women and children, translating science into effective programs and policies, and leadership and workforce development. She received master's and doctoral degrees (1983, 1986) from the Harvard University School of Public Health, specializing in maternal and child health and social policy. For more than two decades, Dr. Peck has worked to build public health capacity to make a measurable difference for women and children. In 1988, Dr. Peck founded CityMatCH (www.citymatch.org), which has become the leading national public health organization dedicated to improving the health and well-being of women, children, and families in America's urban communities. While serving as CityMatCH's chief executive officer (until 2007), she lead the design and dissemination of innovative approaches to improving local understanding and action to address mother-to-baby transmission of human immunodeficiency virus and AIDS, reduce health disparities, and improve women and infant's health, including the perinatal periods of risk approach. She served as a member of the Select Panel for Preconception Care with the Centers for Disease Control and Prevention to shape national recommendations on the care of women prior to pregnancy, and co-led the Public Health Work Group of the National Preconception Health Steering Committee. Dr. Peck has been a pioneer for academic public health in Nebraska. She was founding director of the state's only master of public health program and helped establish the Great Plains Public Health Leadership Institute, which she has directed since 2005. As the new associate dean for community engagement and public health practice of the new UNMC College of Public Health, she ensures a dynamic, mutually beneficial interface between academe and community.

E. Albert Reece, M.D., Ph.D., M.B.A., is currently vice president, University of Maryland, and dean of the School of Medicine. Previously, he was vice chancellor and dean of the University of Arkansas College of Medi-

cine. Dr. Reece received his undergraduate degree (B.S., magna cum laude) from Long Island University, his M.D. degree from New York University, his Ph.D. degree in biochemistry from the University of the West Indies, Kingston, Jamaica, and his M.B.A. degree from the Fox School of Business and Management of Temple University. He completed a residency in obstetrics and gynecology at Columbia University Medical Center and a fellowship in maternal-fetal medicine at Yale University School of Medicine. He served on the faculty at Yale for almost 10 years and was the Abraham Roth Professor and chair of the Department of Obstetrics, Gynecology, and Reproductive Sciences at Temple University. Dr. Reece has published more than 500 journal articles, book chapters, and abstracts, and 9 textbooks, with revisions. He is an associate editor for the *Journal of Maternal-Fetal Medicine* and a reviewer for several scientific journals. He directs a National Institutes of Health-funded laboratory studying the biomolecular mechanisms of diabetes-induced birth defects. Dr. Reece is a member of the Institute of Medicine.

Alina Salganicoff, Ph.D., is vice president and director of Women's Health Policy at the Henry J. Kaiser Family Foundation. She directs the foundation's work on health coverage and access to care for women, with an emphasis on challenges facing underserved women. She also directs KaiserEDU.org, the foundation's educational website. Dr. Salganicoff has written and spoken extensively on a broad range of health policy concerns facing women, ranging from health disparities to long-term care. She was also an associate director of the Kaiser Commission on Medicaid and the Uninsured, specializing on the access challenges facing low-income families, Medicaid managed care, and state health reform. Prior to joining Kaiser, she worked on the program staff of the Pew Charitable Trusts. She has served on numerous federal, state, and nonprofit advisory committees, including the Institute of Medicine's Committee on Women's Health Research. Dr. Salganicoff received a B.S. from the Pennsylvania State University and holds a Ph.D. in health policy from The Johns Hopkins University School of Hygiene and Public Health.

Sally W. Vernon, Ph.D., is director of the Division of Health Promotion and Behavioral Sciences, Blair Justice Professor in Mind-Body Medicine and Public Health, and professor of epidemiology and behavioral sciences at the University of Texas-Houston School of Public Health (UTSPH) and the Center for Health Promotion and Prevention Research. Dr. Vernon's training is in epidemiology and behavioral sciences. She received her B.A. in Spanish from the University of Oklahoma, her M.A. in sociology from New York University, and her Ph.D. in community health sciences from UTSPH. Dr. Vernon conducts interdisciplinary research in cancer prevention and control, with

an emphasis on breast, cervical, and colorectal cancers. Her work has been conducted in community, work-site, and medical care settings, where she has developed and tested interventions to promote cancer screening behaviors. Dr. Vernon has published more than 150 scientific articles and book chapters and is currently a member of several editorial boards including those of the *Journal of National Cancer Institute*, *Cancer Epidemiology*, *Biomarkers & Prevention*, *Preventive Medicine*, and *Cancer Causes and Control*. She is a fellow and past president of the American College of Epidemiology.

Carol S. Weisman, Ph.D., is distinguished professor of public health sciences and obstetrics and gynecology at the Pennsylvania State University College of Medicine, with a joint appointment in the Department of Health Policy and Administration, and associate dean for faculty affairs. Dr. Weisman is a sociologist and health services researcher with a principal interest in women's health care and policy. Her research focuses on improving access and quality in women's primary care and on how health care and health risks affect women's health. She is director of the Central Pennsylvania Center of Excellence for Research on Pregnancy Outcomes and of the Central Pennsylvania Women's Health Study (CePAWHS); Principal Investigator of the Penn State BIRCWH (Building Interdisciplinary Research Careers in Women's Health) K-12 Program; and Associate Editor of *Women's Health Issues*. She received her B.A. from Wellesley College with a major in sociology and anthropology and her Ph.D. in social relations (sociology) from the Johns Hopkins University.

Appendix D

Dissent and Response

This appendix has two parts. The first is a dissent statement from committee member Anthony Lo Sasso, and the second is a response from the chair and the other 14 members of the Committee on Preventive Services for Women.

DISSENTING OPINION

Anthony Lo Sasso

Summary

Given the combination of the unacceptably short time frame for the PSW committee to conduct or solicit meaningful reviews of the evidence associated with the preventive nature of the services considered, this dissent advocates that no additional preventive services beyond those explicitly stated in the Affordable Care Act (ACA) be recommended for consideration by the Secretary for first dollar coverage until such time as the evidence can be objectively and systematically evaluated and an appropriate framework can be developed. The long-run risks associated with making poorly informed decisions, and their likely irreversibility once codified, outweigh the ACA-mandated rapidity with which the committee was confronted.

Rationale

The ACA provided the impetus for the IOM to form a panel to make recommendations about screening and preventive services that "have been shown to be effective for women" that in turn will be considered by the Secretary for coverage on a first-dollar basis by all new private plans in operation in 2014. However, a remarkably short time frame was provided for the task of reviewing all evidence for preventive services beyond the services encompassed by the USPSTF, Bright Futures and ACIP: the final report from the committee was needed barely six months from the time the group was empanelled.

As the Report acknowledges, the lack of time prevented a serious and systematic review of evidence for preventive services. This should in no way reflect poorly on the tireless work of the committee and staff; it instead merely reflects the fact that the process set forth in the law was unrealistic in the time allocated to such an important and time-intensive undertaking. Where I believe the committee erred was with their zeal to recommend something despite the time constraints and a far from perfect methodology.

The Report posits four categories as the basis for the recommendations ranging from "high quality systematic evidence reviews" (Category I) to potentially self-serving guidelines put forth by professional organizations (Category IV). The categories alone on their face provide little basis to exclude many preventive services. For example, Category II asks whether there are any "quality" supportive peer-reviewed studies, but there is no clear benchmark for what quality means in this context; many studies published in peer-reviewed journals (even very well respected journals) are of low quality and are not generalizable. The problematic nature of the categories aside, the relative weights applied to each category vis-à-vis the recommendations were not specified, making it impossible to discern what factors were most important in the decision to recommend one service versus another. The categories were combined with expert judgment from members of the committee and supplemented with committee debate to arrive at the recommendations put forth in the Report. Readers of the Report should be clear on the fact that the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered. Put differently, evidence that use of the services in question leads to lower rates of disability or disease and increased rates of well-being is generally absent.

The view of this dissent is that the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy. An abiding principle in the evaluation of the evidence and the

recommendations put forth as a consequence should be transparency and strict objectivity, but the committee failed to demonstrate these principles in the Report. This dissent views the evidence evaluation process as a fatal flaw of the Report particularly in light of the importance of the recommendations for public policy and the number of individuals, both men and women, that will be affected.

Other Considerations

Another concerning aspect of the Report is the lack of a coherent framework to evaluate coverage apart from the evidence regarding clinical efficacy. Although coverage determinations were not explicitly part of the committee's charge, it is nevertheless difficult to ignore the fact that the committee's recommendations will have important implications for coverage considerations. Thus while the lack of a theoretical or conceptual framework to examine coverage decisions can perhaps be forgiven, it is clear that the "life course" model put forth in the Report does not lend itself to the consideration of coverage decisions. I describe one potential framework below that could inform such thinking around coverage determinations.

The ACA law requires coverage by private insurers of all USPSTF A and B recommendations. The USPSTF process of evidence review represents a "gold standard" based on a critical and scholarly review of all extant literature and therefore is the bar the committee should have aspired to in basing its recommendations to the Secretary. That said, the clinical recommendations from the USPSTF were never intended to provide a basis for insurance coverage determinations; they are intended as guides to physician practice. Given the previous role of the USPSTF it is worth noting that basing coverage decisions categorically on USPSTF recommendations has the potential to jeopardize the objectivity and scientific integrity of the USPSTF review process.

In contrast, while Bright Futures is a body aimed at influencing clinical practice, the evidence bar for its recommendations is considerably lower than that of the USPSTF. Recommendations are considered "evidence-informed" and rely heavily on expert opinion rather than systemic, critical reviews of the literature. This is troubling given the important public policy consequences that will now result from Bright Futures recommendations.

Additions to the Update Recommendations

There are reasons to support the framework for future evaluation of preventive services in the Report (Chapter 6). The proposed framework crucially recognizes the importance of separating the scientific objective

of establishing the effectiveness and potentially the cost effectiveness of preventive services from the policy decision regarding coverage of services. This dissent advocates for a more concrete structure based on sound public policy principles to frame both the evidence review and coverage decision for specific preventive services for women.

A highly regarded framework to examine coverage decisions of preventive services in an insurance context was developed more than twenty years ago by Pauly and Held (1990). The authors consider coverage decisions for a hypothetical preventive service that is presumed to reduce the probability of a covered and potential costly healthcare treatment episode (for example, inpatient treatment of a preventable disease outcome). More formally, if one assumes a preventive service, *S*, that costs *P* is available that when administered changes the probability from p_n to p_y of experiencing an inpatient event with cost *E*, the following can be observed:

1. If $p_n > p_y$ the service is effective in prevention as the treatment *S* reduces the probability of experiencing the negative outcome; this represents the minimum necessary threshold for which "preventive" needs to be defined.
2. If $(p_n - p_y)E > P$ the service is "cost effective"[1] in that the cost associated with the relative reduction in the probability of the negative outcome exceeds the cost of the treatment S; this is a potentially high bar but an important one for a preventive service.

However, it is important to understand that point (1) and even point (2) do not necessarily imply that first-dollar coverage of preventive services leads to an overall reduction in insurer payments (and hence insurance premiums) as many might assume. Whether coverage of preventive service leads to a reduction in healthcare expenditure depends on the fraction of enrollees using the service before the service becomes covered and the magnitude of the response among enrollees who experience the reduction in out-of-pocket price. This latter point is what Pauly and Held term "benign moral hazard" and it points to a critical parameter of interest as the elasticity or responsiveness of preventive service utilization to the user price for the service. Knowing how elastic patient demand is to preventive services is a critical element to a coverage decision even if one already has good estimates of the effectiveness and cost-effectiveness. This is self-evidently a useful parameter to know for any preventive service because it highlights

[1] It is important to note that the statute rules out cost as a consideration by the committee. Cost is included in the example only to demonstrate that the hypothetical preventive service meets a high bar beyond effectiveness.

the impact that first-dollar coverage of the service will have, perhaps in relation to other forms of outreach.

More recently, Pauly and Blavin (2008) incorporate some additional considerations in the wake of research on so-called value-based health insurance designs. First dollar coverage can be justified if enrollees lack information about the benefits of preventive services in order to make correct (or at least fully informed) decisions. Such a determination, however, would depend on the relative efficacy of information provision about the benefits of preventive services versus reducing (or eliminating) cost sharing.

REFERENCES

Pauly, M. V., and F. E. Blavin. 2008. Moral hazard in insurance, value-based cost sharing, and the benefits of blissful ignorance. *Journal of Health Economics* 27:1407–1417.

Pauly, M. V., and P. J. Held. 1990. Benign moral hazard and the cost-effectiveness analysis of insurance coverage. *Journal of Health Economics* 9:447–461.

RESPONSE TO DISSENTING STATEMENT

Linda Rosenstock (Chair), Alfred O. Berg, Claire D. Brindis, Angela Diaz, Francisco Garcia, Kimberly Gregory, Paula A. Johnson, Jeanette H. Magnus, Heidi D. Nelson, Roberta B. Ness, Magda G. Peck, E. Albert Reece, Alina Salganicoff, Sally W. Vernon, and Carol S. Weisman

The dissenting committee member wanted more time and the opportunity to incorporate cost-benefit analysis. At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions. The dissent also includes inaccurate statements regarding the committee process and its approach to the committee charge. The committee members' expertise is diverse and while many have different perspectives, no other member shares the opinion that report recommendations were not soundly evidence based.

EXHIBIT G

Women's Preventive Services Guidelines

On December 20, 2016, HRSA updated the HRSA-supported Women's Preventive Services Guidelines. Read the most current version.

Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 20, 2017. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the 2011 guidelines.

Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being

The Affordable Care Act – the health insurance reform legislation passed by Congress and signed into law by President Obama on March 23, 2010 – helps make prevention affordable and accessible for all Americans by requiring health plans to cover preventive services and by eliminating cost sharing for those services. Preventive services that have strong scientific evidence of their health benefits must be covered and plans can no longer charge a patient a copayment, coinsurance or deductible for these services when they are delivered by a network provider.

Women's Preventive Services Guidelines Supported by the Health Resources and Services Administration

Under the Affordable Care Act, women's preventive health care – such as mammograms, screenings for cervical cancer, prenatal care, and other services – generally must be covered with no cost sharing. However, the law recognizes and HHS understands the need to take into account the unique health needs of women throughout their lifespan.

The HRSA-supported health plan coverage guidelines, developed by the Institute of Medicine (IOM), will help ensure that women receive a comprehensive set of preventive services without having to pay a co-payment, co-insurance or a deductible. HHS commissioned an IOM study to review what preventive services are necessary for women's health and well-being and therefore should be considered in the development of comprehensive guidelines for preventive services for women. HRSA is supporting the IOM's recommendations on preventive services that address health needs specific to women and fill gaps in existing guidelines.

Health Resources and Services Administration Women's Preventive Services Guidelines

Non-grandfathered plans (plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) generally are required to provide coverage without cost sharing consistent with these guidelines in the first plan year (in the individual market, policy year) that begins on or after August 1, 2012.

Type of Preventive Service	HHS Guideline for Health	Frequency

Learn More

- Women's Preventive Services Initiative report
- 2011 IOM Report *Clinical Preventive Services for Women: Closing the Gaps*
- US Preventive Services Task Force
- Bright Futures
- Advisory Committee on Immunization Practices
- Previous Preventive Services Guidelines (August 2011)

For Further Information

Contact
wellwomancare@hrsa.gov.

	Insurance Coverage	
Well-woman visits.	Well-woman preventive care visit annually for adult women to obtain the recommended preventive services that are age and developmentally appropriate, including preconception care and many services necessary for prenatal care. This well-woman visit should, where appropriate, include other preventive services listed in this set of guidelines, as well as others referenced in section 2713.	Annual, although HHS recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.* (see note)
Screening for gestational diabetes.	Screening for gestational diabetes.	In pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.
Human papillomavirus testing.	High-risk human papillomavirus DNA testing in women with normal cytology results.	Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections.	Counseling on sexually transmitted infections for all sexually active women.	Annual.
Counseling and screening for human immune-deficiency virus.	Counseling and screening for human immune-deficiency virus infection for all sexually active women.	Annual
Contraceptive methods and counseling. ** (see note)	All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.	As prescribed
Breastfeeding support, supplies, and counseling.	Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period, and costs for renting breastfeeding equipment.	In conjunction with each birth
Screening and counseling for interpersonal and domestic violence.	Screening and counseling for interpersonal and domestic violence.	

** Refer to guidance issued by the Center for Consumer Information and Insurance Oversight entitled Affordable Care Act Implementation FAQs, Set 12, Q10.*

*** The guidelines concerning contraceptive methods and counseling described above do not apply to women who are participants or beneficiaries in group health plans sponsored by religious employers. Effective August 1, 2013, a religious employer is defined as an employer that is organized and operates as a non-profit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code. HRSA notes that, as of August 1, 2013, group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services under section 2713 of the Public Health Service Act, as incorporated into the Employee Retirement Income Security Act and the Internal Revenue Code. HRSA also notes that, as of January 1, 2014, accommodations are available to group health plans established or maintained by certain eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations, with respect to the contraceptive coverage requirement. See Federal Register Notice: Coverage of Certain Preventive Services Under the Affordable Care Act (PDF - 327 KB)*

HRSA, in concert with an external review committee, will review, and continually update, the *Women's Preventive Services' Guidelines*.

Date Last Reviewed: May 2017

EXHIBIT H

Women's Preventive Services Guidelines

Guideline Development

The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from a Department of Health and Human Services' commissioned study by the Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM). Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. To address these, the Health Resources and Services Administration (HRSA) awarded a five-year cooperative agreement in March 2016 to convene a coalition of clinician, academic, and consumer-focused health professional organizations and conduct a scientifically rigorous review to develop recommendations for updated Women's Preventive Services Guidelines in accordance with the model created by the NAM *Clinical Practice Guidelines We Can Trust.* The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative.

The purpose of the Women's Preventive Services Guidelines is to improve women's health across the lifespan by identifying preventive services and screenings to be used in clinical practice. The Women's Preventive Services Initiative will review the recommendations biennially, or upon the availability of new evidence. Topics for future consideration can also be submitted on a rolling basis at the Women's Preventive Services Initiative website.

Under section 2713 of the Public Health Services Act, non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose.

Updated HRSA-Supported Women's Preventive Services Guidelines

HRSA is supporting the Women's Preventive Services Initiative clinical recommendations listed below for preventive services that address health needs specific to women and fill gaps in existing guidelines.*

Breast Cancer Screening for Average-Risk Women

The Women's Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Breastfeeding Services and Supplies

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during

Learn More

- Women's Preventive Services Initiative report
- 2011 IOM Report *Clinical Preventive Services for Women: Closing the Gaps*
- US Preventive Services Task Force
- Bright Futures
- Advisory Committee on Immunization Practices
- Previous Preventive Services Guidelines (August 2011)

For Further Information

Contact
wellwomancare@hrsa.gov.

the antenatal, perinatal, and the postpartum period to ensure the successful initiation and maintenance of breastfeeding.

Screening for Cervical Cancer

The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.

Contraception**

The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Screening for Gestational Diabetes Mellitus

The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100- g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

The Women's Preventive Services Initiative suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.

Screening for Human Immunodeficiency Virus Infection

The Women's Preventive Services Initiative recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.

Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Screening for Interpersonal and Domestic Violence

The Women's Preventive Services Initiative recommends screening adolescents and women for interpersonal and domestic violence at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive

coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.

Counseling for Sexually Transmitted Infections

The Women's Preventive Services Initiative recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

The Women's Preventive Services Initiative recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement.

Well-Woman Preventive Visits

The Women's Preventive Services Initiative recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services, including preconception, and many services necessary for prenatal and interconception care are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

Implementation Considerations

While not included as part of the HRSA-supported guidelines, the Women's Preventive Services Initiative also developed implementation considerations, available at http://www.womenspreventivehealth.org/, which provide additional clarity on implementation of the guidelines into clinical practice. The implementation considerations are separate from the clinical recommendations, are informational, and are not part of the formal action by the Administrator under Section 2713.

** Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 20, 2017. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the 2011 guidelines.*

***(I)(a) Objecting entities—religious beliefs.*

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (I)(a)(2) of this note. Such non-governmental plan sponsors include, but are not limited to, the following entities:
(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order;
(B) A nonprofit organization;
(C) A closely held for-profit entity;
(D) A for-profit entity that is not closely held; or
(E) Any other non-governmental employer;
(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (I)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted

as references to student enrollees and their covered dependents; and
(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (I)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (I)(a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (I)(a) will apply to the extent that an entity described in paragraph (I)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.
(b) Objecting individuals—religious beliefs. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (I)(b), and nothing in 45 CFR 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(II)(a) Objecting entities—moral convictions.

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (II)(a)(2) of this note:
(A) A nonprofit organization; or
(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);
(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (II)(a) (2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and
(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (II)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (II)(a)(1)(iii), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (II)(a) will apply to the extent that an entity described in paragraph (II)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.
(b) Objecting individuals—moral convictions. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (II)(b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(III) Definition. For the purposes of this note, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of these Guidelines.

See Federal Register Notice: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (PDF - 488 kb).

Date Last Reviewed: October 2017

EXHIBIT I

Federal Register / Vol. 82, No. 88 / Tuesday, May 9, 2017 / Presidential Documents 21675

Presidential Documents

Executive Order 13798 of May 4, 2017

Promoting Free Speech and Religious Liberty

By the authority vested in me as President by the Constitution and the laws of the United States of America, in order to guide the executive branch in formulating and implementing policies with implications for the religious liberty of persons and organizations in America, and to further compliance with the Constitution and with applicable statutes and Presidential Directives, it is hereby ordered as follows:

Section 1. *Policy.* It shall be the policy of the executive branch to vigorously enforce Federal law's robust protections for religious freedom. The Founders envisioned a Nation in which religious voices and views were integral to a vibrant public square, and in which religious people and institutions were free to practice their faith without fear of discrimination or retaliation by the Federal Government. For that reason, the United States Constitution enshrines and protects the fundamental right to religious liberty as Americans' first freedom. Federal law protects the freedom of Americans and their organizations to exercise religion and participate fully in civic life without undue interference by the Federal Government. The executive branch will honor and enforce those protections.

Sec. 2. *Respecting Religious and Political Speech.* All executive departments and agencies (agencies) shall, to the greatest extent practicable and to the extent permitted by law, respect and protect the freedom of persons and organizations to engage in religious and political speech. In particular, the Secretary of the Treasury shall ensure, to the extent permitted by law, that the Department of the Treasury does not take any adverse action against any individual, house of worship, or other religious organization on the basis that such individual or organization speaks or has spoken about moral or political issues from a religious perspective, where speech of similar character has, consistent with law, not ordinarily been treated as participation or intervention in a political campaign on behalf of (or in opposition to) a candidate for public office by the Department of the Treasury. As used in this section, the term ''adverse action'' means the imposition of any tax or tax penalty; the delay or denial of tax-exempt status; the disallowance of tax deductions for contributions made to entities exempted from taxation under section 501(c)(3) of title 26, United States Code; or any other action that makes unavailable or denies any tax deduction, exemption, credit, or benefit.

Sec. 3. *Conscience Protections with Respect to Preventive-Care Mandate.* The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code.

Sec. 4. *Religious Liberty Guidance.* In order to guide all agencies in complying with relevant Federal law, the Attorney General shall, as appropriate, issue guidance interpreting religious liberty protections in Federal law.

Sec. 5. *Severability.* If any provision of this order, or the application of any provision to any individual or circumstance, is held to be invalid, the remainder of this order and the application of its other provisions to any other individuals or circumstances shall not be affected thereby.

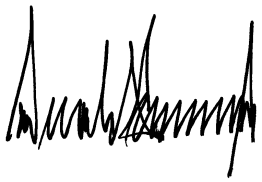
Sec. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
May 4, 2017.

[FR Doc. 2017–09574
Filed 5–8–17; 11:15 am]
Billing code 3295–F7–P

EXHIBIT J

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA : CIVIL ACTION NUMBER 17-4540

VS.

DONALD J. TRUMP, ET AL.

THURSDAY, DECEMBER 14, 2017
COURTROOM 3B
PHILADELPHIA, PA 19106

BEFORE THE HONORABLE WENDY BEETLESTONE, ESQUIRE, J.

PRELIMINARY INJUNCTION HEARING

SUZANNE R. WHITE, RPR, FCRR, CM
OFFICIAL COURT REPORTER
FIRST FLOOR U. S. COURTHOUSE
601 MARKET STREET
PHILADELPHIA, PA 19106
(215)627-1882

PROCEEDINGS RECORDED BY STENOTYPE-COMPUTER,
TRANSCRIPT PRODUCED BY COMPUTER-AIDED TRANSCRIPTION

APPEARANCES:

OFFICE OF THE ATTORNEY GENERAL
JONATHAN SCOTT GOLDMAN, ESQUIRE
NICOLE J. BOLAND, ESQUIRE
STRAWBERRY SQUARE, 16TH FLOOR
HARRISBURG, PA 17120

AND

MICHAEL J. FISCHER, ESQUIRE
NICOLE BROCK, ESQUIRE
21 S. 12TH STREET, 3RD FLOOR
PHILADELPHIA, PA. 19107

COUNSEL FOR THE COMMONWEALTH OF PENNSYLVANIA

UNITED STATES DEPARTMENT OF JUSTICE
CIVIL DIVISION
ETHAN PRICE DAVIS, ESQUIRE
950 PENNSYLVANIA AVENUE, NW
ROOM 3133
WASHINGTON, DC 20530

AND

U.S. DEPARTMENT OF JUSTICE
ELIZABETH L. KADE, ESQUIRE
JUSTIN MICHAEL SANDBERG, ESQUIRE
REBECCA M. KOPPLIN, ESQUIRE
BRIAN STIMSON, ESQUIRE
CHRISTOPHER HEALY, ESQUIRE
20 MASSACHUSETTS AVENUE, NW
WASHINGTON, DC 20530

COUNSEL FOR DONALD TRUMP, ET AL.

(THE CLERK OPENS COURT.)

THE COURT: WE ARE HERE IN THE MATTER OF COMMONWEALTH OF PENNSYLVANIA VERSUS DONALD TRUMP; DONALD WRIGHT, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVE MNUCHIN, UNITED STATES DEPARTMENT OF THE TREASURY, RENE ALEXANDER ACOSTA, UNITED STATES DEPARTMENT OF LABOR. THIS IS CASE NUMBER 17-4540.

TODAY WE HAVE A HEARING ON THE COMMONWEALTH'S MOTION FOR A PRELIMINARY INJUNCTION.

LET ME TELL -- MOSTLY FOR THE FOLKS IN THE COURTROOM, I HAVE ALREADY DETERMINED HOW THIS WILL PROCEED. WE WILL BE WORKING FROM NOW UNTIL 6. IF THE PARTIES FINISH BEFORE 6, THEN WE WILL FINISH BEFORE 6.

THE PARTIES HAVE REQUESTED OPENING STATEMENTS. I HAVE ALLOWED THEM 15 MINUTES EACH FOR OPENING STATEMENTS. THE PARTIES HAVE ALSO ASKED FOR CLOSING STATEMENTS AND I HAVE ALLOWED THEM 15 MINUTES EACH FOR CLOSING STATEMENTS.

IN THE INTERIM, IT IS MY VIEW THAT THIS IS THE PLAINTIFF'S HEARING. I AM NOT GOING TO IMPOSE ANY PARTICULAR RULES. I'M GOING TO ALLOW THEM TO DO WHAT THEY THINK THEY NEED TO DO IN ORDER TO PROCEED.

WITH THAT, PLEASE CAN WE HAVE THE INTRODUCTIONS ON THE PLAINTIFFS' SIDE, MOVING TO THE DEFENSE SIDE.

MR. GOLDMAN: YOUR HONOR, MY NAME IS JONATHAN GOLDMAN, THE EXECUTIVE DEPUTY ATTORNEY GENERAL FOR THE COMMONWEALTH OF PENNSYLVANIA IN CHARGE OF THE CIVIL LAW DIVISION.

MS. BOLAND: GOOD MORNING, YOUR HONOR. MY NAME IS NICOLE BOLAND. I'M THE DEPUTY ATTORNEY GENERAL WITH THE OFFICE OF ATTORNEY GENERAL.

MR. FISCHER: GOOD MORNING, YOUR HONOR. MY NAME IS MICHAEL FISCHER, DEPUTY ATTORNEY GENERAL WITH THE OFFICE OF ATTORNEY GENERAL.

THE COURT: AND NICOLE BROCK, IS SHE HERE?

MS. BROCK: YES, YOUR HONOR. I'M NICOLE BROCK, DEPUTY ATTORNEY GENERAL FROM THE OFFICE OF ATTORNEY GENERAL.

MR. DAVIS: GOOD MORNING, YOUR HONOR. I AM ETHAN DAVIS. I'M A DEPUTY ASSISTANT ATTORNEY GENERAL WITH THE U.S. DEPARTMENT OF JUSTICE.

MS. KADE: GOOD MORNING, YOUR HONOR. MY NAME IS ELIZABETH KADE. I'M A TRIAL ATTORNEY WITH THE DEPARTMENT OF JUSTICE.

MR. SANDBERG: GOOD MORNING, YOUR HONOR. I'M JUSTIN SANDBERG. I'M A CHIEF TRIAL COUNSEL WITH THE DEPARTMENT OF JUSTICE.

MR. HEALY: GOOD MORNING, YOUR HONOR. MY

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NAME IS CHRISTOPHER HEALY. I'M A TRIAL ATTORNEY FOR THE U.S. DEPARTMENT OF JUSTICE.

MS. KOPPLIN: GOOD MORNING, YOUR HONOR. MY NAME IS REBECCA KOPPLIN. I'M ALSO A TRIAL ATTORNEY WITH THE DEPARTMENT OF JUSTICE.

THE COURT: MR. GOLDMAN.

MR. GOLDMAN: MAY I APPROACH, YOUR HONOR?

THE COURT: YOU MAY.

MR. GOLDMAN: BEFORE I BEGIN, YOUR HONOR, IF WE CAN CLARIFY ONE THING. I BELIEVE WE HAD SPOKEN ABOUT ON THE PHONE IN CONFERENCE THAT WE WOULD EACH HAVE A HALF-HOUR FOR OPENINGS AND A HALF-HOUR FOR CLOSINGS.

THE COURT: I DID NOT RECALL IT THAT WAY, BUT IF THAT IS HOW YOU WANT TO USE YOUR TIME, THAT IS FINE. YOU SHOULD OF COURSE ASSUME THAT I HAVE READ ALL THE BRIEFS AND THAT I'M VERY FAMILIAR WITH THE ARGUMENTS THAT YOU MADE IN YOUR BRIEFS AND ALSO THE ATTACHMENTS THERETO. SO TO THE EXTENT THAT IT'S POSSIBLE THAT YOU NOT REPEAT WHAT IS IN THOSE DOCUMENTS, THAT WOULD PROBABLY BE A GOOD THING.

GO AHEAD.

MR. GOLDMAN: THANK YOU, YOUR HONOR. AS I SAID, MY NAME IS JONATHAN GOLDMAN. I'M HERE FOR THE COMMONWEALTH OF PENNSYLVANIA.

IF I MAY ASK THE COURT'S INDULGENCE,

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FOLLOWING OUR CONFERENCE ON TUESDAY EVENING AT WHICH YOUR HONOR URGED THE PARTIES NOT TO BRING LIVE WITNESSES TO REPEAT THE ALLEGATIONS ALREADY MADE UNDER OATH IN THEIR DECLARATIONS, THERE ARE OTHER FACTS THAT ARE ALREADY IN THE RECORD, WE SIGNIFICANTLY RESTRUCTURED OUR CASE. AND SEEKING TO FOLLOWING YOUR HONOR'S GUIDANCE, WE REDUCED THE NUMBER OF WITNESSES FROM SIX TO LIKELY THREE, AND WE SCALED BACK THE TESTIMONY OF THOSE WITNESSES.

THE LAWYERS BESIDE ME AT COUNSEL TABLE AND ALSO BACK THERE ARE MEMBERS OF THE TEAM. WE HAVE ALL WORKED TOGETHER, AND HAD WE HAD ALL SIX WITNESSES HERE, EVERYBODY WOULD HAVE HAD A WITNESS, A SPEAKING ROLE HERE. SOME MEMBERS OF COUNSEL MAY NOT, BUT I JUST WANTED TO ACKNOWLEDGE THEIR HARD WORK FOR THE COURT.

THIS CASE IS ABOUT TWO NEW REGULATIONS PROMULGATED BY THE DEFENDANTS, THE RELIGIOUS EXEMPTION RULE AND THE MORAL EXEMPTION RULE. THESE ARE EXEMPTIONS TO THE CONTRACEPTIVE MANDATE UNDER THE AFFORDABLE CARE ACT, WHICH IS THE LAW OF THE LAND. AND THEY ARE INCREDIBLY BROAD. THEY ARE THE EXCEPTIONS THAT SWALLOW THE RULE. THEY WERE PROMULGATED OUTSIDE THE CONSTRAINTS OF THE ADMINISTRATIVE PROCEDURE ACT AND ON TOP OF ALREADY EXISTING EXCEPTIONS, A RELIGIOUS EXCEPTION AND ACCOMMODATION, WHICH WERE MUCH NARROWER IN SCOPE. THEY

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REQUIRE MORE ACCOUNTABILITY. AND IN THE CASE OF THE ACCOMMODATION, THEY REQUIRE AN EMPLOYER'S INSURER TO STEP IN AND PROVIDE CONTRACEPTIVE CONFERENCE FOR WOMEN IF THE EMPLOYER OPTS OUT. THESE NEW RULES DO NOT DO THAT.

AS A RESULT OF THESE NEW RULES, WOMEN IN PENNSYLVANIA AND ACROSS THE COUNTRY TOO WILL LOSE THEIR INSURANCE COVERAGE FOR CONTRACEPTIVE CARE. THIS WILL COST THE COMMONWEALTH TO SUFFER ECONOMIC DAMAGES AS IT'S FORCED TO STEP INTO THE BREACH, AND -- UNDER THE CURRENT LAWS, AND COVER THE COST OF ADDITIONAL CONTRACEPTIVE CARE FOR THE ADDITIONAL WOMEN WHO WILL NEED IT. AND WHERE WOMEN ARE NOT ABLE TO GET CONTRACEPTIVE COVERAGE THROUGH THE COMMONWEALTH OR ELSEWHERE, THERE WILL BE AN INCREASE IN UNINTENDED PREGNANCIES, WHICH WILL CAUSE THE COMMONWEALTH FURTHER ECONOMIC HARM.

IN ADDITION TO THESE ECONOMIC HARMS, THE NEW RULES WILL CAUSE WOMEN IN THIS COMMONWEALTH AND BEYOND TO SUFFER ECONOMIC HARM AND MEDICAL HARM, WHICH FOR SOME WOMEN MAY BE CATASTROPHIC.

ON TOP OF THIS, THE RULES PLAINLY VIOLATE THE LAW, AS WE HAVE LAID OUT IN OUR MOTION. THE COMMONWEALTH TODAY ASKS ONLY THAT THE COURT ENFORCE THE LAW AND ISSUE A PRELIMINARY INJUNCTION TO MAINTAIN THE STATUS QUO UNTIL WE CAN HAVE A FULL TRIAL.

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THE COURT: MR. GOLDMAN, GIVEN THE ADMONITION THAT A COURT SHOULD NOT REACH CONSTITUTIONAL ISSUES WHEN IT CAN RESOLVE A MATTER ON STATUTORY CLAIMS, ARE YOU, IN THE CONTEXT OF THIS PRELIMINARY INJUNCTION, PURSUING THE CONSTITUTIONAL CLAIMS OR ARE YOU FOCUSING YOUR EFFORTS ON THE APA PROCEDURAL AND SUBSTANTIVE CLAIMS?

MR. GOLDMAN: WE ARE, AS WE DID ON OUR BRIEF, YOUR HONOR, WE'RE FOCUSING ON ALL OF THE CLAIMS. THE REASON WHY IS THIS -- AND TO BE VERY CLEAR, THE PROCEDURAL APA CLAIMS ARE VALID AND THE DEFENDANTS VIOLATED THE PROCEDURAL APA. IF YOU WERE TO ENJOIN THE RULES BASED ON THAT, PRESUMABLY IT WOULD NOT BE VERY EFFICIENT. PRESUMABLY THE DEFENDANTS WOULD GO BACK, TAKE THE SAME RULES, PUT THEM UP FOR NOTICE AND COMMENT FOR 30 DAYS, AND THEN WE WOULD BE RIGHT BACK HERE BEFORE YOUR HONOR ON THE MORE SUBSTANTIVE CLAIMS.

THE COURT: WELL, YOU HAVE TWO APA CLAIMS. ONE IS A PROCEDURAL CLAIM AND ONE IS A SUBSTANTIVE CLAIM UNDER THE APA. I THINK WHAT YOU SAID WOULD OCCUR IF I DETERMINED IT ONLY UNDER THE PROCEDURAL PRONG. BUT IF I ALSO DECIDED IT UNDER THE SUBSTANTIVE PRONG, WOULD THAT SAME ISSUE OCCUR?

MR. GOLDMAN: NO, YOUR HONOR. IF YOU DECIDED IT UNDER THE SUBSTANTIVE APA CLAIM, YOU COULD

ACTUALLY GET TO ALL OF THE CONSTITUTIONAL ISSUES THROUGH THE APA CLAIM BECAUSE IT WOULD SHOW THAT THE LAW -- THE APA WAS SUBSTANTIVELY VIOLATED BECAUSE THE RULES VIOLATE THE LAW ON THE CONSTITUTIONAL GROUNDS, NOT THE GROUNDS WE LAID OUT.

THE COURT: OKAY. GO AHEAD.

MR. GOLDMAN: SO TO YOUR POINT, YOUR HONOR, WE DO HAVE FIVE CLAIMS HERE AND WE ARE URGING YOUR HONOR TO CONSIDER ALL FIVE OF THEM: EQUAL PROTECTION, TITLE VII UNDER THE CIVIL RIGHTS ACT; AND THE PREGNANCY DISCRIMINATION ACT ESTABLISHMENT CLAUSE; AND THEN THE PROCEDURAL AND SUBSTANTIVE APA CLAIMS.

I KNOW YOU ARE WELL AWARE OF THE STANDARD FOR AN INJUNCTION. IT'S LAID OUT ON PAGE 17 OF OUR MOTION. AND WE BELIEVE, YOUR HONOR, THAT WE HAVE SOME WITNESSES TODAY TO ADD PRIMARILY ADDITIONAL TESTIMONY AND COLOR AND NUANCE. WE BELIEVE THAT YOUR HONOR IS IN GOOD STEAD TO ISSUE AN INJUNCTION ALREADY, BASED ON THE FINDINGS OF FACT AND THE FACTS THAT ARE IN OUR MOTION AND OUR PAPERS.

AND IF I MAY, I WOULD LIKE TO LIST THOSE OUT, SINCE THEY ARE ALREADY IN THE RECORD, UNLESS YOUR HONOR WOULD PREFER ME TO MOVE ON.

THE COURT: GO AHEAD.

MR. GOLDMAN: IN THE RECORD, THE FACTS

INCLUDE THE FOLLOWING. UNINTENDED PREGNANCY IS PREVALENT IN THE UNITED STATES. THAT IS IN THE WEISMAN DECLARATION AT PARAGRAPHS 22 THROUGH 23.

PREVENTING UNINTENDED PREGNANCY RESULTS IN FINANCIAL SAVINGS FOR WOMEN. THAT IS IN THE WEISMAN DECLARATION AT PARAGRAPHS 49 THROUGH 50 AND THE STEINBERG DECLARATION AT PARAGRAPH 30.

UNINTENDED PREGNANCY IS A PREVENTABLE HEALTH CONDITION FOR WOMEN, IN THE WEISMAN DECLARATION, PARAGRAPHS 19 THROUGH 20, AND THE CHUANG DECLARATION AT PARAGRAPHS 15 AND 41.

CONTRACEPTIVES ARE ALSO EFFECTIVE IN PREVENTING UNINTENDED PREGNANCY. NOT ONLY IS THAT ON TABLE 5-3 ON PAGE 106 OF THE COMMITTEE'S REPORT ITSELF, IT'S ALSO IN THE WEISMAN DECLARATION AT PARAGRAPH 30, THE CHUANG DECLARATION AT PARAGRAPHS 41 THROUGH 43, AND THE STEINBERG DECLARATION AT PARAGRAPHS 30 AND THE BUTTS DECLARATION AT PARAGRAPH 36.

WOMEN WHO FOREGO CONTRACEPTION OR USE LESS EFFECTIVE CONTRACEPTION ARE AT RISK OF UNINTENDED PREGNANCY. THAT IS ALREADY IN THE RECORD AT WEISMAN DECLARATION, PARAGRAPH 48, CHUANG DECLARATION PARAGRAPH 39, STEINBERG DECLARATION PARAGRAPH 30, AND THE BUTTS DECLARATION AT PARAGRAPH 58.

THE COURT: THERE IS NO NEED TO REFER TO

THE RECORD. I KNOW THE RECORD. JUST SAY WHAT YOU NEED TO SAY, AND I WILL BELIEVE YOU THAT IT'S IN THE RECORD.

MR. GOLDMAN: THANK YOU.

THE COURT: UNLESS OPPOSING COUNSEL SAYS IT'S NOT IN THE RECORD, AND THEN WE WILL HAVE A LITTLE FIGHT ON IT.

MR. GOLDMAN: FAIR ENOUGH.

COST IS A BARRIER TO ASSESSING CONTRACEPTION CARE. BEFORE THE ACA'S CONTRACEPTION MANDATE, PATIENTS WOULD NOT FILL THEIR CONTRACEPTIVE PRESCRIPTIONS, OPTING INSTEAD TO ASK THEIR PHYSICIANS FOR LESS EFFECTIVE BUT CHEAPER METHODS OF CONTRACEPTION AT LEAST UP FRONT, ULTIMATELY NOT CHEAPER IN THE LONG RUN. BEFORE THAT CONTRACEPTIVE MANDATE, PATIENTS WOULD NOT FILL THEIR CONTRACEPTIVE PRESCRIPTIONS, OPTING INSTEAD TO FAIL TO USE CONTRACEPTION SOMETIMES ALTOGETHER BECAUSE OF THE COST. BEFORE THE ACA CONTRACEPTIVE MANDATE, IUDS WERE ONE OF THE MOST EXPENSIVE FORMS OF CONTRACEPTIVES FOR PATIENTS IN TERMS OF THE INITIAL COST WHICH HAS TO BE PAID UP FRONT. AND YET IUDS ARE A MUCH MORE EFFECTIVE METHOD OF CONTRACEPTIVE CARE THAN ARE BIRTH CONTROL PILLS AND OBVIOUSLY THAN ARE NOTHING.

THE CONTRACEPTION MANDATE HAS RESULTED IN MORE WOMEN USING CONTRACEPTIVES GENERALLY AND MORE

EFFECTIVE METHODS OF CONTRACEPTIVES SPECIFICALLY. MORE WOMEN ARE USING IUDS, FOR EXAMPLE, THAN ORAL BIRTH CONTROL PILLS OR NO METHOD OF CONTRACEPTION AT ALL, SUCH THAT AFTER THE CONTRACEPTIVE MANDATE PATIENTS WERE FREE TO MAKE CONTRACEPTIVE CHOICES PURELY ON THE BASIS OF MEDICAL NEEDS, LISTENING TO THE RECOMMENDATIONS OF THEIR DOCTORS, WITHOUT HAVING TO WEIGH THE COST OF CARE, WHICH IS EXACTLY WHAT THE AFFORDABLE CARE ACT INTENDED. AND AS A RESULT, AFTER THE CONTRACEPTIVE MANDATE, PATIENTS HAD MADE MORE MEDICALLY INFORMED CONTRACEPTIVE CHOICES, WHICH HAVE BEEN BETTER FOR THE HEALTH OF THEM AND THEIR FAMILIES.

THE PENNSYLVANIA DEPARTMENT OF HEALTH AND HUMAN SERVICES HAS ENCOURAGED THE USE OF LARCS, LONG-ACTING CONTRACEPTION, AS POST PARTUM CONTRACEPTION TO REDUCE THE RATE OF UNINTENDED PREGNANCIES BY CHANGING ITS FEE FOR SERVICE PAYMENT POLICIES FOR HOSPITAL PROVIDERS, A POLICY OF THE COMMONWEALTH.

MORE THAN 2.5 MILLION WOMEN IN PENNSYLVANIA COULD BENEFIT FROM THE CONTRACEPTIVE CARE MANDATE AND OVER 700,000 PENNSYLVANIANS HAVE ENROLLED IN MEDICAID AS A RESULT OF THE EXPANSION UNDER THE CONTRACEPTIVE CARE MANDATE.

THE DEPARTMENT OF INSURANCE ESTIMATES THAT THE WOMEN IN PENNSYLVANIA WHO HAVE BENEFITED FROM

THE CONTRACEPTIVE CARE MANDATE HAVE SAVED OVER $250 MILLION ANNUALLY, AND THOSE ARE JUST THE DOLLARS. THAT IS NOT THE HEALTH BENEFITS.

HOWEVER, YOUR HONOR, PENNSYLVANIA HAS NO STATUTE OR REGULATION REQUIRING EMPLOYERS OFFERING PLANS REGULATED BY THE PENNSYLVANIA DEPARTMENT OF INSURANCE THAT OPT OUT OF THE CONTRACEPTIVE CARE MANDATE TO PROVIDE CONTRACEPTIVE COVERAGE TO ITS EMPLOYEES OR BENEFICIARIES. OTHER STATES MAY HAVE A LAW LIKE THAT. THIS ONE DOESN'T. AND SIMILARLY, PENNSYLVANIA HAS NO STATUTE OR REGULATION REQUIRING EMPLOYERS OFFERING PLANS REGULATED BY ERISA THAT OPT OUT TO PROVIDE CONTRACEPTIVE COVERAGE TO ITS EMPLOYEES OR BENEFICIARIES.

THEREFORE, DUE TO THE NEW RULES AND REGULATIONS, THESE EXEMPTIONS, WOMEN WILL LOSE CONTRACEPTIVE COVERAGE WHEN THEIR EMPLOYERS OPT OUT OF PROVIDING IT, OR IN SOME CASES THE EMPLOYERS OF THEIR SPOUSES THROUGH WHOM THEY HAVE COVERAGE. AS A RESULT SOME OF THESE WOMEN WILL FAIL TO USE CONTRACEPTIVES OR WILL USE LESS EFFECTIVE CONTRACEPTIVE METHODS DUE TO THE COST. WE HAVE SEEN THIS ALREADY.

MANY WOMEN WHOSE EMPLOYERS REFUSE TO PROVIDE COVERAGE FOR THEIR CONTRACEPTIVE COSTS WILL SEEK FINANCIAL ASSISTANCE THROUGH STATE GOVERNMENT PROGRAMS. THIS GETS TO THE ISSUE OF STATE HARM. THE AMOUNT OF

MONEY THE COMMONWEALTH SPENDS ON MEDICAID AND THE FAMILY PLANNING SERVICES PROGRAM IS CONTINGENT UPON ENROLLMENT SO THAT THE MORE PEOPLE HAVE TO HERE ENROLL IN THESE STATE PROGRAMS, THE MORE MONEY THE COMMONWEALTH MUST SPEND ON THEM. THE NEW RULES WILL IMPOSE ADDITIONAL ECONOMIC AND OTHER BURDENS ON FAMILY PLANNING CLINICS AROUND PENNSYLVANIA, AND THE COMMONWEALTH OF PENNSYLVANIA WILL BEAR MUCH OF THAT BURDEN. LOW INCOME WOMEN WHO ARE NOT ELIGIBLE FOR FUNDING THROUGH STATE GOVERNMENT PROGRAMS WILL BE FORCED TO CHOOSE BETWEEN PAYING OUT OF POCKET, IF THEY CAN, OR GOING WITHOUT CONTRACEPTION ALTOGETHER. WOMEN WHO STOP USING CONTRACEPTION ARE MORE LIKELY TO HAVE UNPLANNED PREGNANCIES AND TO REQUIRE ADDITIONAL MEDICAL ATTENTION. THESE THINGS ARE IN MANY WAYS TRUISMS.

BECAUSE PATIENTS WILL LOSE CONTRACEPTIVE COVERAGE UNDER THE NEW RULES, THEY WILL THEN MAKE LESS MEDICALLY SOUND CONTRACEPTIVE CHOICES AND THEREFORE THEY WILL BE HARMED.

MANY WOMEN WHO NO LONGER RECEIVE CONTRACEPTIVE COVERAGE WILL NOT ONLY FACE FINANCIAL HARM BUT WILL ALSO FACE MEDICAL HARM. AND AGAIN, SOME CASES YOU WILL HEAR AND IT'S ALREADY IN THE RECORD, THAT CAN BE CATASTROPHIC, EVEN FATAL HARM.

IN SUM, THE NEW RULES WILL HAVE A

NEGATIVE EFFECT ON THE HEALTH OF PENNSYLVANIA WOMEN. THAT IS IN ADDITION TO THE ECONOMIC HARM AND OTHER HARM TO THE COMMONWEALTH AS A WHOLE.

THE COURT: MR. GOLDMAN, I JUST NEED TO -- I NEED TO ROLL YOU BACK TO THE VERY BEGINNING, AND THAT ISSUE IS STANDING. I THINK SOME OF THE BRIEFING IS ABOUT STANDING. AND THE QUESTION IS, DOES THE COMMONWEALTH HAVE STANDING TO CHALLENGE AN AFFIRMATIVE ACTION OF AN AGENCY, AND IF SO, WHAT IS YOUR SUPPORT FOR THAT POSITION?

MR. GOLDMAN: THE COMMONWEALTH ABSOLUTELY DOES HAVE THAT STANDING. IT IS STANDING BOTH IN TERMS OF REAL ECONOMIC HARM. IT HAS SUFFERED HARM AND WILL SUFFER HARM. AND THEN ALSO UNDER THE PARENS PATRIAE DOCTRINE WHERE IT IS ABLE TO ASSERT STANDING ON BEHALF OF ITS CITIZENS IN A MORE GLOBAL SENSE.

THE COURT: WHICH CASE ARE YOU RELYING ON OR WHICH SET OF CASES?

MR. GOLDMAN: FORGIVE ME, JUDGE. THE CASES ARE IN OUR BRIEF.

THE COURT: WHO IS THE STANDING ATTORNEY WHO DID THE ANALYSIS FOR THAT? WHY DON'T YOU COME UP AND TELL ME ABOUT THAT.

MR. FISCHER: THANK YOU, YOUR HONOR.

MR. GOLDMAN: MAY I STAND HERE, YOUR

HONOR?

THE COURT: YOU MAY.

MR. FISCHER: GOOD MORNING, YOUR HONOR. MICHAEL FISCHER FOR THE COMMONWEALTH.

AS MR. GOLDMAN SAID, THE COMMONWEALTH DOES HAVE STANDING, BOTH DIRECT STANDING AS A RESULT OF THE FINANCIAL HARM, AS WELL AS PARENS PATRIAE STANDING TO ASSERT ITS INTEREST IN PROTECTING THE HEALTH AND WELFARE OF ITS RESIDENTS. AS WE DISCUSSED IN OUR BRIEF, WE THINK MASSACHUSETTS VERSUS EPA IS A TEXTBOOK EXAMPLE OF WHEN A STATE CAN ASSERT STANDING BASED BOTH ON A DIRECT INJURY AS WELL AS A PARENS PATRIAE THEORY.

THE COURT: WASN'T MASSACHUSETTS A CASE INVOLVING INACTION RATHER THAN AFFIRMATIVE ACTION?

MR. FISCHER: IT WAS AN INACTION CASE, YOU ARE RIGHT. TEXAS VERSUS UNITED STATES IS AN ACTION CASE. NOW AS THE COURT INDICATED IN THE DIRECTION WE WERE SENT, THAT CASE WAS AFFIRMED BY AN EVENLY DIVIDED SUPREME COURT. SO IT IS NOT -- THE COURT'S DECISION IS NOT BINDING ON YOUR HONOR.

HOWEVER, THE FIFTH CIRCUIT'S DECISION WE THINK IS INSTRUCTIVE. THE FIFTH CIRCUIT LOOKED AT THE GOVERNMENT'S POLICY, THE DAPA PROGRAM IN THAT CASE THAT HAD BEEN IMPLEMENTED, DECIDED IT WOULD CAUSE THE STATE OF TEXAS AND OTHER STATES DIRECT FINANCIAL HARM, FOUND

THAT THAT WAS SUFFICIENT TO ESTABLISH STATE STANDING. THAT DECISION AGAIN WAS AFFIRMED BY AN EVENLY DIVIDED COURT. SO AT LEAST FOUR JUSTICES OF THE COURT AT THE TIME WERE CONVINCED THAT THE STATE DID HAVE STANDING.

WE THINK THIS IS REALLY NO DIFFERENT FROM ANY OTHER STANDING ANALYSIS INVOLVING OTHER -- INVOLVING PRIVATE PLAINTIFFS, INVOLVING OTHER GOVERNMENT PLAINTIFFS. THE COMMONWEALTH HERE ALLEGES A DIRECT FINANCIAL HARM. THAT IS INJURY IN FACT. THAT IS TEXTBOOK INJURY IN FACT. IT IS CLEARLY TRACEABLE TO THE DEFENDANT'S ACTIONS. IT IS CLEARLY REDRESSABLE THROUGH RELIEF IN THIS COURT. SO WE BELIEVE IT'S FAIRLY CLEAR THAT WE SATISFY THE ELEMENTS OF STANDING UNDER A DIRECT THEORY.

AND IN ADDITION, UNDER PARENS PATRIAE THEORY, THERE IS SOME, I WILL ADMIT, SOMEWHAT CONFUSING CASE LAW ON PARENS PATRIAE THEORY. BUT ONE THEME THAT EMERGES, AND THIS IS ACTUALLY DISCUSSED AT LENGTH IN THE DISTRICT COURT DECISION IN TEXAS VERSUS UNITED STATES, IS THAT WHERE A STATE IS ASSERTING ITS QUASI SOVEREIGN INTEREST IN PROTECTING THE HEALTH AND WELFARE OF ITS CITIZENS, IT MAY DO SO IN CHALLENGING FEDERAL AGENCY ACTION THAT IT ALLEGES IS IN VIOLATION OF A FEDERAL STATUTE. THAT IS WHAT WE ARE ALLEGING HERE.

THERE ARE CASES GOING BACK TO I BELIEVE

MASSACHUSETTS VERSUS MELLON THAT SAY A STATE CANNOT ASSERT PARENS PATRIAE STANDING AGAINST THE FEDERAL GOVERNMENT IN CHALLENGING A FEDERAL STATUTE.

THE COURT: WELL, IS THIS -- THIS CONCEPT CALLED SPECIAL SOLICITUDE?

MR. FISCHER: YES.

THE COURT: AND I HAVE TO SAY THAT THE CONCEPT OF SPECIAL SOLICITUDE IS, SHALL WE SAY, NOT AS CRYSTAL CLEAR AS IT COULD BE IN THE JURISPRUDENCE.

MR. FISCHER: ABSOLUTELY.

THE COURT: TELL ME, HOW DOES IT APPLY, WHEN DOES IT APPLY, HOW DO I USE IT?

MR. FISCHER: IT APPLIES -- AND THE SPECIAL SOLICITUDE IS DISCUSSED IN MASSACHUSETTS VS. EPA, ALTHOUGH ACTUALLY, THE PHRASE APPEARS FIRST IN, I BELIEVE, THE D.C. CIRCUIT DECISION THAT WE CITED -- I APOLOGIZE, I FORGET THE NAME -- BUT AUTHORED BY THEN JUDGE SCALIA, WHERE HE TALKED AT LENGTH ABOUT PARENS PATRIAE STANDING AND QUASI-SOVEREIGN STANDING.

THE ESSENCE OF SPECIAL SOLICITUDE, WE BELIEVE, IS THAT A STATE HAS -- THAT THE COURT SHOULD GIVE ADDITIONAL DEFERENCE TO STATES IN ANALYZING THE EXTENT OF ANY INJURY THAT IS SUFFERED TO WHETHER OR NOT THAT INJURY CONFERS STANDING.

NOW, HERE -- FRANKLY, WE -- AS I SAID

EARLIER, I DON'T THINK IT'S NECESSARY TO EVEN RELY ON SPECIAL SOLICITUDE, BUT IN MASSACHUSETTS VERSUS EPA, THE COURT ESSENTIALLY SAID THE STATE OF MASSACHUSETTS, COMMONWEALTH OF MASSACHUSETTS, CAN ASSERT ITS INTEREST IN PROTECTING ITS CITIZENS FROM ENVIRONMENTAL HARM. THAT RESPONSIBILITY WAS ACTUALLY DELEGATED TO EPA.

EPA, UNDER THE SUPREMACY CLAUSE, COULD PROHIBIT MASSACHUSETTS FROM ACTING. SO SINCE EPA HAD THAT RESPONSIBILITY, MASSACHUSETTS, BECAUSE IT SIMILARLY HAD A DUTY TO PROTECT ITS CITIZENS, COULD CHALLENGE EPA'S INACTION IN THAT CASE UNDER THIS THEORY THAT AS A SOVEREIGN STATE, IT COULD INITIATE LITIGATION TO PROTECT THE -- IN THAT CASE, THE INTEREST OF ITS CITIZENS, A CLEAN ENVIRONMENT AND PROTECTION FROM THE HARMFUL EFFECTS OF CLIMATE CHANGE.

WE BELIEVE THAT DOES -- THAT EXPLAINS THE CONCEPT OF SPECIAL SOLICITUDE, THAT THERE IS ADDITIONAL DEFERENCE GIVEN TO A STATE WHEN IT'S ASSERTING AN INTEREST IN PROTECTING BOTH ITS OWN SOVEREIGN PREROGATIVES. THERE YOU HAD COASTLINE THAT MASSACHUSETTS ARGUED WAS BEING ERODED, AS WELL AS THE INTEREST OF ITS STATE -- INTEREST OF ITS RESIDENTS.

THE COURT: SO IS THE SPECIAL SOLICITUDE, IS IT, FOR WANT OF A BETTER TERM, A GLOSS OVER THE STANDING INQUIRY THAT I MUST UNDERTAKE OR DOES IT IMPACT

ON ANY OF THE PRONGS OF THE STANDING ANALYSIS IN PARTICULAR?

MR. FISCHER: YOUR HONOR, I BELIEVE -- I WOULD SAY THAT IT'S BOTH TO SOME EXTENT. IT IS A GLOSS, BUT I THINK IT IS PARTICULARLY DIRECTED TO THE INJURY PRONG. IT IS LESS RELEVANT TO I THINK THE CAUSATION AND REDRESSABILITY PRONGS, BUT IT DOES ALLOW THE COMMONWEALTH OR STATE TO ASSERT INJURIES THAT MAY BE IN SOME CASES, FOR A PRIVATE LITIGANT, WOULD NOT BE SUFFICIENT.

IT'S HARD TO THINK OF AN ANALOGOUS SITUATION INVOLVING A PRIVATE LITIGANT TO MASSACHUSETTS VERSUS EPA, BUT IT SEEMS LIKE THE COURT IS SAYING THAT TO THE EXTENT THERE IS ANY AMBIGUITY OR DOUBT HERE ABOUT WHETHER THIS IS A SUFFICIENT INJURY, WE ARE GOING TO RECOGNIZE THE STATE'S SOVEREIGN PREROGATIVE AND QUASI-SOVEREIGN INTEREST IN PROTECTING ITS CITIZENS AND FIND THAT THERE IS SUFFICIENT INTEREST HERE.

THE COURT: OKAY. THANK YOU, MR. FISCHER.

MR. FISCHER: THANK YOU, YOUR HONOR.

THE COURT: MR. GOLDMAN, YOU HAVE MORE TIME IF YOU WANT TO.

MR. GOLDMAN: IF I MAY ASK MR. FISCHER TO STAY HERE FOR ONE MOMENT, BECAUSE I WOULD LIKE TO TRY TO

MARRY UP A LITTLE BIT MASSACHUSETTS V EPA WITH THE CASE HERE.

THE COURT: OKAY.

MR. GOLDMAN: AND THAT IS MASSACHUSETTS VERSUS EPA, THERE WAS A LAW PROTECTING THE ENVIRONMENT WHICH ALSO PROTECTED THE CITIZENS OF MASSACHUSETTS. THE AGENCIES FAILED TO ENFORCE THAT LAW IN A WAY THAT HARMED MASSACHUSETTS. MASSACHUSETTS THEREFORE HAD STANDING.

SIMILARLY HERE, THERE IS A LAW THAT PROTECTS WOMEN AND PEOPLE AROUND THE COUNTRY; THAT'S THE AFFORDABLE CARE ACT AND THE CONTRACEPTIVE CARE MANDATE. THAT ALSO PROTECTS THE CITIZENS OF PENNSYLVANIA, MEN AND WOMEN, AND HERE, THE AGENCIES ARE NOT ENFORCING THE CONTRACEPTIVE CARE ACT. AND IN FACT, THE REGULATIONS AT ISSUE HERE HAVE UNDERMINED THE ACT, AND THAT IS -- IT'S VERY MUCH ON PAR AND IT REINFORCES THE STANDING THAT THE COMMONWEALTH HAS HERE.

THE COURT: OKAY, THANK YOU. PROCEED.

MR. GOLDMAN: SO ALL OF THAT IS ALREADY IN THE RECORD, YOUR HONOR. AND AGAIN, WE BELIEVE YOUR HONOR CAN SAFELY ISSUE AN INJUNCTION RIGHT NOW, AND IF YOU ARE INCLINED TO DO THAT, WE WOULD SIT DOWN, BUT I ASSUME WE WILL KEEP ARGUING OUR CASE.

ON TOP OF THAT, YOUR HONOR, WE ARE POISED TO BRING THREE WITNESSES TO THE COURT TODAY. THE FIRST

IS DR. CAROL WEISMAN. SHE WILL ADD -- THERE'S A DECLARATION IN THE RECORD, AS YOU WELL KNOW. SHE WILL ADD ADDITIONAL PERSPECTIVE TODAY AS ONE OF ONLY 16 MEMBERS OF THE INSTITUTE OF MEDICINES COMMITTEE ON PREVENTATIVE SERVICES FOR WOMEN THAT WAS CONVENED BY THE HEALTH RESOURCES SERVICES ADMINISTRATION, THE HRSA, IN CONNECTION WITH THE AFFORDABLE CARE ACT.

SHE WILL ALSO SPEAK ABOUT HER ROLE IN A STUDY PERFORMED SINCE THE ACA HAS GONE INTO EFFECT THAT DEMONSTRATES THAT THE CONTRACEPTIVE MANDATE HAS IN FACT RESULTED IN WOMEN MAKING BETTER, SAFER, MORE EFFECTIVE AND MORE COST-EFFECTIVE HEALTH CHOICES.

THE COURT: IN PENNSYLVANIA?

MR. GOLDMAN: YES, YOUR HONOR.

DR. SAMANTHA BUTTS WILL ALSO SPEAK TODAY, YOUR HONOR. SHE HAS, AS YOU KNOW, HAS A DECLARATION IN THIS CASE AS WELL. SHE IS GOING TO ADD ADDITIONAL PERSPECTIVE AS A MEDICAL DOCTOR, TEACHER AND RESEARCHER WHO USES A VARIETY OF CONTRACEPTIVES TO TREAT PATIENTS AS PART OF HER PRACTICE, WHICH INCLUDES INFERTILITY, HELPING WOMEN CONCEIVE.

AND YES, YOU WILL HEAR HOW SHE IS USING CONTRACEPTIVES AS PART OF HER PRACTICE AT THE UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE IN WEST PHILADELPHIA. AND SHE WILL ALSO PROVIDE TESTIMONY ABOUT HOW

HER ABILITY TO PRESCRIBE THE BEST CONTRACEPTIVE PRESCRIPTIONS FOR PATIENTS CHANGED PRE AND POST CONTRACEPTIVE CARE MANDATE AND WHAT THAT WILL MEAN THEN FOR HOW WOMEN WILL BE HARMED UNDER THE NEW RULES AS THEIR EMPLOYERS OPT OUT OF PROVIDING COVERAGE.

AND LAST, DR. CYNTHIA CHUANG WILL ALSO TESTIFY TODAY.

THE COURT: CHUANG, T-U-O-N-G?

MR. GOLDMAN: I'M SORRY, IT'S C-H-U-A-N-G.

THE COURT: OKAY.

MR. GOLDMAN: AND IT'S PRONOUNCED CHUANG. SHE WILL ADD ADDITIONAL PERSPECTIVE AS A MEDICAL DOCTOR, TEACHER AND RESEARCHER WHO TREATS PATIENTS AT THE HERSHEY MEDICAL CENTER IN HERSHEY, PENNSYLVANIA.

SHE WILL ALSO PROVIDE SOME TESTIMONY ABOUT SOME OF HER OWN RESEARCH THAT HAS DEMONSTRATED THAT SINCE THE ACA'S CONTRACEPTIVE MANDATE HAS GONE INTO EFFECT IT ALSO HAS IN FACT RESULTED IN WOMEN MAKING BETTER, SAFER, MORE EFFECTIVE AND MORE COST-EFFECTIVE HEALTH CHOICES.

WE WILL DO OUR BEST AS WE RAISE THEM TO NOT BE DUPLICATIVE OF WHAT IS IN THE RECORD, AND YOU HAVE MADE VERY CLEAR, YOUR HONOR, YOUR COUNSEL TO DO THAT. WE HAVE RESTRUCTURED OUR WITNESS OUTLINES. WE DO

HAVE SOME LAYING OF FOUNDATION. IF AT ANY POINT YOU FEEL LIKE YOU HAVE ALREADY HEARD THAT, BY ALL MEANS, SHEPHERD US ALONG, AND WE WILL DO OUR BEST TO DO THAT TO OURSELVES SO YOU DON'T HAVE TO.

THE COURT: I'M ASSUMING THAT THE DEFENDANTS WILL NOT PUT YOU THROUGH THE PROCESS OF SETTING FORTH A DEEP FOUNDATION FOR EVERYTHING THAT IS TO BE ELICITED.

MS. KADE: YOUR HONOR, WE HAVE STIPULATED TO THE ADMISSIBILITY OF EVERYTHING EXCEPT FOR THE DEMONSTRATIVE EXHIBITS.

THE COURT: THANK YOU. OKAY.

MR. GOLDMAN: IN CONCLUSION, YOUR HONOR, WE BELIEVE THAT YOU CAN ISSUE THIS INJUNCTION NOW. WE HOPE THAT YOU WILL DO SO AS SOON AS YOUR HONOR IS READY, AND WILL DO SO CONSIDERING ALL OF THE DIFFERENT CLAIMS TO KEEP THE STATUS QUO IN PLACE AND PROTECT THE CITIZENS OF THE COMMONWEALTH.

THE COURT: SO I UNDERSTAND THERE IS A DATE BY WHICH PENNSYLVANIA THINKS IT WOULD BE USEFUL FOR ME TO HAVE DECIDED THIS MATTER.

MR. GOLDMAN: THERE IS, YOUR HONOR. I WOULD SAY BEYOND USEFUL, I WOULD SAY EVEN NECESSARY. THAT DATE IS JANUARY 1ST, 2018. THE REASON WHY THAT DATE IS IMPORTANT IS BECAUSE MANY ERISA HEALTHCARE PLANS

HAVE AN OPEN ENROLLMENT WHERE THE NEW PLANS START ON THE FIRST OF THE YEAR. NOT ALL OF THEM, BUT MANY. SO THAT WILL BE A -- WE BELIEVE A LARGE WINDOW WHERE POLICIES WILL CHANGE, EMPLOYERS WILL START TAKING ADVANTAGE OF THESE NEW RULES.

THE COURT: OKAY. SO YOU ARE SAYING THAT BECAUSE THE EXEMPTIONS WERE PUT IN PLACE EFFECTIVE IMMEDIATELY THAT WHILE THERE MAY BE NO CHANGE IN PLANS RIGHT NOW, AS OF JANUARY THE 1ST, BECAUSE THERE IS THIS OPEN ENROLLMENT PERIOD, IT IS LIKELY THAT THE PLANS WILL CHANGE AT THAT POINT?

MR. GOLDMAN: CORRECT, YOUR HONOR. AND BY THE WAY, IT IS CERTAINLY POSSIBLE THAT PLANS HAVE ALREADY CHANGED IF APPROPRIATE NOTICE HAS BEEN GIVEN. WE JUST DON'T KNOW THAT YET. WE HAVE NOT SEEN THAT YET.

THE COURT: OKAY. THANK YOU VERY MUCH.

MR. GOLDMAN: THANK YOU, YOUR HONOR.

THE COURT: DEFENSE.

MR. DAVIS: MAY I APPROACH, YOUR HONOR?

THE COURT: YOU MAY.

MR. DAVIS: GOOD MORNING, YOUR HONOR. ETHAN DAVIS FOR THE UNITED STATES.

IF THERE IS ONE THEME WE WOULD ASK YOUR HONOR TO KEEP IN MIND TODAY AS WE HEAR FROM THE WITNESSES, IT IS THAT THIS COURT IS NOT WRITING ON A

BLANK SLATE. OVER THE PAST SIX YEARS, DOZENS OF ENTITIES WITH RELIGIOUS AND MORAL OBJECTIONS HAVE SUED OVER THE CONTRACEPTIVE COVERAGE REQUIREMENT.

THOSE LAWSUITS PRODUCED A PATCHWORK OF PRELIMINARY AND PERMANENT INJUNCTIONS THROUGHOUT THE UNITED STATES, MANY OF WHICH ARE STILL IN EFFECT TODAY. THE SUPREME COURT ALSO WEIGHED IN ON THESE ISSUES FOUR TIMES, FIRST IN HOBBY LOBBY, THEN IN LITTLE SISTERS, THEN IN WHEATON COLLEGE, AND FINALLY IN ZUBIK.

AND THE FEDERAL GOVERNMENT HAS CHANGED THE RULES GOVERNING CONTRACEPTIVE COVERAGE MULTIPLE TIMES SINCE 2011. THERE IS A LOT OF WATER UNDER THE BRIDGE AND THIS POINT MATTERS TO VIRTUALLY ALL OF THE ISSUES IN THIS CASE.

FIRST ON STANDING. THE COMMONWEALTH'S PAPERS GIVE THE IMPRESSION THAT THE NEW RULES ARE GOING TO WITHDRAW CONTRACEPTIVE COVERAGE FROM MILLIONS OF WOMEN WHO ARE CURRENTLY RECEIVING COVERAGE AND THAT THEY ARE THE EXCEPTION THAT WILL SWALLOW THE RULE, BUT IT SHOULD NOT ESCAPE YOUR NOTICE, YOUR HONOR, THAT NONE OF THOSE MILLIONS OF WOMEN WHO WILL SUPPOSEDLY BE AFFECTED BY THESE RULES IS A PLAINTIFF IN THIS CASE, NOR DID ANY OF THEM SUBMIT A DECLARATION EXPLAINING THAT AN EMPLOYER IS ABOUT TO DROP CONTRACEPTIVE COVERAGE.

AND WHY DON'T WE SEE ANY INDIVIDUALS IN

THIS CASE, YOUR HONOR? IT'S BECAUSE YOUR HONOR IS NOT WRITING ON A BLANK SLATE. MANY AND MAYBE ALL OF THE RELIGIOUS EMPLOYERS WHO OBJECT TO PROVIDING CONTRACEPTIVE COVERAGE HAVE ALREADY SUED. MANY ARE ALREADY PROTECTED BY INJUNCTIONS. SO EMPLOYEES WHO WORK FOR THOSE RELIGIOUS ORGANIZATIONS HAVE NOT BEEN RECEIVING CONTRACEPTIVE COVERAGE FOR YEARS.

TAKE THE LITTLE SISTERS AS AN EXAMPLE. AS YOUR HONOR RECOGNIZED IN DENYING THE LITTLE SISTERS MOTION TO INTERVENE, GRANTING AN INJUNCTION IN THIS CASE WOULD NOT CHANGE THE FACT THAT THE LITTLE SISTERS ARE NOT CURRENTLY PROVIDING CONTRACEPTIVE COVERAGE TO THEIR EMPLOYEES.

THE COURT: WELL, I AGREE WITH YOU WITH RESPECT TO THE RELIGIOUS EXEMPTION. QUITE CLEARLY THERE HAS BEEN A LOT OF LITIGATION ABOUT THIS, BUT THE MORAL EXEMPTION IS SOMETHING NEW, ISN'T IT?

MR. DAVIS: THE MORAL EXEMPTION IS NEW, YOUR HONOR, BUT THERE'S ALSO BEEN LITIGATION OVER THAT. THERE WAS A CASE HERE IN PENNSYLVANIA, THE REAL ALTERNATIVES CASE, AND THERE WAS ALSO A CASE IN D.C. CALLED MARCH FOR LIFE. SO I DON'T THINK THE LITIGATION OVER THAT IS NEW.

THE COURT: WELL, BUT IN THE CONTEXT OF THE AFFORDABLE CARE ACT, IT IS NEW, BECAUSE THE MORAL

EXEMPTION WAS ONLY ISSUED A FEW WEEKS AGO. SO THERE HAS BEEN NO LITIGATION IN THE CONTEXT OF THE MORAL EXEMPTION OR A MORAL EXEMPTION AS IT APPLIES TO THE ACA, CORRECT?

MR. DAVIS: I AGREE WITH THAT, YOUR HONOR. THERE HAS BEEN DISCUSSIONS OF CONSCIENCE ISSUES DURING THE RULEMAKINGS, BUT THERE HAS NOT BEEN LITIGATION OVER THIS MORAL EXEMPTION RULE, THIS ONE THAT WAS JUST PASSED IN 2017, UNTIL NOW.

THE COURT: SO I'M A LITTLE PUZZLED BY WHAT THE MORAL EXEMPTION MEANS. HOW DOES ONE DETERMINE -- WELL, A COUPLE OF QUESTIONS. HOW DOES AN ENTITY DETERMINE THAT IT HAS A MORAL CONVICTION? HOW IS THAT CONVICTION INSTANTIATED THROUGHOUT THE ENTIRE ORGANIZATION? WHO MAKES -- IN OTHER WORDS, WHO MAKES THE DETERMINATION? AND HOW DOES ONE DECIDE WHAT IS MORAL AND WHAT IS NOT MORAL?

I UNDERSTAND IN THE CONTEXT OF RELIGION THAT THERE ARE QUITE CLEAR MORAL PRECEPTS, BUT WE ARE A COUNTRY WHERE, RIGHTLY OR WRONGLY, WHETHER YOU AGREE WITH IT OR NOT, PEOPLE HAVE VERY DIFFERENT VIEWS ABOUT WHAT MORALITY IS. SO HELP ME UNDERSTAND THE MORALITY EXEMPTION IN THE CONTEXT OF THOSE QUESTIONS.

MR. DAVIS: SURE. YOUR HONOR, THE FIRST THING I SAY ABOUT THAT IS THAT THE MORAL EXEMPTION RULE DOES NOT APPLY TO PUBLICLY TRADED COMPANIES, UNLIKE THE

RELIGIOUS EXEMPTION RULE, SO WE ARE TALKING ONLY ABOUT CLOSELY-HELD ENTITIES. SO IN TERMS OF DECIDING WHO CAN ASSERT THE MORAL CLAIM, I THINK IT WOULD JUST BE THE OWNERS OF A CLOSELY-HELD ORGANIZATION OR A NONPROFIT.

THE COURT: ARE YOU POSITIVE OF THAT?

MR. DAVIS: YES, YOUR HONOR.

THE COURT: OKAY.

MR. DAVIS: THAT'S NOT TRUE FOR RELIGIOUS.

THE COURT: I'LL HAVE TO REREAD THE MORAL EXEMPTION, BECAUSE I THOUGHT IT SAID SOMETHING CONTRARY TO THAT.

MR. DAVIS: IT DOES NOT, YOUR HONOR.

THE COURT: I WILL TAKE A LOOK AT IT.

MR. DAVIS: SO THE ONLY QUESTION IS WHO CAN ASSERT IT. I THINK THAT WOULD BE JUST THE SAME PEOPLE WHO CAN ASSERT THE CLAIM IN A CONTEXT OF THE RELIGIOUS EXEMPTION, WHICH WOULD BE THE OWNERS OF THE CLOSELY HELD COMPANY OF WHOEVER RUNS A NONPROFIT. SO THAT'S THAT QUESTION.

AS TO YOUR OTHER QUESTION ABOUT WHAT DOES IT LOOK LIKE TO ASSERT THIS KIND OF CLAIM, I THINK IT LOOKS VERY SIMILAR TO WHAT HAPPENS WITH A RELIGIOUS EXEMPTION. I MEAN, THE EMPLOYER WILL JUST ASSERT A SINCERELY-HELD MORAL CONVICTION, AND THEN THAT EMPLOYER

IS EXEMPT.

I WILL SAY I DOUBT THAT THIS WILL BE WIDELY USED, BECAUSE AS THE RULES POINT OUT, PROVIDING CONTRACEPTIVE COVERAGE IS COST NEUTRAL. SO THERE REALLY WOULDN'T BE A REASON TO ASSERT THIS UNLESS AN EMPLOYER ACTUALLY DID HAVE A SINCERE --

THE COURT: WELL, WHAT IF A -- WHAT IF THE CEO OF THE COMPANY HAD A SINCERELY-HELD MORAL CONVICTION THAT WOMEN SHOULD REMAIN AT HOME AND THAT -- AND MADE A DETERMINATION, THEREFORE, NOT TO PROVIDE CONTRACEPTIVE SERVICES IN THE INSURANCE PLAN OF THE COMPANY IN ORDER TO IMPOSE HIS NORMATIVE CONSTRUCT ON HIS WORKFORCE, BUT THE BOARD OF DIRECTORS DOES NOT AGREE WITH THAT. IN FACT, THEY BELIEVE THAT THERE IS A MORAL IMPERATIVE THAT WOMEN BE ALLOWED TO MAKE THEIR OWN CHOICES. HOW DO YOU DETERMINE, ONE, WHAT IS AN APPROPRIATE MORAL CONVICTION, AND TWO, WHO PREVAILS IN THAT CONTEXT?

MR. DAVIS: WELL, A COUPLE OF ANSWERS TO THAT, YOUR HONOR. THE FIRST IS THAT I THINK GENERAL PRINCIPLES OF CORPORATE LAW WOULD ANSWER THE QUESTION ABOUT WHO IS ENTITLED TO ADVANCE THAT KIND OF OBJECTION ON BEHALF OF THE COMPANY. BUT IF YOUR HONOR'S HYPOTHETICAL POSES A SITUATION WHERE THE EMPLOYER ACTUALLY DOES NOT HAVE A SINCERE OBJECTION, IT'S REALLY

A PRETEXT FOR COVERING --

THE COURT: NO, I'M NOT SUGGESTING IT'S A PRETEXT. THE CEO REALLY DOES BELIEVE, AS A MORAL MATTER, THAT WOMEN SHOULD STAY AT HOME.

MR. DAVIS: BUT THE CEO DOES NOT HAVE A MORAL OBJECTION TO PROVIDING CONTRACEPTIVE COVERAGE. THE REAL OBJECTION IS TO -- THE REAL --

THE COURT: HE HAS A MORAL OBJECTION TO PROVIDING COVERAGE BECAUSE HE THINKS THAT WOMEN SHOULD STAY AT HOME AND HE BELIEVES THAT WOMEN SHOULD STAY AT HOME -- IF THEY ARE PREGNANT ALL THE TIME, THEY ARE GOING TO STAY AT HOME.

MR. DAVIS: YOUR HONOR, AGAIN, I THINK --

THE COURT: DON'T BUCK THE HYPOTHETICAL. JUST ANSWER THE QUESTION.

MR. DAVIS: UNDER THAT HYPOTHETICAL, YOUR HONOR, I ASSUME THAT EMPLOYEES WOULD COMPLAIN ABOUT IT TO IRS OR TREASURY OR LABOR, AND THE LABOR DEPARTMENT DOES HAVE A ROLE IN POLICING THE SINCERITY OF RELIGIOUS -- OR NOT -- NOT THE SINCERITY.

THE COURT: SO THE DEPARTMENT OF LABOR WOULD BE POLICING THE MORAL CONVICTIONS OF AN ENTITY?

MR. DAVIS: NO. THE DEPARTMENT OF LABOR COULD CONCEIVABLY, IN THAT CIRCUMSTANCE, ASK WHETHER A PARTICULAR -- POLICE THAT KIND OF SITUATION TO A DEGREE.

IT PROBABLY WOULDN'T --

THE COURT: SO WHO WOULD BE POLICING WHETHER A MORAL CONVICTION IS APPROPRIATELY HELD?

MR. DAVIS: I THINK, AGAIN, IT WOULD DEPEND ON THE CIRCUMSTANCES. IF AN EMPLOYEE WERE TO SAY TO THE GOVERNMENT THAT THERE IS NOT IN FACT A SINCERE MORAL OBJECTION TO PROVIDING CONTRACEPTIVE COVERAGE, THAT IN FACT, WHAT IS GOING ON HERE IS IT'S DISCRIMINATION AGAINST WOMEN, AND THAT IS -- THEN I THINK THAT THE LABOR DEPARTMENT COULD INVESTIGATE THAT.

THE COURT: SO THE LABOR DEPARTMENT WOULD HAVE TO BE DETERMINING WHAT A MORAL CONVICTION -- WHETHER A MORAL CONVICTION IS APPROPRIATE OR NOT?

MR. DAVIS: I WOULD NOT PUT IT THAT BROADLY, YOUR HONOR. I WOULD SAY IF THERE IS A -- AS LONG AS THERE IS A SINCERE MORAL OBJECTION TO PROVIDE CONTRACEPTIVE COVERAGE, THEN THAT EMPLOYER IS EXEMPT, PERIOD. AND ONLY IF THAT --

THE COURT: WELL, YOU ARE STILL BUCKING THE HYPOTHETICAL. IF THERE IS A MORAL CONVICTION RULE OUT THERE, SOMEONE IS GOING TO HAVE TO DETERMINE WHETHER IT IS AN APPROPRIATE MORAL CONVICTION OR NOT, CORRECT?

MR. DAVIS: NO, I DON'T AGREE WITH THAT, YOUR HONOR.

THE COURT: SO IS IT JUST SORT OF A

FREE-FLOATING CONCEPT THAT EVERYBODY DECIDES THEMSELVES AND NOBODY POLICES IT?

MR. DAVIS: YOUR HONOR, I WOULDN'T CALL IT A FREE-FLOATING CONCEPT THAT IS TOTALLY UNPOLICED. I WOULD SAY THAT, LIKE THE RELIGIOUS EXEMPTION, THE ONLY QUESTION THAT IS ASKED IS WHETHER AN EMPLOYER HAS A SINCERE RELIGIOUS OR MORAL OBJECTION TO PROVIDING CONTRACEPTIVE COVERAGE, AND IF THAT IS TRUE, THEN THAT EMPLOYER IS EXEMPT.

THE COURT: OKAY. SO WHAT YOU'RE TELLING ME IS IF THE CEO SAYS I HAVE A SINCERE MORAL CONVICTION TO NOT PROVIDE CONTRACEPTIVES TO WOMEN BECAUSE I WANT THEM TO STAY AT HOME, THAT IS FINE?

MR. DAVIS: I WOULD NOT SAY THAT IS FINE, YOUR HONOR. I WOULD SAY THAT IN THAT CIRCUMSTANCE, AGAIN, AN EMPLOYEE MIGHT COMPLAIN TO THE LABOR DEPARTMENT AND THERE IS SOME ROLE FOR THE LABOR DEPARTMENT --

THE COURT: THE LABOR DEPARTMENT, OKAY.

MR. DAVIS: WE CAN FOLLOW UP ON THAT.

THE COURT: MOVE ON.

MR. DAVIS: I WOULD SAY, RETURNING TO STANDING, YOUR HONOR, BECAUSE THE LITTLE SISTERS ARE PROTECTED BY THE ZUBIK INJUNCTION WHICH PROHIBITS THE FEDERAL GOVERNMENT FROM ENFORCING THE MANDATE AGAINST

THEM. THE SAME IS TRUE OF MANY OTHER RELIGIOUS ORGANIZATIONS. AND THAT IS WHY THE ONLY SPECIFIC EXAMPLE OF AN EMPLOYER WHO'S GOING TO DROP COVERAGE THAT PENNSYLVANIA WAS ABLE TO GIVE WAS THE UNIVERSITY OF NOTRE DAME, BUT AS THE COURT KNOWS, NOTRE DAME LATER ANNOUNCED THAT ITS THIRD-PARTY ADMINISTRATOR WOULD CONTINUE TO OFFER NO COST CONTRACEPTIVE COVERAGE.

I'M NOT SAYING THAT IT'S IMPOSSIBLE THAT ANYONE WOULD EVER HAVE STANDING TO CHALLENGE THESE RULES, YOUR HONOR. WHAT I'M SAYING IS THAT IT'S PENNSYLVANIA'S BURDEN TO SHOW YOUR HONOR SOMEONE WHO IS GOING TO LOSE COVERAGE, AND THEY HAVEN'T BEEN ABLE TO DO THAT, EVEN AFTER CLAIMING THAT MILLIONS OF WOMEN COULD BE AFFECTED BY THIS.

I SUSPECT YOU WILL HEAR TODAY FROM THE COMMONWEALTH'S WITNESS ABOUT THEIR CONCERNS ABOUT THE IMPACT THAT THE NEW RULES WILL HAVE ON WOMEN'S ACCESS TO CONTRACEPTION. WE HAVE NOT DEPOSED THESE WITNESSES. WE DON'T KNOW WHAT THEY ARE GOING TO SAY, BUT I URGE YOUR HONOR TO LISTEN TO WHETHER ANY OF THEM CAN POINT TO A SINGLE PENNSYLVANIA EMPLOYER OR ANY EMPLOYER OR A SINGLE EMPLOYEE WHO IS GOING TO LOSE COVERAGE AS OF JANUARY 1ST.

I WOULD ALSO LIKE TO TALK A LITTLE ABOUT THE PARENS PATRIAE THEORY THAT CAME UP EARLIER. YOUR

HONOR, IT HAS BEEN WELL SETTLED SINCE MASSACHUSETTS VERSUS MELLON, 1923, THAT A STATE CANNOT REPRESENT ITS CITIZENS PARENS PATRIAE AGAINST THE FEDERAL GOVERNMENT. AS MELLON EXPLAINED IT, IT HAS NO POWER -- IT IS NO PART OF ITS DUTY OR POWER TO ENFORCE THEIR RIGHTS IN RESPECT OF THEIR RELATIONS WITH THE FEDERAL GOVERNMENT. AND THAT FIELD IS THE UNITED STATES AND NOT THE STATE WHICH REPRESENTS THEM AS PARENS PATRIAE. THERE IS NO EXCEPTION TO THAT RULE IN MELLON FOR CASES WHERE THE STATE IS CHALLENGING A FEDERAL AGENCY ACTION INSTEAD OF A STATUTE.

AND MASSACHUSETTS VERSUS EPA, YOUR HONOR, THE SPECIAL SOLICITUDE DISCUSSION THAT WE HAD EARLIER, I THINK THE BEST WAY TO UNDERSTAND THE SPECIAL SOLICITUDE POINT IS THAT IT APPLIES WHEN THE STATE IS ABLE TO SHOW AN INJURY TO ITS CONCRETE SOVEREIGN INTEREST. AND IN MASSACHUSETTS VERSUS EPA, THAT WAS AN INJURY TO THE TERRITORY OF THE STATE ITSELF. AND THAT IS WHAT THIS CASE SAYS. I HAVE IT HERE. IT SAYS: GIVEN MASSACHUSETTS STATE IN PROTECTING ITS QUASI SOVEREIGN INTEREST, THE COMMONWEALTH IS ENTITLED TO SPECIAL SOLICITUDE IN ITS STANDING ANALYSIS. I DON'T THINK WE HAVE ANYTHING LIKE THAT HERE. WE DON'T HAVE ANY DAMAGE TO THE STATE'S TERRITORY. ALL WE HAVE IS SPECULATION THAT SOME EMPLOYERS WILL ULTIMATELY SHIFT FROM CURRENTLY

PROVIDING COVERAGE TO NOT PROVIDING COVERAGE.

THE COURT: LET ME TALK TO YOU ABOUT THE TEXAS VERSUS UNITED STATES CASE IN THE CONTEXT OF STANDING. SO IN THAT CASE THE SUPREME COURT CERTIFIED A NUMBER OF ISSUES, INCLUDING WHETHER OR NOT TEXAS HAD STANDING. AND THEN IT AFFIRMED BY AN EQUALLY DIVIDED COURT WITHOUT OPINION.

NOW ONE OF THE QUESTIONS THAT I ASKED YOU TO LOOK AT IS, GIVEN SILLIMAN VERSUS HUDSON RIVER BRIDGE COMPANY, WHICH I KNOW IS AN OLD CASE, 1861. DON'T TELL ME IT'S OLD SO THEREFORE IT DOES NOT APPLY. WHAT IS THE IMPACT IN YOUR VIEW OF SILLIMAN ON TEXAS VERSUS THE UNITED STATES, PARTICULARLY THE STANDING ANALYSIS THAT THE COURT IN TEXAS VERSUS UNITED STATES IN THE 5TH CIRCUIT DID.

MR. DAVIS: YOUR HONOR, I THINK THAT SINCE HUDSON BRIDGE, THE COURT HAS SAID REPEATEDLY THAT AN AFFIRMANCE BY AN EQUALLY DIVIDED COURT IS NOT ENTITLED TO PRECEDENTIAL WEIGHT.

THE COURT: WELL, EXCEPT SILLIMAN TALKED ABOUT THE JURISDICTIONAL CONTEXT, WHICH IS WHY IT IS DIFFERENT.

MR. DAVIS: I DON'T SEE ANY CASE SINCE SILLIMAN THAT SAYS THAT THE JURISDICTIONAL CONTEXT WOULD BE DIFFERENT, THAT SOMEHOW BECAUSE IT'S A JURISDICTIONAL

DECISION THAT THE COURT'S AFFIRMANCE WOULD BE ENTITLED TO --

THE COURT: NO. I THINK THE POINT IS THAT SILLIMAN WAS A JURISDICTIONAL DECISION. AND AS FAR AS WE CAN FIND, THE ONLY ISSUE WHEN THERE WAS AN EQUALLY DIVIDED COURT THAT CONCERNED A JURISDICTIONAL ANALYSIS. SO EVEN THOUGH SUBSEQUENT CASES HAVE SAID GENERALLY EQUALLY DIVIDED COURTS ARE NOT BINDING PRECEDENT, SILLIMAN SUGGESTS THAT THERE IS THIS CARVEOUT IN THE CONTEXT OF STANDING.

AND SO MY QUESTION TO YOU IS, DO I JUST IGNORE SILLIMAN OR DO I SAY THAT IT IS TOO OLD OR DO I SAY THAT SOMEHOW IT HAS BEEN MOOTED AT THIS POINT?

MR. DAVIS: YOUR HONOR, I WOULD SAY YOU SHOULD READ SILLIMAN IN LIGHT OF THE CASES THAT CAME LATER. AND THE CASES THAT CAME LATER SAID FLATLY, WITHOUT CARVING OUT JURISDICTION OR ANYTHING ELSE, THOSE CASES SAID AN AFFIRMANCE BY AN EQUALLY DIVIDED COURT IS NOT ENTITLED TO PRECEDENTIAL EFFECT. I'M NOT AWARE -- I HAVE NOT EXHAUSTIVELY LOOKED AT EVERY CASE SINCE 1861, BUT I'M NOT AWARE OF ANY CASE SINCE THEN THAT HAS HELD THAT A JURISDICTIONAL DECISION -- THAT AFFIRMANCE BY AN EQUALLY DIVIDED COURT OF A JURISDICTIONAL DECISION IS ENTITLED TO PRECEDENTIAL FORCE, OF THE SUPREME COURT.

THE CASES I WOULD CITE TO YOUR HONOR,

NEIL VERSUS BIGGERS, THAT'S N-E-I-L VERSUS B-I-G-G-E-R-S, 409 U.S. 188 AT 192. THAT IS A 1972 SUPREME COURT DECISION.

AND ARKANSAS WRITERS' PROJECT VERSUS RAGLAND, 481 U.S. 221. THAT'S A 1987 SUPREME COURT DECISION THAT HELD: OF COURSE, AN AFFIRMANCE BY AN EQUALLY DIVIDED COURT IS NOT ENTITLED TO ANY PRECEDENTIAL WEIGHT.

THE COURT: I WILL TAKE A LOOK AT THOSE CASES.

MOVE ON.

MR. DAVIS: I WOULD LIKE TO TALK A LITTLE ABOUT THE PROCEDURAL APA ISSUE, YOUR HONOR.

HERE AGAIN, YOUR HONOR IS NOT WRITING ON A BLANK SLATE. LIKE THE LAST ADMINISTRATION DID THREE TIMES IN 2010, 2011 AND 2014, THE AGENCIES ISSUED THE NEW RULES AS INTERIM FINAL RULES. LIKE THOSE PRIOR IFRS, THREE SEPARATE LAWS PROVIDE STATUTORY AUTHORITY: 26 U.S.C. 9833; 29 U.S.C. --

THE COURT: ARE YOU TALKING ABOUT -- YOU'RE CONNECTING WITH THE ORIGINAL RELIGIOUS EXEMPTION, THE SECOND RELIGIOUS EXEMPTION? IS THAT WHAT WE ARE TALKING ABOUT HERE?

MR. DAVIS: NO, YOUR HONOR. WE ARE TALKING ABOUT JUST THE BASIS OF STATUTORY AUTHORITY TO

DO THIS AS AN IFR INSTEAD OF THROUGH NOTICE AND COMMENT. I THINK EVEN APART FROM THE APA, THERE ARE THREE SEPARATE STATUTES THAT GIVE THE AGENCIES INDEPENDENT AUTHORITY TO DO THIS.

THE COURT: OKAY.

MR. DAVIS: AND THOSE STATUTES SAY THAT THE SECRETARY MAY PROMULGATE ANY INTERIM FINAL RULES AS THE SECRETARY DETERMINES ARE APPROPRIATE. THAT IS THE SAME AUTHORITY THAT THE PRIOR ADMINISTRATION RELIED ON TO DO THESE AS INTERIM FINAL RULES, AND WE ARE RELYING ON IT AS WELL.

IF YOUR HONOR DID NOT THINK THAT WAS SUFFICIENT, THERE WAS ALSO GOOD CAUSE DIRECTLY UNDER THE APA, AND THE D.C. CIRCUIT EXPRESSLY UPHELD ONE OF THE LAST ADMINISTRATION'S CONTRACEPTIVE COVERAGE IFRS IN THE PRIESTS FOR LIFE DECISION. AND THERE, LIKE HERE, THE AGENCY MADE A GOOD CAUSE FINDING IN THE RULE THAT IT ISSUED. THERE, LIKE HERE, THE IFR WAS MODIFYING REGULATIONS THAT HAD RECENTLY BEEN ENACTED UNDER NOTICE AND COMMENT RULE MAKING. THERE, LIKE HERE, THE ISSUES THE IFR HAD ADDRESSED HAD ALREADY BEEN SUBJECTED TO THOUSANDS AND THOUSANDS OF COMMENTS. THERE, LIKE HERE, HHS EXPOSED ITS INTERIM FINAL RULE TO COMMENTS BEFORE PERMANENT IMPLEMENTATION. AND THERE, LIKE HERE, THE GOVERNMENT WAS -- THERE THE GOVERNMENT WAS RESPONDING TO

THE SUPREME COURT'S DECISION IN WHEATON COLLEGE. HERE THE GOVERNMENT WAS RESPONDING TO THE SUPREME COURT'S DECISION IN ZUBIK. THERE DELAY AND IMPLEMENTATION OF THE RULE WOULD DELAY THE IMPLEMENTATION OF THE ALTERNATIVE OPT-OUT FOR RELIGIOUS OBJECTORS. AND HERE DELAY WOULD INTERFERE WITH THE IMPLEMENTATION OF THE RELIGIOUS AND MORAL EXEMPTIONS. SO I THINK IF THERE WAS GOOD CAUSE IN PRIESTS FOR LIFE, I THINK THERE IS GOOD CAUSE HERE.

THE COURT: WELL, IN PRIESTS FOR LIFE, THE NEW IFRS WERE PRETTY MUCH IDENTICAL TO PRIOR REGULATIONS, WEREN'T THEY?

MR. DAVIS: I DON'T THINK THEY WERE VIRTUALLY IDENTICAL, YOUR HONOR. THE IFR EXPANDED THE WAY THE ACCOMMODATION COULD BE INVOKED.

THE COURT: WELL, BUT THEY DIDN'T MAKE SIGNIFICANT CHANGES IN THE LAW, DID THEY?

MR. DAVIS: WELL, I DON'T KNOW IF I WOULD EVEN DESCRIBE THIS AS A MORE SIGNIFICANT CHANGE THAN THE ONE AT ISSUE, PRIESTS FOR LIFE, YOUR HONOR.

THE COURT: SO YOU WOULD SAY THAT THE RELIGIOUS EXEMPTION AND THE MORAL EXEMPTIONS ARE NOT SIGNIFICANT CHANGES.

MR. DAVIS: I WOULD NOT SAY IT THAT WAY, YOUR HONOR. I WOULD SAY THEY ARE ARGUABLY NOT MORE

SIGNIFICANT THAN THE CHANGE AT ISSUE IN THE IFR THAT WAS RESPONDING TO WHEATON COLLEGE. THAT IS BECAUSE, LIKE I HAVE DISCUSSED, THERE IS NO INDICATION HERE THAT ANYONE IS GOING TO LOSE CONTRACEPTIVE COVERAGE AS A RESULT OF THESE NEW RULES. BACK THEN IT WAS A -- THERE WAS A RELATIVELY SIGNIFICANT CHANGE TO THE RULES TO EXPAND THE WAY THAT THE ENTITIES COULD INVOKE THE ACCOMMODATION.

BUT I WOULD SAY EVEN IF YOUR HONOR DOES NOT SEE IT THAT WAY AND THINKS THAT THIS CHANGE IS MORE SIGNIFICANT THAN THE ONE BACK IN 2014, THAT IS ONLY ONE OF THE FACTORS IN THE PRIESTS FOR LIFE DECISION.

THE COURT: WELL, THE OTHER ONE WAS GOOD CAUSE. BUT IN PRIESTS FOR LIFE I THINK THE COURT MADE A DETERMINATION THAT THERE WAS GOOD CAUSE AND THUS SAID -- PUTTING ASIDE WHETHER THERE WAS -- THEY WERE IDENTICAL OR WHETHER THERE WAS A SIGNIFICANT CHANGE, THEN SAID IT WAS APPROPRIATE. BUT IN THIS CASE I HAVE TO -- ARE YOU -- DO YOU AGREE THAT I HAVE TO MAKE A THRESHOLD DETERMINATION OF GOOD CAUSE BEFORE I CAN GET INTO THE SAME SPACE THAT PRIESTS FOR LIFE -- THE PRIESTS FOR LIFE COURT WAS OR IS IT YOUR VIEW THAT I DON'T HAVE TO MAKE THAT DETERMINATION OF GOOD CAUSE BEFORE GOING ALONG WITH THE HOLDING IN THAT CASE?

MR. DAVIS: YOUR HONOR, IF I UNDERSTAND THE QUESTION CORRECTLY, I THINK THAT ALL OF THOSE --

THESE FACTORS WE HAVE BEEN DISCUSSING GO TO WHETHER OR NOT THERE WAS GOOD CAUSE TO DO THE IFR IN THAT CASE AS AN IFR INSTEAD OF THROUGH NOTICE AND COMMENT. I THINK THE SIGNIFICANCE OF THE CHANGE IS ALL UNDER THAT HEADING OF WHETHER OR NOT THERE IS GOOD CAUSE. I WOULD SAY YOU DON'T EVEN HAVE TO REACH THE GOOD CAUSE ISSUE AT ALL IN OUR VIEW BECAUSE OF THE SEPARATE BASES OF STATUTORY AUTHORITY. BUT IN THE EVENT YOU WERE TO REACH THE GOOD CAUSE ISSUE, I THINK IF YOU READ THAT PART OF THAT -- OF THE D.C. CIRCUIT'S DECISION, I THINK WE ARE ALMOST ON ALL FOURS WITH IT HERE.

THE COURT: GO AHEAD.

MR. DAVIS: I WOULD LIKE TO MOVE TO THE STATUTORY AUTHORITY FOR THE EXEMPTIONS.

THE COURT: GO AHEAD.

MR. DAVIS: YOUR HONOR, IN OUR VIEW WE HAVE THREE SEPARATE BASES OF STATUTORY AUTHORITY.

THE FIRST IS THE AFFORDABLE CARE ACT ITSELF. HERE AGAIN, YOUR HONOR IS NOT WRITING ON A BLANK SLATE. THIS IS THE SOURCE OF AUTHORITY THAT THE LAST ADMINISTRATION USED TO CRAFT THE ORIGINAL RELIGIOUS EMPLOYER EXEMPTION. THE STATUTE IS A BROADLY WORDED DELEGATION OF AUTHORITY TO THE AGENCIES. IT PROVIDES THAT COVERED GROUP HEALTH PLANS SHALL PROVIDE -- OR SHALL COVER WHATEVER HRSA SPECIFIES IN ITS GUIDELINES.

THE BREADTH OF THE STATUTE IS APPARENT WHEN COMPARED TO THE OTHER THREE SUBSECTIONS OF THAT STATUTE. THOSE SUBSECTIONS ADDRESS EVIDENCE BASED ITEMS OF SERVICES, IMMUNIZATIONS AND SERVICES FOR CHILDREN, ADDRESS GUIDELINES THAT WERE ALREADY IN EXISTENCE AT THE TIME THE AFFORDABLE CARE ACT WAS ENACTED. AND SUBSECTION (A)(4) WAS A GRANT OF AUTHORITY TO DEVELOP GUIDELINES THAT DID NOT ALREADY EXIST.

AND ON PAGE 23 OF ITS BRIEF, PENNSYLVANIA ARGUES THAT NOTHING IN THE LANGUAGE OF THE ACA OR ITS LEGISLATIVE HISTORY SUGGESTS THAT CONGRESS INTENDED TO GIVE DEFENDANTS OR ANY AGENCY BLANKET AUTHORITY TO PERMIT EMPLOYEES TO OPT-OUT. IF THAT IS TRUE, THE ORIGINAL EXEMPTION FOR CHURCHES HAS TO FALL AS WELL, WHICH WOULD EXPOSES CHURCHES AND HOUSES OF WORSHIP TO THE MANDATE FOR THE FIRST TIME. AND THAT RESULT WOULD IMPERIL THE MANDATE ITSELF BECAUSE WE KNOW FROM HOBBY LOBBY THAT IT IMPOSES A SUBSTANTIAL BURDEN.

SO PENNSYLVANIA ALSO ARGUES THAT THE RULES CONFLICT WITH THE PURPOSE OF THE STATUTE, WHICH IS TO INCREASE COVERAGE FOR PREVENTIVE SERVICES. AND THAT ARGUMENT WOULD ALSO WIPE AWAY THE ORIGINAL CHURCH EXEMPTION. IT'S ALSO INCONSISTENT WITH THE BEST EVIDENCE OF A STATUTE'S PURPOSE, WHICH IS ITS TEXT. AND THE ACA DOES NOT REQUIRE GROUP HEALTH PLANS TO COVER

CONTRACEPTION. IT DOES NOT MENTION CONTRACEPTION. INSTEAD IT DELEGATES AUTHORITY TO THE AGENCIES TO DECIDE WHAT KINDS OF PREVENTIVE SERVICES SHOULD BE COVERED.

THE COURT: WELL, THE CONTRACEPTIVE MANDATE WAS ADOPTED. WELL, THE HRSA ADOPTED THE INSTITUTE'S RECOMMENDATION IN AUGUST OF 2011. AND THE CONTRACEPTIVE MANDATE WAS ENACTED OR PROMULGATED UNDER THE AUTHORITY GIVEN BY THE ACA TO THE AGENCY. SO IN THIS CASE DOES THE -- DO THE EXEMPTIONS, THE MORAL AND RELIGIOUS EXEMPTIONS, IMPACT ON THE CONTRACEPTIVE MANDATE? DON'T THEY CARVE OUT EXCEPTIONS TO THE CONTRACEPTIVE MANDATE? SO YOU HAVE AN AGENCY CARVING OUT EXCEPTIONS TO AN AGENCY'S RULES.

MR. DAVIS: THAT'S CORRECT.

THE COURT: THAT IS CORRECT.

MR. DAVIS: YES.

THE COURT: WHAT AUTHORITY IS THERE FOR AN AGENCY TO CARVE OUT AN EXCEPTION TO AN AGENCY'S PREVIOUSLY PROMULGATED RULES?

MR. DAVIS: YOUR HONOR, I THINK IT IS JUST GENERAL REGULATORY AUTHORITY THAT ALL AGENCIES HAVE TO CHANGE THEIR RULES, CARVE OUT EXEMPTIONS TO THEM. I THINK THE STATUTES THAT I MENTIONED EARLIER PROVIDE THAT AUTHORITY. I THINK IT'S JUST INHERENT IN THE APA THAT AGENCIES HAVE THAT ABILITY. AND I THINK IF THE QUESTION

IS WHETHER THERE IS STATUTORY AUTHORITY FOR AGENCIES TO DO THAT, I WOULD JUST POINT YOUR HONOR AGAIN TO THE ACA, 42 U.S.C. 300 GG-13(A)(4), WHICH PROVIDES DISCRETION, A BROAD GRANT OF DISCRETION FOR THE AGENCIES TO DEVELOP RULES GOVERNING WHAT TYPES OF PREVENTIVE SERVICES WILL BE COVERED AND WHO WILL BE COVERED BY THEM. THERE IS NOTHING IN THAT STATUTE THAT PROHIBITS THE AGENCY FROM DOING THAT.

AND HERE I WOULD LIKE TO ADDRESS ANOTHER ONE OF YOUR HONOR'S QUESTIONS, WHICH IS WHETHER THE AGENCIES ARE ENTITLED TO DEFERENCE IN INTERPRETING THE AFFORDABLE CARE ACT. THE ANSWER TO THAT QUESTION IS YES. IT'S CLEAR THAT CONGRESS HAS DELEGATED TO THE AGENCIES THE AUTHORITY TO MAKE RULES CARRYING THE FORCE OF LAW IN THIS CONTEXT AND THE AGENCIES WERE EXERCISING THAT AUTHORITY IN CRAFTING THESE RULES.

THE COURT: BUT IF THE INTERPRETATION CONFLICTS WITH THE STATUTE'S PLAIN LANGUAGE, IT IS NOT ENTITLED TO JUDICIAL DEFERENCE, CORRECT?

MR. DAVIS: THAT'S CORRECT. BUT HERE I DON'T THINK THAT IS TRUE HERE, TO BE CLEAR, YOUR HONOR. I THINK THE STATUTE IS A BROAD GRANT OF AUTHORITY. THERE IS NOTHING IN IT THAT PROHIBITS THE AGENCIES FROM DOING THIS.

THE COURT: I UNDERSTAND.

MR. DAVIS: THE SECOND BASIS OF STATUTORY AUTHORITY FOR THESE EXEMPTIONS, YOUR HONOR, IS RFRA.

THE COURT: BEFORE YOU GO INTO THAT, AS I UNDERSTAND IT, YOU ARE NOT MAKING AN ARGUMENT WITH RESPECT TO THE MORAL EXEMPTION UNDER RFRA. YOUR RFRA ARGUMENT IS FOCUSED SOLELY ON THE RELIGIOUS EXEMPTION.

MR. DAVIS: THAT'S CORRECT, YOUR HONOR. AND THE SOURCE OF STATUTORY AUTHORITY FOR THE MORAL EXEMPTION IS THE ACA.

AS I SAID, THE SECOND BASIS OF STATUTORY AUTHORITY FOR THE EXEMPTIONS IS RFRA. HERE YOU DON'T HAVE TO INCLUDE THAT RFRA ACTUALLY REQUIRES THE EXEMPTIONS. BECAUSE EVEN IF RFRA DOES NOT REQUIRE THEM, RFRA AUTHORIZES THE RELIGIOUS EXEMPTION. AND AGAIN ON THIS POINT, YOUR HONOR, YOU ARE NOT WRITING ON A BLANK SLATE. WE KNOW FROM HOBBY LOBBY AND YEARS OF LITIGATION THAT THE UNADORNED MANDATE IMPOSES A SUBSTANTIAL BURDEN. THE AGENCIES HAVE DISCRETION IN DETERMINING HOW TO ALLEVIATE THAT BURDEN, AND IN EXERCISING THAT DISCRETION, THE AGENCIES REASONABLY DECIDED TO RESPOND WITH AN EXEMPTION RATHER THAN AN ACCOMMODATION.

THE COURT: WELL, LET ME ASK YOU A QUESTION. DOES ANY OF THE AGENCIES HERE HAVE ANY SPECIFIC EXPERTISE WITH RESPECT TO RFRA?

MR. DAVIS: YOUR HONOR, WE ARE NOT

ARGUING THAT THE AGENCIES ARE ENTITLED TO CHEVRON DEFERENCE UNDER RFRA WRIT LARGE. WE DO THINK THAT THE AGENCIES ARE ENTITLED TO DEFERENCE ON SOME OF THE SUBSIDIARY QUESTIONS THAT TRIGGER THEIR EXPERTISE, SUCH AS WHETHER THERE IS A COMPELLING INTEREST UNDER RFRA. A LOT OF THOSE ISSUES ACTUALLY INVOLVE INTERPRETATIONS OF THE AFFORDABLE CARE ACT AND THEY FALL SQUARELY WITHIN THE AGENCY'S TECHNICAL EXPERTISE. BUT RFRA IS A GENERALLY APPLICABLE STATUTE LIKE THE FREEDOM OF INFORMATION ACT OR OTHERS THAT ARE NOT GENERALLY CONSIDERED TO CONFER CHEVRON DEFERENCE.

AND BACK TO MY POINT ABOUT RFRA AUTHORIZING THE AGENCIES TO DO THIS, THE SUPREME COURT HAS RECOGNIZED THAT AN ENTITY FACED WITH CONFLICTING LEGAL OBLIGATIONS SHOULD BE AFFORDED SOME LEEWAY. SO IN THE RICCI VERSUS DESTEFANO CASE IN THE SUPREME COURT, THE CITY OF NEW HAVEN ADMINISTERED AN EXAM FOR FIREFIGHTERS. THE EXAM PRODUCED RACIALLY DISPARATE RESULTS. THE MINORITY FIREFIGHTERS TOLD THE CITY THAT IF IT CERTIFIED THE RESULTS, THEY WOULD SUE THE CITY FOR VIOLATING TITLE VII'S DISPARATE IMPACT PROVISION. AND THE WHITE FIREFIGHTERS TOLD THE CITY THAT IF IT DID NOT CERTIFY THE RESULTS, THEY WOULD SUE THE CITY FOR VIOLATING TITLE VII'S DISPARATE TREATMENT PROVISION. SO THE CITY WAS CAUGHT BETWEEN THE DISPARATE IMPACT

PROVISION ON THE ONE HAND AND THE DISPARATE TREATMENT PROVISION ON THE OTHER HAND. INSTEAD OF REQUIRING THE CITY TO HIT A PERFECT BULLSEYE IN BETWEEN THOSE TWO STATUTES, THE SUPREME COURT GAVE SOME LEEWAY. IT HELD THAT AN EMPLOYER MAY ENGAGE IN INTENTIONAL DISCRIMINATION FOR THE ASSERTED PURPOSE OF AVOIDING OR REMEDYING AN UNINTENTIONAL DISPARATE IMPACT IF THE EMPLOYER HAS A STRONG BASIS IN EVIDENCE TO BELIEVE THAT IT WILL BE SUBJECT TO DISPARATE IMPACT LIABILITY IF IT FAILS TO TAKE THE RISK CONSCIOUS DISCRIMINATORY ACTION. SO THE SAME IS TRUE HERE.

THE COURT: SO YOU ARE TAKING -- YOU ARE BORROWING LAW FROM THE DISCRIMINATORY -- DISCRIMINATION JURISPRUDENCE THAT PERTAINS TO A MUNICIPALITY AND APPLYING IT TO -- WHICH IS A STATE ENTITY, AND APPLYING IT TO A FEDERAL AGENCY THAT FALLS UNDER THE EXECUTIVE FUNCTION, IS THAT CORRECT?

MR. DAVIS: I WOULD NOT PUT IT LIKE THAT. AGAIN, YOUR HONOR --

THE COURT: WELL, THAT IS WHAT YOU ARE DOING, WHETHER YOU PUT IT LIKE THAT OR NOT. SO THE QUESTION IS WHY WOULD YOU TAKE -- WHY WOULD YOU BORROW FROM ONE LINE OF JURISPRUDENCE WHICH HAS NOTHING TO DO WITH WHAT WE ARE TALKING ABOUT HERE. AND IF YOU ARE GOING TO DO THAT, YOU HAVE TO PROVIDE ME WITH SOME

PRETTY STRONG RATIONALE BACKED UP BY APPLICABLE PRECEDENT, SO THAT MEANS THIRD CIRCUIT OR SUPREME COURT PRECEDENT, TO TELL ME THAT THAT IS APPROPRIATE.

MR. DAVIS: YOUR HONOR, I THINK IF YOU LOOK AT THE REASONING OF THIS CASE --

THE COURT: NO, I -- NO, NO. YOU CAN TAKE ANY KIND OF LOGICAL SYLLOGISM IN PRETTY MUCH ANY CASE IN THE LAW AND JUST SAY WELL, IT APPLIES HERE. BUT THAT IS NOT WHAT WE DO WHEN WE ANALYZE CASE LAW. WHAT WE DO IS TAKE A LOOK AT THE JURISPRUDENCE AND DETERMINE WHETHER IT IS APPROPRIATE TO APPLY A PARTICULAR SET OF JURISPRUDENCE IN ONE CONTEXT WHEN IT HAS BEEN DEVELOPED IN ANOTHER CONTEXT.

SO WHAT I NEED IF YOU WANT TO MAKE THAT COMPARISON IS TO DRAW A JURISPRUDENTIAL LINE BETWEEN THE CASE -- THE NEW HAVEN CASE THAT YOU MENTIONED, WHICH CONCERNS DISCRIMINATION, AND THE CASE HERE -- DISCRIMINATION IN THE CONTEXT OF A STATE ENTITY TO HERE, WHICH CONCERNS AN AGENCY'S DETERMINATION AS TO WHETHER IT CAN OR CANNOT ENACT A PARTICULAR REGULATION. IF YOU CAN DRAW -- IF YOU CAN DRAW THAT CONNECTION, FINE, I'M HAPPY TO CONSIDER IT. BUT YOU CAN'T JUST SAY IT.

MR. DAVIS: YOUR HONOR, I RESPECTFULLY DISAGREE WITH HOW YOU CHARACTERIZE THAT. I THINK IT IS APPROPRIATE IN REASONING ON THE BASIS OF CASES NOT TO

USE CASES IN THE EXACT SAME CONTEXT BUT INSTEAD TO USE REASON BY ANALOGY TO CASES THAT MAY INVOLVE A DIFFERENT CONTEXT, IN THAT CASE, THE MUNICIPALITY INSTEAD OF THE FEDERAL GOVERNMENT. BUT STILL THE GENERAL LEGAL PRINCIPLE THAT THAT CASE RECOGNIZES, THAT AN ENTITY FACED WITH CONFLICTING LEGAL OBLIGATIONS SHOULD BE AFFORDED SOME LEEWAY. AND THAT PRINCIPLE FROM THAT CASE APPLIES EQUALLY HERE. EVEN THOUGH IT IS IN A DIFFERENT CONTEXT IN THAT CASE, IT'S THE SAME THING HERE.

THE EXEMPTION RECOGNIZES THE REALITY THAT THE AGENCIES WOULD LIKELY BE SUBJECT TO UNDER RFRA. WELL, IT COULD BE SUBJECT TO LIABILITY UNDER RFRA THAT THE AGENCIES CHOSE THE ACCOMMODATIONS THAT -- BUT EVEN IF YOUR HONOR IS NOT PERSUADED BY THAT POSITION, WHICH I --

THE COURT: I CAN TELL YOU I'M NOT PERSUADED BY THAT.

MR. DAVIS: I UNDERSTAND, YOUR HONOR. THE OTHER BASIS FOR STATUTORY AUTHORITY HERE IS THAT RFRA DOES REQUIRE THE RELIGIOUS RULE, EVEN IF YOU THINK IT DOES NOT AUTHORIZE IT. AND HERE THE AGENCIES HAVE CONCLUDED THAT REQUIRING OBJECTING ENTITIES TO CHOOSE BETWEEN THE MANDATE, THE ACCOMMODATION, OR PENALTIES FOR NONCOMPLIANCE IMPOSES A SUBSTANTIAL BURDEN IN THE AGENCY'S VIEW THE ACCOMMODATION, THE PREVIOUS

ACCOMMODATION WAS NOT ENOUGH TO ALLEVIATE THAT SUBSTANTIAL BURDEN BECAUSE MANY ENTITIES OBJECTED TO THE ACT OF SUBMITTING A SELF-CERTIFICATION FORM. THOSE ENTITIES SINCERELY BELIEVE THAT SUBMITTING THE FORM MADE THEM COMPLICIT IN PROVIDING CONTRACEPTIVE COVERAGE. EVEN IF A COURT WERE TO DISAGREE WITH THAT BELIEF, HOBBY LOBBY PROHIBITS QUESTIONING IT, AND AS THE SUPREME COURT EXPLAINED, I BELIEVE, IMPLICATES A DIFFICULT AND IMPORTANT QUESTION OF RELIGION AND MORAL PHILOSOPHY THAT COURTS SHOULD NOT BE WADING INTO.

ON COMPELLING INTEREST, THE AGENCIES HAVE NOW TAKEN THE POSITION THAT THE MANDATE DOES NOT SERVE A COMPELLING GOVERNMENT INTEREST. AND THIS GOES TO THE LAST OF YOUR HONOR'S QUESTIONS, WHICH I PREVIOUSLY ADDRESSED. EVEN THOUGH THE AGENCIES DON'T GET CHEVRON DEFERENCE UNDER RFRA, ON THE SUBSIDIARY QUESTIONS UNDER RFRA, I THINK THEY DO ON THE COMPELLING INTEREST ISSUE, AND THAT IS BECAUSE THE COMPELLING INTEREST ISSUE IS TIED IN PART TO THE AGENCY'S INTERPRETATION OF THE AFFORDABLE CARE ACT AND IT GOES RIGHT TO THE AREAS WHERE THE AGENCIES HAVE DEFERENCE.

AND BEFORE I GO FURTHER, YOUR HONOR, I JUST WANT TO MAKE SURE I'M NOT GOING OVER TIME.

THE COURT: NO, I THINK YOU ARE ACTUALLY -- YOU STARTED ABOUT EIGHT MINUTES PAST AND IT

IS NOW 20 MINUTES TO, SO YOU ARE EXACTLY ON TIME. I THINK I DID GIVE THE OTHER SIDE A LITTLE BIT MORE. SO IF YOU HAVE ANYTHING ELSE YOU NEED TO SAY, FEEL FREE.

MR. DAVIS: I'LL JUST SAY THAT ON THE COMPELLING INTEREST ISSUE, THE AGENCIES MADE A VARIETY OF DIFFERENT CONCLUSIONS IN A WELL-REASONED PART OF THE RULE THAT SPANS SEVERAL PAGES. AND FIRST CONGRESS DID NOT MANDATE THAT CONTRACEPTION BE COVERED AT ALL. AS AN INTERPRETATION OF THE AFFORDABLE CARE ACT, THAT IS ENTITLED TO DEFERENCE. SECOND, CONGRESS EXPRESSLY DECIDED NOT TO APPLY THE PREVENTIVE SERVICES REQUIREMENT TO GRANDFATHER PLANS COVERING TENS OF MILLIONS OF EMPLOYEES.

THE COURT: LET ME TALK TO YOU ABOUT THOSE GRANDFATHERED HEALTH PLANS. I THINK ONE OF THE REASONS THAT WERE GIVEN IN THE IFRS FOR BYPASSING THE NOTICE AND COMMENT RULE MAKING WAS, I THINK IT WAS: DELAYING AVAILABILITY OF THE EXEMPTION WOULD ALSO INCREASE THE COST OF HEALTH INSURANCE BECAUSE GROUPS WITH GRANDFATHERED HEALTH PLANS WISH TO MAKE CHANGES TO THEIR HEALTH PLANS THAT WILL REDUCE THE COST OF INSURANCE COVERAGE FOR THEIR BENEFICIARIES OR POLICY HOLDERS BUT WHICH COULD CAUSE THE PLANS TO LOSE GRANDFATHERED STATUS.

DO YOU RECALL THAT --

MR. DAVIS: YES, YOUR HONOR.
THE COURT: -- RATIONALE?
SO THERE WERE 54,000 COMMENTS, AND I THINK YOU PROVIDED THEM TO US. WE HAVE THEM IN THE RECORD. SO IN ORDER TO MAKE SURE THAT THAT WAS BACKED UP BY THE RECORD, BECAUSE IT WAS JUST A BOLD STATEMENT, IT WAS A CONCLUSION, WE SEARCHED ALL THOSE 54,000 COMMENTS, AND WE COULD NOT LOCATE A SINGLE COMMENT THAT REFERENCED A GRANDFATHERED HEALTH PLAN. SO WE WONDER IS THERE ANY WAY THAT THEY COULD POSSIBLY BE IN THE COMMENTS UNDER A DIFFERENT TERMINOLOGY THAN GRANDFATHERED HEALTH PLAN.
MR. DAVIS: IF YOUR HONOR DOES NOT MIND, WE WILL GET BACK TO YOU ON THAT QUESTION.
THE COURT: WELL, IF YOU COULD, I THINK -- I'M SURE YOU HAVE SOMEONE THAT CAN DO IT NOW, BUT IF YOU COULD GET BACK TO ME BEFORE THE END OF THE DAY. WHAT I WOULD LIKE YOU TO DO IS TO SEARCH THE 54,000 COMMENTS AND TELL ME -- AND PROVIDE ME A LIST OF THE CASE -- OF THE INSTANCES IN WHICH THERE WAS SOME COMMENTARY FROM A GRANDFATHERED HEALTH PLAN WHICH SUGGESTED THAT THEY WISH TO MAKE CHANGES TO THEIR HEALTH PLANS IN A FASTER FASHION THAN WOULD OTHERWISE BE THE CASE. I THINK YOU CAN DO THAT OVER LUNCH AND GET BACK TO ME.

MR. DAVIS: YES.
THE COURT: OKAY. ANYTHING ELSE?
MR. DAVIS: I WILL STOP THERE, YOUR HONOR.
THE COURT: OKAY. SO WHAT WE ARE GOING TO DO NOW -- ARE YOU NOW READY TO GO TO YOUR WITNESSES?
MR. GOLDMAN: I AM, YOUR HONOR.
THE COURT: WELL, I THINK WE SHOULD TAKE A QUICK BREAK IN ORDER TO GET EVERYONE SORTED. WE WILL BE BACK HERE IN TEN MINUTES, SO THAT IS JUST ABOUT EIGHT MINUTES TO.
THE CLERK: ALL RISE.
(BREAK TAKEN.)
THE COURT: ARE YOU READY TO GO?
MR. GOLDMAN: YES, YOUR HONOR. MAY I APPROACH?
THE COURT: YOU MAY APPROACH. AND THE WITNESS MAY TAKE THE WITNESS STAND.
(CAROL WEISMAN, COMMONWEALTH'S WITNESS, SWORN.)
THE CLERK: STATE AND SPELL YOUR FULL NAME FOR THE RECORD, PLEASE.
THE WITNESS: CAROL WEISMAN, C-A-R-O-L W-E-I-S-M-A-N.
DIRECT EXAMINATION

BY MR. GOLDMAN:
Q. WHERE ARE YOU FROM, DR. WEISMAN?
A. **ORIGINALLY FROM PITTSBURGH, PENNSYLVANIA.**
Q. AND WHAT DO YOU DO FOR A LIVING?
A. **I'M A PROFESSOR AT THE PENN STATE COLLEGE OF MEDICINE.**
Q. AND IF I MAY, YOU HAVE AN EXHIBIT BINDER BEFORE YOU.
MR. DAVIS: AND, YOUR HONOR, IF I UNDERSTAND YOUR RULES, YOU WOULD LIKE THE EXHIBITS MOVED INTO EVIDENCE BEFORE THE WITNESS IS QUESTIONED?
THE COURT: IT DOES NOT REALLY MATTER BECAUSE WE DON'T HAVE A JURY, SO JUST DO IT -- IT WOULD BE BETTER IF YOU DID NOT QUESTION HER.
BUT HAVE YOU STIPULATED TO EVERYTHING?
MS. KADE: EVERYTHING EXCEPT FOR DEMONSTRATIVE.
THE COURT: OKAY. SO CAN WE JUST STIPULATE THAT EXHIBITS 1 THROUGH -- WHICH ONE IS THE DEMONSTRATIVE?
MS. KADE: IT IS 18, YOUR HONOR.
THE COURT: CAN WE JUST STIPULATE AT THIS POINT THAT EVERYTHING EXCEPT EXHIBIT 18 IS ADMITTED?
MR. GOLDMAN: YES, YOUR HONOR.
MS. KADE: YES, YOUR HONOR.

THE COURT: THEY ARE ALL ADMITTED, AND THEREFORE YOU DO NOT HAVE TO LAY A FOUNDATION OR AUTHENTICATION.
(GOVERNMENT EXHIBIT 18 ADMITTED INTO EVIDENCE.)
BY MR. GOLDMAN:
Q. IF YOU WOULD TURN, DR. WEISMAN, TO TAB 4, WHICH WOULD BE EXHIBIT 4.
DO YOU KNOW WHAT THAT DOCUMENT IS?
A. **YES. THAT IS MY CV.**
Q. AND IF YOU WOULD JUST FLIP THROUGH IT BRIEFLY. CAN YOU CONFIRM THAT THE CONTENTS OF THAT ARE ACCURATE?
A. **YES.**
Q. AND EXHIBIT 3 OF THE TAB, IF YOU CAN FLIP THROUGH THAT.
A. **YES.**
Q. ARE YOU FAMILIAR WITH THAT DOCUMENT?
A. **YES. THAT IS MY DECLARATION.**
Q. AND IF YOU COULD REVIEW THAT BRIEFLY AND IF YOU CAN CONFIRM IF YOU ARE COMFORTABLE WITH THE STATEMENTS CONTAINED THERE?
A. **YES, I AM.**
Q. I WOULD LIKE TO ASK YOU BRIEFLY ABOUT YOUR EDUCATION. WHERE DID YOU GO TO COLLEGE -- AND BY THE WAY, YOUR HONOR, IF YOU WOULD PREFER US NOT TO GO

THROUGH THIS, WE CAN STIPULATE OVER IT.
THE COURT: I DON'T NEED IT.
DO YOU NEED IT?
MS. KADE: NO, YOUR HONOR.
THE COURT: WE DON'T NEED IT.
BY MR. GOLDMAN:
Q. I MAY ASK SOME TARGETED QUESTIONS IN THERE, IF I MAY. WHAT WAS THE FOCUS OF YOUR ACADEMIC WORK AT WELLESLEY AND THEN JOHNS HOPKINS UNIVERSITY?
A. I STUDIED SOCIOLOGY.
Q. AND WAS THERE A FOCUS WITHIN THAT?
A. AT THE UNDERGRADUATE LEVEL, NOT REALLY AT THE GRADUATE LEVEL, I BECAME INTERESTED IN GENDER RELATED ISSUES.
Q. AND DID THAT INCLUDE HEALTHCARE AT THAT TIME?
A. YES.
Q. YOU ARE NOT A MEDICAL DOCTOR, ARE YOU?
A. I AM NOT.
MR. DAVIS: YOUR HONOR, MAY I HAVE PERMISSION TO LEAD FOR SOME OF THESE FOUNDATIONAL QUESTIONS.
THE COURT: ARE YOU OKAY WITH THAT?
MS. KADE: UNTIL I SEE WHAT THE QUESTIONS ARE, YOUR HONOR, I'M NOT SURE, BUT AT THIS POINT, YES.
THE COURT: OKAY. PERMISSION TO LEAD FOR

THE MOMENT -- I'M SORRY, WHAT IS YOUR NAME?
MS. KADE: ELIZABETH, YOUR HONOR.
THE COURT: ELIZABETH WHAT?
MS. KADE: KADE.
THE COURT: THE MOMENT MS. KADE OBJECTS, THEN WE MAY HAVE TO CHANGE TASKS.
BY MR. GOLDMAN:
Q. AM I CORRECT THAT YOU -- AFTER YOU GOT YOUR PH.D. FROM JOHNS HOPKINS, YOU WORKED AS AN ASSOCIATE RESEARCH SCIENTIST THERE?
A. YES.
Q. AND WHY DID YOU CHOOSE TO WORK AT JOHNS HOPKINS UNIVERSITY?
A. I WAS OFFERED A FACULTY POSITION IN WHICH I COULD CONDUCT RESEARCH AS WELL AS TEACH AT THE GRADUATE LEVEL.
Q. AND DID THEY HAVE A PRETTY GOOD PROGRAM?
A. OH, THEY HAVE THE TOP PROGRAM IN PUBLIC HEALTH IN THE COUNTRY.
Q. DID YOU WORK IN THE -- YOU WORKED IN RESEARCH HEALTH SERVICES. AT THE TIME YOU JOINED JOHNS HOPKINS UNIVERSITY, DID THAT INCLUDE THE FIELD OF WOMEN'S HEALTHCARE?
A. THE FIELD OF HEALTH SERVICES RESEARCH WAS JUST BEING ESTABLISHED AT THAT TIME. IT'S AN

INTERDISCIPLINARY FIELD, PEOPLE FROM DIFFERENT TRAINING BACKGROUNDS STUDYING HOW HEALTHCARE IS DELIVERED, THE COST OF CARE, THE QUALITY OF CARE. AND I BECAME INVOLVED WITH THOSE RESEARCHERS SPECIFICALLY TO LOOK AT WOMEN'S HEALTHCARE.
Q. IS IT FAIR TO SAY THAT YOU PLAYED A PART IN THE CREATION OF WOMEN'S HEALTHCARE AS A FIELD WITHIN RESEARCH HEALTH SERVICES?
A. YES.
Q. AND YOU WORKED AT JOHNS HOPKINS UNIVERSITY FOR 24 YEARS?
A. YES.
Q. AND I'M NOT GOING TO ASK YOU ABOUT YOUR PROMOTIONS DURING THAT TIME, BUT GENERALLY SPEAKING, CAN YOU DESCRIBE THE WORK THAT YOU DID WHILE AT JOHNS HOPKINS UNIVERSITY?
A. I DESIGNED AND LED A NUMBER OF RESEARCH PROJECTS ON DIFFERENT TOPICS. I TAUGHT MASTERS LEVEL STUDENTS. I SUPERVISED DOCTORAL STUDENTS, ESPECIALLY IN THEIR DISSERTATION PROJECTS, AND I CO-LED A COUPLE OF ACADEMIC PROGRAMS.
Q. AND IS ALL THAT TEACHING WORK? DID YOU ALSO DO RESEARCH DURING THAT TIME?
A. YES, RESEARCH WAS A GREAT PART OF MY RESPONSIBILITIES.

Q. AND DID YOU ALSO GIVE PRESENTATIONS AND MAKE PUBLICATIONS AS WELL?
A. YES.
Q. SO AFTER JOHNS HOPKINS UNIVERSITY YOU WENT TO UNIVERSITY OF MICHIGAN AFTER 24 YEARS?
A. CORRECT.
Q. AND THEN YOU WENT TO PENN STATE COLLEGE OF MEDICINE, CORRECT?
A. CORRECT.
Q. AND WHEN DID YOU GO TO PENN STATE COLLEGE OF MEDICINE?
A. IN 2003, SO I HAVE BEEN THERE 15 YEARS.
Q. AND IS THAT YOUR CURRENT JOB?
A. YES.
Q. WHAT IS YOUR POSITION THERE?
A. A DISTINGUISHED PROFESSOR OF PUBLIC HEALTH SCIENCES AND OBSTETRICS AND GYNECOLOGY IN THE COLLEGE OF MEDICINE.
Q. AND YOU ARE NOT A DOCTOR?
A. I AM NOT.
Q. A MEDICAL DOCTOR.
A. NOT A PHYSICIAN.
Q. ARE THERE MANY NON-DOCTORS WHO ARE DISTINGUISHED PROFESSORS IN THAT PROGRAM WITHIN THE MEDICAL SCHOOL?
A. YES. MEDICAL SCHOOLS TYPICALLY HAVE M.D.'S AND

PH.D.'S ON FACULTY.
Q. WHAT IS THE FOCUS OF YOUR WORK AT PENN STATE?
A. AGAIN, THE FOCUS OF MY WORK IS CONDUCTING RESEARCH ON WOMEN'S HEALTHCARE TOPICS. I ALSO TEACH MASTERS LEVEL STUDENTS, PARTICULARLY IN THE MPH PROGRAM, AND DOCTORAL STUDENTS IN THE DOCTOR OF PUBLIC HEALTH PROGRAM.
I ALSO SPEND PART OF MY TIME AS ASSOCIATE DEAN FOR FACULTY AFFAIRS.
Q. DO YOU, IN ADDITION TO TEACHING AND RESEARCHING, DO YOU PUBLISH ARTICLES?
A. YES.
Q. AND GIVE PRESENTATIONS?
A. YES.
Q. IN THE CONTEXT OF YOUR RESEARCH, ARE THOSE CLINICAL INVESTIGATIONS?
A. SOMETIMES THEY ARE CLINICAL INVESTIGATIONS, SOMETIMES THEY ARE POPULATION-BASED STUDIES. SO IT'S A VARIETY OF DIFFERENT KINDS OF STUDIES.
Q. AND WHEN IT IS A CLINICAL INVESTIGATION, DO YOU EVER SERVE AS WHAT'S CALLED AN INVESTIGATOR IN THOSE STUDIES?
A. YES.
Q. WHAT IS AN INVESTIGATOR? WHAT METHODS DOES AN INVESTIGATOR USE?

A. AN INVESTIGATOR IS RESPONSIBLE FOR OVERSEEING THE CONDUCT OF A RESEARCH PROJECT. THE METHODS THAT WE USE CAN BE QUITE DIVERSE. THE RESEARCH I DO SOMETIMES INVOLVES SURVEY RESEARCH, IN WHICH WE ASK PEOPLE QUESTIONS IN A SYSTEMATIC WAY. SOMETIMES IT INVOLVES ANALYSIS OF HEALTH CLAIMS DATA TO LOOK AT COST OF CARE. SOMETIMES WE TEST INTERVENTIONS TO SEE IF THEY WORK WITH PATIENTS OR OTHERS.
Q. IS IT FAIR TO SAY THAT WHEN DO YOU THAT KIND OF WORK, THE WORK YOU DO IS BASED ON SCIENCE AND EVIDENCE?
A. YES.
Q. HAVE ANY OF THE INVESTIGATIONS THROUGHOUT YOUR CAREER BEEN RELATED TO CONTRACEPTIVE USE?
A. YES.
Q. YOU DON'T HAVE TO COUNT. I KNOW YOUR RÉSUMÉ IS VERY EXTENSIVE, BUT CAN YOU ESTIMATE ROUGHLY HOW MANY INVESTIGATIONS HAVE INVOLVED CONTRACEPTIVE USE?
A. WELL, I ESTIMATE I HAVE DONE OVER 40 PROJECTS IN MY CAREER, AND I WOULD SAY A THIRD TO A HALF OF THEM HAVE TO DO WITH WOMEN'S REPRODUCTIVE HEALTH GENERALLY.
Q. AND HAVE YOU AUTHORED ANY PUBLICATIONS SPECIFICALLY RELATING TO ACCESS TO CONTRACEPTIVE CARE?
A. YES.
Q. CAN YOU GIVE SOME EXAMPLES OF SPECIFIC AREAS IN WHICH YOU HAVE PUBLISHED ARTICLES RELATED TO

CONTRACEPTIVE CARE?
A. YES. SO I'VE CONDUCTED STUDIES OF ADOLESCENTS' CONTRACEPTIVE DECISION-MAKING. I HAVE CONDUCTED WORK ON WOMEN'S RECEIPT OF CONTRACEPTIVE COUNSELING IN THE CONTEXT OF MANAGED CARE PLANS. I HAVE CONDUCTED STUDIES IN INTEGRATION OF REPRODUCTIVE HEALTH SERVICES INTO WOMEN'S PRIMARY CARE SETTINGS, AND I HAVE CONDUCTED STUDIES OF WOMEN'S PRECONCEPTION HEALTHCARE, WHICH INCLUDES CONTRACEPTIVE USE BUT NOT EXCLUSIVELY.
AND THEN MORE RECENTLY I HAVE BEEN INVOLVED IN SOME STUDIES LOOKING AT WOMEN'S CONTRACEPTIVE BEHAVIOR FOLLOWING THE AFFORDABLE CARE ACT.
Q. SO IS IT FAIR TO SAY THAT YOU ARE FAMILIAR WITH THE AFFORDABLE CARE ACT?
A. YES.
Q. AND HAVE YOU TAUGHT, RESEARCHED, WRITTEN AND GIVEN PRESENTATIONS ON IT?
A. I HAVE.
Q. AND ARE YOU ALSO FAMILIAR WITH THE CONTRACEPTIVE MANDATE CONTAINED IN THE AFFORDABLE CARE ACT?
A. YES.
Q. AND HAVE YOU TAUGHT, RESEARCHED, WRITTEN AND GIVEN PRESENTATIONS ABOUT THAT AS WELL?
A. YES.

Q. HAS ANY OF THE SCHOLARLY WORK YOU HAVE DONE ON THIS TOPIC RELATED TO PEOPLE IN PENNSYLVANIA?
A. YES.
Q. AND HAS ANY OF THE SCHOLARLY WORK YOU'VE PERFORMED ON THIS TOPIC ALSO RELATED TO PEOPLE OUTSIDE OF PENNSYLVANIA AS WELL?
A. YES, BOTH NATIONAL STUDIES AND SOME STUDIES IN PENNSYLVANIA.
Q. AM I CORRECT THAT YOU WERE CHOSEN AS ONE OF ONLY 16 MEMBERS OF THE INSTITUTE OF MEDICINE'S COMMITTEE ON PREVENTATIVE SERVICES FOR WOMEN THAT WAS CONVENED BY THE HEALTH RESOURCES SERVICES ADMINISTRATION IN CONNECTION WITH THE AFFORDABLE CARE ACT?
A. YES.
MR. GOLDMAN: YOUR HONOR, IF I MAY AT THIS TIME, I WOULD LIKE TO PROFFER THIS WITNESS, DR. CAROL WEISMAN, BASED ON HER KNOWLEDGE, EDUCATION, EXPERIENCE AND TRAINING, AS AN EXPERT IN THE AREA OF PREVENTATIVE MEDICAL CARE FOR WOMEN, INCLUDING CONTRACEPTIVE CARE.
THE COURT: ANY OBJECTIONS?
MS. KADE: YOUR HONOR, WE OBJECT UNDER FEDERAL RULE 26(A) REQUIRES DISCLOSURE OF EXPERT TESTIMONY UNDER FEDERAL RULE 702, 703, AND 705. THE PLAINTIFF HAS NOT PROVIDED US WITH THE REQUIRED

DISCLOSURE OF THIS PERSON AS AN EXPERT OR THE SUBJECT MATTER ON WHICH THE WITNESS IS EXPECTED TO PRESENT EXPERT TESTIMONY.

MR. GOLDMAN: OBVIOUSLY, YOUR HONOR, THIS IS THE CONTEXT OF AN INJUNCTION PROCEEDING. THERE HAVE NOT BEEN ANY DEPOSITIONS, THERE'S NO TIME FOR THAT. AND IN FACT, MUCH OF DR. WEISMAN'S CONTENT OF HER TESTIMONY HAS BEEN DISCLOSED IN THE FORM OF HER DECLARATION WHICH IS ATTACHED TO OUR MOTION OVER A MONTH AGO.

MS. KADE: YOUR HONOR, THEY WERE NOT DISCLOSED AS AN EXPERT TESTIMONY.

THE COURT: OKAY. I OVERRULE YOUR OBJECTION. SHE IS ADMITTED AS AN EXPERT IN PREVENTATIVE MEDICAL CARE INCLUDING CONTRACEPTION. IS THAT WHAT YOU WANTED?

MR. GOLDMAN: YES, YOUR HONOR. AND JUST FOR THE RECORD, COUNSEL HAD OBJECTED TO DR. WEISMAN AS AN EXPERT, SO IT SEEMS THAT THEY MUST HAVE KNOWN FROM THE DECLARATION THAT SHE WAS BEING OFFERED AS AN EXPERT.

THE COURT: YOU JUST WON, YOU DIDN'T HAVE TO MAKE AN ARGUMENT.

MR. GOLDMAN: I'M SORRY?

THE COURT: YOU JUST WON, YOU DIDN'T HAVE TO MAKE ANOTHER ARGUMENT.

MR. GOLDMAN: THANK YOU, YOUR HONOR. I

UNDERSTAND.

THE COURT: IT'S OVER.

BY MR. GOLDMAN:

Q. WHAT IS THE INSTITUTE OF MEDICINE?

THE COURT: MS. KADE, WHAT'S UP?

MS. KADE: YOUR HONOR, TO THE EXTENT THAT THIS EXPERT TESTIMONY IS GOING TO BE OFFERED IN ORDER TO DETERMINE THE CORRECTNESS OR WISDOM OF THE AGENCY'S DECISION, IT SHOULD NOT BE PERMITTED, AND THAT IS A QUOTE FROM ASARCO V EPA AT 1160. IT'S A 9TH CIRCUIT 1980 DECISION THAT THE COURT REFERRED TO IN HER MOTION IN LIMINE THAT WAS ISSUED YESTERDAY.

THE COURT: OKAY, YOUR OBJECTION IS TAKEN.

GO AHEAD.

BY MR. GOLDMAN:

Q. WHAT IS THE INSTITUTE OF MEDICINE AND WHAT DO THEY DO?

A. THE INSTITUTE OF MEDICINE IS NOW CALLED THE NATIONAL ACADEMY OF MEDICINE AND IT IS A NONGOVERNMENTAL PRIVATE GROUP OF MEDICAL AND SCIENTIFIC EXPERTS WHO CONDUCT STUDIES AND PROVIDE RECOMMENDATIONS TO GOVERNMENT AND POLICYMAKERS AND OTHERS, WHEN ASKED.

Q. AND THIS SPECIFIC COMMITTEE THAT YOU WERE ONE OF 16 MEMBERS OF, WHAT WAS THE PURPOSE OF THAT COMMITTEE?

A. THAT COMMITTEE WAS CHARGED WITH MAKING RECOMMENDATIONS TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES FOR SPECIFIC PREVENTIVE SERVICES FOR WOMEN THAT WERE NOT MENTIONED IN THE AFFORDABLE CARE ACT BUT MIGHT HAVE SUBSTANTIAL EVIDENCE TO SUPPORT THEIR PROVISION AS PART OF WOMEN'S PREVENTIVE CARE.

Q. AND WAS THE PURPOSE OF THAT COMMITTEE, WAS IT LIMITED TO RECOMMENDATIONS INVOLVING CONTRACEPTIVE CARE OR WAS IT BROADER THAN THAT?

A. OH, NO. OUR CHARGE WAS TO SCAN THE EXISTING RECOMMENDATIONS FOR WOMEN'S PRIMARY CARE AND WHAT WE KNEW OF THE SCIENTIFIC LITERATURE AROUND SPECIFIC PREVENTIVE SERVICES AND MAKE RECOMMENDATIONS FOR WHAT OUGHT TO BE INCLUDED IN ROUTINE PREVENTIVE CARE FOR WOMEN IN GENERAL.

Q. AND DID THE COMMITTEE ULTIMATELY ISSUE RECOMMENDATIONS?

A. YES, WE ISSUED EIGHT RECOMMENDATIONS.

Q. AND HOW MANY OF THEM, IF ANY, INVOLVED CONTRACEPTIVE CARE?

A. ONE OF THE EIGHT.

Q. DID THE COMMITTEE ULTIMATELY ISSUE A REPORT WITH ITS RECOMMENDATIONS?

A. YES.

Q. I WOULD LIKE TO TURN YOUR ATTENTION TO

EXHIBIT 5, IT SHOULD BE TAB 5 IN YOUR BINDER, AND ASK IF YOU HAVE EVER SEEN THIS DOCUMENT BEFORE?

A. YES, THIS IS THE REPORT OF THE COMMITTEE.

Q. AND THAT IS ALREADY IN EVIDENCE. THROUGHOUT YOUR TESTIMONY, I MAY BE REFERRING TO IT BRIEFLY.

IF YOU COULD FIRST, WOULD YOU TURN TO PAGE 223 OF THE REPORT. IT IS APPENDIX C. AND IT GOES -- THAT SECTION GOES THROUGH PAGE 230.

A. YES, I'M THERE.

Q. ARE THOSE THE BIOGRAPHIES OF THE PEOPLE ON THE COMMITTEE?

A. YES, THEY ARE.

Q. IF YOU'D TURN TO THE LAST PAGE, ON PAGE 230, THE LAST BIOGRAPHY, IS THAT YOUR BIOGRAPHY?

A. YES.

Q. DO YOU KNOW WHY YOU WERE LAST?

A. IT IS ALPHABETICAL. I THINK EXCEPT FOR THE CHAIR, SHE IS FIRST.

Q. UNDERSTOOD.

IN FORMING ITS RECOMMENDATIONS, WHAT WAS THE COMMITTEE ASKED TO CONSIDER?

A. WE WERE ASKED FIRST TO SCAN THE SOURCES OF PREVENTIVE CARE GUIDELINES THAT ARE NAMED IN THE AFFORDABLE CARE ACT. THOSE INCLUDE THE U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS, THE ADVISORY

COMMITTEE ON IMMUNIZATION PRACTICE RECOMMENDATIONS AND THE BRIGHT FUTURES RECOMMENDATIONS.

AND WE WERE ASKED TO LOOK FOR GAPS: IS THERE ANY ASPECT OF WOMEN'S PREVENTIVE CARE THAT IS NOT COVERED ALREADY BY THOSE EXISTING GUIDELINES. AND THEN WE WERE ASKED TO REVIEW THE SCIENTIFIC LITERATURE AND LISTEN TO SOME EXPERT TESTIMONY AND COME TO SOME CONCLUSIONS ABOUT WHAT SERVICES IN ADDITION TO THOSE ALREADY COVERED IN THOSE THREE SOURCES OUGHT TO BE PART OF WOMEN'S ROUTINE PREVENTIVE CARE.

Q. WAS THE COMMITTEE ASKED TO CONSIDER COSTS?

A. NO. WE WERE IN FACT SPECIFICALLY TOLD NOT TO CONSIDER COSTS.

Q. DID THE COMMITTEE, AS PART OF ITS STUDY AND RECOMMENDATION, DID IT FOCUS AT ALL ON THE ISSUE OF UNINTENDED PREGNANCY?

A. YES, THAT WAS ONE OF THE TOPIC AREAS IDENTIFIED AS A GAP BECAUSE IT WAS NOT ADDRESSED IN EXISTING GUIDELINES.

Q. DO YOU KNOW ROUGHLY HOW COMMON UNINTENDED PREGNANCY IS IN WOMEN?

A. UNINTENDED PREGNANCY IN THE UNITED STATES IS QUITE PREVALENT. AT THE TIME THE COMMITTEE WAS MEETING, 49 PERCENT OF ALL U.S. PREGNANCIES WERE UNINTENDED, AND THAT MEANS THEY WERE EITHER MISTIMED OR NOT WANTED BY

THE WOMAN AT THE TIME THAT SHE BECAME PREGNANT.

Q. YOU SAID THAT IT WAS 49 PERCENT AT THE TIME THE COMMITTEE MET. DO YOU KNOW IF IT HAS CHANGED TODAY?

A. IT CHANGED. IT WENT UP TO 51 PERCENT IN 2008, AND THEN SINCE 2008, IT HAS DECLINED. IT IS NOW AT 45 PERCENT.

Q. AND IS THAT -- THE 45 PERCENT NUMBER, IS THAT AS OF TODAY? DO YOU KNOW WHEN THAT NUMBER --

A. THAT IS AS OF 2011. THERE IS ALWAYS A GAP BETWEEN DATA COLLECTION AND WHEN WE KNOW THE EXACT RATES. SO THAT IS THE MOST RECENT DATA THAT WE HAVE.

Q. AM I CORRECT THAT IN 2011 THAT 45 PERCENT NUMBER HAD GONE DOWN BEFORE THE CONTRACEPTIVE CARE MANDATE WENT INTO EFFECT?

A. CORRECT.

Q. DO YOU KNOW WHY THE 45 -- THE NUMBER DECREASED BEFORE THE CONTRACEPTIVE CARE MANDATE?

A. THERE WAS AN ARTICLE PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE IN 2016 BY FINER AND ZOLNA THAT ANALYZED THAT DECLINE IN THE UNINTENDED PREGNANCY RATE FROM THE HIGH OF 51 PERCENT TO 45 PERCENT, AND IT ATTRIBUTED THE DECLINE TO IMPROVED ACCESS TO CONTRACEPTION AND WOMEN USING MORE EFFECTIVE CONTRACEPTION.

Q. BUT HOW WAS THAT SO GIVEN THAT THAT WAS BEFORE

THE CONTRACEPTIVE CARE MANDATE WENT INTO EFFECT?

A. BECAUSE IN THAT PERIOD OF TIME, INCREASING NUMBERS OF EMPLOYER-BASED PLANS AND OTHER PLANS WERE BEGINNING TO COVER CONTRACEPTION AS A RESULT, IT'S MY UNDERSTANDING, OF STATE LEGISLATION AND CASES INVOLVING DISCRIMINATION IN PRESCRIPTION DRUG COVERAGE.

Q. SO THEN INCREASED ACCESS TO CONTRACEPTION LOWERED THE RATE OF UNINTENDED PREGNANCY?

A. THAT WAS THE INTERPRETATION OF THESE AUTHORS, YES.

Q. IS AN UNINTENDED PREGNANCY A BAD THING? DOES IT MATTER?

A. UNINTENDED PREGNANCY HAS A NUMBER OF NEGATIVE CONSEQUENCES. TO BEGIN WITH, 42 PERCENT OF UNINTENDED PREGNANCIES RESULT IN ABORTION. OF THOSE PREGNANCIES THAT CONTINUE, THERE IS A LOT OF EVIDENCE OF NEGATIVE HEALTH CONSEQUENCES FOR THE WOMEN AND FOR THE BABIES.

WOMEN, FOR EXAMPLE, CAN BECOME DEPRESSED DURING AN UNINTENDED PREGNANCY. THEY MIGHT NOT HAVE GONE INTO THE PREGNANCY WITH OPTIMAL HEALTH STATUS. FOR EXAMPLE, A DIABETIC WOMAN WHO HAS AN UNINTENDED PREGNANCY MIGHT NOT HAVE HAD HER GLUCOSE LEVELS UNDER CONTROL AT THE TIME THAT SHE BECAME PREGNANT, LEADING TO POTENTIAL CONSEQUENCES DURING THE PREGNANCY.

UNINTENDED PREGNANCIES OFTEN RESULT IN

DELAYED ENTRY INTO PRENATAL CARE BECAUSE THE WOMAN WAS NOT EXPECTING TO BECOME PREGNANT, MAY NOT HAVE REALIZED SHE WAS PREGNANT IN TIME TO GET OPTIMAL PRENATAL CARE.

THERE ARE ALSO A NUMBER OF STUDIES THAT SHOW THAT BABIES BORN OF UNINTENDED PREGNANCIES ARE MORE LIKELY TO BE BORN PRETERM OR WITH LOW BIRTH WEIGHT.

AND IN ADDITION TO THE HEALTH CONSEQUENCES, UNINTENDED PREGNANCIES ARE KNOWN TO BE DISRUPTIVE OF WOMEN'S PLANS FOR EDUCATION, FOR WORK, AND FOR SPACING THEIR CHILDREN, AND THEREFORE, CAN HAVE NEGATIVE ECONOMIC CONSEQUENCES FOR THE WOMAN AND HER FAMILY.

Q. SO WHO IS AT RISK FOR HAVING AN UNINTENDED PREGNANCY?

A. SO REALLY, ANY WOMAN OF REPRODUCTIVE CAPACITY WHO IS HAVING SEXUAL RELATIONS WITH MEN IS AT RISK OF AN UNINTENDED PREGNANCY.

Q. ARE THERE SOME WHO ARE MORE IMPACTED THAN OTHERS? ARE THERE CERTAIN RISK GROUPS?

A. UNINTENDED PREGNANCIES TEND TO BE MORE COMMON IN YOUNGER WOMEN AND LOW INCOME WOMEN AND WOMEN WITH LOWER EDUCATIONAL LEVELS.

Q. AM I AT RISK FOR UNINTENDED PREGNANCY?

A. NO, YOU ARE NOT.

Q. SORRY, I'M A LAWYER, BUT WHY IS THAT?

A. BECAUSE YOU ARE NOT A WOMAN.
Q. SO?
A. YOU DO NOT HAVE THE CAPACITY TO BECOME PREGNANT.
Q. AND CAN UNINTENDED PREGNANCY BE ADDRESSED THROUGH MEDICAL CARE AND PREVENTIVE MEDICAL SERVICES?
A. YES. 95 PERCENT OF UNINTENDED PREGNANCIES OCCUR IN WOMEN WHO ARE EITHER NOT USING CONTRACEPTION OR ARE USING CONTRACEPTION INCONSISTENTLY. AND WE HAVE VERY EFFECTIVE CONTRACEPTIVE METHODS AVAILABLE TODAY.
Q. LET ME TAKE A BRIEF STEP ASIDE FOR A MOMENT AND ASK YOU YOUR SPECIFIC ROLE ON THE COMMITTEE. DID YOU HAVE A SPECIFIC FOCUS WITHIN THE COMMITTEE?
A. NO. AS A MEMBER OF THE COMMITTEE, I PARTICIPATED IN ALL OF THE COMMITTEE DISCUSSIONS AND DELIBERATIONS. AND WHAT WE DID WAS IDENTIFY SOME KEY TOPICS FOR FURTHER INVESTIGATION AND BROKE UP INTO SUBGROUPS TO INVESTIGATE THOSE TOPICS.
Q. WERE YOU PART OF ONE OF THOSE SUBGROUPS OR ONE OR MORE?
A. I WAS PART OF TWO SUBGROUPS, ONE OF WHICH WAS THE SUBGROUP ON CONTRACEPTION AND UNINTENDED PREGNANCY.
Q. WHAT WAS THE OTHER?
A. IT WAS A SUBGROUP ON PRECONCEPTION CARE.
Q. ROUGHLY HOW MANY MEMBERS OF THE COMMITTEE WERE ON THE SUBGROUP INVOLVING CONTRACEPTION?

A. I DON'T REALLY REMEMBER. I WOULD SAY THREE TO FIVE.
Q. AND WAS THERE A ROBUST DISCUSSION ON THE ISSUE OF PREVENTATIVE CARE RECOMMENDATIONS ABOUT CONTRACEPTION?
A. OH, YES.
Q. WERE ANY NEGATIVE SIDE EFFECTS OF CONTRACEPTION CONSIDERED?
A. OH, YES. WE CONSIDERED ALL OF THE LITERATURE BOTH ON EFFECTIVENESS OF CONTRACEPTION, SIDE EFFECTS OF CONTRACEPTION, OTHER BENEFITS OF TAKING CONTRACEPTION THAN PREVENTING PREGNANCY, BECAUSE ALL OF THOSE FACTORS ARE IMPORTANT IN DECISIONS ABOUT USING CONTRACEPTION.
Q. AND IS CONTRACEPTION, IN FACT, EFFECTIVE AT PREVENTING UNINTENDED PREGNANCY?
A. YES, IT IS.
Q. I WOULD LIKE TO DIRECT YOU BACK TO THE REPORT AT EXHIBIT 5 TO PAGE 105. THAT'S TABLE 5.3. AND I'M GOING TO PUT THAT UP ON THE ELMO IF YOU'LL GIVE ME ONE QUICK MOMENT. BUT MY FIRST QUESTION IS, ARE YOU FAMILIAR WITH THIS TABLE?
A. YES. IT'S PAGE 106.
Q. 106. I'M SORRY.
A. YES, I AM. THAT IS IT.
Q. I WAS HOPING YOU COULD BRIEFLY WALK US THROUGH

THAT CHART AND EXPLAIN IT TO US.
A. SURE. SO THESE ARE DATA FROM CONTRACEPTIVE TECHNOLOGY, WHICH IS THE DEFINITIVE SOURCE ABOUT CONTRACEPTIVE EFFECTIVENESS USED BY PHYSICIANS.
AND THESE ARE THE DATA OF AVAILABLE -- ON CONTRACEPTIVE EFFECTIVENESS AT THE TIME THAT THE COMMITTEE WAS MEETING. AND WHAT THIS DOES IS SHOW ALL OF THE METHODS OF CONTRACEPTION AVAILABLE AT THE TIME INCLUDING NONE, AT THE TOP. AND THEN IT DESCRIBES THE EFFECTIVENESS OF EACH CONTRACEPTIVE METHOD BASED ON DATA. AND THE WAY EFFECTIVENESS OF CONTRACEPTION IS LOOKED AT IS BY LOOKING AT FAILURES, WHICH MEANS THE NUMBER OF PREGNANCIES THAT OCCUR IN A YEAR WITH USE OF THAT CONTRACEPTIVE METHOD.
SO THERE ARE TWO COLUMNS IN THE TABLE, THERE IS ONE CALLED TYPICAL USE AND ONE CALLED PERFECT USE. PERFECT USE IS IN A PERFECT WORLD WHERE PEOPLE DON'T MAKE MISTAKES. SO WHAT WE REALLY LOOK AT IS THE TYPICAL USE COLUMN, WHICH IS BASED ON DATA OF ACTUAL BEHAVIOR AND OUTCOMES OF PEOPLE USING CONTRACEPTION. AND WHAT THIS COLUMN SHOWS YOU IS THE NUMBER OF EXPECTED PREGNANCIES IN A YEAR PER 100 WOMEN USING THAT METHOD UNDER THE CONDITIONS OF TYPICAL USE.
Q. SORRY. GO ON.
A. SO IF NO CONTRACEPTION IS USED, WHICH IS THE TOP

ROW, WE WOULD EXPECT TO SEE 85 WOMEN BECOME PREGNANT IN A YEAR.
Q. SO THEN IF WITHDRAWAL WAS USED, AM I CORRECT THAT YOU WOULD EXPECT TO SEE 27 WOMEN GET PREGNANT WITHIN ONE YEAR IF THE WITHDRAWAL METHOD WAS USED?
A. CORRECT. AND THEN GOING DOWN THE COLUMN, WE GET TO THE MOST EFFECTIVE METHODS OF CONTRACEPTION TOWARD THE BOTTOM. AT THE VERY BOTTOM ARE MALE AND FEMALE STERILIZATION, BUT JUST ABOVE THAT ARE IMPLANTS AND INTRAUTERINE DEVICES, WHICH RESULT IN ONE LESS THAN ONE PREGNANCY PER YEAR.
Q. IF I UNDERSTAND THIS CHART CORRECTLY, UNDER INTRAUTERINE DEVICES -- AND THAT IS AN IUD, RIGHT, THAT'S THE SAME THING?
A. CORRECT.
Q. THERE IS ONE CALLED A MIRENA IUD. THAT LOOKS LIKE OUT OF 100 WOMEN WHO ARE USING THAT IN A YEAR, THERE WOULD BE A .2 CHANCE OF GETTING PREGNANT, CORRECT?
A. CORRECT.
Q. AND THAT IS ACTUALLY LESS THAN FEMALE STERILIZATION, CORRECT --
A. YES.
Q. -- ON THE CHART?
A. THAT IS CORRECT.
Q. AND IMPLANTED, WHAT IS THAT?

A. THAT IS THE IMPLANT. THAT IS A HORMONAL CONTRACEPTIVE THAT IS IMPLANTED UNDER THE SKIN.
Q. THERE THAT IS OUT OF A HUNDRED WOMEN, YOU WOULD HAVE .05?
A. RIGHT. THE BOTTOM LINE IS WITH THESE MOST EFFECTIVE METHODS AT THE BOTTOM, YOU WOULD EXPECT TO SEE LESS THAN ONE PREGNANCY IN A YEAR OF USE.
Q. AND --
A. OUT OF 100 WOMEN.
Q. SO THE ONES AT THE BOTTOM, ARE THEY PRESCRIPTION CONTRACEPTIVES?
A. ALL OF THE METHODS OF CONTRACEPTION ARE PRESCRIPTION METHODS WITH THE EXCEPTION OF SPERMICIDES, WITHDRAWAL, FERTILITY AWARENESS METHODS, AND THE SPONGE AND THE CONDOM. ALL THE OTHERS ARE PRESCRIPTION METHODS.
Q. AND NONE I ASSUME ALSO?
A. AND NONE, YES. THANK YOU.
Q. AM I CORRECT, FOR STERILIZATION YOU WOULD NEED A PRESCRIPTION? IS THAT CONSIDERED A PRESCRIPTION?
A. WELL, YES. IT IS A SURGICAL PROCEDURE, SO IT HAS TO BE PROVIDED BY A HEALTHCARE PROFESSIONAL WHO AGREES TO PROVIDE THE SERVICE.
Q. GIVEN THE STUDIES -- SORRY. GIVEN THE COMMITTEE STUDY OF CONTRACEPTION, INCLUDING NEGATIVE HEALTH

EFFECTS AND EFFICACY AS YOU EXPLAINED FROM THAT TABLE, DID THE COMMITTEE MAKE ANY RECOMMENDATION REGARDING CONTRACEPTION?
A. THE COMMITTEE RECOMMENDED THAT ALL FDA, THAT IS FOOD AND DRUG ADMINISTRATION, APPROVED CONTRACEPTIVES SHOULD BE PROVIDED AS PART OF WOMEN'S PREVENTIVE CARE, ALONG WITH COUNSELING REGARDING CONTRACEPTION.
Q. WHAT WAS THE COSTS TO WOMEN SUPPOSED TO BE FOR THIS EXPANDED CARE?
A. WELL, THE COMMITTEE DID NOT DISCUSS THE COST TO WOMEN, BUT WE WERE MAKING RECOMMENDATIONS TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES THAT WOULD THEN DECIDE WHETHER TO ADOPT THESE RECOMMENDATIONS, WHICH WE KNEW WOULD THEN MEAN IF THEY WERE ADOPTED THAT THEY WOULD BECOME PART OF WOMEN'S PREVENTIVE CARE WITHOUT COST SHARING UNDER THE AFFORDABLE CARE ACT.
Q. I WANT TO MAKE SURE I UNDERSTAND THAT CORRECTLY. DID I UNDERSTAND YOU TO SAY THAT BY MAKING THE RECOMMENDATIONS THAT THE FULL RANGE OF THIS CONTRACEPTIVE CARE BE MADE AVAILABLE, INHERENT IN THE RECOMMENDATIONS THAT WOULD BE RECOMMENDED WITHOUT ADDITIONAL COSTS TO WOMEN?
A. WHAT THE COMMITTEE WAS ASKED TO DO WAS RECOMMEND EFFECTIVE PREVENTIVE SERVICES FOR WOMEN THAT OUGHT TO BE PART OF ROUTINE PREVENTIVE CARE. SO WE DETERMINED THAT

CONTRACEPTION IS HIGHLY EFFECTIVE AT PREVENTING UNINTENDED PREGNANCY, WHICH IS A MAJOR WOMEN'S HEALTH PROBLEM, AND THEREFORE OUGHT TO BE PART OF PREVENTIVE CARE.
Q. ARE YOU AWARE WHETHER OR NOT THE COST OF CONTRACEPTION AFFECTS WOMEN'S USE OF CONTRACEPTION?
A. YES.
Q. AND HOW DOES THAT WORK?
A. PRIOR TO THE AFFORDABLE CARE ACT, SOME WOMEN HAD CONTRACEPTIVE COVERAGE, SOME DID NOT. THOSE WHO DID HAVE CONTRACEPTIVE COVERAGE ALWAYS HAD COST SHARING, SO THAT MEANS IF THEY WERE IN AN EMPLOYER-BASED OR OTHER PRIVATE HEALTH PLAN, THEY EITHER PAID A CO-PAY FOR CONTRACEPTIONS, CONTRACEPTIVE SERVICES SUCH AS STERILIZATION WOULD BE APPLIED TO THEIR DEDUCTIBLE. SO TYPICALLY WOMEN WOULD HAVE TO PAY SOMETHING OUT OF POCKET FOR THEIR CONTRACEPTIVE SERVICES.
Q. CO-PAYS ARE GENERALLY PRETTY SMALL, RIGHT?
A. THAT DEPENDS ON THE HEALTH PLAN, AND IT ALSO WOULD DEPEND ON THE NATURE OF THE CONTRACEPTION BEING USED. IF IT IS A MONTHLY METHOD LIKE ORAL CONTRACEPTIVES, THAT MEANS THERE WOULD BE A CO-PAY EVERY TIME A PRESCRIPTION WAS REFILLED. THERE IS AN ABUNDANT BODY OF LITERATURE SHOWING THAT EVEN VERY SMALL CO-PAYS AS SMALL AS $6 CAN DISCOURAGE PEOPLE FROM USING HEALTH

SERVICES.
Q. DO I UNDERSTAND THAT RIGHT, THAT EVEN A $6 CO-PAY COULD MAKE WOMEN OR CAUSE SOME WOMEN TO NOT USE CONTRACEPTION THAT WAS PRESCRIBED BY THEIR DOCTOR THAT THEY WOULD USE OTHERWISE?
A. YES.
MS. KADE: OBJECTION, LEADING.
THE COURT: SUSTAINED.
GO AHEAD. REASK THE QUESTION.
BY MR. GOLDMAN:
Q. IS -- SO WHAT COULD BE THE EFFECT OF EVEN A SMALL $6 CO-PAY?
A. A SMALL $6 CO-PAY TO A LOW INCOME WOMAN COULD MEAN THAT SHE DIDN'T HAVE -- WOULD NOT HAVE THE MONEY TO RENEW A PRESCRIPTION FOR BIRTH CONTROL PILLS, FOR EXAMPLE.
Q. SO BASED ON THE CHART THEN ON PAGE 106 OF TABLE 5.3, IS THAT IF A WOMAN HAD A $6 CO-PAY, DID NOT RENEW THE PRESCRIPTION AND DID NOT USE CONTRACEPTION, AM I RIGHT THAT HER RATE OF UNINTENDED PREGNANCY WITHIN ONE YEAR WOULD GO TO AN 85 PERCENT CHANCE?
A. WELL, IF SHE USED ORAL CONTRACEPTIVES INCONSISTENTLY BECAUSE SHE DID NOT RENEW A PRESCRIPTION OR IF SHE DISCONTINUED USE OF ORAL CONTRACEPTIVES BECAUSE SHE COULD NOT AFFORD TO RENEW HER PRESCRIPTIONS,

HER RISK OF UNINTENDED PREGNANCY WOULD INCREASE, YES.
Q. TO 85 PERCENT IF NO CONTRACEPTION WAS USED?
A. THAT I DON'T KNOW.
Q. I WOULD LIKE TO REFER YOU TO PAGE 107 ON THE CHART, SPECIFICALLY THE LAST FULL PARAGRAPH.
A. YES.
Q. I'M GOING TO PLACE THAT UP ON THE ELMO. I WOULD LIKE YOU TO TAKE A MOMENT TO READ THAT PARAGRAPH. AND IF I MAY, I WILL SORT OF READ IT ALONG WITH YOU:
ALTHOUGH IT IS BEYOND THE SCOPE OF THE COMMITTEE'S CONSIDERATION, IT SHOULD BE NOTED THAT CONTRACEPTION IS HIGHLY COST EFFECTIVE. THE DIRECT MEDICAL COSTS OF UNINTENDED PREGNANCY IN THE UNITED STATES WAS ESTIMATED TO BE NEARLY 5 BILLION IN 2002 WITH COST SAVINGS DUE TO CONTRACEPTIVE USE ESTIMATED TO BE AT 19.3 BILLION. THEN IT SAYS IN PARENTHESES TRUSSELL 2007.
WHAT DOES THAT REFER TO?
A. WELL, THAT REFERS TO A STUDY OF THE POTENTIAL SAVINGS IN PUBLIC AND PRIVATE DOLLARS TO AVERTING UNINTENDED PREGNANCIES AT THE NATIONAL LEVEL.
Q. SO THAT IS A CITATION TO BACK UP THE PREMISE?
A. CORRECT. TRUSSELL IS THE AUTHOR, YES.
Q. AND THEN IT SAYS: THE COST EFFECTIVENESS OF FAMILY PLANNING IS ALSO DOCUMENTED IN AN EVALUATION OF FAMILY PACT, CALIFORNIA'S 1115 MEDICAID FAMILY PLANNING

WAIVER PROGRAM. THE UNINTENDED PREGNANCIES AVERTED IN THIS PROGRAM IN 2002 WOULD HAVE COST THE STATE $1.1 BILLION WITHIN TWO YEARS AND $2.2 BILLION WITHIN FIVE YEARS FOR PUBLIC SECTOR HEALTH AND SOCIAL SERVICES THAT OTHERWISE WOULD HAVE BEEN NEEDED.
AND IS THAT ANOTHER CITATION TO PROVE THAT PREMISE?
A. YES. THAT IS A STATE LEVEL STUDY.
Q. SO YOU HAD TOLD THE COURT THAT YOU WERE INSTRUCTED TO NOT CONSIDER COSTS, AND YET THIS PARAGRAPH SEEMS TO TALK ABOUT COSTS, AND I WAS WONDERING WHY THAT IS?
A. THE COMMITTEE DECIDED, SINCE THERE WAS A BODY OF LITERATURE ASSESSING THE COST EFFECTIVENESS OF CONTRACEPTION, TO PUT THE INFORMATION INTO OUR REPORT FOR THE DECISION-MAKERS WHO WERE GOING TO LOOK AT THE REPORT AND DECIDE WHETHER TO APPROVE THE RECOMMENDATIONS OR NOT. WE WANTED THE INFORMATION TO BE AVAILABLE TO THE DECISION-MAKERS.
Q. IF I MAY DIRECT YOU TO PAGE 109. I WOULD LIKE TO, IF I MAY, DIRECT YOU TO THAT MIDDLE PARAGRAPH?
A. DESPITE INCREASES?
Q. YES, THAT IS THE ONE.
THAT PARAGRAPH ALSO TALKS ABOUT COSTS, DOESN'T IT?

A. YES, IT DOES.
Q. AND WITHOUT READING THE WHOLE THING BECAUSE I KNOW THE COURT HAS IT, DOES THAT TALK ABOUT WHAT YOU WERE JUST TELLING THE COURT BEFORE ABOUT THE EFFECT OF CO-PAYMENTS IN AFFECTING WOMEN'S CONTRACEPTIVE CHOICES?
A. YES. AND IT SPECIFICALLY POINTS OUT TOWARD THE BOTTOM OF THE PARAGRAPH THAT IT WAS KNOWN AT THE TIME BECAUSE OF RECENT STUDIES THAT COST SHARING WAS A BARRIER TO WOMEN CHOOSING THE MOST EFFECTIVE FORMS OF CONTRACEPTION, THE IUD'S AND THE IMPLANTS.
Q. AND AM I CORRECT THAT THERE ARE CITATIONS TO EVIDENCE IN THIS PARAGRAPH AS WELL, TO HUDMAN AND O'MALLEY, A 2003, I ASSUME IT'S A PAPER; TRIVEDI, ET AL., 2008; AND THEN A RECENT STUDY CONDUCTED BY KAISER PERMANENTE?
A. CORRECT.
Q. WAS ALL THAT OBJECTIVE EVIDENCE THAT THE COMMITTEE BASED ITS FINDINGS ON?
A. YES. THIS EVIDENCE DOES NOT HAVE TO DO WITH THE EFFECTIVENESS OF CONTRACEPTION. THIS EVIDENCE HAS TO DO WITH HOW WOMEN'S CONTRACEPTIVE CHOICES MIGHT BE AFFECTED IF COST SHARING WERE ELIMINATED.
Q. I WANT TO TURN YOUR ATTENTION TO SORT OF THE FINALIZATION OF THE REPORT. BEFORE THE COMMITTEE FINALIZED ITS REPORT, DID ANYONE NOT ON THE COMMITTEE

REVIEW IT?
A. YES. WHEN THE COMMITTEE HAD FORMALIZED ITS FINAL DRAFT OF THE REPORT, IT WAS REVIEWED BY A GROUP OF OUTSIDE EXPERTS WHOSE NAMES ARE LISTED IN THIS DOCUMENT. DO YOU KNOW THE PAGE?
Q. I DO. IF I MAY DIRECT YOU AND THE COURT TO THE BEGINNING OF ROMAN -- SMALL ROMAN 7 THROUGH SMALL ROMAN 8.
THE COURT: WHAT PAGES ARE WE ON?
THE WITNESS: ROMAN NUMERAL 7 AND 8, AT THE VERY BEGINNING.
BY MR. GOLDMAN:
Q. SO ARE THERE APPROXIMATELY 11 OUTSIDE REVIEWERS WHO REVIEWED THIS --
A. YES.
Q. -- REPORT.
I WOULD ALSO LIKE TO DIRECT YOU TO PAGE 231 OF THE REPORT, IF I MAY. IT'S APPENDIX D. IT'S ENTITLED DISSENT AND RESPONSE. DO YOU SEE THAT?
A. YES.
Q. AM I CORRECT THAT A MEMBER OF THE COMMITTEE DISSENTED FROM THE REPORT?
A. YES.
Q. DO YOU KNOW WHY -- WAS THAT PERSON A MR. SASSO OR DR. SASSO MAYBE?

A. YES. DR. LO SASSO.
Q. DO YOU KNOW WHY HE DISSENTED?
A. DR. LO SASSO IS AN ECONOMIST, AND AS HIS DISSENT DESCRIBES, HIS MAIN OBJECTION TO THE REPORT WAS THAT HE WOULD HAVE PREFERRED THAT THE COMMITTEE CONSIDER COSTS AND COST EFFECTIVENESS IN MAKING ITS RECOMMENDATIONS.
HE ALSO WOULD HAVE PREFERRED THAT THE COMMITTEE HAD MORE TIME, AND HE CRITICIZES THE COMMITTEE'S DECISION-MAKING AS BEING NOT EVIDENCE-BASED.
MS. KADE: OBJECTION, YOUR HONOR. THE QUESTION DOES NOT NECESSARILY ASK FOR HEARSAY BUT THE ANSWER HAS PROVIDED HEARSAY.
THE COURT: SUSTAINED. I WILL NOT TAKE THAT INTO ACCOUNT.
BY MR. GOLDMAN:
Q. DID THAT DISSENT, WAS THAT FOCUSED ON ONE OF THE EIGHT RECOMMENDATIONS INVOLVING CONTRACEPTION OR DID IT APPLY TO THE ENTIRE COMMITTEE REPORT?
A. THE DISSENT APPLIED TO THE ENTIRE REPORT.
Q. AND WHAT, IF ANYTHING, DID YOU THINK OF DR. LOSASSO'S DISSENT?
A. WELL, I AND THE OTHER COMMITTEE MEMBERS DISAGREED WITH THE DISSENT.
Q. AND WHY IS THAT?
A. WELL, ON THE FIRST POINT, WE HAD SPECIFICALLY

BEEN TOLD IN OUR CHARGE THAT OUR JOB WAS NOT TO CONSIDER COST EFFECTIVENESS OF THESE SERVICES BUT TO LOOK ONLY AT EFFECTIVENESS, IN OTHER WORDS, DO THEY IMPROVE HEALTH.
AND OF COURSE, THE AMOUNT OF TIME THAT THE COMMITTEE HAD TO WORK WAS OUT OF OUR CONTROL, AND WE FELT THAT WE HAD BEEN VERY EVIDENCE BASED IN OUR DELIBERATIONS.
MS. KADE: YOUR HONOR, WE OBJECT TO THE EXTENT THAT DR. WEISMAN IS SPEAKING FOR ANYONE OTHER THAN HERSELF.
THE COURT: SUSTAINED.
BY MR. GOLDMAN:
Q. IF I MAY DIRECT YOU TO PAGE 235, A FEW PAGES IN AT THE BOTTOM, IT SAYS "RESPONSE TO DISSENTING STATEMENT."
DO YOU SEE THAT?
A. YES.
Q. AND THERE ARE A BUNCH OF NAMES AT THE TOP.
WHO ARE THOSE PEOPLE?
A. THOSE ARE ALL THE MEMBERS OF THE COMMITTEE OTHER THAN DR. LO SASSO, AND THAT IS OUR RESPONSE TO HIS DISSENT.
Q. YOUR NAME IS LAST AGAIN, HUH?
A. YEP.
Q. SO WHAT HAPPENED TO THIS REPORT AFTER THE

COMMITTEE WAS FINISHED WITH IT?
A. THE COMMITTEE'S REPORT WENT TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, WHO ACCEPTED THE RECOMMENDATIONS.
Q. ALL EIGHT OF THEM?
A. YES.
Q. IF YOU KNOW, WHEN YOU SAY THAT HRSA ACCEPTED THE RECOMMENDATIONS, DO YOU KNOW IF THAT HAD ANY EFFECT ON THE AFFORDABLE CARE ACT?
A. IT IS MY UNDERSTANDING THAT WHEN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ACCEPTED THESE RECOMMENDATIONS, THEY THEN BECAME PART OF THE AFFORDABLE CARE ACT DESIGNATED PREVENTIVE SERVICES TO BE COVERED WITHOUT COST SHARING.
Q. AND THAT IS THE LAW THEN, CORRECT?
A. THAT IS MY UNDERSTANDING.
Q. I'D LIKE TO TURN YOUR ATTENTION NOW TO THE RULES WHICH ARE AT ISSUE IN THIS PARTICULAR MATTER. ARE YOU GENERALLY FAMILIAR WITH THESE NEW RULES?
THE COURT: BEFORE YOU GO THERE, MR. GOLDMAN. IF YOU ARE GOING TO GET INTO THIS EITHER LATER ON WITH THIS WITNESS OR WITH ANOTHER WITNESS, PLEASE STOP ME. I WANT TO FOCUS IN ON PENNSYLVANIA. IS THAT SOMETHING THAT YOU INTEND TO RAISE WITH THIS WITNESS LATER ON?

MR. GOLDMAN: IT IS IN SOME WAY, BUT IF YOUR HONOR HAS QUESTIONS --
THE COURT: WELL, LET'S TALK ABOUT -- YOU TALKED ABOUT DATA, AND YOU SAID, I THINK, THAT THE LATEST DATA YOU COULD GET WAS 2011 BECAUSE THE DATA TAKES SOME TIME TO ROLL IN, CORRECT?
THE WITNESS: THE DATA ON UNINTENDED PREGNANCIES?
THE COURT: UNINTENDED PREGNANCIES, OKAY. SO HAVE YOU, EITHER IN THIS CONTEXT OR OUTSIDE OF THIS CONTEXT, LOOKED INTO DATA WITH RESPECT TO UNINTENDED PREGNANCIES IN PENNSYLVANIA?
THE WITNESS: YES.
THE COURT: AND TELL ME THE PERCENTAGE. WHAT IS THE PERCENTAGE OF UNINTENDED PREGNANCIES IN PENNSYLVANIA?
THE WITNESS: IT'S CLOSE TO THE NATIONAL AVERAGE. IT MIGHT BE A LITTLE BIT LOWER, AND I CANNOT REMEMBER THE CURRENT NUMBER.
THE COURT: FAIR TO SAY SOMEWHERE BETWEEN 45 AND 49 PERCENT?
THE WITNESS: THE NATIONAL RATE CURRENTLY IS 45 PERCENT. WE ARE A LITTLE BIT LOWER IN PENNSYLVANIA.
THE COURT: SO SOMEWHERE BETWEEN 40 AND

45 PERCENT?
THE WITNESS: I THINK SO.
THE COURT: AND WHEN YOU SAY YOU THINK SO, WHAT DEGREE OF CERTAINTY DO YOU BRING TO THAT "I THINK SO"?
THE WITNESS: PRETTY CERTAIN. THE GUTTMACHER INSTITUTE PUBLISHES THE STATE-BY-STATE DATA. SO IT WOULD BE EASY TO CHECK ON.
THE COURT: IS THERE ANY POSSIBILITY THAT IT IS BELOW 40 PERCENT?
THE WITNESS: IT COULD BE IN THE HIGH THIRTIES, I'M NOT TOTALLY SURE.
THE COURT: SO IF I WERE TO SAY IT'S SOMEWHERE BETWEEN 35 PERCENT AND 45 PERCENT, THAT WOULD BE ABOUT RIGHT?
THE WITNESS: YES.
THE COURT: OKAY. HAVE YOU DONE ANY RESEARCH INTO THE COSTS OF UNINTENDED PREGNANCIES IN PENNSYLVANIA?
THE WITNESS: I HAVE INVESTIGATED ESTIMATES OF COSTS, BUT NOT RECENTLY.
THE COURT: OKAY. AND WHAT ABOUT HAVE YOU INVESTIGATED THE IMPACT OF PROVIDING NO COST CONTRACEPTION TO WOMEN IN PENNSYLVANIA?
THE WITNESS: YES.

THE COURT: TELL ME ABOUT THAT.
THE WITNESS: SO WE AT PENN STATE DID A RECENT STUDY OF A COHORT OF PRIVATELY-INSURED WOMEN WHO HAD EMPLOYER-BASED HEALTH INSURANCE IN PENNSYLVANIA, AND IN A TWO-YEAR PERIOD FOLLOWING THE PASSAGE OF THE AFFORDABLE CARE ACT, WHICH MEANT THAT THEY ALL HAD CO-PAY -- NO CO-PAYS FOR CONTRACEPTION, THEIR USE OF IUD'S AND IMPLANTS, WHICH ARE THE MOST EFFECTIVE REVERSIBLE FORMS OF CONTRACEPTION, MORE THAN DOUBLED.
THE COURT: SO LOOKING AT YOUR CHART THAT SHOWED THE EFFECTIVENESS OF VARIOUS FORMS OF CONTRACEPTION, IUD'S ARE --
MR. GOLDMAN: PAGE 106, AND IT IS ON THE ELMO, YOUR HONOR.
THE COURT: WHERE DOES IT SAY -- I DON'T SEE THE WORDS IUD.
THE WITNESS: INTRAUTERINE DEVICES, SIX LINES UP.
THE COURT: OKAY. SO DEPENDING ON WHETHER IT'S PARAGARD OR MIRENA --
THE WITNESS: CORRECT.
THE COURT: -- IT'S EITHER -- UNDER "TYPICAL USE," IT'S EITHER .8 OR .20.
THE WITNESS: CORRECT.
THE COURT: AND --

THE WITNESS: AND THE IMPLANT IS RIGHT BELOW THAT.
THE COURT: OKAY. WAS THERE ANY INDICATION, WAS THERE ANY CONTROL DATA SHOWING WHAT THESE WOMEN HAD USED PRIOR TO USING IUD'S?
THE WITNESS: YES, WE KNEW THAT FROM THE STUDY, AND MOST OF THEM HAD BEEN USING BIRTH CONTROL PILLS, BUT SOME HAD BEEN USING NOTHING OR A COMBINATION.
THE COURT: WHEN YOU SAY "MOST," DO YOU RECALL APPROXIMATELY HOW MANY PERCENTAGE WERE USING BIRTH CONTROL PILLS?
THE WITNESS: NO, I DON'T.
THE COURT: BUT THERE IS A DISTINCTION -- I LOOK AT THE BIRTH CONTROL PILLS, IS THAT -- WHERE DO I FIND THAT?
THE WITNESS: SO THAT IS THE "COMBINED PILL AND PROGESTIN-ONLY PILL" WHICH WOULD PRODUCE EIGHT PREGNANCIES PER YEAR OUT OF 100 WOMEN.
THE COURT: SO THERE IS A REDUCTION IN -- TO THE EXTENT YOU CAN HAVE A .2 PREGNANCY, EITHER YOU ARE PREGNANT OR YOU ARE NOT PREGNANT, BUT IT IS, WHAT, A 7.2 REDUCTION --
THE WITNESS: YEAH. I MEAN, ESTIMATING, IT'S ALMOST AN EIGHTFOLD INCREASE, SLIGHTLY LESS THAN THAT RISK.

THE COURT: IF ONE WERE TO USE BIRTH CONTROL RATHER THAN IUD'S?
THE WITNESS: CORRECT.
THE COURT: SO LOOKING AT --
THE WITNESS: IN REDUCING THE RISK.
THE COURT: REDUCING THE RISK BY ABOUT EIGHT PERCENT IF ONE WERE TO USE INTRAUTERINE DEVICES.
THE WITNESS: CORRECT.
THE COURT: SO WHY -- DID YOU REACH ANY CONCLUSIONS AS TO WHY THESE WOMEN WOULD MOVE TO USING IUD'S RATHER THAN OTHER FORMS OF BIRTH CONTROL?
THE WITNESS: YES. BECAUSE HISTORICALLY, COST HAS BEEN A BARRIER TO ADOPTING THESE MOST EFFECTIVE METHODS BECAUSE THE UPFRONT COST OF GETTING AN IUD OR AN IMPLANT IS CONSIDERABLE. AN IUD CAN COST UP TO A THOUSAND DOLLARS, WHEN YOU CONSIDER THE COST OF THE DEVICE ITSELF AND THE VISIT TO HAVE THE DEVICE IMPLANTED. AND AN IMPLANT I BELIEVE COSTS UP TO $500 UP FRONT, AND MANY WOMEN SIMPLY DON'T HAVE THAT KIND OF MONEY TO PAY OUT OF POCKET.
THE COURT: YOU INDICATED THAT THIS STUDY WAS PERFORMED RECENTLY. HOW RECENTLY?
THE WITNESS: BETWEEN 2012 AND 2014.
THE COURT: AND WHAT WAS THE COHORT OF WOMEN IN THE STUDY?

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THE WITNESS: IT WAS ABOUT -- OVER 900 PRIVATELY-INSURED WOMEN IN PENNSYLVANIA.

THE COURT: AND YOU AND WHO ELSE DID THE STUDY?

THE WITNESS: COLLEAGUES AT PENN STATE COLLEGE OF MEDICINE, DR. CYNTHIA CHUANG AND OTHERS.

THE COURT: WAS IT PUBLISHED?

THE WITNESS: SOME RESULTS FROM THAT STUDY HAVE BEEN PUBLISHED. THE RESULT I JUST CITED TO YOU HAS NOT YET BEEN PUBLISHED BECAUSE THAT PAPER IS STILL IN PREPARATION.

THE COURT: IF YOU WANT TO FOLLOW UP ON THE QUESTIONS I HAVE ASKED IN THIS PARTICULAR AREA, FEEL FREE IF YOU THINK I'VE MISSED SOMETHING.

MR. GOLDMAN: I THOUGHT YOU DID AN EXCELLENT JOB.

THE COURT: WELL, I APPRECIATE IT.

BY MR. GOLDMAN:

Q. IF I MAY, THE STUDY YOU JUST SPOKE ABOUT CONCERNED ONLY WOMEN IN PENNSYLVANIA.

HAVE YOU BEEN INVOLVED IN ANOTHER STUDY OF LATE INVOLVING -- BASED ON CLAIMS DATA WITH A LARGER COHORT OF WOMEN, NOT JUST IN PENNSYLVANIA BUT AROUND THE COUNTRY?

A. YES. WE HAVE JUST RECENTLY CONCLUDED A NATIONAL

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STUDY OF PRIVATELY-INSURED WOMEN USING A HEALTH CLAIMS DATABASE CALLED MARKETSCAN. AND WE WERE ABLE TO LOOK AT TRENDS IN CONTRACEPTIVE USE FROM 2006 THROUGH 2014. AND AS PART OF THAT ANALYSIS, WE FIRST OF ALL LOOKED AT COSTS TO WOMEN, WHICH DECLINED PRECIPITOUSLY TO ZERO, BASICALLY, AFTER THE AFFORDABLE CARE ACT MANDATE WENT INTO EFFECT.

WE ALSO LOOKED AT THE METHODS OF CONTRACEPTION THAT THEY USED OVER THIS TIME PERIOD, AND WE WERE ABLE TO SHOW THAT AFTER THE AFFORDABLE CARE ACT MANDATE WENT INTO EFFECT, THERE WAS A SIGNIFICANT INCREASE IN THE USE OF IUD'S AND IMPLANTS AMONG THESE INSURED WOMEN.

Q. AND THAT STUDY WAS BASED ON CLAIMS DATA?

A. CORRECT.

Q. IS CLAIMS DATA A RELIABLE WAY TO STUDY THIS SORT OF THING?

A. SOME PEOPLE THINK IT'S THE MOST RELIABLE WAY TO STUDY THE USE OF PRESCRIPTION MEDICATIONS IN GENERAL BECAUSE EVERY TIME A PRESCRIPTION IS PROVIDED THERE IS A CLAIM GENERATED, AND SO IT IS A GOOD WAY TO FOLLOW PATTERNS OF PRESCRIBING AND USE OF MEDICATIONS.

Q. AND WHAT STATES WAS THE CLAIMS DATA FROM THE STUDY FROM, IF YOU KNOW?

A. IT'S A NATIONAL DATABASE, SO EMPLOYER-BASED

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INSURERS FROM ALL OVER THE COUNTRY PUT THEIR CLAIMS INTO THIS DATABASE. AND I THINK IT IS MOST STATES BUT I CAN'T SAY DEFINITIVELY.

Q. DO YOU KNOW IF PENNSYLVANIA WAS ONE OF THE STATES INCLUDED?

A. YES, IT WAS.

Q. IF I MAY TAKE YOU TO THE RULES NOW THAT ARE AT ISSUE BEFORE THE COURT. AND I WILL -- I DON'T THINK WE HAVE TO LOOK AT THEM SPECIFICALLY HERE, BUT I WOULD LIKE TO NOTE THAT THE RELIGIOUS EXEMPTION RULE IS MARKED AND ADMITTED AS EXHIBIT 1. THE MORAL EXEMPTION RULE IS EXHIBIT 2.

I KNOW THEY ARE LONG, BUT HAVE YOU HAD OCCASION TO READ THE RELIGIOUS EXEMPTION RULE?

A. YES.

Q. AND DO YOU BELIEVE YOU UNDERSTAND IT?

A. I UNDERSTAND PARTS OF IT.

Q. DO YOU UNDER -- DO YOU BELIEVE YOU UNDERSTAND IT SO FAR AS IT WOULD AFFECT WOMEN'S CONTRACEPTIVE CARE?

A. YES.

Q. DO YOU -- HAVE YOU ALSO SIMILARLY READ THE MORAL EXEMPTION RULE?

A. YES.

Q. AND DO YOU SIMILARLY BELIEVE THAT YOU UNDERSTAND IT AS IT WOULD IMPACT WOMEN'S CONTRACEPTIVE CHOICES?

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A. YES.

Q. IN YOUR CAPACITY AS AN EXPERT IN THE FIELD OF PREVENTIVE MEDICAL CARE FOR WOMEN, INCLUDING CONTRACEPTIVE CARE, DO YOU HAVE AN OPINION TO A REASONABLE DEGREE OF CERTAINTY AS TO THE LIKELY EFFECT OF THE RULES ON THE HEALTH OF WOMEN IN PENNSYLVANIA?

A. YES.

Q. AND WHAT IS THAT OPINION?

A. THESE RULES OPEN UP THE OPPORTUNITY FOR MORE EMPLOYERS TO OPT OUT OF CONTRACEPTIVE COVERAGE WITHOUT CO-PAYS BY WOMEN. AND WE KNOW FROM A LARGE BODY OF RESEARCH INVOLVING USE OF HEALTHCARE IN GENERAL AND CONTRACEPTION IN PARTICULAR THAT EVEN VERY SMALL CO-PAYS CAN DISCOURAGE USE.

SO IF WOMEN WHO HAVE HAD CO-PAYS UNDER THE AFFORDABLE CARE ACT WERE -- SUDDENLY HAD THAT BENEFIT REMOVED, I FEEL BASED ON WHAT I KNOW OF THIS LITERATURE THAT WE WOULD SEE MORE WOMEN FAILING TO RENEW THEIR PILL PRESCRIPTIONS, NOT OPTING FOR A MORE EFFECTIVE METHOD THAT WOULD HAVE HIGHER UPFRONT COSTS, AND AS A RESULT OF THAT, WE WOULD EXPECT TO SEE AN INCREASE IN THE UNINTENDED PREGNANCY RATE AND MORE ABORTIONS.

Q. DID THAT OPINION YOU SO CLEARLY EXPRESSED, DOES THAT ALSO HOLD TRUE FOR WOMEN OUTSIDE OF PENNSYLVANIA

AND AROUND THE COUNTRY?
A. YES.
Q. DO YOU HOLD ALL OF YOUR OPINIONS THAT YOU HAVE SHARED WITH THE COURT TODAY WITHIN A REASONABLE DEGREE OF CERTAINTY FOR AN EXPERT IN PREVENTIVE MEDICAL CARE FOR WOMEN, INCLUDING CONTRACEPTIVE CARE?
A. YES.
MR. GOLDMAN: YOUR HONOR, IF I MAY HAVE ONE MOMENT TO CONSULT WITH MY CO-COUNSEL.
THE COURT: YES.
MR. GOLDMAN: YOUR HONOR, NOTHING FURTHER WITH THIS WITNESS.
THE COURT: MS. KADE.
MS. KADE: THANK YOU, YOUR HONOR.
PERMISSION TO APPROACH, YOUR HONOR.
THE COURT: YOU MAY.
MS. KADE: THANK YOU, YOUR HONOR.

CROSS EXAMINATION

BY MS. KADE:
Q. DR. WEISMAN, GOOD MORNING.
A. GOOD MORNING.
Q. MY NAME IS ELIZABETH KADE. HOW ARE YOU DOING THIS MORNING?
A. GOOD, THANKS.
Q. FIRST, WHAT DOCUMENTS DID YOU REVIEW IN ORDER TO

PROVIDE YOUR DECLARATION -- TO PREPARE YOUR DECLARATION?
A. MY CV, AND I REREAD THE IOM COMMITTEE REPORT, AND RE-FAMILIARIZED MYSELF WITH SOME OF THE REFERENCES IN THAT REPORT.
Q. IS THAT EVERYTHING?
A. I BELIEVE SO.
Q. AND WHO DID YOU MEET WITH IN ORDER TO PREPARE YOUR DECLARATION?
A. I SPOKE ON THE PHONE WITH JONATHAN AND NICOLE. THAT'S IT.
THE COURT: AND BY JONATHAN AND NICOLE, YOU MEAN JONATHAN GOLDMAN AND NICOLE BOLAND?
THE WITNESS: YES.
THE COURT: THANK YOU. MAKING SURE THE RECORD IS CLEAN.
BY MS. KADE:
Q. TURNING TO YOUR DECLARATION, LOOKING AT PARAGRAPH 44, YOU HAVE TESTIFIED THAT IT IS YOUR OPINION THAT THE NEW RULES WILL CAUSE IMMEDIATE AND IRREVERSIBLE HARM BECAUSE THEY WILL CAUSE WOMEN TO LOSE PREVENTIVE CONTRACEPTIVE CARE UNDER THEIR EMPLOYER GROUP --
I APOLOGIZE. YOU TESTIFIED THAT IT IS YOUR OPINION THAT THE NEW RULES WILL CAUSE IMMEDIATE AND IRREVERSIBLE HARM BECAUSE THEY WILL CAUSE WOMEN TO LOSE PREVENTIVE CONTRACEPTION CARE UNDER THEIR EMPLOYER GROUP

HEALTH PLANS, CORRECT?
A. YES.
Q. DO YOU KNOW HOW MANY RELIGIOUS EMPLOYERS ARE CURRENTLY PROTECTED BY INJUNCTION?
A. I DO NOT. I HAVE SEEN AN ESTIMATE THAT 10 PERCENT OF NONPROFITS HAVE CLAIMED THE EXEMPTION UNDER THE EXISTING RULES.
Q. SO THIS IS BEFORE THE NEW RULES THAT JUST WENT INTO EFFECT. CORRECT?
A. YES, CORRECT.
Q. DO YOU -- AND SO YOU KNOW THAT THE EMPLOYERS THAT ARE PROTECTED BY INJUNCTIONS ARE NOT CURRENTLY PROVIDING CONTRACEPTIVE COVERAGE, CORRECT?
A. YES.
Q. DO YOU KNOW ABOUT THE 2016 ZUBIK INJUNCTION?
A. ONLY IN VERY GENERAL TERMS. I AM NOT A LAWYER.
Q. I APPRECIATE THAT, THANK YOU.
DO YOU HAVE ANY REASON TO DOUBT THAT THERE WAS ANOTHER INJUNCTION IN 2016 THAT WE'RE REFERRING TO COLLECTIVELY AS THE ZUBIK INJUNCTION?
A. NO.
Q. DO YOU KNOW THAT THE ENTITIES PROTECTED BY THE ZUBIK INJUNCTION ARE ALSO NOT CURRENTLY PROVIDING CONTRACEPTIVE COVERAGE?
A. YES.

Q. WHEN WAS THE "MY NEW OPTIONS" STUDY THAT YOU WERE REFERRING TO EARLIER, WHEN WAS THAT CONDUCTED?
A. THAT WAS CONDUCTED IN 2012 -- 2012 THROUGH 2014.
Q. CAN YOU IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS LOST COVERAGE AS A RESULT OF THE NEW RULES?
A. NO.
Q. CAN YOU IDENTIFY A SINGLE WOMAN IN THE UNITED STATES WHO HAS LOST COVERAGE AS A RESULT OF THE NEW RULES?
A. NO.
Q. YOU HAVE NOT BEEN PRESENTED TO THIS COURT AS AN EXPERT ON INSURANCE MARKETPLACES, RIGHT?
A. CORRECT.
Q. AND YOU HAVE NOT BEEN PRESENTED TO THIS COURT AS AN EXPERT ON THE GOVERNMENT'S DECISION-MAKING PROCESS UNDER THE ADMINISTRATIVE PROCEDURE ACT, CORRECT?
A. CORRECT.
Q. I WANT TO TURN TO ANOTHER PARAGRAPH IN YOUR DECLARATION, PARAGRAPH 22. YOU HAVE TESTIFIED THAT IT IS YOUR OPINION THAT THE NEW RULES ARE NOT BASED UPON SOUND SCIENTIFIC OR EMPIRICAL EVIDENCE; IS THAT RIGHT?
A. CORRECT.
Q. AND HAVE YOU READ THE RULES THAT ARE AT ISSUE IN THIS CASE IN THEIR ENTIRETY?
A. YES, ALTHOUGH I FOCUSED ON THE SECTIONS HAVING

TO DO WITH CONTRACEPTION EFFECTIVENESS AND THE IOM REPORT.

Q. HAVE YOU READ ALL OF THE EVIDENCE THAT THE RULES RELY UPON AND CITE?

A. I WOULD NOT SAY ALL OF IT, BUT SOME OF IT.

Q. I'M GOING TO TURN TO A SPECIFIC PAGE, 47804 OF THE FEDERAL REGISTER, SO THIS IS EXHIBIT 1, AND IT SHOULD BE PAGE 46 OF THAT EXHIBIT.

A. WHAT TAB IS THAT?

Q. IT IS THE FIRST TAB. I'M ALSO GOING TO PUT IT ON THE ELMO FOR EVERYONE.

THIS IS TAB 1, PAGE 47804 OF THE FEDERAL REGISTER.

A. GOT IT.

Q. YOU HAVE SERVED ON THE EDITORIAL BOARD OF WOMEN'S HEALTH ISSUES SINCE 1990, CORRECT?

A. CORRECT.

Q. SO WOULD YOU SAY THAT IS A PUBLICATION THAT IS GENERALLY ACCEPTED IN THE RELEVANT SCIENTIFIC COMMUNITY?

A. YES.

Q. AND THE RULES SAY -- I'M LOOKING AT THE FIRST -- START OF THE FIRST FULL PARAGRAPH THAT STARTS WITH "SIMILARLY" ON THE LEFT-HAND SIDE: SIMILARLY, AT A STUDY INVOLVING OVER 8,000 WOMEN BETWEEN 2012 AND 2015 CONDUCTED TO DETERMINE WHETHER CONTRACEPTIVE COVERAGE

UNDER THE MANDATE CHANGED CONTRACEPTIVE USE PATTERNS, THE GUTTMACHER INSTITUTE CONCLUDED THAT WE HAVE OBSERVED NO CHANGES IN CONTRACEPTIVE USE PATTERNS AMONG SEXUALLY ACTIVE WOMEN. AND THAT CITES FOOTNOTE 31, WHICH IS AN ARTICLE ENTITLED: DID CONTRACEPTIVE USE HABITS CHANGE AFTER THE AFFORDABLE CARE ACT? A DESCRIPTIVE ANALYSIS, WHICH WAS PUBLISHED IN THE MAY TO JUNE 2017 ISSUE OF WOMEN'S HEALTH ISSUES; IS THAT CORRECT?

A. YES.

Q. YOU WERE ON THE COMMITTEE THAT PRODUCED THE 2011 IOM REPORT, CORRECT?

A. YES.

Q. SO LOOKING JUST BELOW WHERE THE REFERENCE TO PARAGRAPH 31, THE SENTENCE THAT STARTS WITH "WITH," THE RULES SAY: WITH RESPECT TO TEENS, THE SANTELLI AND MELNIKAS STUDY CITED BY IOM IN 2011 OBSERVES THAT BETWEEN 1960 AND 1990 AS CONTRACEPTIVE USE INCREASED, TEEN SEXUAL ACTIVITY OUTSIDE OF MARRIAGE LIKEWISE INCREASED, ALTHOUGH THE STUDY DID NOT ASSERT A CAUSAL RELATIONSHIP. IS THAT CORRECT?

A. YES.

Q. THE NATIONAL INSTITUTES OF HEALTH IS A ORGANIZATION THAT IS GENERALLY ACCEPTED IN THE SCIENTIFIC COMMUNITY; IS THAT CORRECT?

A. YES.

Q. THE RULES ALSO CITE IN THIS MIDDLE PARAGRAPH, JUST AGAIN, CONTRACEPTION'S ASSOCIATION, BUT I WILL START READING FROM THE SECOND SENTENCE IN THAT PARAGRAPH: THE RULES SAY, IN 2013, THE NATIONAL INSTITUTES OF HEALTH INDICATED IN FUNDING OPPORTUNITY ANNOUNCEMENT FOR THE DEVELOPMENT OF NEW CLINICALLY USEFUL FEMALE CONTRACEPTIVE PRODUCTS --

THE COURT: I'M SORRY. I'M NOT FOLLOWING YOU. WHERE ARE YOU IN THIS PARAGRAPH?

MS. KADE: I'M SORRY, YOUR HONOR. I'M IN THE MIDDLE COLUMN, THE PARAGRAPH THAT STARTS WITH CONTRACEPTION'S ASSOCIATION.

THE COURT: GOT IT.

MS. KADE: AND IN 2013, THE NATIONAL INSTITUTES OF HEALTH.

THE COURT: OKAY.

BY MS. KADE:

Q. SO THEY INDICATED THAT HORMONAL CONTRACEPTIVES HAVE THE DISADVANTAGE OF HAVING MANY UNDESIRABLE SIDE EFFECTS, ARE ASSOCIATED WITH ADVERSE EVENTS, AND OBESE WOMEN ARE AT HIGHER RISK FOR SERIOUS COMPLICATIONS SUCH AS DEEP VENOUS THROMBOSIS; IS THAT CORRECT?

A. YES.

Q. JAMA PSYCHIATRY IS A PUBLICATION THAT IS GENERALLY ACCEPTED IN THE RELEVANT SCIENTIFIC COMMUNITY,

CORRECT?

A. YES.

Q. IT'S PUBLISHED BY THE AMERICAN MEDICAL ASSOCIATION?

A. CORRECT.

Q. IT IS PEER REVIEWED?

A. YES.

Q. I'M GOING TO FOCUS EVERYONE'S ATTENTION TO FOOTNOTE 39. I REALIZE THE FONT IS GETTING SMALLER. BUT FOOTNOTE 39 CITES A 2016 JAMA PSYCHIATRY PUBLICATION ON THE ASSOCIATION OF HORMONAL CONTRACEPTION WITH DEPRESSION; IS THAT CORRECT?

A. YES.

Q. I WANT TO TURN TO THE 2011 IOM REPORT. THE 2011 IOM REPORT DID NOT STUDY THE EFFECT OF RELIGIOUS EXEMPTIONS, CORRECT?

A. CORRECT.

Q. AND THE 2011 IOM REPORT DID NOT STUDY THE EFFECT OF MORAL EXEMPTIONS, CORRECT?

A. YES.

Q. AND THE IOM PANEL DID NOT INVITE ANY SPEAKERS TO TESTIFY CONCERNING EXEMPTIONS FROM THE MANDATE, CORRECT?

A. CORRECT.

MS. KADE: THANK YOU, DR. WEISMAN.

THANK YOU, YOUR HONOR. I HAVE NOTHING

FURTHER.

THE COURT: OKAY. THANK YOU VERY MUCH.

DO YOU HAVE ANY RECROSS?

MR. GOLDMAN: VERY BRIEFLY, IF I MAY APPROACH, YOUR HONOR.

RECROSS EXAMINATION

BY MR. GOLDMAN:

Q. COUNSEL ASKED YOU IF YOU HAD READ ALL OF THE SOURCES CITED IN THE COMMITTEE'S REPORT. I WANT TO ASK YOU, ARE YOU FAMILIAR WITH ALL OF THE SOURCES CITED IN THE COMMITTEE'S REPORT, SPECIFICALLY IN THE AREA OF CONTRACEPTION?

A. I AM FAMILIAR WITH REFERENCES 30 AND 31.

Q. I'M SORRY, DR. WEISMAN. I BELIEVE COUNSEL WAS REFERRING TO THE COMMITTEE'S REPORT AND NOT THE FEDERAL REGISTER.

A. WELL, I'M CONFUSED BECAUSE SHE ASKED ABOUT BOTH.

THE COURT: AS I UNDERSTAND IT, THE QUESTION WAS ABOUT HAVE YOU READ THE FEDERAL REGISTER. YOU SAID YES, I HAVE AND I FOCUSED ON THE CONTRACEPTIVE AND PREVENTIVE CARE COMPONENTS.

THE WITNESS: YES.

BY MR. GOLDMAN:

Q. ARE YOU FAMILIAR WITH THE SOURCES THAT COUNSEL ASKED YOU ABOUT?

A. YES. MOST OF THEM.

Q. AND DO YOU AGREE WITH THEM FOR THE PREMISES THEY ARE CITED FOR HERE?

A. NO.

Q. AND WHY IS THAT?

A. BECAUSE I THINK THEY ARE SELECTIVE COMMENTS WHICH DO NOT FULLY REFLECT THE BODY OF EVIDENCE THAT IS AVAILABLE. DO YOU WANT ME TO SAY MORE?

Q. PLEASE. GO ON.

A. SO THE FIRST REFERENCE THAT I WAS ASKED ABOUT WAS THIS FOOTNOTE 31, BEARAK AND JONES FOOTNOTE, THE PUBLICATION FROM THE GUTTMACHER INSTITUTE. AND IT IS CORRECT THAT THE ABSTRACT FOR THAT ARTICLE SAYS WE OBSERVE NO CHANGES IN CONTRACEPTIVE USE PATTERNS AMONG SEXUALLY ACTIVE WOMEN, BUT THAT STUDY FOUND AN IMPROVEMENT IN CONTRACEPTIVE USE, AN INCREASED USE OF CONTRACEPTION AMONG YOUNG WOMEN WHO WERE NOT SEXUALLY ACTIVE IN THE LAST MONTH, WHICH SUGGESTS THAT YOUNGER WOMEN WERE RESPONSIBLY -- MORE RESPONSIBLY USING CONTRACEPTION IN THAT STUDY. THAT IS NOT NOTED HERE.

Q. AND HOW ABOUT THE OTHER SOURCES?

A. SO THE SANTELLI REFERENCE WHICH COMES NEXT REGARDING TEEN PREGNANCIES, SANTELLI AND CO-AUTHORS JUST PUBLISHED A PAPER IN 2016 SHOWING THAT TEEN PREGNANCIES HAVE DECLINED MORE RECENTLY AND THAT THERE HAS BEEN NO

CONCOMITANT INCREASE IN SEXUAL ACTIVITY AMONG TEENS.

Q. DO YOU HAVE ANY OTHER EXAMPLES OF REASONS WHY YOU DISAGREE WITH THE CONCLUSIONS DRAWN FROM THE STUDIES THAT WERE CITED?

A. WELL, THE POINT ABOUT RISKS OF HORMONAL CONTRACEPTION AND THE POINT ABOUT RISK OF DEPRESSION IN CONTRACEPTIVE USE, I WOULD SAY THAT THE IMPLICATION IS THAT THIS IS SOMETHING NEW OR IMPORTANT, WHEN, IN FACT, THE MEDICAL COMMUNITY IS AWARE OF SIDE EFFECTS OF ALL KINDS OF CONTRACEPTION, AND THAT IS TAKEN INTO ACCOUNT IN COUNSELING WOMEN ABOUT THE APPROPRIATENESS OF THE METHODS THAT THEY CHOOSE, AND IT'S ANOTHER REASON WHY THE INSTITUTE OF MEDICINE COMMITTEE RECOMMENDED THAT ALL METHODS BE MADE AVAILABLE TO WOMEN SO THAT THEY CAN OPTIMALLY CHOOSE A METHOD THAT IS APPROPRIATE FOR THEM.

Q. AND, IN FACT, YOU TESTIFIED BEFORE THAT THE COMMITTEE TOOK NEGATIVE EFFECTS OF CONTRACEPTION INTO ACCOUNT IN MAKING ITS RECOMMENDATIONS, CORRECT?

A. YES.

Q. IF I MAY, ARE YOU FAMILIAR WITH A NEW REPORT INVOLVING MODERN HORMONAL CONTRACEPTION THAT WAS PERFORMED IN DANISH WOMEN THAT WAS RECENTLY IN THE FRONT PAGE -- IN THE NEW YORK TIMES?

A. YES.

Q. AND CAN YOU TELL US ABOUT THAT STUDY?

A. THAT STUDY WAS JUST PUBLISHED, AND IT'S BASED ON A LARGE SAMPLE OF DANISH WOMEN, AND IT FOUND A 1.2 RELATIVE RISK FOR BREAST CANCER AMONG WOMEN WHO USED HORMONAL METHODS OF CONTRACEPTION OVER TIME. WHAT THIS STUDY CONTRIBUTES IS THAT IT OBSERVED WOMEN WHO WERE USING THE MORE MODERN HORMONAL METHODS OF CONTRACEPTION AS OPPOSED TO OLDER ONES, BUT ITS FINDING OF A SMALL ELEVATED RISK FOR BREAST CANCER ASSOCIATED WITH USE OF HORMONAL METHODS IS NOT NEW. THAT HAS BEEN KNOWN FOR SOME TIME BASED ON STUDIES OF THE OLDER HORMONAL METHODS. AND IT IS TAKEN INTO ACCOUNT IN COUNSELING WOMEN ABOUT THE RISKS AND SIDE EFFECTS OF CONTRACEPTION. AND IT NEEDS TO BE BALANCED AGAINST OTHER STUDIES THAT SHOW HORMONAL METHODS OF CONTRACEPTION TO BE PROTECTIVE, THAT IS TO REDUCE THE RISKS OF OTHER CANCERS, OVARIAN CANCER, ENDOMETRIAL CANCER AND COLORECTAL CANCER. SO THERE ARE -- THERE IS A BALANCING REQUIRED IN MAKING A DECISION ABOUT A CONTRACEPTIVE CHOICE.

MS. KADE: YOUR HONOR, WITH THIS ANSWER, WE APPEAR TO BE BEYOND THE SCOPE OF CROSS.

THE COURT: WELL, I DON'T THINK WE ARE, BECAUSE YOU TALKED SPECIFICALLY ABOUT THOSE IMPACTS OF CONTRACEPTION.

BUT I DO THINK YOU SHOULD MOVE ON BECAUSE THIS IS NOT A FOCUS OF MY CONCERN.

MR. GOLDMAN: NOTHING FURTHER, YOUR HONOR.

THE COURT: OKAY. LET ME TALK TO YOU ABOUT A FOCUS OF MY CONCERN. I WANT YOU -- YOU SAID YOU HAD READ THE GUTTMACHER INSTITUTE STUDY SET FORTH IN FOOTNOTE 31.

THE WITNESS: BEARAK AND JONES, YES.

THE COURT: RIGHT. YOU ALSO TOLD ME ABOUT A STUDY WHICH IS CURRENTLY UNPUBLISHED THAT YOU PERFORMED. I WANT TO COMPARE AND CONTRAST THEM TO SEE WHETHER WE ARE TALKING ABOUT APPLES AND ORANGES OR JUST APPLES.

SO THE GUTTMACHER INSTITUTE STUDY WAS TO DETERMINE WHETHER CONTRACEPTIVE COVERAGE UNDER THE MANDATE CHANGED CONTRACEPTIVE USAGE PATTERNS. WAS THAT THE SAME PROPOSITION THAT YOU WERE ANALYZING IN YOUR STUDY?

THE WITNESS: YES, ALTHOUGH OUR STUDY LOOKED AT BOTH COSTS AND CONTRACEPTIVE USE PATTERNS.

THE COURT: AND DO YOU KNOW WHEN -- THIS IS -- THIS IS WOMEN BETWEEN 2012 AND 2015 IN THIS GUTTMACHER STUDY, IS THAT CORRECT?

WELL, THAT IS WHAT IT SAYS HERE.

THE WITNESS: THAT IS -- YES.

THE COURT: SO WHEN WAS YOUR STUDY DONE,

WHAT COHORT? WHAT WAS THE TIME FRAME OF YOURS?

THE WITNESS: THE PENNSYLVANIA STUDY?

THE COURT: YES.

THE WITNESS: 2012 THROUGH 2014.

THE COURT: AND HERE IT SAYS THE GUTTMACHER FOLKS DID 8,000 WOMEN. AND YOU TOLD ME YOU HAD HOW MANY WOMEN?

THE WITNESS: IN OUR PENNSYLVANIA STUDY, 900-SOME.

THE COURT: SO DO YOU KNOW WHETHER IN THOSE 8,000 WOMEN THERE WERE ANY PENNSYLVANIA WOMEN?

THE WITNESS: I DON'T, BECAUSE THESE WERE TWO SURVEYS DONE BY THE GUTTMACHER INSTITUTE, AND I DON'T KNOW HOW THEY SELECTED THOSE PARTICIPANTS.

THE COURT: WHAT IS THE GUTTMACHER INSTITUTE?

THE WITNESS: THE GUTTMACHER INSTITUTE IS A PRIVATE NOT-FOR-PROFIT RESEARCH INSTITUTE THAT FOCUSES ON REPRODUCTIVE HEALTH ISSUES IN THE UNITED STATES AND GLOBALLY.

THE COURT: IS IT AFFILIATED WITH ANY POLITICAL VIEWPOINT?

THE WITNESS: NO.

THE COURT: DO YOU KNOW WHETHER THIS PAPER, THE BEARAK AND JONES PAPER WAS PEER REVIEWED?

THE WITNESS: YES, IT WAS.

THE COURT: WHAT I HAVE BEEN TRYING TO ESTABLISH WAS SIMILARITIES AND DIFFERENCES. ARE THERE ANY DIFFERENCES THAT I HAVE NOT IDENTIFIED AT THIS POINT BETWEEN YOUR STUDY AND THE GUTTMACHER INSTITUTE STUDY APART FROM THE CONCLUSION AS SET FORTH IN THE FEDERAL REGISTER AS MODIFIED BY YOUR TESTIMONY WITH RESPECT TO THE CONCLUSION?

THE WITNESS: I DON'T THINK SO.

THE COURT: OKAY. THANK YOU.

BY MR. GOLDMAN:

Q. VERY BRIEFLY. IS THIS GUTTMACHER INSTITUTE STUDY, DO YOU KNOW IF THIS WAS BASED ON CLAIMS DATA IN THE WAY THE OTHER STUDY YOU SPOKE ABOUT?

A. IT WAS NOT. IT WAS BASED ON SURVEY DATA.

Q. AND IS THERE A DIFFERENCE IN RELIABILITY BETWEEN SURVEY DATA AND CLAIMS DATA?

A. THERE ARE THOSE WHO THINK THAT SURVEY DATA ARE LESS RELIABLE IN STUDYING CONTRACEPTIVE USE PATTERNS BECAUSE PEOPLE HAVE RECALL PROBLEMS AND MAY NOT RESPOND ACCURATELY. BUT HAVING SAID THAT, OUR MOST DEFINITIVE SOURCE OF INFORMATION ABOUT CONTRACEPTIVE USE AND UNINTENDED PREGNANCY IS THE NATIONAL SURVEY OF FAMILY GROWTH WHICH IS AN ONGOING NATIONAL SURVEY OF WOMEN ACROSS THE COUNTRY CONDUCTED BY THE FEDERAL GOVERNMENT.

Q. AND YOU HAD REFERRED BEFORE WHEN WE WERE SPEAKING TO A NATIONAL STUDY INCLUDING PENNSYLVANIA WOMEN THAT WAS BASED ON CLAIMS DATA?

A. CORRECT.

Q. AND HOW DO THE FINDINGS YOU HAVE FOUND FROM THAT STUDY COMPARE WITH THE GUTTMACHER INSTITUTE STUDY?

A. SO THE GUTTMACHER STUDY WAS NOT LOOKING AT COSTS. I BELIEVE IT WAS ONLY LOOKING AT CONTRACEPTIVE USE PATTERNS. OUR STUDY LOOKED AT BOTH, BUT WE FOUND, AS I MENTIONED BEFORE, A STATISTICALLY SIGNIFICANT INCREASE IN USE OF IUD'S AND IMPLANTS IN THE YEARS FOLLOWING THE AFFORDABLE CARE ACT. AND UNLIKE THE GUTTMACHER STUDY, WE HAD DATA BEFORE THE AFFORDABLE CARE ACT WENT INTO EFFECT AND AFTER THE AFFORDABLE CARE ACT WENT INTO EFFECT. THEIR DATA ARE ALL POST, POST AFFORDABLE CARE ACT.

MR. GOLDMAN: NOTHING FURTHER, YOUR HONOR, UNLESS YOU HAVE ANYTHING ELSE.

THE COURT: I HAVE NOTHING.

ANY RECROSS?

MS. KADE: NO, YOUR HONOR. JUST FOR THE RECORD, WE WOULD RENEW OUR OBJECTION TO THE EXPERT TESTIMONY TO THE EXTENT IT IS BEING OFFERED TO DETERMINE THE CORRECTNESS OF THE WISDOM OF THE AGENCY'S DECISION IN THIS APA CASE, YOUR HONOR.

THE COURT: YES, I UNDERSTAND.
YOU CAN LEAVE THE BENCH. THANK YOU.
WE WILL TAKE A BRIEF BREAK, AND WE WILL BE BACK IN TEN MINUTES.
THE CLERK: ALL RISE.
(WITNESS EXCUSED.)
(BREAK TAKEN.)
MR. GOLDMAN: THE COMMONWEALTH WOULD LIKE TO CALL DR. SAMANTHA BUTTS TO THE STAND, PLEASE.
MAY I APPROACH, YOUR HONOR.
THE COURT: YOU MAY.
SWEAR THE WITNESS.
THE CLERK: PLEASE RAISE YOUR RIGHT HAND AND STATE YOUR NAME FOR THE RECORD.
THE WITNESS: SAMANTHA BUTTS.
(DR. SAMANTHA BUTTS, COMMONWEALTH'S WITNESS, SWORN.)
THE CLERK: STATE AND SPELL YOUR FULL NAME FOR THE RECORD, PLEASE.
THE WITNESS: FIRST NAME IS S-A-M-A-N-T-H-A. LAST NAME IS BUTTS, B-U-T-T-S.

DIRECT EXAMINATION

BY MR. GOLDMAN:
Q. WILL YOU PLEASE STATE YOUR NAME FOR THE RECORD, DR. BUTTS?

A. SAMANTHA BUTTS.
Q. AND WHAT DO YOU DO FOR A LIVING?
A. I AM AN OBSTETRICIAN GYNECOLOGIST. I SPECIALIZE IN THE AREA OF REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY.
Q. THERE IS A WITNESS EXHIBIT BINDER IN FRONT OF YOU. IF I COULD DIRECT YOU TO EXHIBITS 8 AND 9 WHICH ARE ALREADY ADMITTED INTO EVIDENCE, I'D LIKE YOU JUST TO LOOK AT THOSE AND TELL ME IF YOU RECOGNIZE THEM, AND ASK YOU WHAT THEY ARE?
A. THESE ARE MY DECLARATIONS PURSUANT TO THIS CASE.
Q. AND THE WAY THE COPY IS ON TAB 9, IF YOU LOOK TO THE BACK OF THAT FIRST PAGE, WHAT IS THAT DOCUMENT?
A. THIS LOOKS LIKE MY CURRICULUM VITAE.
Q. OKAY. THE QUESTIONS ARE NOT HARD. I JUST WANTED YOU TO IDENTIFY.
ARE YOU ABLE TO BRIEFLY LOOK THROUGH THOSE DOCUMENTS AND JUST CONFIRM IF THERE ARE ANY INACCURACIES IN THEM OR IF YOU BELIEVE THEY ARE ACCURATE?
A. THE DOCUMENTS LOOK ACCURATE AND CURRENT.
Q. THANK YOU.
I WANTED TO ASK YOU BRIEFLY ABOUT YOUR EDUCATION. WHERE DID YOU GO TO COLLEGE?
A. I WENT TO HARVARD COLLEGE.

Q. AND WHEN DID YOU GRADUATE?
A. IN 1994.
Q. AND WHAT DID YOU DO AFTER THAT?
A. I WENT TO MEDICAL SCHOOL, ALSO AT HARVARD.
Q. AND WHEN DID YOU GRADUATE FROM THERE?
A. IN 1998.
Q. DID YOU DO A RESIDENCY AFTER THAT?
A. I DID. I DID A RESIDENCY IN OBSTETRICS AND GYNECOLOGY AT THE UNIVERSITY OF PENNSYLVANIA.
Q. AND DURING WHAT YEARS DID YOU DO YOUR RESIDENCY?
A. FROM 1992 -- PARDON ME, 1998 TO 2002.
Q. AND DID YOU DO A FELLOWSHIP ALSO?
A. I DID A SUBSPECIALTY FELLOWSHIP IN REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY FROM 2002 UNTIL 2005, ALSO AT THE UNIVERSITY OF PENNSYLVANIA.
Q. SO YOU'VE USED THE PHRASE REPRODUCTIVE ENDOCRINOLOGY AT LEAST TWICE.
A. YES.
Q. WHAT DOES THAT MEAN?
A. SO REPRODUCTIVE ENDOCRINOLOGY IS THE FIELD OF MEDICINE THAT INVESTIGATES HOW HORMONES AFFECT REPRODUCTIVE FUNCTIONING AND DISORDERS IN WOMEN.
Q. DO YOU HAVE ANY OTHER RELEVANT EDUCATION HERE TODAY?
A. I RECEIVED A MASTERS IN CLINICAL EPIDEMIOLOGY

AND BIOSTATISTICS AT THE UNIVERSITY OF PENNSYLVANIA DURING MY FELLOWSHIP IN REPRODUCTIVE ENDOCRINOLOGY.
Q. HOW MANY YEARS WAS THAT MASTERS PROGRAM?
A. THREE YEARS, 2003 UNTIL 2006.
Q. ARE YOU BOARD CERTIFIED?
A. I AM BOARD CERTIFIED BOTH IN GENERAL OBSTETRICS AND GYNECOLOGY AND IN REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY.
Q. WAS THE REPRODUCTIVE ENDOCRINOLOGY AND FERTILITY, IS THAT PART OF YOUR BOARD CERTIFICATION OR IS THAT A SUBSPECIALITY?
A. IT'S SUBSPECIALTY BOARD CERTIFICATION.
Q. I WOULD LIKE TO ASK YOU BRIEFLY ABOUT YOUR CURRENT WORK. WHERE DO YOU CURRENTLY WORK?
A. I AM ON -- I WORK AT THE UNIVERSITY OF PENNSYLVANIA HOSPITAL AS A REPRODUCTIVE ENDOCRINOLOGIST THERE, AND I'M ON THE FACULTY OF THE MEDICAL SCHOOL AT THE UNIVERSITY OF PENNSYLVANIA.
MR. GOLDMAN: YOUR HONOR, JUST IN THE INTEREST OF TIME FOR THESE BACKGROUND QUESTIONS, MAY I ASK FOR PERMISSION TO LEAD?
THE COURT: YOU CAN GO AHEAD, AND IF YOU ARE GOING TO OBJECT -- AT A POINT YOU FEEL IT IS OBJECTIONABLE, YOU'RE GOING TO GET UP AND TELL ME.
MS. KADE: THANK YOU, YOUR HONOR.

BY MR. GOLDMAN:
Q. AT THE UNIVERSITY OF PENNSYLVANIA MEDICAL SCHOOL AND HOSPITAL, DO YOU WORK AS A DOCTOR?
A. YES.
Q. DO YOU ALSO WORK AS A PROFESSOR?
A. I DO.
Q. DO YOU ALSO DO CLINICAL RESEARCH?
A. I DO.
Q. DO YOU ALSO PUBLISH ARTICLES AND SPEAK?
A. I DO.
Q. GENERALLY SPEAKING, WHAT KIND OF DOCTOR ARE YOU? WHAT DO YOU DO FOR YOUR PATIENTS?
A. I SEE PATIENTS WHO COME FOR THE EVALUATION OF INFERTILITY, SO HAVING DIFFICULTY ACHIEVING A PREGNANCY. IN THE REPRODUCTIVE ENDOCRINE COMPONENT OF WHAT I DO, I SEE WOMEN WHO SUFFER FROM A VARIETY OF DISORDERS, INCLUDING DISORDERS OF MENSTRUATION, CHRONIC PELVIC PAIN AND OTHER REPRODUCTIVE DISORDERS THAT I TREAT.
Q. IN YOUR FERTILITY WORK, YOU ACTUALLY HELP WOMEN HAVE BABIES?
A. THAT'S CORRECT.
Q. IN YOUR ROLE AS PROFESSOR, IS YOUR TITLE ASSOCIATE PROFESSOR?
A. YES.
Q. AND ARE YOU TENURED?

A. YES, I AM.
Q. AND DO YOU TEACH AND RESEARCH AS PART OF THAT ROLE AS PROFESSOR?
A. I DO.
Q. WHO DO YOU TEACH?
A. I TEACH MEDICAL STUDENTS, RESIDENTS IN OBSTETRICS AND GYNECOLOGY, AND FELLOWS TRAINING IN REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY.
Q. I WILL COME BACK TO YOUR MEDICAL PRACTICE WITH PATIENTS, BUT YOUR PROFESSORIAL DUTIES, ROUGHLY HOW MANY HOURS A WEEK DOES THAT TAKE?
A. APPROXIMATELY 5 TO 10 HOURS PER WEEK.
Q. MOVING ON TO YOUR WORK AS A CLINICAL RESEARCHER, ROUGHLY HOW MANY HOURS A WEEK DOES THAT TAKE?
A. THERE IS OVERLAP WITH MY RESPONSIBILITIES AS AN ASSOCIATE PROFESSOR, BUT I WOULD SAY APPROXIMATELY 5 TO 10 HOURS PER WEEK, WITH SOME OVERLAP BETWEEN THEM.
Q. SO THAT NUMBER INCLUDES THE OVERLAP, CORRECT?
A. CORRECT.
Q. HAS ANY OF YOUR RESEARCH BEEN FUNDED BY GRANTS?
A. YES.
Q. AND COULD YOU NAME A FEW OF THE GRANTS YOU HAVE BEEN FUNDED BY?
A. I HAVE BEEN FUNDED BY THE NATIONAL INSTITUTES OF HEALTH, THE NATIONAL INSTITUTES OF ENVIRONMENTAL HEALTH

SERVICES, AND OTHER FOUNDATIONS AND INTRAMURAL SOURCES AT THE UNIVERSITY OF PENNSYLVANIA.
MR. GOLDMAN: YOUR HONOR, I'M GOING TO SKIP OVER QUESTIONS ABOUT HER -- THE DOCTOR'S CURRENT PROJECTS AND PUBLICATIONS, SINCE THEY ARE IN THE RECORD, BUT I JUST WANTED TO POINT OUT THAT THEY ARE AVAILABLE.
BY MR. GOLDMAN:
Q. BUT I WOULD LIKE TO FOCUS ON YOUR WORK AS A MEDICAL DOCTOR. ROUGHLY HOW MANY HOURS A WEEK DO YOU WORK?
A. ROUGHLY 50 TO 70 HOURS PER WEEK IS THE RANGE.
Q. AND WHY IS THERE THAT RANGE?
A. THERE IS A RANGE THAT DEPENDS ON PROCEDURES THAT I ALSO DO. I FAILED TO MENTION BEFORE THAT AS PART OF MY WORK I ALSO DO SURGICAL PROCEDURES FOR WOMEN, AND I ALSO TAKE CALL ON AN APPROXIMATELY MONTHLY BASIS. SO THAT REQUIRES WORK AT NIGHTS AND ON THE WEEKENDS WHEN I AM ON CALL.
Q. AND THAT 50 TO 70 HOURS A WEEK, THAT IS ON TOP OF YOUR TEACHING AND RESEARCH?
A. CORRECT.
Q. DO YOU PRESCRIBE CONTRACEPTION WHEN YOU TREAT YOUR PATIENTS?
A. I DO.
Q. AND ARE YOU FAMILIAR WITH THE AFFORDABLE CARE

ACT?
A. I AM.
Q. ARE YOU FAMILIAR WITH THE CONTRACEPTIVE MANDATE THAT IS PART OF THE AFFORDABLE CARE ACT?
A. YES.
Q. ARE YOU FAMILIAR WITH THE NEW MORAL EXEMPTION RULE AND RELIGIOUS EXEMPTION RULE --
A. I AM.
Q. -- WHICH ARE AT ISSUE BEFORE THE COURT TODAY?
MR. GOLDMAN: BEFORE I PROCEED FURTHER, YOUR HONOR, I WOULD LIKE TO PROFFER THIS WITNESS, DR. SAMANTHA BUTTS, BASED ON HER KNOWLEDGE, EDUCATION, TRAINING AND EXPERIENCE, AS AN EXPERT IN THE AREA OF WOMEN'S REPRODUCTIVE HEALTH.
THE COURT: ANY OBJECTION?
MS. KADE: YES, YOUR HONOR. WE OBJECT FOR FAILURE TO DISCLOSE AS AN EXPERT AS WELL AS TO HER EXPERT TESTIMONY TO THE EXTENT IT IS BEING OFFERED TO DETERMINE THE CORRECTNESS OR WISDOM OF THE AGENCY'S DECISION IN THIS ACA CASE, YOUR HONOR.
THE COURT: I UNDERSTAND.
IS THE SCOPE AS NARROW OR -- THAN DESCRIBED BY MS. KADE OR IS IT --
MR. GOLDMAN: THE TESTIMONY WILL BE ABOUT WHAT SHE HAS SEEN IN HER OWN PRACTICE AS IT APPLIES TO

WOMEN'S REPRODUCTIVE HEALTH.

THE COURT: OKAY. SO SHE IS NOT GOING TO TESTIFY SPECIFICALLY ABOUT WHETHER OR NOT THE TWO EXEMPTIONS ARE APPROPRIATE?

MR. GOLDMAN: NO.

THE COURT: OKAY. SO THAT IS ONE OF YOUR OBJECTIONS, CORRECT?

MS. KADE: YES, YOUR HONOR.

THE COURT: AND THE OTHER ONE I OVERRULE.

MS. KADE: THANK YOU, YOUR HONOR.

THE COURT: GO AHEAD.

BY MR. GOLDMAN:

Q. RETURNING TO YOUR PATIENT WORK, DOCTOR, WHERE DO YOU -- WHERE DO YOUR PATIENTS COME FROM?

A. MY PATIENTS -- I HAVE A DIVERSE PATIENT POPULATION. THEY COME FROM MANY SOURCES. MANY ARE SELF-REFERRED. SOME ARE REFERRED FROM OTHER PHYSICIANS IN THE HEALTH SYSTEM AND SOME ARE EMPLOYEES IN THE UNIVERSITY OF PENNSYLVANIA -- AT THE UNIVERSITY OF PENNSYLVANIA, BUT THEY COME FROM MANY SOURCES.

Q. DO PATIENTS COME TO SEE YOU FROM AROUND THE WORLD?

A. YES.

Q. DO YOU ALSO SERVE AS A WEST PHILADELPHIA COMMUNITY HOSPITAL DOCTOR?

A. I DO.

Q. AND YOU ALSO HAVE PATIENTS WHO ARE STUDENTS AND PROFESSORS AT PENN, CORRECT?

A. YES.

Q. ROUGHLY HOW MANY PATIENTS DO YOU SEE A YEAR?

A. APPROXIMATELY 1500 PATIENTS PER YEAR, AND THERE CAN BE SOME VARIATION WHERE THAT IS CONCERNED.

Q. ARE THOSE INDIVIDUAL PATIENTS OR PATIENT VISITS?

A. WHEN I CALCULATE BOTH INDIVIDUAL PATIENTS THAT I SEE FROM A VARIETY OF SOURCES IN MY OWN PATIENT PRACTICE, WORKING IN OUR GROUP INFERTILITY PRACTICE, TAKING CALL AND DOING SURGICAL PROCEDURES, THAT NUMBER REPRESENTS INDIVIDUAL PATIENTS.

Q. AND DOES THAT NUMBER INCLUDE THE SURGERIES THAT YOU PERFORM?

A. IT DOES.

Q. IT DOES. AND DOES IT INCLUDE PATIENTS YOU WOULD SEE WHEN YOU WERE ON CALL?

A. IT DOES.

Q. AND DOES IT INCLUDE PATIENTS YOU WOULD SEE IN CONNECTION WITH YOUR TEACHING OF RESIDENTS AND FELLOWS?

A. IT DOES.

Q. HAVE YOU KEPT UP THIS PACE OF SEEING PATIENTS OVER THE MORE THAN 12 YEARS YOU HAVE BEEN SEEING PATIENTS?

A. GENERALLY, WITH SOME VARIATION FROM YEAR TO YEAR, YES.

Q. I WOULD LIKE TO ASK YOU A LITTLE BIT MORE ABOUT YOUR SPECIFIC MEDICAL PRACTICE. YOU MENTIONED THAT YOU TREAT WOMEN FOR DISORDERS OF MENSTRUATION, CHRONIC PELVIC PAIN AND PREMATURE OVARIAN FAILURE; IS THAT CORRECT?

A. THAT IS CORRECT.

Q. CAN YOU DESCRIBE BRIEFLY WHAT IS A DISORDER OF MENSTRUATION?

A. THE DISORDERS OF MENSTRUATION THAT I SEE INCLUDE MENSTRUATION THAT IS EXCESSIVELY HEAVY, EXCESSIVELY FREQUENT OR IRREGULAR IN FREQUENCY. AND SO THIS CAN SIGNIFICANTLY IMPACT QUALITY OF LIFE, AND TO THE EXTENT AND THE DEGREE OF THE CHRONICITY OF THE CONDITION CAN SIGNIFICANTLY IMPACT HEALTH OUTCOMES, RISKS AND SEVERE CONDITIONS FOR A WOMAN, AND IMPACT HER ABILITY TO BE A PRODUCTIVE MEMBER OF THE WORKFORCE IF SHE IS IMPAIRED IN HER ABILITY TO DO THAT BECAUSE SHE NEEDS TO ATTEND TO THE SERIOUS MEDICAL DISORDER.

Q. FORGIVE ME, DOCTOR, I WOULD BE LYING IF I TOLD YOU I HAD FIRSTHAND KNOWLEDGE OF WHAT THIS MEANS. AND YOU ARE USING WORDS LIKE CHRONICITY.

CAN YOU TELL ME IN PRACTICAL TERMS HOW THESE DISORDERS AFFECT WOMEN? WHAT DOES IT MEAN FOR

THEM IF YOU HAVE A MENSTRUATION DISORDER?

A. SO WHAT IT MEANS IS THAT A WOMAN HAS A MENSTRUAL PERIOD THAT IS SIGNIFICANTLY MORE LONG IN DURATION OR HEAVIER IN VOLUME THAN WE CONSIDER TO BE NORMAL, AND THIS CAN OBVIOUSLY BE INCREDIBLY JARRING AND UPSETTING FOR A PATIENT AND CREATE AN IMPACT ON QUALITY OF LIFE.

BUT TO THE EXTENT THAT THAT PROBLEM LASTS FOR A SIGNIFICANT AMOUNT OF TIME, IT CAN LEAD TO CHRONIC PROBLEMS, ONE OF THE MOST SEVERE OF WHICH IS MODERATE TO SEVERE ANEMIA, WHICH CAN ALSO LEAD TO SIGNIFICANT PROBLEMS FOR A PATIENT. IN THE MOST SEVERE CASE, SEVERE ANEMIA CAN REQUIRE A PATIENT TO NEED TO BE HOSPITALIZED AND RECEIVE A BLOOD TRANSFUSION.

Q. HAVE YOU EVER HAD TO PERFORM A BLOOD TRANSFUSION ON A PATIENT WITH MENSTRUATION DISORDER?

A. YES.

Q. AND ROUGHLY HOW MANY TIMES IN YOUR CAREER --

A. IN MY CAREER, I WOULD SAY AT LEAST 50 TIMES.

Q. AND DOES THIS SORT OF THING CAUSE WOMEN TO LOSE WORK?

A. YES.

Q. SORRY, HAVE TO MISS WORK?

A. YES.

Q. CAN IT AFFECT THEIR JOBS?

A. YES.

Q. TURNING TO THE DISORDERS OF CHRONIC PELVIC PAIN, ROUGHLY HOW MANY WOMEN FACE THIS TYPE OF DISORDER?
A. SO IT'S BEEN SUGGESTED THAT UP TO 10 PERCENT OF PATIENT VISITS TO THE GYNECOLOGIST HAVE TO DO WITH CHRONIC PELVIC PAIN. THERE ARE A NUMBER OF CAUSES OF CHRONIC PELVIC PAIN, BUT IT IS SOMETHING THAT I SEE COMMONLY IN MY PRACTICE BECAUSE IT'S SOMETHING THAT IS REFERRED TO ME ON A REGULAR BASIS.
Q. AND IS THAT THE SAME AS ENDOMETRIOSIS?
A. ENDOMETRIOSIS IS A COMMON CAUSE OF CHRONIC PELVIC PAIN AND SEVERE PAIN WITH PERIODS. THEY ARE VERY SIMILAR THINGS.
Q. ARE THERE TYPES OF CHRONIC PELVIC PAIN THAT ARE NOT CAUSED BY ENDOMETRIOSIS?
A. THERE ARE SOME, AND WE SEE THOSE NOT UNCOMMONLY AS WELL, BUT ENDOMETRIOSIS IS ONE OF THE MOST COMMON.
Q. IN PLAIN LANGUAGE, HOW DOES CHRONIC PELVIC PAIN AFFECT THE REAL LIVES OF WOMEN WHO SUFFER FROM THAT DISORDER?
A. SO I SEE PATIENTS WHO HAVE SEVERE DEBILITATING PELVIC PAIN, EITHER WITH THEIR PERIODS OR OUTSIDE OF THEIR PERIODS. WHEN PATIENTS COME TO SEE ME, IT'S USUALLY DEBILITATING TO THE POINT THAT OVER-THE-COUNTER MEDICATIONS HAVE NOT HELPED THEM AND THEY ARE LOOKING FOR ADDITIONAL LEVELS OF ASSESSMENT AND CARE. SO THESE

ARE WOMEN WHO SOMETIMES CANNOT GO TO WORK AND CANNOT FUNCTION ALONG THEIR ACTIVITIES OF DAILY LIVING BECAUSE THEY ARE DEBILITATED BY PAIN AND SOMETIMES CAN'T GET OUT OF BED.
Q. I'M GOING TO RETURN TO YOUR TREATMENT OF THESE DISORDERS, BUT I WANTED TO FIRST ASK YOU ABOUT THE DISORDER OF PREMATURE OVARIAN FAILURE. WHAT IS THAT?
A. IT'S A DISORDER WHERE THERE IS PREMATURE DEPLETION OF NORMAL OVARIAN FUNCTIONING RESULTING IN SIGNIFICANTLY DECREASED PRODUCTION OF NORMAL FEMALE HORMONES THAT THE OVARIES ARE SUPPOSED TO PRODUCE, AND SIGNIFICANTLY DECREASED ODDS OF BECOMING PREGNANT.
Q. IS THAT LIKE EARLY MENOPAUSE?
A. IT'S A SIMILAR CONDITION, YES.
Q. AND IF THERE IS AN AGE, ROUGHLY HOW OLD ARE YOUR PATIENTS WHO SUFFER FROM PREMATURE OVARIAN FAILURE?
A. THE STRICT DEFINITION MEANS THAT THE ONSET OF SYMPTOMS ARE HAPPENING BEFORE THE AGE OF 40. I SEE PATIENTS WHO SUFFER FROM THIS DISEASE ANYWHERE FROM THEIR 20S, 30S AND UP TO THE AGE OF 40.
Q. AND ROUGHLY HOW COMMON IS PREMATURE OVARIAN FAILURE?
A. IT AFFECTS APPROXIMATELY ONE PERCENT OF WOMEN.
Q. SO IT'S ONE OUT OF A HUNDRED WOMEN?
A. CORRECT.

Q. AND IS THAT ONE OUT OF A HUNDRED WOMEN IN PENNSYLVANIA OR IN THE COUNTRY OR --
A. THAT IS A NATIONAL PREVALENCE.
Q. AND AM I CORRECT THAT WITH THAT DISORDER, WOMEN'S OVARIES DON'T PRODUCE ESTROGEN?
A. THAT'S CORRECT.
Q. CAN THEY STILL GET PREGNANT?
A. THEY HAVE A DIMINISHED ODDS OF BECOMING PREGNANT BUT THEY CAN STILL ACHIEVE A PREGNANCY IN SOME CASES.
Q. WHAT HAPPENS TO WOMEN WHOSE OVARIES DO NOT PRODUCE ESTROGEN?
A. SO IF A WOMAN IS DIAGNOSED WITH THIS DISEASE IN HER 20S, FOR INSTANCE, AND WE KNOW THAT THE AVERAGE AGE OF NATURAL MENOPAUSE WHEN THESE CHANGES ARE SUPPOSED TO HAPPEN IS 51 YEARS OLD, THAT MEANS THAT SHE CAN STAND TO EXPERIENCE 30 YEARS OF HER ADULT LIFE WITHOUT ONE OF THE MOST CRITICAL HORMONES THAT HER BODY PRODUCES.
SO THE SHORT-TERM CONSEQUENCES OF THAT ARE SIGNIFICANT IMPAIRMENT OF QUALITY OF LIFE; HOT FLASHES, NIGHT SWEATS AND SYMPTOMS OF LOW ESTROGEN. SOME OF THE MORE SERIOUS LONG-TERM CONSEQUENCES INCLUDE INCREASED RISK OF CARDIOVASCULAR DISEASE. WHEN WOMEN ARE PREMATURELY DEPRIVED OF ESTROGEN, INCREASED RISK OF BONE LOSS AND HIP FRACTURE. AND THOSE ARE TWO OF THE MOST COMMON SERIOUS CONSEQUENCES THAT WE SEE.

Q. CAN WOMEN WHO SUFFER FROM LOSS OF ESTROGEN DIE FROM THAT?
A. WELL, I WOULD ARGUE THAT SINCE HEART DISEASE AND HEART ATTACK IS THE NUMBER ONE KILLER OF WOMEN AND ALL AMERICANS, ANYTHING THAT PUTS YOU AT GREATER RISK OF EXPERIENCING THAT INCREASES YOUR RISK OF DEATH.
Q. IN ADDITION TO THOSE THREE CATEGORIES OF DISORDERS, YOU ALSO TREAT INFERTILITY, CORRECT?
A. YES.
Q. I THINK WE ALL KNOW GENERALLY WHAT THAT IS, NOT TO YOUR DEGREE OF KNOWLEDGE, BUT I WOULD JUST LIKE TO INCLUDE THAT IN THE CONVERSATION.
SO HOW DO YOU TREAT YOUR PATIENTS WITH THOSE THREE DISORDERS AND THE PATIENTS SUFFERING FROM INFERTILITY?
A. SO FOR THE PATIENTS WE DESCRIBED, THE THREE DISORDERS OF ABNORMAL MENSTRUATION, CHRONIC PELVIC PAIN, SEVERE PAIN WITH PERIODS AND PREMATURE OVARIAN FAILURE, THERE ARE INDICATIONS FOR ALL THREE OF THOSE TO INCORPORATE HORMONAL CONTRACEPTION TO MANAGE THOSE DISORDERS AND TO MITIGATE SOME OF THE ASSOCIATED RISKS THAT WE TALKED ABOUT THAT ARE ASSOCIATED WITH THEM.
Q. WHEN YOU SAY HORMONAL CONTRACEPTION, DOES THAT MEAN THE BIRTH CONTROL PILL OR CAN THAT ALSO REFER TO IUD'S?

A. IT REFERS TO BOTH.
Q. AND DO YOU ALSO USE CONTRACEPTIVES ON PATIENTS WHO SUFFER FROM INFERTILITY?
A. WE INTEGRATE HORMONAL CONTRACEPTION TO HELP WITH THE PROTOCOLS THAT ARE BUILT INTO THE TREATMENTS THAT WE OFFER. IT HELPS MANAGE THE CYCLES THAT WE BUILD FOR PATIENTS WHEN WE ARE DOING TREATMENTS LIKE IN VITRO FERTILIZATION, FOR INSTANCE.
Q. I FEEL LIKE I'M A LITTLE BIT IN A SCIENCE CLASS. IT'S OKAY, IT'S BEEN A WHILE, BUT I'M GETTING THERE.
WHEN YOU TREAT WOMEN WITH -- WHO ARE SUFFERING FROM INFERTILITY WITH CONTRACEPTIVES, TO ME THAT SEEMS COUNTERINTUITIVE.
A. WE USE THE MEDICATIONS TO ACHIEVE SEVERAL THINGS WITH THE INFERTILITY TREATMENTS THAT WE HAVE TO OFFER. IN A CERTAIN POPULATION OF WOMEN, IT HELPS CREATE A SAFER PROCESS FOR THE PATIENT, SO BIRTH CONTROL PILLS, WE TAKE ADVANTAGE OF SOME OF THEIR NONCONTRACEPTIVE BENEFITS TO HELP PERFORM INFERTILITY TREATMENTS IN A WAY THAT IS -- ENHANCES THE SAFETY AND EFFICACY OF THOSE TREATMENTS OVERALL.
IT HELPS US WITH THE TIMING OF INITIATING THOSE TREATMENTS AS WELL. IT CAN ALSO HELP IN CERTAIN WOMEN WHO HAVE ENDOMETRIOSIS, WHICH IS ONE OF THE CONDITIONS I MENTIONED. IT CAN HELP THOSE WOMEN WITH

CONTROLLING SOME OF THEIR SYMPTOMS PRIOR TO TREATMENT AND MAY IN SOME WOMEN INCREASE THE LIKELIHOOD THAT THOSE TREATMENTS WILL WORK FOR THEM.
Q. SO WHEN YOU PRESCRIBE CONTRACEPTIVES TO THESE CATEGORIES OF YOUR PATIENTS, FOR SOME PATIENTS DO YOU PRESCRIBE THEM PURELY TO PREVENT PREGNANCY?
A. YES.
Q. AND IN OTHERS, DO YOU PRESCRIBE THEM NOT AT ALL TO PREVENT PREGNANCY?
A. THAT IS CORRECT.
Q. THAT MIGHT BE, FOR EXAMPLE, SOMEONE WHO IS POSTMENOPAUSAL BUT HAS CHRONIC PELVIC PAIN?
A. SOMETHING LIKE THAT, YES.
Q. AND ARE THERE TIMES WHEN YOU PRESCRIBE CONTRACEPTION FOR BOTH PURPOSES, TO PREVENT PREGNANCY BUT ALSO FOR NONPREGNANCY-PREVENTION PURPOSES?
A. YES.
Q. GENERALLY SPEAKING, WHAT TYPES OF CONTRACEPTIVES DO YOU PRESCRIBE TO YOUR PATIENTS?
A. THE CONTRACEPTIVES THAT I USE MOST REGULARLY INCLUDE THE ORAL CONTRACEPTIVE PILL AND THE MIRENA INTRAUTERINE DEVICE.
Q. I WOULD LIKE TO ASK YOU ABOUT YOUR EXPERIENCE IN PRESCRIBING CONTRACEPTIVES TO YOUR PATIENTS.
DO YOU HAVE EXPERIENCE PRESCRIBING

CONTRACEPTIVES TO YOUR PATIENTS BEFORE THE AFFORDABLE CARE ACT AND ITS CONTRACEPTIVE MANDATE WERE THE LAW?
A. YES.
Q. HAVE YOU ALSO PRESCRIBED CONTRACEPTIVES TO PATIENTS SINCE THE AFFORDABLE CARE ACT AND ITS CONTRACEPTIVE MANDATE BECAME THE LAW?
A. YES.
Q. SO YOU HAVE EXPERIENCE IN BOTH WORLDS, PRE-ACA AND POST?
A. YES, I DO.
Q. HAVE YOU SEEN ANY DIFFERENCES IN YOUR PRACTICE OF PRESCRIBING CONTRACEPTIVES TO PATIENTS DURING THESE TWO TIME PERIODS?
A. I HAVE EXPERIENCED THAT, YES.
Q. AND CAN YOU DESCRIBE FIRST, WHAT IT WAS LIKE PRESCRIBING CONTRACEPTIVES BEFORE THE CONTRACEPTIVE MANDATE WAS IN PLACE?
A. SO PRIOR TO THE MANDATE, THERE WAS FAR LESS CERTAINTY ABOUT PATIENT ABILITY TO ACCESS SOME OF THESE TREATMENTS FOR THE STATED PURPOSES WE DISCUSSED, DUE TO CONCERN ABOUT AFFORDABILITY AND COVERAGE AND WHETHER PATIENTS WOULD BE ABLE TO GET ACCESS ON THAT BASIS.
Q. SO AM I CORRECT THAT AS A DOCTOR, YOU WOULD ACCESS THE PATIENTS' NEEDS --
A. YES.

Q. -- MEDICAL NEEDS, AND THEN YOU WOULD PRESCRIBE THE BEST MEDICATION FOR THEM AND THEIR CONDITION; IS THAT RIGHT?
A. THAT'S CORRECT.
MS. KADE: OBJECTION, LEADING.
THE COURT: SUSTAINED. ASK THE QUESTION AGAIN.
BY MR. GOLDMAN:
Q. HOW WOULD YOU -- HOW DO YOU CHOOSE WHICH KIND OF PRESCRIPTION TO PRESCRIBE TO PATIENTS?
A. SO I PERFORM A THOROUGH AND COMPREHENSIVE EVALUATION OF THE PATIENT'S SYMPTOMS AND THE UNDERPINNINGS FOR THEIR CONDITION. I CONSIDER THE INDIVIDUAL CHARACTERISTICS OF THE PATIENT IN TERMS OF PRIOR ASSESSMENTS, PRIOR TREATMENTS, WHAT HAS WORKED, WHAT HAS NOT WORKED, AND ANY SPECIFIC RISK THEY MAY HAVE FOR ANY MEDICAL TREATMENT THAT I MAY OFFER.
AND I INDIVIDUALIZE THE CARE FOR THEIR PARTICULAR UNIQUE SET OF DIAGNOSES AND NEEDS, MAKING THE BEST DECISION THAT I CAN IN CONSULTATION WITH THE PATIENT.
Q. PRE-ACA, ONCE YOU DO YOUR ANALYSIS AND YOU MAKE YOUR PRESCRIPTION OF THE BEST MEDICATION FOR A PATIENT, WERE PATIENTS ALWAYS FILLING IT?
A. NOT ALWAYS.

Q. WERE THERE TIMES WHEN THEY WOULD COME BACK TO YOU AND ASK YOU FOR A DIFFERENT PRESCRIPTION OR NO PRESCRIPTION?

MS. KADE: OBJECTION, LEADING.

THE COURT: SUSTAINED. REASK THE QUESTION IN A NONLEADING WAY.

BY MR. GOLDMAN:

Q. WHEN PATIENTS WOULD NOT FILL THE PRESCRIPTION YOU GAVE THEM, WHAT WOULD HAPPEN?

A. WE WOULD -- I WOULD TRY TO GET AN UNDERSTANDING OF THE LACK OF COMPLIANCE FROM MY PERSPECTIVE OF NOT TAKING OR FILLING THE PRESCRIPTION, AND IN GETTING TO THE BOTTOM OF THIS, FOR MANY PATIENTS IT HAD TO DO WITH SIGNIFICANT COSTS AND INAFFORDABILITY OF THOSE TREATMENTS.

Q. AND DID THAT REASONING TAKE PLACE WHEN YOU PRESCRIBED ORAL BIRTH CONTROL PILLS?

A. IN SOME CASES, YES.

Q. CAN YOU ESTIMATE ROUGHLY WHAT PERCENTAGE OF YOUR PATIENTS WOULD REFUSE A PRESCRIPTION FOR ORAL BIRTH CONTROL PILLS PRE-ACA?

A. IN MY EXPERIENCE DURING THAT TIME, MY ESTIMATE WOULD BE ROUGHLY 10 TO 20 PERCENT OF PATIENTS WOULD HAVE A FINANCIAL BARRIER TO THOSE TYPES OF PRESCRIPTIONS.

Q. AND HOW ABOUT WHEN YOU WOULD PRESCRIBE AFTER

YOUR ANALYSIS IUD'S, WHAT WAS THE PERCENTAGE OF YOUR PATIENTS WHO WOULD REJECT THAT PRESCRIPTION?

A. IT WAS APPROXIMATELY AT LEAST 30 PERCENT.

Q. IS THAT BECAUSE IUDS ARE MORE EXPENSIVE THAN BIRTH CONTROL PILLS?

A. IT HAS TO DO WITH THE COSTS, TOTAL COSTS AROUND THE IUD DEVICE AND THE INSERTION, WHICH HAS A SIGNIFICANT ONE-TIME UP-FRONT COST WHICH, WHEN COMPARED TO THE INTERVAL COST OF THE BIRTH CONTROL PILL, IS SIGNIFICANTLY GREATER. BUT BECAUSE THE IUD THAT I PRESCRIBE REGULARLY, THE MIRENA, LASTS FOR FIVE YEARS, WHEN YOU EXTEND THAT ONE-TIME COST OVER FIVE YEARS, IT ACTUALLY ENDS UP BECOMING LESS EXPENSIVE, ESPECIALLY IF YOU COMPARE IT TO SOME PREPARATIONS WHERE THERE IS A MONTHLY COST THAT, OVER TIME, CAN BE SIGNIFICANTLY ADDITIVE.

Q. SO I WOULD LIKE TO DIG INTO THAT JUST A LITTLE BIT MORE.

YOU SAID THAT A MIRENA LASTS FIVE YEARS?

A. YES.

Q. AND WHAT IS THE UP-FRONT COST?

A. ALL FEES, THE DEVICE AND THE INSERTION, CAN BE ANYWHERE FROM ABOUT 800 TO $1,000.

Q. AND AFTER THE DEVICE IS PURCHASED AND INSERTED FOR 800 TO $1,000, ARE THERE ANY FURTHER COSTS OVER THE

FIVE-YEAR LIFE OF THE MIRENA IUD?

A. IF THE PATIENT HAS NO ISSUES AND DECIDES TO KEEP THE DEVICE IN PLACE FOR FIVE YEARS, THERE ARE NO ADDITIONAL COSTS.

Q. BY CONTRAST, THE ORAL BIRTH CONTROL PILL, YOU HAD SAID THAT IS A MONTHLY PRESCRIPTION?

A. YES.

Q. ROUGHLY HOW MUCH DOES THAT COST?

A. IT DEPENDS, OBVIOUSLY, ON THE PREPARATION. YOU KNOW, THERE ARE SOME PATIENTS WHO CAN PAY ON AVERAGE $30 PER MONTH OR MORE FOR A MONTHLY PRESCRIPTION. SO YOU CAN SEE HOW OVER TIME THE NUMBERS CAN CHANGE.

Q. SO ROUGHLY -- $30 A MONTH IS ROUGHLY, ROUGHLY $360 A YEAR?

A. YES.

Q. AND THEN OVER FIVE YEARS, WHICH IS THE TERM OF THE MIRENA IUD, IT WOULD COST ROUGHLY FIVE TIMES THAT?

A. YES.

Q. AND THAT IS ROUGHLY $1,800, IS THAT CORRECT?

A. YES.

Q. SO WHICH OF THOSE DEVICES IS MORE EFFECTIVE, OR PRESCRIPTION IS MORE EFFECTIVE?

A. THE INTRAUTERINE DEVICE IS A MORE EFFECTIVE CONTRACEPTIVE AND CAN BE MORE EFFECTIVE IN TERMS OF MANAGING HEAVY MENSTRUAL PERIODS FOR SOME WOMEN COMPARED

HEAD TO HEAD TO THE BIRTH CONTROL PILL.

Q. AM I CORRECT THEN TO UNDERSTAND YOU CORRECTLY THAT BECAUSE OF THE COST, WOMEN END UP PAYING MORE MONEY FOR LESS GOOD CARE?

A. THAT IS POTENTIALLY THE CASES FOR SOME WOMEN, YES.

MR. GOLDMAN: COURT'S INDULGENCE, YOUR HONOR.

(PAUSE.)

BY MR. GOLDMAN:

Q. WHEN YOU -- STRIKE THAT.

SO ALL THAT WAS BEFORE THE ACA. AFTER THE ACA AND THE CONTRACEPTIVE MANDATE WENT INTO EFFECT, DID ANYTHING CHANGE?

A. YES. SIGNIFICANT NOTABLE CHANGE IN MY OWN PRACTICE I CAN SPEAK TO WITH THE MOST AUTHORITY IN ACCESS TO THE IUD BASED ON AFFORDABILITY OF THE IUD.

Q. AFTER THE ACA, HOW OFTEN DID YOUR PATIENTS PUSH BACK ON YOUR PRESCRIPTIONS TO THEM?

A. FOR BOTH FORMS OR FOR EITHER?

Q. EITHER.

A. OKAY. FAR LESS. I CAN, YOU KNOW, TRY TO GIVE YOU A NUMBER IN TERMS OF THE ESTIMATE, BUT I'M VERY HARD-PRESSED TO THINK OF A PATIENT THAT I HAVE MANAGED IN RECENT MEMORY FOR WHOM I HAVE RECOMMENDED A MIRENA

IUD WHO HAS HAD DIFFICULTY ACQUIRING IT.
Q. LET ME MAKE SURE I UNDERSTAND THAT. SINCE THE ACA WENT INTO EFFECT, YOU CANNOT THINK OF A SINGLE PATIENT WHO HAS REJECTED YOUR PRESCRIPTION OF A MIRENA IUD?
A. I CAN'T THINK OF ONE THAT EASILY COMES TO MEMORY.
Q. AND BEFORE THE ACA, ROUGHLY 30 PERCENT WERE REJECTING THE MIRENA?
A. YES.
Q. DO YOU TREAT PATIENTS FOR WHOM IT IS DANGEROUS TO GET PREGNANT?
A. I DO.
Q. WHAT HAPPENS TO THEM IF THEY GET PREGNANT ANYWAY?
A. WELL, THERE ARE A VARIETY OF DISORDERS FOR WHICH PREGNANCY CAN BE INCREDIBLY COMPLICATED IF YOU GO INTO PREGNANCY WITH THOSE DISORDERS. THEY CAN BECOME MORE SEVERE AND POTENTIALLY LIFE-THREATENING TO A WOMAN WHO BECOMES PREGNANT IF SHE CARRIES THAT DISORDER INTO PREGNANCY.
Q. I WOULD LIKE TO TURN YOUR ATTENTION TO THE RULES, AND THEY ARE -- I DON'T THINK WE HAVE TO GO THROUGH THEM SPECIFICALLY, BUT IF YOU'D LIKE TO LOOK AT THEM, THEY ARE IN YOUR EXHIBIT BINDER. THE RELIGIOUS

EXEMPTION RULE IS MARKED AS EXHIBIT 1 AND THE MORAL EXEMPTION RULE I BELIEVE IS EXHIBIT 2.
ARE YOU GENERALLY FAMILIAR WITH THESE NEW RULES THAT ARE AT ISSUE IN THIS PROCEEDING?
A. YES.
Q. AND I KNOW IT'S A LONG DOCUMENT, BUT HAVE YOU READ THE RELIGIOUS EXEMPTION RULE?
A. I HAVE.
Q. AND DO YOU BELIEVE YOU UNDERSTAND THAT RULE INSOFAR AS IT WOULD AFFECT PATIENTS LIKE THE ONES YOU TREAT IN PENNSYLVANIA?
A. I BELIEVE I DO.
Q. AND THE MORAL EXEMPTION RULE IS SIMILARLY LONG, BUT HAVE YOU READ IT?
A. YES.
Q. DO YOU BELIEVE YOU UNDERSTAND IT AND CAN UNDERSTAND THE IMPACT IT MIGHT HAVE ON THE PATIENTS YOU TREAT?
A. I DO.
Q. IN YOUR CAPACITY AS AN EXPERT IN WOMEN'S REPRODUCTIVE HEALTH, DO YOU HAVE AN OPINION TO A REASONABLE DEGREE OF CERTAINTY AS TO WHETHER THESE SAME RULES WOULD AFFECT THE REPRODUCTIVE HEALTH OF WOMEN IN PENNSYLVANIA.
MS. KADE: OBJECTION, YOUR HONOR. THIS

GOES BEYOND THE SCOPE OF HER EXPERTISE. WE ARE NOW GETTING INTO STATISTICS.
THE COURT: THAT WAS THE BASIS OF YOUR OBJECTION, ESSENTIALLY. THE OBJECTION THAT YOU LODGED AT BEGINNING INCORPORATES, I THINK, THE OBJECTION YOU ARE MAKING NOW.
MS. KADE: WELL, MY CURRENT OBJECTION IS TO HIS CURRENT QUESTION AND WHAT HE IS ASKING FOR, WHICH IS A STATISTICAL QUESTION ASKING FOR A STATISTICAL ANSWER, AND SHE HAS NOT BEEN QUALIFIED AS THAT TYPE OF AN EXPERT, YOUR HONOR.
THE COURT: SUSTAINED.
MR. GOLDMAN: IF I MAY RESPOND TO THAT, YOUR HONOR, I DON'T ACTUALLY THINK THAT IS WHAT I'M ASKING FOR.
THE COURT: THAT IS -- OKAY. SO WHY DON'T YOU ASK THE QUESTION AGAIN SO THAT WE CAN MAKE SURE IT IS NOT WHAT YOU --
MR. GOLDMAN: SURE.
BY MR. GOLDMAN:
Q. YOU'VE TESTIFIED BASED ON YOUR EXPERIENCE THAT BEFORE THE AFFORDABLE CARE ACT WOMEN WERE NOT UNIFORMLY ACCEPTING YOUR PRESCRIPTION CARE, CORRECT?
A. CORRECT.
Q. AND THEN YOU ALSO TESTIFIED THAT AFTER THE

AFFORDABLE CARE ACT, THAT YOU CAN'T RECALL A SINGLE PATIENT WHO HAS REFUSED A PRESCRIPTION FOR AN IUD, CORRECT?
A. BASED ON -- BASED ON AFFORDABILITY ISSUES, YES.
Q. AND I BELIEVE YOU TESTIFIED THAT THE BASIS FOR THE CHANGES THAT -- POST-ACA CONTRACEPTIVE MANDATE, YOUR PATIENTS HAVE COVERAGE SO THEY DON'T HAVE TO PAY OUT OF POCKET FOR THESE PRESCRIPTIONS, CORRECT?
A. YES.
Q. UNDER THE RULES AS YOU UNDERSTAND THEM, DO YOU BELIEVE THE RULES WILL CHANGE THE NUMBER OF WOMEN IN PENNSYLVANIA WHO HAVE CONTRACEPTIVE CARE COVERAGE?
MS. KADE: OBJECTION, YOUR HONOR. AGAIN, SINCE SHE HAS NO PERSONAL KNOWLEDGE OF ANY OF HER PATIENTS THAT ARE AFFECTED BY THE NEW RULES, THIS IS ASKING FOR STATISTICAL PREDICTION.
THE COURT: IF YOU CAN ANSWER THE QUESTION WITHOUT A STATISTICAL PREDICTION, YOU ARE FREE TO ANSWER.
THE WITNESS: I CAN ANSWER THIS QUESTION SPEAKING TO MY EXPERIENCE OVER 12 YEARS OF PRACTICING WOMEN'S HEALTH IN MY CURRENT POSITION AND MY EXPERIENCE OF MORE DIFFICULT ACCESS AND UTILIZATION PRIOR TO THE MANDATE, AND MY SENSE THAT ANY THREAT TO ACCESS BASED ON RULES SUCH AS THESE MAY CHALLENGE THAT ACCESS AGAIN IN

WAYS THAT I PERSONALLY HAVE EXPERIENCE WITH IN MY PATIENT POPULATION.
BY MR. GOLDMAN:
Q. SO BASED ON THAT EXPERIENCE THAT YOU DESCRIBED, DO YOU HAVE AN OPINION AS TO THE RULES WHICH ALLOW MORE EXEMPTIONS TO THE MANDATORY COVERAGE, WHAT EFFECT THEY WOULD HAVE ON WOMEN IN PENNSYLVANIA?
MS. KADE: SAME OBJECTION, YOUR HONOR. TO THE EXTENT THAT SHE IS BEING ASKED TO PROVIDE HER SENSE OF WHAT MIGHT HAPPEN NOT BASED ON ANY ACTUAL WOMEN IN PENNSYLVANIA THAT SHE KNOWS ABOUT, IS OUTSIDE THE SCOPE OF HER EXPERTISE.
THE COURT: OVERRULED.
YOU CAN ANSWER.
THE WITNESS: SO I JUST WANT TO MAKE SURE I UNDERSTAND THE QUESTION ONE MORE TIME. SPEAK TO THE CONSEQUENCES OF THE EXEMPTIONS?
BY MR. GOLDMAN:
Q. SURE. THE RULES WHICH CREATE EXEMPTIONS TO CARE, WHAT EFFECT IF ANY DO YOU BELIEVE THEY WILL HAVE ON WOMEN IN PENNSYLVANIA?
A. MY SENSE IS THAT IT WILL MAKE AN IMPACT NEGATIVELY ON THE ABILITY OF WOMEN TO ACCESS THESE TREATMENTS, AND IN SO DOING LIMIT OUR ABILITY TO TREAT THE TYPES OF DISORDERS THAT I HAVE DISCUSSED WHICH

WILL -- COULD INCREASE PAIN AND SUFFERING FOR WOMEN WHO HAVE THOSE DISORDERS, WORSENING OF SOME OF THE SERIOUS MEDICAL CONSEQUENCES OF THOSE DISORDERS, AND RESULT IN UNINTENDED PREGNANCIES IN GENERAL. AND TO THE EXTENT THAT SOME OF THOSE UNINTENDED PREGNANCIES ARE IN WOMEN WITH VERY SERIOUS MEDICAL DISORDERS FOR WHOM PREGNANCY MAY BE CONTRA -- EXCUSE ME, PREGNANCY MAY BE RELATIVELY OR ABSOLUTELY CONTRAINDICATED, THAT CAN INCREASE RISKS IN A LIFE-THREATENING WAY FOR SOME WOMEN.
Q. PATIENTS MAY DIE?
A. YES.
Q. DOES THAT OPINION HOLD, IF YOU HAVE ONE, FOR WOMEN OUTSIDE OF PENNSYLVANIA AS WELL BECAUSE OF THE RULES?
MS. KADE: YOUR HONOR, WE ARE SO FAR OUTSIDE THIS WITNESS' EXPERTISE, WE CONTINUE TO OBJECT TO THIS LINE OF QUESTIONING.
THE COURT: SUSTAINED.
MR. GOLDMAN: NOTHING FURTHER.
THE COURT: YOUR WITNESS.
MS. KADE: THANK YOU, YOUR HONOR.
CROSS-EXAMINATION
BY MS. KADE:
Q. GOOD MORNING, DR. BUTTS.
A. GOOD MORNING.

Q. MY NAME IS ELIZABETH KADE.
A. HELLO.
Q. FIRST, WHAT DOCUMENTS DID YOU REVIEW IN ORDER TO PREPARE YOUR DECLARATION?
A. TO PREPARE THE DECLARATION I REVIEWED MY OWN CURRICULUM VITAE. THAT WAS THE PRIMARY DOCUMENT THAT I REVIEWED AND -- PRIMARILY, YES.
Q. WAS THERE ANYTHING ELSE YOU CAN REMEMBER RIGHT NOW?
A. OFF THE TOP OF MY HEAD, NO OTHER DOCUMENTS.
Q. WHO DID YOU MEET WITH IN ORDER TO PREPARE YOUR DECLARATION?
A. I MET WITH COUNSEL SITTING BEFORE ME FROM THE ATTORNEY GENERAL'S OFFICE TO DISCUSS PROCESS AND THE DECLARATION.
Q. ANYBODY ELSE?
A. NO.
Q. TURNING TO YOUR DECLARATION, YOU HAVE TESTIFIED IN PARAGRAPH 53 OF YOUR DECLARATION THAT --
THE COURT: CAN YOU JUST TELL ME WHAT TAB THAT IS AGAIN?
MS. KADE: SURE, I BELIEVE IT IS TAB 8.
THE COURT: I SEE IT. 8, YES.
BY MS. KADE:
Q. I'M AT PARAGRAPH 53, WHICH IS PAGE 9 OF 35 AT

THE TOP, IF THAT IS HELPFUL, AND PAGE 8 AT THE BOTTOM?
A. OKAY.
Q. SO YOU HAVE TESTIFIED THAT AS A RESULT OF THE RULES, SOME WOMEN WILL LOSE COVERAGE, INSURANCE COVERAGE, FOR PREVENTIVE CONTRACEPTIVE CARE, CORRECT?
A. YES.
Q. DO YOU KNOW HOW MANY RELIGIOUS EMPLOYERS ARE CURRENTLY PROTECTED BY INJUNCTION?
A. I DO NOT.
Q. DO YOU KNOW THAT THOSE EMPLOYERS THAT HAVE INJUNCTIONS ARE NOT CURRENTLY PROVIDING CONTRACEPTIVE COVERAGE?
A. I DO NOT.
Q. ARE YOU AWARE OF THE 2016 ZUBIK INJUNCTION?
A. I'M NOT AWARE OF THAT INJUNCTION.
Q. DO YOU KNOW THAT ENTITIES PROTECTED BY THAT INJUNCTION ARE NOT CURRENTLY PROVIDING CONTRACEPTIVE COVERAGE THEN?
A. AGAIN, NOT FAMILIAR WITH THAT CASE.
Q. DO YOU KNOW THAT THERE WERE EXEMPTIONS TO THE MANDATE BEFORE THE NEW RULE WENT INTO EFFECT?
A. CAN YOU REPHRASE THAT QUESTION?
Q. ARE YOU AWARE THAT EVEN BEFORE THE NEW RULES WENT INTO EFFECT, CERTAIN EMPLOYERS WERE NOT REQUIRED TO PROVIDE CONTRACEPTIVE COVERAGE PURSUANT TO THE MANDATE

BECAUSE THEY FELL UNDER ANY ONE OF A NUMBER OF EXEMPTIONS, LIKE THEY WERE A GRANDFATHERED PLAN, THEY WERE A CHURCH PLAN, SOMETHING LIKE THAT?

A. I AM AWARE OF THAT PHENOMENON TO AN EXTENT.

Q. NONE OF YOUR PATIENTS HAS HAD TO ASK FOR A CHEAPER FORM OF CONTRACEPTION SINCE THE MANDATE WENT INTO EFFECT?

A. I'M NOT SURE THAT THAT IS WHAT I TESTIFIED.

MY TESTIMONY WAS THAT SINCE THE MANDATE WENT INTO EFFECT, THERE HAS BEEN OVERALL MUCH BROADENED ACCESS AND FAR LESS PUSHBACK AGAINST ACCESSING THESE TREATMENTS BASED PURELY ON AFFORDABILITY.

Q. SO SOME OF YOUR PATIENTS HAVE STILL ASKED FOR A CHEAPER FORM OF CONTRACEPTION SINCE THE MANDATE WENT INTO EFFECT?

A. I CAN RECALL SOME, BASED ON SOME OF THE INDIVIDUAL VARIATION IN COVERAGE IN TERMS OF GENERIC FORMS OF THE BIRTH CONTROL PILL OR VERSUS BRAND NAMES, BUT IN GENERAL AND ON BALANCE, THIS HAS BEEN FAR LESS OF A PROBLEM POST MANDATE THAN PRE MANDATE.

Q. SO POST MANDATE, IN A POST MANDATE WORLD, WERE ANY OF THE PATIENTS THAT YOU HAD THAT WERE PUSHING BACK ON COST CONCERNS, WERE ANY OF THEM CONCERNED ABOUT THIS BECAUSE OF A DIFFERENCE IN CONTRACEPTIVE COVERAGE FROM THEIR INSURANCE BECAUSE OF AN EXEMPTION?

A. I DON'T THINK WE HAD THAT LEVEL OF CONVERSATION, AND I CAN'T -- I COULD NOT SPEAK TO THAT SPECIFICALLY.

Q. SO YOU ALSO WOULD NOT KNOW IF ANY OF THEM WERE CONCERNED BECAUSE THEIR EMPLOYER WAS SUBJECT TO AN INJUNCTION?

A. I HAVE -- I DO NOT KNOW.

Q. DR. BUTTS, CAN YOU IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS LOST CONTRACEPTIVE COVERAGE AS A RESULT OF THE NEW RULES?

A. AS A RESULT OF THE NEW RULES. I CANNOT IDENTIFY A SPECIFIC INDIVIDUAL PERSON AT THIS MOMENT.

Q. AND CAN YOU IDENTIFY A SINGLE WOMAN IN THE UNITED STATES WHO HAS LOST COVERAGE AS A RESULT OF THE NEW RULES?

A. NOT AT THIS MOMENT, NO.

Q. SO JUST LOOKING BACK AT YOUR DECLARATION, LOOKING AT PARAGRAPH 54 OF YOUR DECLARATION, YOU CANNOT IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHOSE COST OF CONTRACEPTIVE CARE WILL RISE AS A RESULT OF THE RULES, RIGHT?

A. NOT A SPECIFIC INDIVIDUAL PERSON AT THIS MOVEMENT IN TIME, NO.

Q. AND LOOKING AT PARAGRAPH 55, YOU CANNOT IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO WILL HAVE THIS BARRIER TO WOMEN'S ACCESS TO AND USE OF THE

CONTRACEPTIVE THAT IS MEDICALLY RECOMMENDED FOR THEM?

A. WELL, I CAN'T IDENTIFY AT THIS MOMENT, BUT I THINK CERTAINLY A CONCERN AS A PROVIDER IS THE POTENTIALLY EXPANDING NATURE OF THESE BARRIERS. SO THE REASON THAT I CAN'T IDENTIFY SOMEBODY TODAY DOES NOT MEAN THAT IT MAY NOT BE APPLICABLE TO FUTURE PATIENTS.

Q. BUT AGAIN, SITTING HERE TODAY, YOU CAN'T IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS LOST COVERAGE AS A RESULT OF THE NEW RULES, RIGHT?

A. NOT AT THIS MOMENT.

Q. AND SO ALL OF THE HARMS THAT YOU DESCRIBE IN PARAGRAPHS 54 THROUGH 58 OF YOUR DECLARATION, YOU CANNOT IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO WILL SUFFER THOSE HARMS, CORRECT?

A. AS I SAID BEFORE --

MR. GOLDMAN: OBJECTION, YOUR HONOR. THE QUESTION IS A QUESTION ABOUT WHETHER THE DOCTOR CAN IDENTIFY SOMETHING THAT HAS NOT HAPPENED YET. IT'S IMPOSSIBLE TO ANSWER.

THE COURT: SUSTAINED.

BY MS. KADE:

Q. DR. BUTTS, FOR ALL OF THE HARMS THAT YOU LIST IN PARAGRAPHS 54 THROUGH 58, YOU CANNOT IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS CURRENTLY SUFFERED ANY OF THOSE HARMS, CORRECT?

A. I'M JUST LOOKING AT THE DOCUMENT AS I CONSIDER MY ANSWER TO YOUR QUESTION.

MR. GOLDMAN: OBJECTION, YOUR HONOR. SORRY IT'S LATE, BUT IT'S VAGUE BECAUSE IT'S NOT CLEAR IF COUNSEL IS ASKING AS A RESULT OF THE RULES OR IN GENERAL PEOPLE HAVE SUFFERED THOSE CONSEQUENCES.

THE COURT: WELL, THE PROBLEM IS IT'S COMPOUND. IF ALL OF THE AREAS LISTED IN PARAGRAPH 53, 54 THROUGH 58 -- THAT IS A LOT OF AREAS.

MS. KADE: I'M HAPPY TO WALK THROUGH THEM INDIVIDUALLY, YOUR HONOR.

THE COURT: GO AHEAD.

MS. KADE: OKAY.

BY MS. KADE:

Q. OKAY. SO LOOKING AT PARAGRAPH 54, YOU CAN'T IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHOSE COSTS FOR CONTRACEPTIVE CARE HAS RISEN, CORRECT?

MR. GOLDMAN: OBJECTION. AGAIN, HAS RISEN AT ALL OR AS A RESULT OF ANYTHING ELSE?

MS. KADE: AS A RESULT OF THE NEW RULES, CORRECT?

THE WITNESS: NO.

BY MS. KADE:

Q. AND IN PARAGRAPH 55, YOU CANNOT IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS HAD A BARRIER TO

WOMEN'S ACCESS TO AND USE OF CONTRACEPTIVES THAT IS MEDICALLY RECOMMENDED FOR THEM AS A RESULT OF THE NEW RULES, CORRECT?

A. NO.

Q. AND IN PARAGRAPH 56, YOU CANNOT IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS FACED FINANCIAL HARM OR HAS FACED MEDICAL HARM AS A RESULT OF THE NEW RULES, CORRECT?

A. NO.

Q. AND IN PARAGRAPH 57, YOU CAN'T IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS HAD DISRUPTIONS OF THEIR MEDICAL TREATMENT AS A RESULT OF THE NEW RULES, CORRECT?

A. CORRECT.

Q. AND IN PARAGRAPH 58, YOU CANNOT IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS FACED UNINTENDED PREGNANCY AND OTHER ADVERSE MEDICAL CONSEQUENCES AS A RESULT OF THESE NEW RULES, CORRECT?

A. CORRECT.

Q. SO ZOOMING OUT A LITTLE BIT TO CONTRACEPTIVES IN GENERAL, CONTRACEPTIVES ARE USED BY BOTH MEN AND WOMEN, CORRECT?

A. YES.

Q. ARE YOU AWARE THAT SOME EMPLOYERS ONLY HAVE SINCERE RELIGIOUS OR MORAL OBJECTIONS TO JUST A SUBSET OF THE RANGE OF AVAILABLE BIRTH CONTROL METHODS?

MR. GOLDMAN: OBJECTION, YOUR HONOR. I DON'T KNOW HOW THE WITNESS WOULD KNOW WHETHER SOMEONE'S OBJECTION IS SINCERE OR NOT.

THE COURT: SUSTAINED. SUSTAINED. IT'S ALSO BEYOND THE SCOPE.

BY MS. KADE:

Q. DR. BUTTS, THE COST OF PREGNANCIES THAT USE PRENATAL CARE, THOSE ARE TYPICALLY COVERED BY INSURANCE; IS THAT RIGHT?

A. YES.

Q. AND THAT COVERAGE DOES NOT VARY DEPENDING ON WHETHER IT IS AN INTENDED OR UNINTENDED PREGNANCY, RIGHT?

A. WHETHER -- YOU ARE ASKING ME WHETHER INSURANCE COVERAGE VARIES WHETHER THE PERSON INTENDED OR DID NOT INTEND TO BECOME PREGNANT?

Q. CORRECT.

MR. GOLDMAN: JUDGE, IF I MAY OBJECT, I BELIEVE THIS IS BEYOND THE SCOPE OF THE DIRECT.

THE COURT: SUSTAINED.

MS. KADE: IT IS WITHIN THE SCOPE OF HER DECLARATION. SHE TALKS ABOUT THE COSTS OF UNINTENDED PREGNANCIES.

THE COURT: WHERE IS -- POINT ME TO THAT.

MS. KADE: PARAGRAPH 58: SOME OF THESE

WOMEN WILL FACE UNINTENDED PREGNANCY AND OTHER ADVERSE MEDICAL CONSEQUENCES, AND THE COST OF THESE UNINTENDED PREGNANCIES IS THE BASIS OF --

THE COURT: WAIT, WAIT, STOP.

MS. KADE: I APOLOGIZE.

THE COURT: WHICH PARAGRAPH ARE YOU READING?

MS. KADE: IN PARAGRAPH 58, DR. BUTTS SAYS: SOME OF THESE WOMEN WILL FACE UNINTENDED PREGNANCIES AND OTHER ADVERSE MEDICAL CONSEQUENCES.

THE COURT: THAT IS ALL IT SAYS.

MS. KADE: AND THE HARM THAT PLAINTIFFS ARE ALLEGING IN THEIR COMPLAINT IS -- THE COST OF UNINTENDED PREGNANCIES IS ONE OF THEIR ALLEGATIONS.

THE COURT: YOUR QUESTION WAS ABOUT INSURANCE COVERAGE.

MS. KADE: MY NEXT QUESTION IS GOING TO BE ABOUT THE COST OF COVERING UNINTENDED PREGNANCIES ARE COVERED BY AN EMPLOYEE'S HEALTH PLAN. SO IT WOULD NOT BE BORNE BY THE STATE, YOUR HONOR.

MR. GOLDMAN: YOUR HONOR, THIS GOES FAR BEYOND THE DIRECT OR THE DECLARATION.

THE COURT: SUSTAINED. MOVE ON.

BY MS. KADE:

Q. DR. BUTTS, HAVE YOU READ THE RULES THAT ARE AT

ISSUE IN THIS CASE IN THEIR ENTIRETY?

A. I HAVE REVIEWED THE RULES, YES.

Q. HAVE YOU READ ALL OF THE EVIDENCE THAT THE RULES RELY UPON?

A. CAN YOU CLARIFY THAT QUESTION?

Q. SO THE RULES CITE DIFFERENT EVIDENCE AND STUDIES THROUGHOUT THE RULES. HAVE YOU READ ALL OF THOSE STUDIES?

A. NO.

Q. AND YOU HAVE NOT BEEN PRESENTED TO THIS COURT AS AN EXPERT ON INSURANCE MARKETPLACES, RIGHT?

A. NO, I HAVE NOT.

Q. AND YOU HAVE NOT BEEN PRESENTED TO THIS COURT AS AN EXPERT ON THE GOVERNMENT'S DECISION-MAKING PROCESS UNDER THE ADMINISTRATIVE PROCEDURE ACT, RIGHT?

A. NO, I HAVE NOT.

Q. THANK YOU, DR. BUTTS.

MS. KADE: THANK YOU, YOUR HONOR.

THE WITNESS: THANK YOU.

THE COURT: ANY REDIRECT?

MR. GOLDMAN: YES, YOUR HONOR.

REDIRECT EXAMINATION

BY MR. GOLDMAN:

Q. DR. BUTTS, IF -- SINCE THE RULES WENT INTO EXISTENCE, IF A PATIENT CAME TO YOU AND TOLD YOU THAT

THEY COULD NOT AFFORD THE PRESCRIPTION YOU GAVE THEM, WOULD YOU NECESSARILY KNOW THAT IT WAS BECAUSE THEY LOST COVERAGE UNDER THE RULES?

A. I WOULD NOT NECESSARILY KNOW THAT WITHOUT A SIGNIFICANT INVESTIGATION INTO THE REASON FOR THE LOSS, WHICH USUALLY INVOLVES SOMEBODY WITH EXPERTISE IN BILLING AND COVERAGE TO HELP WITH THAT INVESTIGATION.

Q. DO YOU KNOW IF A PATIENT WHO CAME TO YOU WOULD EVEN KNOW THAT THE REASON THEIR PRESCRIPTION ALL OF A SUDDEN HAD A CO-PAY WAS BECAUSE OF THESE NEW RULES?

A. I'M NOT SURE THEY WOULD.

Q. YOU AGREED WITH COUNSEL THAT CONTRACEPTIVES ARE USED FOR BOTH MEN AND WOMEN. ARE PRESCRIPTION CONTRACEPTIVES USED BY BOTH MEN AND WOMEN?

A. NO. JUST WOMEN.

Q. THE WOMEN WHO -- AGAIN, ONLY IF YOU KNOW, WHO CAME BACK TO YOU POST ACA, OR MAY HAVE, WHO HAD CONCERNS AND HAD TO REJECT THEIR PRESCRIPTIONS, DO YOU KNOW IF THOSE WOMEN WERE PRIVATELY INSURED?

A. POST ACA OR --

Q. YES.

A. POST ACA WITH CONCERNS. I BELIEVE, AGAIN, TO THE BEST OF MY RECOLLECTION THAT MANY WERE.

Q. DO YOU KNOW THE PERCENT OF WOMEN WHO SUFFER FROM UNINTENDED PREGNANCY IN PENNSYLVANIA?

A. I BELIEVE THAT NUMBER IS 53 PERCENT.

Q. AND DO YOU KNOW IF THAT IS HIGHER OR LOWER THAN THE NATIONAL AVERAGE?

A. ACCORDING TO DATA FROM THE GUTTMACHER INSTITUTE, WHICH IS A CLEARINGHOUSE FOR INFORMATION ABOUT REPRODUCTIVE HEALTH AND PREGNANCY, IT IS HIGHER, AS THE NUMBER IN THE UNITED STATES IS 45 PERCENT.

Q. AND IS THAT INFORMATION AVAILABLE ON THE WEBSITE OF THE GUTTMACHER INSTITUTE?

A. IT IS.

Q. ONE OTHER LAST LINE OF QUESTIONING I JUST WANT TO CLARIFY.

COUNSEL ASKED YOU WHAT YOU REVIEWED PRIOR TO YOUR TESTIMONY. IN ADDITION TO YOUR RÉSUMÉ, DID YOU ALSO REVIEW YOUR PATIENT RECORDS?

A. I REVIEWED MY PATIENT RECORDS IN AN ATTEMPT TO GET AN UNDERSTANDING OF PRACTICE PATTERNS OVER TIME AND FLUCTUATIONS, BASED ON THE NATURE OF THIS CASE.

Q. AND DID YOU LOOK AT THOSE PATIENT RECORDS FOR A TIME PERIOD BEFORE THE AFFORDABLE CARE ACT?

A. I DID.

Q. DID YOU ALSO LOOK AT THE RECORDS FOR AFTER THE AFFORDABLE CARE ACT?

A. I DID.

Q. DID YOU NOTICE ANY TRENDS WITH RESPECT TO WHAT

PRESCRIPTIONS PATIENTS WERE FILLING?

A. SO THE DATA THAT I CAN SPEAK TO WITH THE MOST -- IN THE MOST DEPTH WOULD PERTAIN TO THE MIRENA IUD. AND I CAN TELL YOU, IN MY OWN INDIVIDUAL PRACTICE, WHICH I THINK REFLECTS OTHERS, BUT I CERTAINLY CANNOT SPEAK TO ANYONE ELSE'S PRACTICE WITH AS MUCH ACCURACY AS MY OWN, IN MY OWN PRACTICE, PRIOR TO THE ACA AND AFTER, THERE HAS BEEN A FIVEFOLD INCREASE IN THE NUMBER OF MIRENA IUD'S I HAVE INSERTED INTO -- INSERTED IN PATIENTS IN MY PRACTICE. SO A SIGNIFICANTLY ELEVATED INCREASE OVER TIME.

Q. SO PRE AND POST ACA, THE NUMBER OF PATIENTS WHO HAVE HAD A MIRENA IUD IMPLANTED INCREASED FIVE TIMES?

A. YES, IN MY PRACTICE.

Q. AND HAVE YOUR PRESCRIBING PRACTICES CHANGED SIGNIFICANTLY OVER THOSE YEARS?

A. MY MANAGEMENT OF THE CONDITIONS FOR WHICH I UTILIZE THIS TREATMENT HAS NOT CHANGED, NOR HAS THE EVIDENCE SUPPORTING THE USE OF A MIRENA IUD FOR THESE TREATMENTS. THE BULK OF THE EVIDENCE SUPPORTING THIS AS AN EXCELLENT AND OUTSTANDING TREATMENT FOR CHRONIC PELVIC PAIN AND HAVING MENSTRUAL BLEEDING WAS WELL ESTABLISHED PRIOR TO THE MANDATE. SO MY PRACTICE APPROACH AND THE EVIDENCE WERE ESTABLISHED WELL BEFORE THE MANDATE.

Q. SO TO WHAT DO YOU ATTRIBUTE THIS FIVEFOLD INCREASE IN YOUR PATIENTS WHO ARE NOW USING MIRENA IUD'S MORE EFFECTIVE FORM OF BIRTH CONTROL SINCE THE ACA WENT INTO EFFECT?

A. OF COURSE, IT CAN BE MULTIFACTORIAL. I THINK ONE OF THE FACTORS THAT WE HAVE TO CONSIDER AS INCREDIBLY INFLUENTIAL IS THE ACCESS GRANTED TO WOMEN TO UTILIZE THIS TREATMENT AS A BYPRODUCT OF THE MANDATE.

Q. COST?

A. YES. SIGNIFICANT REDUCTION, ELIMINATION OF COSTS SUCH THAT WOMEN CAN NOW GET ACCESS TO SOMETHING THAT I HAVE ALWAYS HAD IN MY MIND TO UTILIZE FOR THEIR CARE, JUST HAVE A GREATER ABILITY TO DO SO.

Q. DO YOU KNOW IF THAT IS THE PRIMARY REASON FOR THE FIVEFOLD INCREASE, DO YOU KNOW?

A. I MEAN, AGAIN, I THINK IT IS CERTAINLY MULTIFACTORIAL, BUT IN MY OPINION, BASED ON THE THINGS I MENTIONED ABOUT MY APPROACH TO CARE FOR THESE PATIENTS AND THE EVIDENCE, NOT SIGNIFICANTLY CHANGING SINCE THE MANDATE, I WOULD HAVE TO CONCEDE THAT THE MANDATE IS A PRIMARY DRIVING FORCE FOR THE FIVEFOLD INCREASED UTILIZATION OF MIRENA IUDS IN MY PRACTICE.

MR. GOLDMAN: NOTHING FURTHER, YOUR HONOR.

THE COURT: OKAY. ONE QUESTION, I HAVE

ONE QUESTION. WHAT PERCENTAGE OF YOUR PATIENTS ARE FROM PENNSYLVANIA?

THE WITNESS: THE MAJORITY. IF I COULD GIVE YOU A NUMBER, I WOULD SAY PROBABLY 80 PERCENT OR MORE.

THE COURT: OKAY. THANK YOU, YOU CAN LEAVE THE STAND.

THE WITNESS: THANK YOU.

(WITNESS EXCUSED.)

THE COURT: IT IS NOW 12:30, WHICH IS A PERFECT TIME FOR LUNCH. WHAT WE WILL DO IS WE WILL HAVE LUNCH BREAK FOR AN HOUR AND WE WILL BE BACK AT 1:30, AND WHEN WE COME BACK, I UNDERSTAND THAT YOU HAVE BEEN DOING THE RESEARCH ON THE GRANDFATHERING. I HAVE SEEN YOU RUNNING AROUND.

MR. HEALY: APOLOGIZE FOR THE RUNNING AROUND.

THE COURT: NOT A PROBLEM. I'M HAPPY TO SEE THAT YOU'RE DOING IT. SO I WILL TALK TO YOU AFTER THE THIRD AND FINAL WITNESS FROM THE COMMONWEALTH. THANK YOU.

THE CLERK: ALL RISE.

(LUNCHEON BREAK TAKEN.)

MS. BOLAND: OUR NEXT WITNESS IS CYNTHIA CHUANG.

MR. GOLDMAN: YOUR HONOR, IF I MAY ADDRESS A QUICK PROCEDURAL MATTER WITH THE COURT. MAY I APPROACH, YOUR HONOR?

THE COURT: YOU MAY.

MR. GOLDMAN: I HAVE A DOCUMENT THAT I WOULD LIKE TO BE ABLE TO PASS UP TO YOUR HONOR. THIS IS A DOCUMENT THAT IS CITED IN OUR COMPLAINT WITH A HYPERLINK AT PARAGRAPH 99.

THE COURT: OKAY.

MR. GOLDMAN: SO THE COMMONWEALTH WOULD LIKE TO MOVE THIS DOCUMENT INTO EVIDENCE ALONG WITH THE ATTACHMENT WHICH IS PART OF THE ARTICLE. WE APPROACHED THE GOVERNMENT DURING BREAK, AND I BELIEVE THEY WILL STIPULATE TO THE AUTHENTICITY AND ADMISSIBILITY OF THE ARTICLE, BUT NOT TO THE ATTACHMENT.

THE COURT: WHAT DO YOU THINK THE ATTACHMENT IS?

MR. GOLDMAN: THE ARTICLE SAYS THAT IT IS A LEAKED COPY OF THE RULES, THE DRAFT RULES THAT ARE BEFORE US NOW.

THE COURT: SO LET ME -- LET'S ASSUME --

LET ME HEAR FROM YOU JUST ON THE PROCEDURAL MATTER OF WHAT YOU'RE OBJECTING TO HERE. YOU ARE OKAY WITH THE ARTICLE BUT NOT THE ATTACHMENT?

MS. KADE: THANK YOU, YOUR HONOR. YES.

THE ATTACHMENT, WE WERE JUST HANDED THIS, YOU KNOW, 125-PAGE DOCUMENT, SO WE ARE NOT ABLE TO STIPULATE AS TO THE AUTHENTICITY OF IT AT THIS POINT, BUT WE ALSO ARE NOT ABLE TO STIPULATE TO THE ADMISSIBILITY OF IT BECAUSE IT'S CLEARLY LABELED CONFIDENTIAL DRAFT AND COVERED BY PRIVILEGES. SO WE ARE NOT ABLE TO STIPULATE TO EITHER THE AUTHENTICITY OR THE ADMISSIBILITY AT THIS POINT.

THE COURT: I ACCEPT THAT YOU ARE NOT ABLE TO DO IT. I'M NOT SURE WHETHER YOU ARE RIGHT WITH RESPECT TO THE CONFIDENTIALITY AND DRAFT, THAT COMPONENT OF WHAT YOU JUST SAID.

SO WHAT IS THE POINT OF THIS IN THE CONTEXT OF THIS PRELIMINARY INJUNCTION HEARING? I MEAN, IT'S NOT THE REGULATIONS. I DON'T KNOW WHAT IT IS. AND THEN THERE IS A VOX ARTICLE. SO HOW DOES IT PERTAIN TO WHAT WE ARE DOING HERE?

MR. GOLDMAN: RIGHT. SO -- AND THIS IS PART OF THE REASON WHY WE STATED IT IN OUR COMPLAINT, WE CITED IT. SO THIS -- IT'S A PUBLIC DOCUMENT NOW, NO MATTER WHAT IT SAYS ON IT. WE DIDN'T CHANGE IT. IT IS EXACTLY WHAT WAS ATTACHED TO THE ARTICLE, BUT IT PURPORTS TO BE A DRAFT OF THE REGULATIONS WHICH WAS LEAKED. IT IS -- I HAVE NOT LINED IT UP AGAINST THE ACTUAL FINAL REGULATIONS, BUT THEY ARE REMARKABLY SIMILAR. AND SO IF YOU ARE LOOKING AT WHAT THE AGENCIES

WERE DOING IN TERMS OF RULE MAKING AND CONSIDERATION, YOU CAN LOOK -- WELL, AT THIS MOMENT IN TIME, THIS IS WHAT PURPORTS TO BE A DRAFT. LATER IN TIME, THERE IS THESE -- THERE HAS BEEN NO -- THERE WERE NO DRAFT RULES PUT FORTH FOR COMMENT, FOR NOTICE OR COMMENT. SO YOU CAN LOOK AT WHAT CHANGES, IF ANY, TOOK PLACE BETWEEN THIS POINT IN TIME, THE ARTICLE IS MAY 31, AND WHEN THE RULES WERE ACTUALLY PROMULGATED.

THE COURT: THAT IS AN INTERESTING EXERCISE, BUT I STILL DON'T UNDERSTAND WHY IT IS RELEVANT HERE, BECAUSE YOUR POINT IS THAT THE NEW RULES WERE ISSUED WITHOUT NOTICE AND COMMENT AND WITHOUT GOOD CAUSE. SO HOW DOES -- HOW DOES THIS -- I MEAN, ASSUMING THAT THIS IS A DRAFT VERSION OF THE RULES ISSUED SOME MONTHS BEFORE THE FINAL VERSION WAS ISSUED, HOW DOES IT IMPACT ON WHAT WE ARE DOING HERE TODAY, WHICH IS DECIDING THE PRELIMINARY INJUNCTION MOTION?

MR. GOLDMAN: COURT'S INDULGENCE, YOUR HONOR, JUST TO CLARIFY.

(PAUSE.)

MR. GOLDMAN: YES, SO THE BEARAK ARTICLE FROM THE GUTTMACHER INSTITUTE WAS A FOOTNOTE TO THE RULES IN THE IFRS, AND THE GOVERNMENT IS TAKING THE POSITION THAT THE RULES HAVE RELIED HEAVILY ON THIS ARTICLE, WHICH IS IN THE FOOTNOTE OF THE FINAL.

THE ISSUE HERE IS, IN THIS DRAFT, IT'S NOT IN HERE BUT THE RULES ARE THE SAME.

THE COURT: OKAY. WELL, I DON'T THINK I CAN ADMIT THE ATTACHMENT BECAUSE WE DON'T KNOW WHERE IT CAME FROM, WE DON'T -- IT SAYS "DRAFT" ON IT. IT SAYS "DEPARTMENT OF THE TREASURY" BUT IT CERTAINLY DOES NOT LOOK LIKE THE FORM THE RULES USUALLY TAKE. I DON'T KNOW WHETHER ONCE THE DOCUMENT IS FINISHED IN THE AGENCY IT THEN GOES OFF TO SOME DEPARTMENT AND GETS TRANSFORMED INTO WHAT THE RULES USUALLY LOOK LIKE, SO I JUST DON'T KNOW WHAT IT IS. WE DON'T HAVE ANYONE HERE TO TELL US WHAT IT IS, SO I CAN'T ADMIT THAT.

AND I THINK THAT THE GOVERNMENT HAS NOT OBJECTED TO THE ARTICLE BEING ADMITTED, CORRECT?

MS. KADE: CORRECT, YOUR HONOR.

THE COURT: I'M HAPPY TO ADMIT THE ARTICLE, BUT I HAVE TO TELL YOU, I DON'T THINK I'M GOING TO RELY ON IT BECAUSE IT'S A NEWSPAPER ARTICLE SAYING THINGS THAT I -- THERE IS JUST NO TESTIMONY TO DETERMINE WHETHER IT IS IN FACT THE CASE.

MR. GOLDMAN: I UNDERSTAND. MAY I JUST TRY ONE OTHER LINE AND THEN --

THE COURT: GO AHEAD.

MR. GOLDMAN: AND THAT IS JUST THAT WE DON'T KNOW -- WE ARE NOT SAYING THAT THIS IS IN FACT A

DRAFT OF THE RULES AT THAT TIME. THIS IS JUST WHATEVER THE ARTICLE SAID.

THE COURT: I UNDERSTAND. SO WE ARE JUST GOING TO -- WE WILL PUT IT IN THE RECORD IN THE LIMITED WAY THAT IT IS. WE WILL PUT IT IN THE RECORD, BUT I CAN TELL YOU NOW THAT I WON'T BE RELYING ON IT.

MR. GOLDMAN: FAIR ENOUGH, YOUR HONOR.

THE COURT: OKAY. YOUR NEXT WITNESS.

MS. BOLAND: MAY I APPROACH?

THE COURT: YOU MAY.

MS. BOLAND: GOOD AFTERNOON, YOUR HONOR. IT'S NICOLE BOLAND AGAIN FROM THE COMMONWEALTH, AND WE CALL DR. CYNTHIA CHUANG.

MS. KOPPLIN: YOUR HONOR, WE WOULD OBJECT TO THIS WITNESS AS CUMULATIVE.

THE COURT: OKAY. HOLD ON A SEC AND LET ME -- BEFORE YOU DO, LET ME JUST HAVE HER SWORN.

(CYNTHIA CHUANG, COMMONWEALTH'S WITNESS, SWORN.)

THE CLERK: PLEASE STATE AND SPELL YOUR NAME FOR THE RECORD.

THE WITNESS: CHUANG IS SPELLED C-H-U-A-N-G.

THE COURT: OKAY. BEFORE I ADDRESS YOUR OBJECTION, GIVE ME IN A NUTSHELL WHAT YOU INTEND TO

ELICIT FROM THIS WITNESS.

MS. BOLAND: SURE, YOUR HONOR. DR. CHUANG WAS ACTUALLY THE LEAD AUTHOR ON THE "MY NEW OPTIONS" STUDY THAT DR. WEISMAN PREVIOUSLY TESTIFIED ABOUT, SO SHE CAN OFFER ADDITIONAL INFORMATION ABOUT THAT STUDY. AND WE ALSO HAVE A DEMONSTRATIVE EXHIBIT REFLECTING THOSE FINDINGS.

THE COURT: IS THE "MY NEW" STUDY THE PENNSYLVANIA STUDY THAT WEISMAN TALKED ABOUT?

MS. BOLAND: YES.

THE COURT: OKAY. THE ONE THAT IS NOT PUBLISHED YET.

MS. BOLAND: CORRECT, YOUR HONOR. AND DR. CHUANG IS ACTUALLY THE LEAD, AND THERE'S A FEW POINTS TO CLARIFY WITH RESPECT TO THE PRIOR TESTIMONY. AND ALSO, DR. CHUANG IS A PRACTICING PHYSICIAN SO SHE HAS THE CLINICAL PERSPECTIVE THAT DR. WEISMAN DID NOT OFFER PREVIOUSLY.

THE COURT: OKAY. DO YOU INTEND TO GO OVER ALL THE FACTS THAT YOU HAVE ALREADY GONE OVER WITH PROFESSOR WEISMAN?

MS. BOLAND: REGARDING THE "MY NEW OPTIONS" STUDY?

THE COURT: YES.

MS. BOLAND: TO A SMALL DEGREE, JUST FOR

CLARIFICATION OF SOME DATES OF THE STUDY. SHE IS MORE PREPARED TO SPEAK TO MORE OF THE DETAILS OF THE STUDY. I WON'T GO IN DEPTH AND REPEAT EVERYTHING THAT DR. WEISMAN SAID, BUT JUST A VERY GENERAL OVERVIEW OF THE STUDY AND JUST TO CLARIFY THE TIME FRAMES OF THE STUDY FOR THE RECORD.

THE COURT: OKAY. WHAT IS YOUR RATIONALE FOR --

MS. KOPPLIN: YOUR HONOR, AS PLAINTIFFS' COUNSEL ALLUDES TO, THE TESTIMONY WOULD BE HIGHLY DUPLICATIVE OF WHAT PROFESSOR WEISMAN AND DR. BUTTS HAVE ALREADY TESTIFIED TO. BASED ON THE WITNESS' DECLARATION, SHE REACHES MANY OF THE SAME CONCLUSIONS AND RELIES ON MUCH OF THE SAME EVIDENCE.

SPECIFICALLY I WOULD POINT YOU TOWARDS, IN THE THIRD CIRCUIT, ROBERT V STETSON SCHOOL INC., THAT'S 256 F.3D 159, WHERE THE EXCLUSION OF AN EXPERT WAS UPHELD ON CUMULATIVE GROUNDS WHEN TWO OTHER EXPERTS HAD ALREADY TESTIFIED AT LENGTH ON THE SAME ISSUE.

THE COURT: OKAY. I UNDERSTAND THAT PRECEDENT, BUT, YOU KNOW, THERE IS NO REASON WHY IT APPLIES HERE. AND WE ARE ALL HERE, WE ARE ALL FRIENDS HERE. YOU KNOW, WE MIGHT AS WELL JUST GO FOR IT. WE DON'T HAVE A JURY SO THEY CAN'T BE PREJUDICED BY WHAT WE ARE ABOUT TO HEAR. IT'S ONLY ME.

OKAY. GO AHEAD.

MS. BOLAND: THANK YOU, YOUR HONOR.

DIRECT EXAMINATION

BY MS. BOLAND:

Q. JUST A FEW HOUSEKEEPING MATTERS TO START OFF. DR. CHUANG, WILL YOU KINDLY REFER TO TAB 6 IN THE BINDER?

A. YES.

Q. CAN YOU IDENTIFY THAT DOCUMENT FOR THE COURT, PLEASE?

A. YES, THAT IS MY DECLARATION.

Q. WILL YOU JUST KINDLY FLIP THROUGH AND TELL US IF IT APPEARS TO BE COMPLETE AND ACCURATE?

A. YES.

Q. GREAT. I WOULD LIKE TO POINT YOU NOW TO TAB 7. WILL YOU KINDLY IDENTIFY THAT DOCUMENT FOR THE COURT?

A. YES, THAT IS MY CV.

Q. AND WILL YOU KINDLY JUST FLIP THROUGH AND CONFIRM THAT IT IS COMPLETE AND ACCURATE.

A. YES.

Q. GREAT. THANK YOU, DOCTOR.

SO THE COURT HAS YOUR CV TO CONSIDER. I'M NOT GOING TO REVIEW EVERYTHING ON IT BUT I DO WANT TO HIGHLIGHT A FEW POINTS.

TO START OFF, WHO'S YOUR EMPLOYER?

A. I WORK AT THE PENN STATE HERSHEY MEDICAL CENTER.

Q. AND HOW ARE YOU EMPLOYED AT PENN STATE HERSHEY?

A. I'M A PHYSICIAN THERE. I'M A GENERAL INTERNIST. I'M CHIEF OF THE DIVISION OF GENERAL INTERNAL MEDICINE AND I'M A PROFESSOR OF MEDICINE AND PUBLIC HEALTH SCIENCES.

Q. SO YOU ARE A PRACTICING DOCTOR AND A PROFESSOR?

A. CORRECT.

Q. DO YOU ALSO CONDUCT RESEARCH?

A. I DO.

Q. ARE YOU FAMILIAR WITH THE CONTRACEPTIVE MANDATE?

A. YES, I AM.

Q. WHAT IS YOUR UNDERSTANDING OF THE CONTRACEPTIVE MANDATE?

A. THE MANDATE SAYS THAT FOR MOST PRIVATELY INSURED WOMEN, THAT CONTRACEPTION -- FDA-APPROVED CONTRACEPTION WOULD BE COVERED WITH NO OUT-OF-POCKET COSTS.

Q. AND HAVE YOU RESEARCHED THE CONTRACEPTIVE MANDATE AS PART OF YOUR WORK?

A. YES, I HAVE.

Q. AND BEFORE WE GET INTO THAT RESEARCH, JUST A COUPLE OF QUESTIONS ON YOUR BACKGROUND. WILL YOU JUST VERY BRIEFLY DESCRIBE YOUR EDUCATIONAL BACKGROUND FOR THE COURT?

A. SURE. I COMPLETED MY UNDERGRADUATE TRAINING AT

THE UNIVERSITY OF MICHIGAN, WHERE I GRADUATED WITH HONORS. I THEN SPENT A YEAR LIVING IN NORTHERN CALIFORNIA WHERE I WORKED IN A FAMILY PLANNING CLINIC FOR A YEAR, PROVIDING REPRODUCTIVE HEALTHCARE SERVICES AT A FAMILY PLANNING CLINIC.

I THEN STARTED MEDICAL SCHOOL AT NEW YORK UNIVERSITY, AND FOLLOWING MY MEDICAL DEGREE, I COMPLETED MY INTERNAL MEDICINE RESIDENCY TRAINING AT TEMPLE HOSPITAL HERE IN PHILADELPHIA AS WELL AS MY CHIEF RESIDENCY. THAT WAS IN 2001, AND THEN FOLLOWING THAT, I DID A GENERAL INTERNAL MEDICINE FELLOWSHIP AT BOSTON UNIVERSITY. I DID A GENERAL INTERNAL MEDICAL FELLOWSHIP, WHICH INCLUDED A MASTERS OF EPIDEMIOLOGY AS WELL AS A RESIDENCY IN PREVENTIVE MEDICINE.

Q. DID YOU CONDUCT RESEARCH AS PART OF YOUR FELLOWSHIP?

A. I DID. THE PRIMARY PURPOSE OF THE FELLOWSHIP WAS RESEARCH TRAINING, YES.

Q. AND WHAT WAS THE FOCUS OF YOUR RESEARCH?

A. I HAD ALREADY HAD A STRONG INTEREST IN WOMEN'S HEALTH AND REPRODUCTIVE HEALTHCARE. THE PRIMARY FOCUS OF MY RESEARCH THERE WAS EMERGENCY CONTRACEPTION.

Q. THANK YOU, DOCTOR.

I CAN SEE FROM YOUR RÉSUMÉ THAT YOU'VE AUTHORED NUMEROUS SCHOLARLY ARTICLES. DO YOU MIND

GIVING THE JUDGE JUST A BALLPARK IDEA OF HOW MANY SCHOLARLY ARTICLES YOU HAVE WRITTEN THROUGHOUT YOUR CAREER?

A. I BELIEVE THERE'S 70 PUBLICATIONS RIGHT NOW.

Q. HAVE YOU AUTHORED ANY PUBLICATIONS REGARDING CONTRACEPTION?

A. YES, THAT'S -- PROBABLY THE MAJORITY OF THE PUBLICATIONS ARE ABOUT CONTRACEPTION.

Q. AND CAN YOU JUST KINDLY GIVE SOME EXAMPLES OF SOME OF THE TOPICS THAT WOULD INCLUDE?

A. YEAH, SURE. SO LIKE I SAID, WHEN I STARTED IN MY FELLOWSHIP TRAINING, THE BULK OF ARTICLES AROUND THAT TIME WERE ABOUT EMERGENCY CONTRACEPTION. FOLLOWING THAT, WHEN I CAME TO PENN STATE, MY FOCUS TURNED TOWARD UNINTENDED PREGNANCY AND CONTRACEPTIVE USE IN WOMEN WITH CHRONIC MEDICAL CONDITIONS.

THERE IS ALSO SOME PUBLICATIONS ABOUT GESTATIONAL WEIGHT GAIN DURING PREGNANCY, AND THEN MORE RECENTLY, MY PUBLICATIONS ARE ABOUT CONTRACEPTIVE BEHAVIOR AND REPRODUCTIVE LIFE PLANNING AS A TOOL TO ASSIST WITH CONTRACEPTIVE DECISION-MAKING.

Q. AND ARE SOME OF THOSE ARTICLES SPECIFICALLY ABOUT THE CONTRACEPTIVE MANDATE?

A. SEVERAL OF THEM ARE IN THE CONTEXT OF THE CONTRACEPTIVE MANDATE, YES.

Q. AND ARE ALL THOSE PUBLICATIONS THE PRODUCT OF RESEARCH THAT YOU'VE PERSONALLY CONDUCTED?
A. YES.
Q. AND SEPARATE FROM THAT WORK, DO YOU ALSO SERVE AS A PEER REVIEWER FOR ARTICLES IN OTHER PUBLICATIONS?
A. YES. I AM FREQUENTLY ASKED TO PEER REVIEW FOR JOURNALS. I'M ON THE EDITORIAL BOARD OF A JOURNAL CALLED WOMEN'S HEALTH ISSUES, SO I REVIEW FOR THEM REGULARLY. AND I'M ALSO FREQUENTLY ASKED BY OTHER JOURNALS TO REVIEW, USUALLY AROUND TOPICS RELATED TO WOMEN'S HEALTH OR PREVENTIVE HEALTHCARE.
Q. I NOTICE FROM YOUR CV THAT YOU ARE AN INVESTIGATOR. AND WHAT DOES IT MEAN TO BE AN INVESTIGATOR?
A. IT MEANS YOU ARE A RESEARCHER.
Q. AND HOW ARE YOUR PROJECTS FUNDED WHEN YOU DO INVESTIGATIONS?
A. SO RESEARCH CAN BE FUNDED IN ANY NUMBER OF WAYS. THEY CAN BE FUNDED THROUGH THE FEDERAL GOVERNMENT LIKE THROUGH THE NATIONAL INSTITUTES OF HEALTH OR THE CDC, FOR EXAMPLE. THERE'S ALSO SOME NONFEDERAL AGENCIES LIKE PCORI, WHICH IS THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE WHERE SOME OF MY WORK WAS BEEN FUNDED, AS WELL AS THE NIH. IT CAN BE FUNDED BY PRIVATE FOUNDATIONS. IT CAN BE FUNDED ALSO BY INSTITUTIONS, BUT SO --

ACADEMIC INSTITUTIONS.
Q. ABOUT HOW MANY PROJECTS HAVE YOU BEEN INVOLVED IN AS AN INVESTIGATOR THROUGHOUT YOUR CAREER?
A. I THINK ABOUT 20.
Q. AND HAVE THOSE PROJECTS BEEN FUNDED BY GRANTS?
A. YES, THOSE ARE ALL THE ONES THAT ARE FUNDED.
Q. DO YOU HAVE ANY OFFICIAL ROLES AT HERSHEY WITH REGARD TO RESEARCH?
A. LIKE I MENTIONED EARLIER, I'M THE CHIEF OF THE DIVISION OF GENERAL INTERNAL MEDICINE SO I OVERSEE ALL ASPECTS OF THE DIVISION, INCLUDING THE RESEARCH ACTIVITIES IN THE DIVISION.
PRIOR TO BECOMING DIVISION CHIEF TWO YEARS AGO, I WAS THE ASSOCIATE DIRECTOR FOR RESEARCH FOR THE DIVISION. I'M ALSO THE RESEARCH DIRECTOR FOR THE PENN STATE BIRCWH PROGRAM. BIRCWH STANDS FOR BUILDING INTERDISCIPLINARY RESEARCH CAREERS IN WOMEN'S HEALTH, WHICH IS AN NIH-FUNDED PROGRAM TO HELP PROVIDE SUPPORT FOR JUNIOR INVESTIGATORS TRYING TO BUILD THEIR CAREERS IN WOMEN'S HEALTH RESEARCH.
Q. HAVE ANY OF YOUR PROJECTS INVOLVED THE IMPACT OF THE CONTRACEPTIVE MANDATE?
A. YES.
Q. CAN YOU TELL US ABOUT A PROJECT TO THAT EFFECT?
A. SURE. SO THE PROJECT THAT WAS REFERRED TO

EARLIER, THE "MY NEW OPTIONS" STUDY, IS A STUDY THAT WAS FUNDED BY PCORI, THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE. AND THE "MY NEW OPTIONS" STUDY WAS A TWO-YEAR STUDY WHERE WE LOOKED AT THE EFFECT OF WEB-BASED CONTRACEPTIVE INTERVENTIONS TO SEE IF THEY HELPED WOMEN WITH THEIR CONTRACEPTIVE DECISION-MAKING.
Q. OKAY. WE WILL DISCUSS THAT PROJECT A LITTLE BIT MORE AT LENGTH IN A FEW MINUTES.
I WANTED TO TURN NOW TO YOUR MEDICAL PRACTICE. IN ADDITION TO YOUR WORK AS A PROFESSOR, YOU TESTIFIED THAT YOU ALSO MAINTAIN AN ACTIVE MEDICAL PRACTICE; IS THAT RIGHT, DOCTOR?
A. CORRECT.
Q. WHERE IS YOUR PRACTICE LOCATED?
A. I PRACTICE AT THE HERSHEY MEDICAL CENTER, AT THE INTERNAL MEDICINE EAST CLINIC, WHICH IS LOCATED AT 35 HOPE DRIVE IN HERSHEY.
Q. AND WHAT KIND OF PRACTICE DO YOU HAVE?
A. IT'S AN INTERNAL MEDICINE PRACTICE, SO IT'S ADULT PRIMARY CARE. MY PRACTICE HAS MOSTLY WOMEN PATIENTS, AND SO ADULT WOMEN.
Q. HOW LONG HAVE YOU BEEN PRACTICING MEDICINE?
A. WELL, I GRADUATED FROM MEDICAL SCHOOL 20 YEARS AGO, SO 20 YEARS.
Q. AND ARE CONTRACEPTIVES PART OF YOUR MEDICAL

PRACTICE?
A. YES.
Q. HOW SO?
A. ANY TIME I HAVE A FEMALE PATIENT WHO'S OF REPRODUCTIVE AGE WHO'S CAPABLE OF PREGNANCY, IT'S A PART OF EVERY VISIT TO DISCUSS WHAT HER DESIRES ARE AROUND PREGNANCY OR -- EITHER ACHIEVING PREGNANCY OR AVOIDING PREGNANCY, AND SO OBVIOUSLY, CONTRACEPTION BECOMES AN IMPORTANT PART OF THAT CONVERSATION.
Q. THANK YOU.
MS. BOLAND: AT THIS TIME, YOUR HONOR, I WOULD LIKE TO OFFER DR. CHUANG AS AN EXPERT IN THE AREAS OF PREVENTATIVE MEDICAL CARE FOR WOMEN, INCLUDING CONTRACEPTIVE CARE.
MS. KOPPLIN: WE WOULD OBJECT TO THAT, YOUR HONOR.
THE COURT: REASON?
MS. KOPPLIN: FIRST, FOR THE SAME REASONS AS THE OTHER EXPERTS. THIS EXPERT WAS NOT DISCLOSED TO US AS REQUIRED BY FEDERAL RULE OF CIVIL PROCEDURE 26(A) OR FEDERAL RULES OF EVIDENCE 702, 703 AND 705. AND SECOND, FOR THE SAME AS THE OTHER EXPERTS, IT'S IMPROPER TO ADMIT EXPERT EVIDENCE TO THE EXTENT THAT IT IS BEING USED TO DETERMINE THE CORRECTNESS OR WISDOM OF AN AGENCY'S DECISION IN AN APA CASE.

THE COURT: ARE YOU GOING TO USE HER -- IS SHE GOING TO ISSUE AN OPINION ON THE CORRECTNESS OF THE AGENCY IN COMING UP WITH THE EXEMPTIONS?

MS. BOLAND: NO, YOUR HONOR.

THE COURT: SO THAT PARTICULAR OBJECTION IS MOOT, I THINK, AND THEN WITH RESPECT TO THE RULE 26 OBJECTION, OVERRULING YOU ON THAT ONE.

GO AHEAD.

BY MS. BOLAND:

Q. DR. CHUANG, SINCE CONTRACEPTIVES PLAY A ROLE IN YOUR PRACTICE, DO YOU COUNSEL PATIENTS REGARDING CONTRACEPTIVE OPTIONS?

A. YES, I DO.

Q. AND WHAT ARE SOME CONSIDERATIONS THAT GO INTO RECOMMENDING A PARTICULAR CONTRACEPTION?

A. WELL, THERE IS MANY THINGS TO CONSIDER, AND SO, LIKE I MENTIONED EARLIER, IF A WOMAN IS INTENDING TO BECOME PREGNANT OR TRYING TO AVOID PREGNANCY AND WHAT HER TIMING IS FOR THAT; WHEN DOES SHE THINK SHE MIGHT WANT TO BE PREGNANT IN THE FUTURE.

I CERTAINLY ALSO ASK HER ABOUT HER EXPERIENCE WITH PRIOR CONTRACEPTIVE METHODS IN THE PAST; WHAT HAS WORKED WELL OR NOT WORKED WELL FOR HER PERSONALLY. CERTAINLY CONSIDERING HER HEALTH SITUATION, IF SHE HAS ANY CHRONIC MEDICAL ISSUES, OTHER MEDICATIONS

SHE IS TAKING THAT MAY AFFECT THE SAFETY OF ANY CONTRACEPTIVE METHODS, THAT IS OBVIOUSLY VERY IMPORTANT TO DISCUSS.

SIDE EFFECTS OF DIFFERENT CONTRACEPTIVE METHODS, WHAT A PARTICULAR WOMAN IS WILLING TO TOLERATE OR NOT TOLERATE IN TERMS OF SIDE EFFECTS. AND ALSO JUST, YOU KNOW, HER OWN PERSONAL PREFERENCE. WOMEN SOMETIMES HAVE VERY STRONG OPINIONS ABOUT WHAT KIND OF METHODS THEY WANT TO USE OR NOT USE, AND THOSE ARE VERY IMPORTANT PARTS OF THE DECISION FOR HER.

Q. AND DO -- THE EFFECTIVENESS OF A PARTICULAR CONTRACEPTION, DOES THAT PLAY INTO YOUR COUNSELING HOW EFFECTIVE A PARTICULAR METHOD OF CONTRACEPTION IS?

A. ABSOLUTELY. BUT INTERESTINGLY, IT CAN VARY FROM WOMAN TO WOMAN. THERE ARE SOME WOMEN WHO ARE WILLING TO TOLERATE LESS EFFECTIVE METHODS BECAUSE OF ALL THE OTHER CONSIDERATIONS THAT SHE HAS. BUT YES, TALKING ABOUT CONTRACEPTIVE EFFECTIVENESS IS VERY IMPORTANT.

Q. AND WHAT ARE THE MOST EFFECTIVE FORMS OF CONTRACEPTION?

A. SURE. SO THE MOST EFFECTIVE REVERSIBLE METHODS ARE WHAT WE COMMONLY CALL LARCS, L-A-R-C-S, WHICH STANDS FOR LONG-ACTING REVERSIBLE CONTRACEPTIVE. THE LARCS INCLUDE THE CONTRACEPTIVE IMPLANT, WHICH IS A ROD THAT GETS IMPLANTED ON THE INNER PART OF THE ARM, AS WELL AS

THE INTRAUTERINE DEVICE OR THE IUD.

Q. THEY ARE THE MOST EFFECTIVE. AND THEN WHAT WOULD YOU SAY WOULD BE THE NEXT LEVEL DOWN?

A. RIGHT. SO THE LARCS ARE THE HIGHEST TIER OF EFFICACY. THE NEXT TIER DOWN ARE OTHER HORMONAL METHODS, SO THAT INCLUDES THE BIRTH CONTROL PILL, THE BIRTH CONTROL PATCH, THE CONTRACEPTIVE VAGINAL RING, THE CONTRACEPTIVE INJECTABLE OR DEPO-PROVERA. THAT WOULD BE IN THE NEXT TIER OF EFFECTIVENESS. AND THEN THE LOWEST TIER OF EFFECTIVENESS ARE METHODS SUCH AS WITHDRAWAL, NATURAL FAMILY PLANNING, BARRIER METHODS SUCH AS CONDOMS. THOSE ARE IN THE LOWEST TIER OF EFFECTIVENESS.

Q. DO YOU USE ANY PARTICULAR TEACHING TOOLS IN COUNSELING PATIENTS REGARDING THE VARIOUS METHODS?

A. I COMMONLY USE -- THERE IS A CHART THAT IS AVAILABLE ON THE CDC WEBSITE. SO I USUALLY HAVE THAT HANDY IN MY EXAMINATION ROOM SO WE CAN LOOK AT THE EFFECTIVENESS TOGETHER.

Q. THANK YOU, DOCTOR.

I WOULD LIKE TO POINT YOU TO TAB 17 OF THE BINDER.

A. OKAY.

Q. WILL YOU KINDLY IDENTIFY THAT DOCUMENT.

A. YEAH, THIS IS THE CDC CHART I WAS JUST REFERRING TO.

Q. ALL RIGHT, DOCTOR. JUST VERY BRIEFLY, IF YOU CAN WALK THROUGH WHAT THIS CHART REFLECTS.

A. SURE. SO THE CHART IS ORGANIZED IN THREE ROWS SEPARATED BY THOSE BLACK LINES, SO AT THE VERY TOP ROW, THOSE ARE THE MOST EFFECTIVE METHODS, THE HIGHEST TIER. SO THAT IS WHERE THE LARCS ARE. YOU CAN SEE THE CONTRACEPTIVE IMPLANT AND THE IUD UP THERE, AND YOU CAN SEE THEIR EFFECTIVENESS RATES THERE. IT IS LISTED AS LESS THAN ONE PREGNANCY PER 100 WOMEN PER YEAR. THEY ARE LINED UP RIGHT NEXT TO THE PERMANENT STERILIZATION METHODS. YOU MIGHT BE INTERESTED TO SEE THAT THE IMPLANT AND THE IUD ARE ACTUALLY MORE EFFECTIVE THAN THOSE PERMANENT STERILIZATION METHODS.

THE NEXT TIER AFTER THAT IS WHERE YOU SEE THE SHOT, THE PILL, THE PATCH, THE RING, AND THOSE ARE THE ONES THAT ARE THE NEXT LEVEL EFFECTIVENESS, SO YOU CAN SEE ON THE LEFT SIDE OF THE CHART IT SAYS 6 TO 12 PREGNANCIES PER 100 WOMEN IN A YEAR. WOMEN ARE OFTEN SURPRISED THAT THE PILL IS ASSOCIATED WITH THAT MANY PREGNANCIES.

AND THEN IN THE LOWEST TIER AT THE BOTTOM ARE THAT -- THE BARRIER METHODS WE TALKED ABOUT BEFORE, THE CONDOMS, WITHDRAWAL, SPERMICIDE AND THE NATURAL FAMILY PLANNING METHOD.

Q. ARE SOME CONTRACEPTIVES MORE EXPENSIVE THAN

OTHERS?
A. YES. IT SO HAPPENS THAT THE MOST EFFECTIVE METHODS, SO THE LARCS AT THE TOP ROW, ARE THE MOST EXPENSIVE METHODS, AND THEN THE SECOND TIER AND THEN THE LOWEST TIER.
Q. THANK YOU, DOCTOR.
DO CONTRACEPTIVES ALSO PLAY A ROLE IN PLANNING CHILDREN?
A. YEAH. SO I THINK CONTRACEPTION CAN BE VERY HELPFUL, IMPORTANT IN HELPING WOMEN TIME THEIR PREGNANCIES AND THE SPACING BETWEEN THEIR PREGNANCIES, SO THERE ARE SEVERAL GUIDELINES THAT SUGGEST THAT WOMEN SHOULD WAIT AT LEAST 18 MONTHS AFTER THE BIRTH OF A CHILD BEFORE GETTING PREGNANT AGAIN, AND THAT IS BECAUSE MORE CLOSELY-SPACED PREGNANCIES ARE ASSOCIATED WITH PRE-TERM BIRTH AND LOW BIRTH WEIGHT. SO BEING ABLE TO CONTROL THE SPACING OF THE PREGNANCIES CAN BE VERY IMPORTANT.
BUT AS IMPORTANT IS ALLOWING WOMEN TO BE EMPOWERED TO COMPLETE THEIR GOALS IN LIFE, SO BE ABLE TO FINISH SCHOOL, BE ABLE TO ACHIEVE THEIR JOB AND CAREER GOALS, REACH THEIR FINANCIAL GOALS SO THEY CAN HAVE THEIR CHILDREN WHEN THEY FEEL FINANCIALLY STABLE. SO I THINK BEING ABLE TO HAVE THE CHILDREN, THE NUMBER OF CHILDREN THEY WANT AND WHEN IT'S RIGHT FOR THEM IS VERY

IMPORTANT, AND WITHOUT CONTRACEPTION, THEY WOULD NOT BE ABLE TO DO THAT.
Q. DO MOST OF YOUR PATIENTS HAVE HEALTH INSURANCE?
A. YES. MY PRACTICE IN HERSHEY IS A MOSTLY INSURED POPULATION, YES.
Q. PRIOR TO THE CONTRACEPTIVE CARE MANDATE, WAS COST SOMETHING THAT YOU COUNSELED ABOUT IN THE CONVERSATION ABOUT CONTRACEPTION?
A. YES. SO WHEN I WOULD PULL OUT THIS CHART, I WOULD ALSO TALK ABOUT THE COSTS OF THE DIFFERENT METHODS AND OBVIOUSLY FOR SOME WOMEN, THERE WERE SOME METHODS THAT WE COULD NOT TALK ABOUT BEYOND COSTS BECAUSE THEY WERE COST-PROHIBITIVE.
Q. AND SINCE THE AFFORDABLE CARE ACT, DO YOU STILL COUNSEL YOUR PRIVATELY-INSURED PATIENTS REGARDING COSTS?
A. I'M ABLE TO TELL WOMEN WHO HAVE PRIVATE HEALTH INSURANCE THAT THEIR HEALTH INSURANCE COVERS ALL THE FDA-APPROVED METHODS WITH NO OUT-OF-POCKET COSTS, SO I'M ABLE TO PUT THIS CHART IN FRONT OF THEM AND REASSURE THEM THAT THEY WOULD HAVE NO CO-PAYS OR DEDUCTIBLES AND WE CAN TALK ABOUT THE DIFFERENT METHODS WITHOUT COSTS.
Q. IN YOUR EXPERIENCE IN YOUR PRACTICE PRIOR TO THE CONTRACEPTIVE MANDATE, DID YOU HAVE ANY EXPERIENCE WHERE PATIENTS WOULD RETURN TO YOU AND DECIDE NOT TO CHOOSE THE CONTRACEPTION THAT YOU RECOMMENDED OR TO FORGO

CONTRACEPTION ALTOGETHER BECAUSE OF COST?
A. YES, ABSOLUTELY. THERE WERE MANY OCCASIONS I CAN THINK OF WHERE A WOMAN MIGHT REALLY DESIRE TO GET AN IUD BUT IT WAS COST PROHIBITIVE SO SHE WOULD HAVE TO CHOOSE A DIFFERENT METHOD.
Q. HAVE YOU EXPERIENCED THAT PHENOMENON WITH ANY PATIENTS SINCE THE CONTRACEPTIVE MANDATE, PRIVATELY-INSURED PATIENTS?
A. NO, I HAVE NOT.
Q. WHAT DO YOU DO WHEN YOU ENCOUNTER A WOMAN WHO DOES NOT HAVE INSURANCE AND IS NEEDING CONTRACEPTIVE CARE?
A. IN OUR PRACTICE WE HAVE A SOCIAL WORKER, WE HAVE A FINANCIAL DEPARTMENT AT THE HERSHEY MEDICAL CENTER, SO IF SOMEONE IS UNINSURED, I AM ABLE TO REFER THEM TO THOSE SERVICES. IF THE PATIENT QUALIFIES FINANCIALLY, THEY MAY BE ABLE TO HELP THAT PATIENT APPLY FOR MEDICAID OR FIND OTHER ASSISTANCE, BUT IF THE PATIENT DOES NOT QUALIFY FOR MEDICAID OR IS UNABLE TO OBTAIN INSURANCE IN ANY OTHER WAY, I PERSONALLY WOULD REFER THAT PERSON TO PLANNED PARENTHOOD OR A FEDERALLY-QUALIFIED HEALTH CENTER FOR THEM TO RECEIVE THEIR CONTRACEPTIVE SERVICES.
THE COURT: DID YOU SAY FEDERALLY-QUALIFIED HEALTH CENTER?
THE WITNESS: YEAH.

BY MS. BOLAND:
Q. OKAY, DOCTOR. I WOULD NOW LIKE TO TURN YOUR ATTENTION TO THE "MY NEW OPTIONS" STUDY, WHICH WAS REFERENCED BEFORE. CAN YOU TELL US GENERALLY ABOUT THIS STUDY? I UNDERSTAND YOU BEGAN TO EXPLAIN, BUT IF YOU CAN TELL THE COURT EXACTLY WHAT WERE THE PARAMETERS OF THE STUDY AND WHAT WAS YOUR GOAL IN CONDUCTING THE STUDY?
A. SURE. SURE. SO THE "MY NEW OPTIONS" STUDY WAS FUNDED THROUGH PCORI, THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE. WE RECEIVED FUNDING IN THE FALL OF 2013 AND WE STARTED RECRUITING THE RESEARCH PARTICIPANTS IN THE SPRING OF 2014. IT WAS A TWO-YEAR STUDY, SO IT RAN UNTIL THE MIDDLE OF 2016.
THE PURPOSE OF THE STUDY WAS TO RECRUIT REPRODUCTIVE-AGE WOMEN WHO ARE PRIVATELY INSURED, AND WE RECRUITED PRIVATELY-INSURED WOMEN BECAUSE WE WANTED THEM TO HAVE COVERAGE FOR CONTRACEPTION. AND WE RECRUITED THEM AND THEY WERE RANDOMIZED INTO THREE DIFFERENT GROUPS IN ORDER TO SEE DIFFERENT -- AND SOME OF THE GROUPS RECEIVED CERTAIN WEB-BASED COUNSELING INTERVENTIONS TO SEE IF IT WOULD HELP THEM WITH THEIR CONTRACEPTIVE DECISION-MAKING.
Q. OKAY. AND SO TO CLARIFY, THE TIME FRAME FOR THIS STUDY WAS 2014 THROUGH 2016?

A. THAT'S CORRECT.
Q. SO IF DR. WEISMAN TESTIFIED EARLIER IT WAS 2012 THROUGH 2014, WAS THAT MISTAKEN?
A. THAT WAS MISTAKEN, YES.
Q. OKAY. AND WHAT DID YOU FIND AS A RESULT OF THIS STUDY?
A. YES, SO WE ACTUALLY FOUND THAT OUR WEB-BASED INTERVENTIONS DID NOT MAKE A DIFFERENCE; THEY DID NOT PARTICULARLY HELP WOMEN OR CHANGE WOMEN IN THEIR CONTRACEPTIVE DECISION-MAKING. HOWEVER, WE WERE ABLE TO TAKE THE OPPORTUNITY TO SEE THAT WE WERE ABLE TO FOLLOW THESE WOMEN FROM PENNSYLVANIA OVER THE COURSE OF TWO YEARS, AND AS A PARTICIPANT IN THE STUDY, THEY COMPLETED A LOT OF SURVEYS FOR US AND THE SURVEYS HAD A LOT OF QUESTIONS ABOUT CONTRACEPTIVE USE AND BEHAVIOR. SO WE WERE ABLE TO SEE WHAT WOMEN REPORTED THEY WERE DOING ABOUT CONTRACEPTION AT THE BEGINNING OF THE STUDY, THROUGHOUT THE STUDY, AND AT THE END OF THE STUDY.
Q. AND THE CONTRACEPTIVE MANDATE WAS ALREADY IN PLACE --
MS. KOPPLIN: YOUR HONOR, I'M SORRY, WE WOULD OBJECT TO THIS LINE OF QUESTIONING. WE HAVE NOT HAD ANY DISCLOSURE ABOUT THE METHODOLOGY THAT WAS USED IN THIS STUDY OR WHERE THIS DATA CAME FROM.
THE COURT: OVERRULED.

ARE YOU GOING TO TALK ABOUT THAT?
MS. BOLAND: YES.
BY MS. BOLAND:
Q. WILL YOU SPEAK TO THE METHODOLOGY BEHIND THIS STUDY, PLEASE, DR. CHUANG?
A. SURE. THIS WAS A RANDOMIZED TRIAL. WE RECRUITED -- YOU WANT TO HEAR THE DETAILS OF THE RECRUITMENT METHODS? OKAY.
SO WE PARTNERED WITH HIGHMARK, A PRIVATE INSURANCE PROVIDER. FOR THE REASON I STATED EARLIER, WE WERE SPECIFICALLY INTERESTED IN RECRUITING PRIVATELY INSURED WOMEN WHO LIVED IN THE STATE OF PENNSYLVANIA, AND SO WE SENT OUT INVITATIONS TO WOMEN WHO HAD HEALTH INSURANCE, WERE BETWEEN THE AGES OF 18 AND 40, AND INVITED THEM TO PARTICIPATE IN THE STUDY.
AND FOR WOMEN WHO CONSENTED, ENROLLED IN THE STUDY, THEY COMPLETED A SURVEY AT THE BEGINNING OF THE STUDY AND THEY WERE RANDOMIZED INTO ONE OF THREE GROUPS. ONE GROUP WAS A CONTROL GROUP; THEY DID NOT GET ANY PARTICULAR INTERVENTION AT ALL. AND THE OTHER TWO GROUPS WERE TWO DIFFERENT GROUPS WHERE THEY WOULD SEE TWO DIFFERENT TYPES OF WEBSITES THAT PROVIDED INFORMATION ABOUT CONTRACEPTION TO SEE IF THOSE WEBSITES WOULD HELP THEM WITH THEIR DECISION-MAKING.
HOWEVER AT THE END OF THE STUDY, AT THE

END OF THE TWO YEARS, WE FOUND THAT ALL THREE GROUPS BEHAVED SIMILARLY AND THERE WAS NO DIFFERENCE BETWEEN THE GROUPS THAT GOT THE WEBSITE INTERVENTION AND THE GROUP THAT DID NOT. SO UNFORTUNATELY FOR ME, WE DIDN'T SEE ANY DIFFERENCES WITH OUR WEBSITE INTERVENTION, BUT WE WERE ABLE TO SEE WHAT THE CONTRACEPTIVE BEHAVIORS WERE AMONGST THE WOMEN WHO WERE PARTICIPATING IN THE STUDY.
AND I DON'T THINK I SAID BEFORE, THERE WERE 984 WOMEN WHO WERE IN THE STUDY.
Q. AND WHAT DID YOU LEARN THAT THE CONTRACEPTIVE BEHAVIORS WERE OVER THIS PERIOD OF TIME FOR ALL THREE GROUPS INCLUDING THE CONTROL GROUP, RIGHT?
A. SURE. YES. SO WE WERE ABLE TO SEE WHAT TYPES OF CONTRACEPTIVE METHODS WERE BEING USED THROUGHOUT THE STUDY. SO IN THE BEGINNING OF THE STUDY, THERE WERE RELATIVELY FEW WOMEN USING LARCS, THE LONG-ACTING REVERSIBLE CONTRACEPTIVES. THERE WERE ABOUT 8 PERCENT OF WOMEN USING LARCS, AND BY THE END OF THE STUDY THERE WERE ALMOST 18 PERCENT OF WOMEN USING LARCS IN THE STUDY. AND SO WE THOUGHT THAT WAS AN INTERESTING FINDING.
Q. DOCTOR, I WOULD LIKE TO POINT YOU TO TAB 18 IN THE BINDER.
A. OKAY.

Q. WILL YOU PLEASE IDENTIFY THIS DOCUMENT FOR THE COURT?
A. SURE. THIS IS A RESULTS TABLE THAT IS TAKEN FROM SOME OF OUR -- TAKEN FROM A PRESENTATION THAT WE HAD DONE PRESENTING THE "MY NEW OPTIONS" STUDY AT A NATIONAL CONFERENCE.
Q. THANK YOU. IF YOU PUT --
MS. KOPPLIN: YOUR HONOR -- I'M SORRY -- WE WOULD OBJECT. WHAT IS THE SOURCE OF THIS DATA?
THE COURT: WELL, WHY DON'T YOU -- OFFER OF PROOF. WHAT IS THE SOURCE OF DATA?
MS. BOLAND: DR. CHUANG HERSELF DRAFTED THIS CHART AND SHE PUT IN THE DATA HERSELF. SHE HAS ALREADY TESTIFIED AS TO THE METHODOLOGY BEHIND IT. THIS IS JUST PUTTING HER TESTIMONY IN CHART FORM TO DEMONSTRATE FOR THE COURT.
THE COURT: SO MS. -- MS. CHUANG, DID YOU CREATE THIS FOR THIS PARTICULAR PROCEEDING OR YOU CREATED IT FOR THE STUDY?
THE WITNESS: I CREATED IT FOR THE STUDY. THIS TABLE IS ACTUALLY TAKEN FROM A PRESENTATION WE DID AT THE SOCIETY OF GENERAL INTERNAL MEDICINE MEETING BACK IN THE SPRING. I ALSO GAVE A PRESENTATION AT THE SOCIETY FOR FAMILY PLANNING MEETING, AND THIS TABLE WAS TAKEN FROM THOSE PRESENTATIONS.

THE COURT: AND THE DATA INCLUDED IN THE TABLE IS TAKEN FROM WHERE?

THE WITNESS: THIS IS FROM THE "MY NEW OPTIONS" RESULTS.

THE COURT: OKAY. OVERRULED.

GO AHEAD.

BY MS. BOLAND:

Q. IF YOU FLIP TO THE NEXT PAGE, CAN YOU JUST TELL US WHAT THAT IS?

A. THAT IS ANOTHER TABLE FROM THE SAME PRESENTATIONS.

Q. REFLECTING THE SAME DATA?

A. YES.

Q. IS IT JUST REPACKAGED A DIFFERENT WAY?

A. YES. SO THE FIRST TABLE SHOWS THE CONTRACEPTIVE TYPES THAT ARE USED IN THE STUDY DIVIDED INTO THE FOUR CATEGORIES THAT ARE SIMILAR TO THOSE TIERS THAT WE LOOKED AT ON THE CDC WEBSITE. SO THE FIRST ROW IS LARCS, THE SECOND ROW IS OTHER PRESCRIPTION METHODS, THIRD ROW IS NONPRESCRIPTION METHODS, AND THE LAST ROW IS NO METHOD. THE SECOND TABLE REALLY IS THE SAME DATA BUT IT'S JUST LOOKING AT WOMEN WHO WERE ON ANY CONTRACEPTIVE METHOD AT ALL VERSUS NO METHOD. SO IN THE SECOND TABLE, IT JUST REALLY COLLAPSES THOSE FIRST THREE ROWS INTO ONE ROW, SO IT IS REALLY SHOWING THE SAME DATA

IN TWO DIFFERENT FORMATS.

Q. AND I THINK YOU JUST TESTIFIED THAT YOU SAW A STATISTICAL JUMP FROM THE NUMBER OF WOMEN USING LARCS AT THE BEGINNING OF THE STUDY TO THE NUMBER OF WOMEN USING LARCS AT THE END OF THE STUDY. IS THAT REFLECTED SOMEWHERE ON THESE DOCUMENTS?

A. SO I'M LOOKING AT TABLE 1, AND SO IN THAT FIRST ROW WHERE IT SAYS LARCS, AND THEN IF YOU LOOK AT THE NEXT COLUMN WHERE IT SAYS BASELINE, THAT IS THE BEGINNING OF THE STUDY WHERE THERE ARE 984 WOMEN ENROLLED IN THE STUDY.

SO 83 WOMEN AT THE BEGINNING OF THE STUDY, WHICH WAS 8.4 PERCENT OF THE SAMPLE, AT THAT TIME WERE USING LARCS. AND THEN IF YOU GO OVER TO THE NEXT ROW, WHERE IT SAYS 24 MONTHS, THERE WERE 130 WOMEN OUT OF 727 WOMEN USING LARCS AT THE END OF THE STUDY, WHICH WAS 17.9 PERCENT.

IF YOU LOOK AT THE NEXT TWO ROWS, THERE ARE REALLY NO DIFFERENCES. IF YOU LOOK AT THE PERCENTAGES OF OTHER PRESCRIPTION METHODS IT WAS 49.7 PERCENT BOTH AT BASELINE AND 24 MONTHS. AND THEN IN THE THIRD ROW, NOT MUCH DIFFERENCE EITHER IN THE NONPRESCRIPTION METHOD. BUT THEN IF YOU LOOK AT THE LAST ROW, THE NO-METHOD ROW, YOU WILL SEE THAT BASELINE THERE WERE 11.5 PERCENT OF WOMEN NOT USING ANY METHOD

AND THAT HAD DROPPED TO 5.1 PERCENT BY THE END OF THE STUDY.

AND THEN IN THE THIRD COLUMN WHERE IT SAYS P VALUE. THE P VALUE IS OUR TEST OF STATISTICAL SIGNIFICANCE, AND IN BIOMEDICAL RESEARCH WE GENERALLY ACCEPT A P VALUE OF LESS THAN .05 TO INDICATE STATISTICAL SIGNIFICANCE. SO THE P VALUE WE HAD FOR THESE RESULTS WAS LESS THAN .001, WHICH SHOWS THAT THERE WAS A STATISTICALLY SIGNIFICANT CHANGE IN THESE NUMBERS THAT I JUST REVIEWED.

Q. AND JUST A COUPLE OF POINTS OF CLARIFICATION. IT LOOKS LIKE ALTHOUGH THE PERCENTAGE IS THE SAME FOR OTHER PRESCRIPTION METHODS, THE NUMBER OF -- THE OTHER NUMBER CHANGED. CAN YOU EXPLAIN WHAT WE ARE SEEING HERE AND WHY THE PERCENTAGE IS THE SAME BUT THE NUMBER OF PEOPLE DIFFERS?

A. SURE. SO I WILL TAKE YOU BACK UP TO THE HEADER ROW WHERE IT SAYS BASELINE, N EQUALS 984, AND 24 MONTHS, N EQUALS 727. SO IT MIGHT SEEM PECULIAR THAT THERE WAS SUCH A DIFFERENT -- A DROP IN THE NUMBERS BETWEEN THE BEGINNING AND THE END OF THE STUDY.

HOWEVER, WE JUST INCLUDED WOMEN IN THE STUDY WHO WERE ACTIVELY TRYING TO AVOID PREGNANCY. SO I SHOULD HAVE MENTIONED BEFORE WHEN I WAS DESCRIBING THE STUDY THAT WE ENROLLED WOMEN WHO SAID THEY WERE TRYING

TO AVOID PREGNANCY FOR THE NEXT YEAR.

OVER THE COURSE OF THE TWO-YEAR STUDY, WOMEN CHANGED THEIR MIND AND SOME WOMEN THEN DECIDED THEY WERE TRYING TO GET PREGNANT. AND SO THOSE WOMEN WERE NO LONGER COUNTED BECAUSE THEY DIDN'T HAVE AN INDICATION TO USE BIRTH CONTROL ANYMORE. SO THAT IS WHY THERE WAS ONLY 727 WOMEN AT 24 MONTHS.

THERE WERE SOME OTHER REASONS THAT WOMEN WERE EXCLUDED TOO. THERE WERE SOME WHO GOT A HYSTERECTOMY DURING THAT TIME FRAME OR THEY GOT THEIR TUBAL STERILIZATION DURING THAT TIME FRAME, SO THAT ACCOUNTED FOR SOME OF THE REDUCED NUMBERS AS WELL.

Q. DOES THE FACT THAT SOME WOMEN DROPPED OUT, DID THAT AFFECT THE RELIABILITY OF YOUR FINDINGS?

A. NO, BECAUSE THAT IS ACCOUNTED FOR WHEN YOU DO THE STATISTICAL TEST AND GENERATE THE P VALUE. IT CONSIDERS THE SAMPLE SIZE NUMBER.

Q. SO WHAT IS YOUR OPINION WITH A REASONABLE DEGREE OF CERTAINTY AS TO WHY WOMEN CHANGED THEIR BEHAVIOR OVER THIS TIME FRAME?

A. WELL, WHAT I CAN SAY IS THAT THE STUDY, SINCE WE STARTED THE STUDY IN 2014, IT OCCURRED PRETTY SHORTLY AFTER THE CONTRACEPTIVE MANDATE WENT INTO EFFECT. WE DIDN'T SEE AN EFFECT OF OUR STUDY INTERVENTION AND REALLY THE ONLY OTHER THING THAT WAS GOING ON AT THE

TIME WAS THIS CHANGE IN CONTRACEPTIVE -- IN THE CONTRACEPTIVE MANDATE.

SO MY HYPOTHESIS WOULD BE THAT WHAT WE ARE SEEING IS THE CHANGE IN CONTRACEPTIVE BEHAVIOR THAT COULD HAVE RESULTED FROM THE CONTRACEPTIVE MANDATE.

Q. AND IS THAT CONSISTENT WITH OTHER RESEARCH OUT THERE, TO YOUR KNOWLEDGE?

A. YEAH. ACTUALLY THERE HAS BEEN SEVERAL OTHER STUDIES IN THE LITERATURE THAT HAVE SHOWN THAT SINCE THE CONTRACEPTIVE MANDATE, WE DO KNOW THAT OUT-OF-POCKET COSTS FOR WOMEN HAVE GONE DOWN SINCE THE CONTRACEPTIVE MANDATE. THERE'S BEEN SOME STUDIES TO SHOW THAT THERE MAY BE SOME CHANGES IN METHODS THAT WOMEN ARE CHOOSING WITH MORE LARCS BEING USED. SO I THINK THIS IS CONSISTENT WITH THOSE OTHER STUDIES.

Q. IS THIS CONSISTENT WITH YOUR EXPERIENCE IN YOUR OWN PRACTICE IN TERMS OF WOMEN'S DECISION-MAKING AFTER THE MANDATE WAS PUT IN PLACE?

A. WELL, I CAN SAY THAT I CERTAINLY HAD SOME PATIENTS WHO, AFTER LEARNING ABOUT THE MANDATE, HAVE RETHOUGHT THEIR CONTRACEPTIVE DECISION-MAKING. SOME OF THEM THAT HAS HELPED THEM CHANGE THEIR MIND. I HAVE HAD SOME WOMEN WHO WERE PREVIOUSLY NOT USING A METHOD OR USING A LESS-EFFECTIVE METHOD THAT HAVE THEN CHOSEN TO USE A MORE-EFFECTIVE METHOD, WHETHER THAT BE A LARC OR

PILL OR SOMETHING ELSE, YES.

Q. IN YOUR OPINION, DOCTOR, HAS THE CONTRACEPTIVE MANDATE BENEFITED WOMEN?

A. YES, I THINK IT HAS.

Q. AND FOR WHAT REASON?

A. I THINK BECAUSE IT HAS ALLOWED WOMEN TO HAVE THAT FULL RANGE OF CHOICES THAT ARE ON THAT CDC CHART WE LOOKED AT. SO INSTEAD OF ONLY HAVING A COUPLE OF THOSE AVAILABLE TO WOMEN TO CONSIDER, THEY HAVE THE WHOLE SPECTRUM OF CHOICES TO CONSIDER, AND IT GIVES THE PATIENT A LOT MORE FREEDOM TO TALK WITH THEIR PROVIDER ABOUT WHAT METHODS ARE REALLY BEST SUITED FOR THEM AS AN INDIVIDUAL. WHEN THEY CONSIDER WHAT THEIR OWN HEALTH CONDITIONS ARE, WHAT THEIR OWN PREFERENCES ARE, WHAT SIDE EFFECTS ARE OKAY OR NOT OKAY FOR THEM, IT REALLY ALLOWS THEM TO CONSIDER THE FULL SET OF OPTIONS.

Q. HAVE YOU HAD THE OPPORTUNITY TO READ THE RELIGIOUS AND MORAL EXEMPTION RULES AT ISSUE IN THIS CASE?

A. YES, I HAVE READ THEM.

Q. WHAT DO YOU BELIEVE THE IMPACT OF THOSE RULES WILL BE ON PRIVATELY-INSURED WOMEN -- ON SOME PRIVATELY-INSURED WOMEN IN PENNSYLVANIA?

MS. KOPPLIN: OBJECTION, YOUR HONOR. THIS IS NOT AN OPINION THAT IS GOING TO BE -- THAT THERE

IS ANY EVIDENCE IT'S GOING TO BE THE PRODUCT OF RELIABLE PRINCIPLES AND METHODS BY THE WITNESS.

THE COURT: OVERRULED.

THE WITNESS: I --

THE COURT: WHAT YOU KNOW FROM YOUR EXPERIENCE.

THE WITNESS: SURE. SO BASED ON MY EXPERIENCE, I WOULD IMAGINE THAT IT WOULD BE SIMILAR TO BEFORE THE CONTRACEPTIVE MANDATE WHEN CONTRACEPTIVE COUNSELING HAD TO INCLUDE COSTS. SO I WOULD IMAGINE THAT WOULD BE THE CASE AGAIN.

BY MS. BOLAND:

Q. IS IT YOUR OPINION THAT COST IS A BARRIER TO ACCESS TO CONTRACEPTIVE CARE, OR CAN BE A BARRIER TO CONTRACEPTIVE CARE?

A. YES, I HAVE SEEN THAT BE THE CASE.

Q. AND IN YOUR OPINION, WHAT WILL HAPPEN IF WOMEN FORGO CONTRACEPTIVE CARE BECAUSE OF COST?

A. I THINK THAT IF WOMEN CAN'T CHOOSE FROM THE FULL SET OF OPTIONS, THEY MAY BE MORE LIKELY TO CHOOSE THE LESS EXPENSIVE OPTIONS, WHICH ARE, UNFORTUNATELY, THE LESS EFFECTIVE OPTIONS. AND SO MY FEAR WOULD BE THAT WE WOULD SEE A RISE IN UNINTENDED PREGNANCIES AND CONCOMITANTLY A RISE IN ABORTIONS.

Q. THANK YOU, DR. CHUANG.

MS. BOLAND: BEAR WITH ME ONE MOMENT, YOUR HONOR.

THE COURT: OKAY.

BY MS. BOLAND:

Q. TWO POINTS FOR CLARIFICATION, DOCTOR. EARLIER I ASKED YOU ABOUT THE MOST EXPENSIVE METHODS OF CONTRACEPTION. SPEAKING IN TERMS OF UP-FRONT COST, WHAT IS THE MOST EXPENSIVE METHOD OF CONTRACEPTION?

A. THE LARCS ARE THE MOST EXPENSIVE WITH UP-FRONT COSTS, BECAUSE YOU HAVE TO PAY FOR THE DEVICE AND THE INSERTION FEE ALL AT ONCE UP FRONT.

Q. IN REGARD TO THE "MY NEW OPTIONS" STUDY, WHY WAS THERE A DELAY IN THE CHANGES OVER TIME IF THE MANDATE WENT INTO EFFECT IN 2012? IN OTHER WORDS, WHY WASN'T IT INSTANTANEOUS THAT YOU WOULD SEE CHANGES IN WOMEN'S BEHAVIOR?

A. WELL, A COUPLE OF THINGS.

WOMEN MAY NOT HAVE BEEN AWARE OF THE CHANGES IN THEIR CONTRACEPTIVE COVERAGE RIGHT AWAY. IN FACT, I HAD PATIENTS COME TO ME AND SAY, OH, I THINK THEY MADE A MISTAKE AT THE PHARMACY, THEY DID NOT CHARGE ME A CO-PAY THIS MONTH. SO THEY DID NOT REALIZE THAT THERE WAS A CHANGE IN POLICY. SO THAT IS NUMBER ONE.

SECONDLY, YOU KNOW, WOMEN DON'T RUSH TO THE DOCTOR EVERY DAY, SO THEY MIGHT -- MOST WOMEN WHO

ARE HEALTHY REPRODUCTIVE-AGE WOMEN MIGHT ONLY SEE THEIR PHYSICIAN ONCE A YEAR, SO PROBABLY JUST THE TIMING OF WHEN THEY WERE SEEING THEIR PROVIDERS AND MAKING CHANGES IN THEIR CONTRACEPTION IS WHAT I WOULD GUESS.

MS. BOLAND: THANK YOU VERY MUCH, DOCTOR. I HAVE NO FURTHER QUESTIONS.

THE COURT: MS. KOPPLIN.

MS. KOPPLIN: YOUR HONOR, MAY I APPROACH?

THE COURT: YOU MAY.

CROSS-EXAMINATION

BY MS. KOPPLIN:

Q. GOOD AFTERNOON. DR. CHUANG, MY NAME IS REBECCA KOPPLIN. I'M JUST GOING TO ASK YOU A COUPLE QUESTIONS.

HOW ARE YOU DOING?

A. GOOD, THANK YOU.

Q. DR. CHUANG, WHAT DOCUMENTS DID YOU CONSIDER IN PREPARING YOUR DECLARATION? COULD YOU LIST THE DOCUMENTS?

A. I'M NOT SURE WHAT TYPES OF DOCUMENTS YOU MIGHT BE REFERRING TO.

Q. LET'S SAY ALL TYPES OF DOCUMENTS.

A. WELL, BEING A PRIMARY CARE PROVIDER AND BEING A RESEARCHER IN THIS FIELD AND A LECTURER IN THIS AREA, THE DECLARATION INCLUDED YEARS OF READING MANY SCIENTIFIC ARTICLES AND DOING YEARS OF RESEARCH AND THE

BODY OF KNOWLEDGE THAT HAS ACCUMULATED FROM THAT.

Q. OTHER THAN THE GENERAL BODY OF KNOWLEDGE YOU HAD WHEN YOU STARTED WORKING AND PREPARING THE DECLARATION, WHAT SPECIFIC SOURCES DID YOU SEEK OUT AND REVIEW?

A. I'M NOT SURE I UNDERSTAND THE QUESTION.

Q. FOR EXAMPLE, DID YOU READ THE RULES WHEN YOU WERE PREPARING YOUR DECLARATION?

A. AT THE TIME THAT I PREPARED MY DECLARATION -- I'M ACTUALLY -- I CANNOT PRECISELY REMEMBER IF I HAD ALREADY READ THE RULES AT THE TIME OF THE DECLARATION.

Q. SO YOU DO NOT RECALL IF YOU HAD READ THE RULES OR NOT WHEN YOU WROTE YOUR DECLARATION?

A. I DO NOT RECALL.

Q. DID YOU READ ANY OF THE ARTICLES THAT ARE CITED IN THE RULES?

A. IN READING -- WHEN I DID READ THE RULES, A LOT OF THE ARTICLES ARE COMMONLY-CITED ARTICLES IN FAMILY PLANNING LITERATURE, SO MANY OF THEM I WAS ALREADY FAMILIAR WITH AND SINCE SOME OF THEM I READ SUBSEQUENT TO READING THE RULES, BUT I DID NOT READ EVERY SINGLE ONE OF THEM, NO.

Q. DO YOU RECALL ANY OTHER THINGS THAT YOU WOULD HAVE LOOKED AT IN PREPARING YOUR DECLARATION, FOR EXAMPLE, NEWSPAPER ARTICLES, BLOG POSTS?

A. I WOULD NOT HAVE REFERRED TO THE LAY PRESS FOR

MY INFORMATION, NO.

Q. DO YOU RECALL IN PARTICULAR ANY STUDIES THAT YOU READ OTHER THAN THOSE CITED IN THE RULES?

A. I CONSIDER AS PART OF MY DAILY WORK TO BE READING RESEARCH ARTICLES ABOUT CONTRACEPTION, SO YES, I READ ARTICLES ON A NEAR-DAILY BASIS ABOUT THIS FIELD.

Q. SURE. MY QUESTION WAS IF YOU RECALLED IN PARTICULAR ANY ARTICLES THAT YOU READ TO PREPARE FOR THE DECLARATION?

A. SURE. I HAVE READ MANY ARTICLES IN THE LAST COUPLE OF WEEKS, PERHAPS MAYBE MORE FREQUENCY THAN USUAL BECAUSE I KNEW THAT I WOULD BE HERE TODAY.

Q. SURE. IF YOU RECALL ANY IN PARTICULAR, WHO WAS THE AUTHOR OF THAT STUDY AND WHAT WAS ITS TITLE?

A. SO I KNOW, FOR EXAMPLE, THAT YOU GUYS HAVE THE BEARAK AND JONES ARTICLES, SO I HAVE READ -- I READ THAT AGAIN IN PREPARATION FOR TODAY. THERE ARE SEVERAL OTHER ARTICLES THAT -- AS I MENTIONED BEFORE, THERE'S OTHER RESEARCH THAT HAS DOCUMENTED A -- CHANGES IN CONTRACEPTIVE BEHAVIOR AND UPTAKE OF MORE EFFECTIVE METHODS, SO I READ, REVIEWED SOME OF THOSE ARTICLES. THERE WAS AN ARTICLE BY LYDIA PACE THAT WAS PUBLISHED IN HEALTH AFFAIRS LAST YEAR. THERE WAS ANOTHER ARTICLE PUBLISHED IN HEALTH AFFAIRS LAST YEAR REGARDING THE SAME TOPIC. THERE IS AN ARTICLE BY KAVANAUGH AND COLLEAGUES

THAT WAS PUBLISHED IN CONTRACEPTION THIS YEAR THAT ALL RELATE TO INCREASES IN MORE EFFECTIVE CONTRACEPTIVE USE FOLLOWING THE CONTRACEPTIVE MANDATE. THOSE ARE ALL ARTICLES THAT I REREAD RECENTLY IN PREPARATION FOR THIS.

Q. WHO DID YOU MEET WITH TO PREPARE FOR YOUR DECLARATION?

A. I MET WITH THE LAWYERS HERE.

Q. ANYONE ELSE?

A. NO.

Q. SO YOU ARE HERE TODAY TO TESTIFY ABOUT THE NEW EXEMPTION TO THE CONTRACEPTIVE COVERAGE MANDATE, CORRECT?

A. YES.

Q. NOW, BEFORE THESE NEW EXEMPTIONS EXISTED, YOU ARE AWARE THAT THERE WERE SOME GRANDFATHERED PLANS THAT WERE ALREADY EXEMPT FROM THE COVERAGE MANDATE?

A. YES.

Q. AND YOU'RE AWARE THAT SOME OF THESE PLANS WERE THEREFORE NOT PROVIDING COVERAGE FOR CONTRACEPTIVES?

A. COULD YOU REPEAT THAT? SORRY.

Q. SO YOU WOULD AGREE WITH ME THAT BECAUSE SOME OF THESE PLANS WERE GRANDFATHERED, THOSE PLANS WERE NOT PROVIDING COVERAGE FOR CONTRACEPTIVES?

A. YES.

Q. DO YOU HAVE AN IDEA OF HOW MANY OF THOSE PLANS

THERE WERE IN PENNSYLVANIA?
A. I DO NOT PRECISELY KNOW THE NUMBER, BUT I KNOW THE NUMBER HAS BEEN DECLINING WITH EVERY YEAR.
Q. BUT YOU COULD NOT EVEN GIVE ME AN ESTIMATE OF A NUMBER?
A. I KNOW AT THE TIME THE CONTRACEPTIVE MANDATE WENT INTO PLACE, I RECALL THAT MAYBE THE NUMBER OF GRANDFATHERED PLANS WAS AROUND 20 PERCENT, AND I UNDERSTAND THAT IT HAS DECLINED IN EVERY YEAR SINCE THEN, BUT I DON'T KNOW WHAT THE PRECISE NUMBER IS NOW.
Q. AND YOU ARE AWARE THAT PRIOR TO THE CURRENT EXEMPTIONS, THERE WAS ALREADY AN EXEMPTION FOR HOUSES OF WORSHIP?
A. YES.
Q. AND SO THEREFORE THERE WERE SOME HOUSES OF WORSHIP THAT WERE NOT PROVIDING CONTRACEPTIVE COVERAGE?
A. CORRECT.
Q. ARE YOU AWARE ABOUT HOW MANY OF THOSE THERE WERE IN PENNSYLVANIA?
A. NO, I DON'T KNOW HOW MANY.
Q. AND YOU ARE AWARE THAT PRIOR TO THIS LITIGATION, THERE WAS OTHER LITIGATION CHALLENGING THE CONTRACEPTIVE MANDATE, AND AS A RESULT OF THAT, SOME ENTITIES OBTAINED INJUNCTIONS SO THEY DID NOT HAVE TO PROVIDE CONTRACEPTION COVERAGE, CORRECT?

A. SO IF YOU ARE REFERRING TO ACCOMMODATIONS, YES, I'M FAMILIAR WITH THAT.
Q. AND DO YOU KNOW HOW MANY OF THOSE ACCOMMODATED ENTITIES WERE IN PENNSYLVANIA?
A. NO, I DO NOT KNOW. I DO KNOW THAT THE COMPANIES THAT WERE INVOLVED, LIKE HOBBY LOBBY, ARE PENNSYLVANIA COMPANIES, BUT I DO NOT KNOW BEYOND THAT HOW MANY ARE FROM PENNSYLVANIA.
Q. SO I'M LOOKING AT YOUR DECLARATION NOW, WHICH IS AT TAB 6 IN THE BINDER. AT PARAGRAPH 31, YOU STATED THAT: SINCE THE ACA HAS PASSED, NO PATIENT HAS CONTACTED ME TO ASK FOR A DIFFERENT, CHEAPER METHOD OF CONTRACEPTION THAN THE ONE I HAD PRESCRIBED DUE TO THE COST UNDER PRIVATE INSURANCE PLANS.
DID I READ THAT CORRECTLY?
A. YOU DID.
Q. SO YOU WOULD AGREE WITH ME THEN THAT SINCE THE ACA PASSED, NONE OF YOUR PATIENTS ASKED FOR CHEAPER METHODS OF CONTRACEPTION EVEN THOUGH ALL OF THESE EXEMPTIONS THAT WE JUST TALKED ABOUT WERE IN EXISTENCE?
A. THAT'S RIGHT.
Q. NOW, LET'S TURN TO THE NEW EXEMPTIONS THAT ARE AT ISSUE HERE. THE NEW EXEMPTIONS ARE FOR ENTITIES WITH SINCERE RELIGIOUS AND MORAL OBJECTIONS, CORRECT?
A. CORRECT.

Q. BUT YOU ARE NOT AWARE OF ANY EMPLOYERS IN PENNSYLVANIA THAT HAVE INVOKED THE NEW EXEMPTIONS SO FAR, CORRECT?
A. I'M NOT AWARE, NO.
Q. SO YOU ARE NOT AWARE OF ANY INDIVIDUALS IN PENNSYLVANIA WHO HAVE LOST THEIR CONTRACEPTIVE COVERAGE DUE TO THE NEW EXEMPTIONS?
A. NO, I'M NOT. I DON'T KNOW.
Q. AND NOT JUST IN PENNSYLVANIA, BUT YOU ARE NOT AWARE OF ANY PEOPLE NATIONALLY EITHER WHO HAVE LOST COVERAGE BECAUSE OF THE EXEMPTION?
A. I'M NOT AWARE OF ANY, NO.
Q. AND YOU DON'T KNOW OF ANY PEOPLE EITHER IN PENNSYLVANIA OR IN THE ENTIRE COUNTRY WHO WILL LOSE COVERAGE, LIKE THEIR PLANS HAVE ALREADY ANNOUNCED THAT THEY ARE GOING TO CHANGE, FOR EXAMPLE?
A. NO.
Q. LOOKING AT YOUR DECLARATION AT PARAGRAPH 23, YOU STATED: SOME OF MY PATIENTS ALSO WORK FOR AND RECEIVE THEIR HEALTH INSURANCE THROUGH CATHOLIC SCHOOLS AND OTHER INSTITUTIONS WHICH MIGHT SEEK TO ELIMINATE CONTRACEPTIVE COVERAGE THROUGH THEIR EMPLOYER-SPONSORED PLANS UNDER THE NEW RELIGIOUS AND MORAL EXEMPTIONS.
DID I READ THAT CORRECTLY?
A. YES, YOU DID.

Q. SO NOW HERE TODAY IN DECEMBER, YOU STILL CAN'T IDENTIFY ANY ACTUAL PATIENTS WHO WILL LOSE COVERAGE, CORRECT?
A. I HAVE PATIENTS WHO ARE EMPLOYED OR -- AND HAVE HAD PATIENTS WHO HAVE BEEN EMPLOYED AT THESE INSTITUTIONS, SO THEY MAY ALREADY NOT HAVE COVERAGE.
Q. DO YOU KNOW OF ANY THAT HAVE ALREADY LOST COVERAGE?
A. NOT AS A RESULT OF THE NEW RULES, NO.
Q. SO ALTHOUGH YOU DO HAVE SOME PATIENTS WHO ARE EMPLOYED AT THESE, AS OF RIGHT NOW YOU DON'T KNOW ANY OF THEM WHO ARE ACTUALLY GOING TO LOSE THEIR COVERAGE BECAUSE OF THE NEW RULES?
A. THEY MAY ALREADY HAVE NOT HAD COVERAGE, BUT I DO NOT KNOW OF ANY PATIENTS WHO MAY BE LOSING COVERAGE.
Q. RIGHT. AND YOU DO KNOW OF ANY PATIENTS WHOSE SITUATION IS CHANGING FOR THE WORSE BECAUSE OF THE RULES?
A. I DO NOT KNOW INDIVIDUALS IN THAT CASE RIGHT NOW, NO.
Q. NOW, IN PARAGRAPH 34, YOU STATED THAT: AS A RESULT OF THESE RULES, SOME WOMEN WILL LOSE CONTRACEPTIVE -- SORRY -- SOME WOMEN WILL LOSE INSURANCE COVERAGE FOR PREVENTATIVE CONTRACEPTIVE CARE.
DID I READ THAT CORRECTLY?

A. YES.
Q. BUT AS OF TODAY, YOU CAN'T IDENTIFY ANY ACTUAL WOMEN WHO HAVE LOST COVERAGE BECAUSE OF THE NEW RULES, CORRECT?
A. CORRECT.
Q. IN PARAGRAPH 35, REFERRING TO THESE WOMEN WHO WOULD LOSE COVERAGE, YOU STATED: AS A RESULT THEIR COSTS FOR CONTRACEPTIVE CARE WILL RISE.
DID I READ THAT CORRECTLY?
A. YES.
Q. BUT STILL WE CAN'T IDENTIFY ANY ACTUAL WOMEN WHO COSTS HAVE RISEN BECAUSE OF THE EXEMPTION?
A. NO.
Q. AND IN PARAGRAPH 36, YOU STATED THAT: UNDER THE NEW RULES, COSTS WILL AGAIN BECOME A BARRIER TO WOMEN'S ACCESS TO AND USE OF THE CONTRACEPTIVE THAT IS MEDICALLY RECOMMENDED FOR THEM.
BUT TODAY YOU CAN'T IDENTIFY ANY ACTUAL WOMEN WHO ARE EXPERIENCING SUCH A BARRIER BECAUSE OF THE NEW RULES, CORRECT?
A. CORRECT.
Q. AND IN PARAGRAPH 37, REFERRING TO THE SAME WOMEN, YOU STATED THAT THEY WOULD FACE MEDICAL HARM, BUT AS OF TODAY, YOU CAN'T IDENTIFY ANY ACTUAL WOMEN WHO ARE FACING THAT MEDICAL HARM BECAUSE OF THE RULES, CORRECT?

A. CORRECT.
Q. AND IN PARAGRAPH 38, REFERRING TO THESE SAME WOMEN, YOU STATED THAT THERE WOULD BE A DISRUPTION OF THESE PATIENTS' MEDICAL TREATMENT, BUT AS OF TODAY, WE DON'T KNOW -- YOU DON'T KNOW OF ANY ACTUAL WOMEN WHOSE MEDICAL TREATMENT HAS BEEN DISRUPTED BY THE RULES, CORRECT?
A. CORRECT.
Q. IN PARAGRAPH 39, YOU STATED THAT: SOME OF THESE WOMEN WILL FACE UNINTENDED PREGNANCIES AND OTHER ADVERSE MEDICAL CONSEQUENCES, BUT AS OF TODAY, YOU DON'T KNOW OF ANY ACTUAL WOMEN WHO ARE FACING UNINTENDED PREGNANCIES OR OTHER ADVERSE MEDICAL CONSEQUENCES BECAUSE OF THE RULES, CORRECT?
A. CORRECT.
Q. AND IN PARAGRAPH 45, YOU STATED THAT YOU BELIEVED AN INJUNCTION OF THE RULES IS NECESSARY TO PREVENT IMMEDIATE AND IRREPARABLE HARM TO WOMEN IN PENNSYLVANIA AND AROUND THE COUNTRY WHO WILL LOSE ONGOING PREVENTATIVE CARE COVERAGE UNDER THEIR GROUP HEALTH PLANS DUE TO THE RULES, BUT AS OF TODAY, YOU DON'T KNOW OF ANY ACTUAL WOMEN WHO HAVE LOST THEIR ONGOING PREVENTATIVE CARE COVERAGE DUE TO THE RULES, CORRECT?
A. IT SAY "PREVENTIVE," NOT "PREVENTATIVE," BUT

OTHERWISE, CORRECT.
Q. APOLOGIES. THANK YOU.
HAVE YOU HEARD FROM -- I'M SORRY. IN YOUR MEDICAL PRACTICE, DO YOU PRACTICE WITH OTHER DOCTORS?
A. I DO.
Q. HAVE YOU HEARD FROM ANY OF THEM THAT LIKE THEY DON'T -- HAVE YOU LEARNED THROUGH ANY OTHER MEANS ABOUT ANY OTHER PATIENTS IN YOUR PRACTICE WHO MIGHT HAVE THIS PROBLEM?
A. I HAVE NOT HAD THOSE CONVERSATIONS WITH MY COLLEAGUES.
Q. HAVE YOU LEARNED, FOR EXAMPLE, THROUGH CALLS FROM PHARMACIES OR PHARMACISTS ABOUT ANY PATIENTS WHO ARE HAVING PROBLEMS GETTING THEIR PRESCRIPTIONS BECAUSE OF THE NEW RULES?
MS. BOLAND: OBJECTION, CALLS FOR HEARSAY.
THE COURT: SUSTAINED.
MS. KOPPLIN: IF I MIGHT CONFER WITH MY COLLEAGUES FOR JUST A MOMENT, YOUR HONOR.
(PAUSE.)
MS. KOPPLIN: THANK YOU FOR YOUR TESTIMONY.
YOUR HONOR, NO FURTHER QUESTIONS.

THE COURT: ANY REDIRECT?
MS. BOLAND: NO REDIRECT, YOUR HONOR.
THE COURT: THANK YOU VERY MUCH. YOU ARE EXCUSED.
OKAY. WHAT I THINK WHAT WE WILL DO NOW IF YOU ARE READY, YOU ARE UP. TELL US WHAT YOU FOUND.
MR. HEALY: PERMISSION TO APPROACH, YOUR HONOR?
THE COURT: YES. AND YOU ARE MR. HEALY.
MR. HEALY: CHRISTOPHER HEALY.
THE COURT: OKAY.
MR. HEALY: THANK YOU, YOUR HONOR. I APOLOGIZE AGAIN FOR THE SCRAMBLING BACK AND FORTH.
THE COURT: NOT A PROBLEM. I THINK I ASKED YOU TO DO IT. YOU WERE PERFECTLY WITHIN YOUR RIGHTS.
MR. HEALY: SO I LOOKED INTO THE AGENCY'S RATIONALE BEHIND THE STATEMENT YOUR HONOR READ FROM THE BENCH THIS MORNING, WHICH I BELIEVE, IF I HAVE IT CORRECT, I PUT ON THE SCREEN HERE.
THE COURT: WHAT ARE WE LOOKING AT HERE?
MR. HEALY: THIS IS THE STATEMENT I BELIEVE -- IF YOU COULD CONFIRM FOR ME, THE STATEMENT THAT YOU READ FROM THE BENCH THIS MORNING THAT WAS: AS REFLECTED IN LITIGATION PERTAINING TO THE MANDATE --

THE COURT: YES.
MR. HEALY: -- THEY WISH TO MAKE CHANGES TO THEIR HEALTH PLANS THAT WILL REDUCE THE COST OF INSURANCE COVERAGE FOR THE BENEFICIARIES, ET CETERA.
SO THIS STATEMENT READS: AS REFLECTED IN LITIGATION PERTAINING TO THE MANDATE, SOME ENTITIES ARE IN GRANDFATHERED HEALTH PLANS THAT DO NOT COVER CONTRACEPTION. THEY WISH TO MAKE CHANGES TO THEIR HEALTH PLANS THAT WILL REDUCE THE COST OF INSURANCE COVERAGE FOR THEIR BENEFICIARIES OR POLICYHOLDERS BUT WHICH WOULD CAUSE THE PLANS TO LOSE GRANDFATHERED STATUS. THEY ARE REFRAINING FROM MAKING THOSE CHANGES AND THEREFORE ARE CONTINUING TO INCUR AND PASS ON HIGHER INSURANCE COSTS TO PREVENT THE MANDATE FROM APPLYING TO THEIR PLANS IN VIOLATION OF THEIR CONSCIENCES.
THE COURT: SO WHEN I ASKED YOU -- I SAID WE HAD GONE THROUGH 58,000 COMMENTS, AND WE HAD PUT IN THE WORD "GRANDFATHER" OR "GRANDFATHERED" AND HAVE FOUND NOTHING THAT WENT DIRECTLY TO THAT FINDING. SO WHAT YOU WERE GOING TO DO WAS FIND ME -- PERHAPS THERE WAS A DIFFERENT WORD THAT WAS USED IN THE COMMENTS.
MR. HEALY: SO THOSE 54,000 COMMENTS THAT YOUR HONOR MENTIONED WERE COMMENTS WITH REGARD TO THE 2016 REQUEST FOR INFORMATION, WHICH HAD TO DO WITH WAYS THAT THE DEPARTMENT MIGHT AMEND THE ACCOMODATION, NOT

THE GRANDFATHERED HEALTH PLANS, SO THAT MAY HAVE BEEN THE REASON.
WE'VE ASKED THE AGENCY, AND THE AGENCY POINTED OUT TWO PARTICULAR PREVIOUS COURT CASES THAT THE AGENCY RELIED ON. AS THEY MENTION IN THE RULE -- THEY WROTE -- THEN IT SAYS: AS REFLECTED IN LITIGATION PERTAINING TO THE MANDATE.
SO THOSE TWO CASES THAT THE AGENCY --
THE COURT: WHICH CASES ARE THOSE?
MR. HEALY: THOSE ARE THE DIOCESE OF FORT WAYNE VERSUS SEBELIUS. THAT'S 988 F.SUPP.2D 958. AND ALSO ARCHDIOCESE OF ATLANTA. SO ARCHDIOCESE OF ATLANTA, THIS IS THE COMPLAINT FROM THAT CASE. THAT IS CASE NUMBER 1:12-CV-3489 IN THE NORTHERN DISTRICT OF GEORGIA. I APOLOGIZE THAT I DON'T HAVE A FEDERAL CITATION FOR THAT, BUT THAT IS THE CASE NUMBER.
AND THIS IS FROM THE COMPLAINT IN THAT CASE. IT SAYS: BASED ON THE LEGAL OPINION OF COUNSEL, PLAINTIFFS BELIEVE THAT THE ATLANTA PLAN AND SAVANNAH PLAN CURRENTLY MEET THE AFFORDABLE CARE ACT'S DEFINITION OF GRANDFATHERED PLAN. AND LATER ON: PLAINTIFFS WILL LOSE THEIR GRANDFATHERED STATUS IN THE NEAR FUTURE FOR REASONS THAT CANNOT BE AVOIDED --
THE COURT: WHICH CASE IS THIS?
MR. HEALY: THIS IS THE ARCHDIOCESE OF

ATLANTA CASE.
THE COURT: WHAT DATE WAS THIS DOCUMENT YOU ARE SHOWING ME?
MR. HEALY: THAT WAS FROM 2012.
THE COURT: SINCE THE CONTRACEPTIVE MANDATE -- SINCE THE NEW IFR HAS BEEN PUT INTO PLACE, HAVE THESE FOLKS CHANGED THEIR PLAN?
MR. HEALY: I'M NOT AWARE WHETHER THESE FOLKS HAVE CHANGED THEIR PLAN.
THE SECOND CASE THAT THE AGENCY RELIED ON IS THIS, WHICH IS THE DIOCESE OF FORT WAYNE CASE, WHICH HAS THIS HIGHLIGHTED PORTION HERE ON THE SCREEN. MAYBE I CAN ZOOM OUT SO EVERYONE CAN SEE IT. THIS WAS ONE OF THE PREVIOUS CHALLENGES TO THE CONTRACEPTIVE COVERAGE MANDATE. IT SAYS THAT -- THIS IS FROM THE COURT'S OPINION IN THAT CASE FROM THE NORTHERN DISTRICT OF INDIANA.
THE COURT: WHAT IS THE CITE?
MR. HEALY: THAT WAS THE ONE I READ BEFORE FROM 2013. AND THAT SAYS: CURRENTLY THE DIOCESAN HEALTH PLAN ALSO MEETS THE ACA'S DEFINITION OF A GRANDFATHERED PLAN AND INCLUDES A STATEMENT IN PLAN MATERIALS PROVIDED TO PARTICIPANTS OR BENEFICIARIES THAT IT BELIEVES IS A GRANDFATHERED PLAN AS IT IS REQUIRED TO MAINTAIN ITS GRANDFATHERED STATUS. BUT IN ORDER TO

MAINTAIN ITS GRANDFATHERED STATUS, THE DIOCESE FORGOES APPROXIMATELY $180,000 A YEAR IN INCREASED PREMIUMS SO THAT IT CAN PROTECT CATHOLIC CHARITIES FROM THE CONTRACEPTIVE MANDATE.
ABSENT MAINTAINING ITS GRANDFATHERED STATUS AT A GREAT EXPENSE, THE ONLY OTHER OPTIONS WOULD BE EITHER, ONE, SPONSOR A PLAN THAT WOULD PROVIDE THE EMPLOYEES OF CATHOLIC CHARITIES WITH ACCESS TO FREE CONTRACEPTION, ABORTION, INDUSTRY PRODUCTS, STERILIZATION, AND RELATED COUNSELING; OR TWO, NO LONGER EXTEND ITS PLAN TO CATHOLIC CHARITIES, SUBJECTING IT TO MASSIVE FINES IF IT DOES NOT CONTRACT WITH ANOTHER INSURANCE PROVIDER THAT WILL PROVIDE THE OBJECTIONABLE COVERAGE.
THE COURT: DO WE KNOW WHETHER THE PLAINTIFF IN THIS CASE HAS -- SUBSEQUENT TO THE ENACTMENT OF THE NEW -- RATHER THE ISSUANCE OF THE NEW IFRS HAS CHANGED THEIR PLAN?
MR. HEALY: I DO NOT KNOW THAT THEY HAVE.
THE COURT: SO APART FROM THESE TWO CASES, THAT IS -- THAT IS WHAT YOU GOT?
MR. HEALY: THERE MAY BE OTHER COMMENTS. WE HAD LOOKED THROUGH AS MANY OF THEM AS WE COULD IN THE TIME WE HAD. HOWEVER, WE HAVE IDENTIFIED NO PARTICULAR COMMENTS. THAT SAID, ALTHOUGH THESE TWO CASES WERE NOT

IN THE ADMINISTRATIVE RECORD, IT'S NOT GENERALLY THE PRACTICE TO INCLUDE PRIOR COURT CASES IN ADMINISTRATIVE RECORDS. HOWEVER -- BASICALLY BECAUSE OF THE FACT THAT THEY ARE ALREADY JUDICIALLY NOTICEABLE. HOWEVER, THEY WERE CITED IN THE RULES AND IT WAS SOMETHING THAT THE AGENCY RELIED ON.

THE COURT: SO TO THE EXTENT THAT THIS ISSUE, THE GRANDFATHER HEALTH PLANS WANTING TO MAKE CHANGES AND NOT LOSE THEIR GRANDFATHER STATUS, TO THE EXTENT THAT THAT WAS A UNDERLYING RATIONALE FOR THE NEW IFRS, WE HAVE TWO PLANS RIGHT NOW? TWO COURT CASES THAT YOU HAVE BEEN UNABLE TO IDENTIFY, WHICH WARRANTED THE CONCLUSION THAT THERE WAS GOOD LAW?

MR. HEALY: YES, THAT IS CORRECT, YOUR HONOR, AND WE ARE HAPPY TO CONTINUE LOOKING THROUGH OTHER COMMENTS THAT HAVE COME SINCE THEN. WE HAD AN OPEN COMMENT PERIOD THAT ENDED ON DECEMBER 5TH. HOWEVER, AT THIS TIME WE HAVE NOT BEEN ABLE TO IDENTIFY FURTHER COMMENTS.

THE COURT: WELL, I THINK THAT THE ISSUE IS WHAT COMMENTS HAD COME IN AT THE TIME THE NEW IFRS WERE ISSUED, BECAUSE THAT WAS THE REASON THAT THE AGENCIES WERE SAYING THEY HAD GOOD CAUSE WAS BECAUSE OF THOSE. SO TO THE EXTENT THAT THINGS HAVE HAPPENED SUBSEQUENTLY, I DON'T THINK IT'S RELEVANT TO MY

ANALYSIS.

MR. HEALY: THAT MAKES SENSE. THAT'S CORRECT, YOUR HONOR.

THE COURT: OKAY. LET'S TAKE A BRIEF BREAK AND THEN -- DID YOU WANT HALF AN HOUR TO CLOSE OR 15 MINUTES TO CLOSE?

MR. FISCHER: YOUR HONOR, HALF AN HOUR, ALTHOUGH I WILL TRY NOT TO TAKE ALL OF IT.

MR. DAVIS: I THINK HALF AN HOUR IS FINE. I WILL ALSO TRY NOT TO TAKE ALL OF IT.

THE COURT: OKAY. WE'RE DOING VERY WELL. IT'S ONLY QUARTER TO 3. I HAD GIVEN YOU UNTIL 6 SO WE CAN PROBABLY GET OUT EARLIER THAN WE ANTICIPATED.

THE CLERK: ALL RISE.

(BREAK TAKEN.)

THE COURT: WHO'S DOING CLOSINGS FOR THE COMMONWEALTH?

MR. FISCHER: YOUR HONOR, I'M GOING TO DO CLOSING FOR THE COMMONWEALTH.

THE COURT: OKAY.

MR. FISCHER: GOOD AFTERNOON, YOUR HONOR.

THE COURT: GOOD AFTERNOON.

MR. FISCHER: I THINK IT IS IMPORTANT TO START BY REMEMBERING EXACTLY WHAT WE ARE CHALLENGING AND WHAT WE ARE NOT CHALLENGING IN THESE PROCEEDINGS.

MR. DAVIS SAID IN THE BEGINNING THAT THESE RULES WERE NOT ISSUED ON A BLANK SLATE, AND THAT IS ABSOLUTELY CORRECT. A LOT HAS HAPPENED IN THIS AREA BEFORE WE GET TO THIS POINT.

WE ARE NOT CHALLENGING THE ORIGINAL EXEMPTION FOR CHURCHES AND CLOSELY-RELATED INSTITUTIONS. WE ARE NOT CHALLENGING THE ACCOMMODATION PROCESS THAT WAS ORIGINALLY CREATED AND THEN EXPANDED AS A RESULT OF THE SUPREME COURT'S HOBBY LOBBY DECISION.

WHAT WE ARE CHALLENGING ARE TWO RULES THAT ARE SWEEPING IN THEIR SCOPE. THERE ARE A LOT OF CONCERNS WE HAD ABOUT THESE RULES, BUT THERE ARE THREE ASPECTS IN PARTICULAR THAT I WANT TO FOCUS ON.

THE FIRST IS THAT FOR THE FIRST TIME, THE RELIGIOUS EXEMPTION RULE ALLOWS PUBLICLY-TRADED COMPANIES TO OPT OUT OF THE CONTRACEPTIVE MANDATE. THAT WAS NEVER THE CASE BEFORE. THERE IS A LIMITED JUSTIFICATION FOR THAT DECISION IN THE RULES, AND IT POTENTIALLY THREATENS CONTRACEPTIVE COVERAGE FOR A SIGNIFICANT NUMBER OF WOMEN.

THE SECOND FACTOR THAT I'D LIKE TO MENTION IS THAT AS A RESULT OF THESE TWO RULES, THE ACCOMMODATION PROCESS IS NOW OPTIONAL.

THE COURT: IS NOW WHAT?

MR. FISCHER: OPTIONAL. THERE IS NO

REQUIREMENT THAT COMPANIES THAT WISH TO OPT OUT NOTIFY THEIR INSURANCE COMPANY OR THEIR THIRD-PARTY ADMINISTRATOR OF THEIR DECISION SO THAT THEIR EMPLOYEES CAN GET COVERAGE. SO AS A RESULT OF THAT, WOMEN EMPLOYED BY THE COMPANIES THAT ARE CURRENTLY USING THAT PROCESS FACE A LOSS OF COVERAGE.

AND THEN FINALLY, THE THIRD ISSUE I WOULD LIKE TO TOUCH ON, WHICH YOUR HONOR DISCUSSED EARLIER, IS THE MORAL EXEMPTION. THE MORAL EXEMPTION IS INCREDIBLY VAGUE, DOES NOT DEFINE EXACTLY WHAT'S MEANT BY A SINCERELY-HELD MORAL BELIEF, AND AS I THINK YOUR HONOR'S QUESTIONING REFLECTED, OPENS UP ALL SORTS OF POTENTIAL PROBLEMS OF HOW DO FEDERAL AGENCIES DETERMINE WHETHER A BELIEF IS SINCERELY HELD, WHAT THE NATURE OF THE BELIEF IS, WHAT BELIEFS DO QUALIFY TO ALLOW SOMEBODY TO OPT OUT, WHAT BELIEFS MAY NOT QUALIFY. SO I THINK THAT RULE BY ITSELF IS SIGNIFICANTLY PROBLEMATIC.

WHAT WE ARE SEEKING AS A RESULT OF THIS IS AN INJUNCTION THAT WOULD ESSENTIALLY TAKE US BACK TO THE STATUS QUO BEFORE THESE RULES WERE ISSUED, BACK TO OCTOBER 5TH OF THIS YEAR.

IT IS OUR HOPE THAT AS A RESULT, AT THE VERY LEAST, THE AGENCIES WILL FOLLOW THE CORRECT PROCESS IF THEY TRY TO DO THIS AGAIN, BECAUSE WHAT WE HAVE HERE IS A FLAWED PROCESS THAT PRODUCED A FLAWED RESULT.

WE THINK IT IS CLEAR THAT THE AGENCY HAS VIOLATED THE PROCEDURAL REQUIREMENTS OF THE APA AND CAME UP WITH A RESULT THAT VIOLATES THE SUBSTANTIVE REQUIREMENTS OF THE APA, IS ARBITRARY AND CAPRICIOUS, VIOLATES THE AFFORDABLE CARE ACT, AND HAS OTHER SIGNIFICANT PROBLEMS.

THE COURT: LET ME FOLLOW UP WITH YOU ON THAT ONE.

WHEN YOUR COLLEAGUE OPENED, I ASKED HIM WHETHER -- THERE CLEARLY IS A DISTINCTION BETWEEN THE CLAIMS THAT ARE BROUGHT UNDER THE APA AND THE CLAIMS THAT ARE THE CONSTITUTIONAL CLAIMS.

THE FISCHER: YES, THAT'S CORRECT.

THE COURT: AND AS YOU KNOW, WHEN A COURT CAN REACH A STATUTORY CLAIM RATHER THAN A CONSTITUTIONAL CLAIM, THE ADMONITION AT ALL LEVELS ALL OF THE WAY UP TO THE SUPREME COURT AND THE THIRD CIRCUIT IS THAT THE COURT SHOULD NOT REACH THE CONSTITUTIONAL ISSUES BUT SHOULD PROCEED WITH THE PROCEDURAL ISSUES.

SO IF I WERE TO PROCEED WITH THE PROCEDURAL ISSUES ALONE, AND ASSUMING THAT I WOULD DO IT UNDER BOTH THE PROCEDURAL COMPONENT, THE NOTICE OF COMMENT, AND THE SUBSTANTIVE COMPONENT, THE LACK OF GOOD CAUSE, WHAT KIND OF INJUNCTION WOULD THE COMMONWEALTH BE LOOKING FOR?

IN THOSE CIRCUMSTANCES, I THINK YOUR COLLEAGUE SAID IF IT WAS ONLY THE PROCEDURAL, THEY WOULD JUST GO BACK AND GO THROUGH THE PROCEDURE AND STILL HAVE THE SAME RULES.

SO WHAT INJUNCTION WOULD YOU BE ASKING FOR IN THOSE LIMITED CIRCUMSTANCES?

MR. FISCHER: WE WOULD BE SEEKING AN INJUNCTION PREVENTING THEM FROM ENFORCING THESE RULES, AND OUR HOPE IS THAT, PARTICULARLY IF THERE IS A SUBSTANTIVE COMPONENT TO YOUR HONOR'S RULING, IT WOULD BE TAKEN BY THE AGENCIES -- AGENCIES AS AN INDICATION THAT THE NEXT RULE THEY COME OUT WITH BETTER EITHER HAVE MORE SUBSTANTIVE SUPPORT BEHIND IT OR ADDRESS THESE ISSUES DIFFERENTLY, PARTICULARLY THE THREE THAT I MENTIONED.

THE COURT: SO HOW DOES THAT ISSUE -- HOW IS THAT ISSUE LINED UP IN AN ORDER? BECAUSE YOU ARE NOT, YOU HAVE NOT ASKED FOR A MANDATORY INJUNCTION, YOU HAVE NOT ASKED ME TO TELL THEM TO DO RULES IN A PARTICULAR WAY, SO HOW WOULD AN ORDER LOOK THAT DEALS WITH THE GOOD CAUSE COMPONENT IF I WERE TO RULE IN THAT WAY.

MR. FISCHER: AN ORDER COULD SIMPLY PRECLUDE THEM FROM ENFORCING THESE TWO SPECIFIC RULES, WHICH WOULD THEN REQUIRE THEM TO, AT THE VERY LEAST, GO

THROUGH THE PROCESS AGAIN, AND DEPENDING ON WHAT COMES OUT OF THAT PROCESS, WE MAY BE BACK HERE AGAIN. OUR HOPE WOULD BE THAT THEY WOULD COME UP WITH A DIFFERENT RESULT.

BUT I DON'T BELIEVE THERE IS ANYTHING THIS COURT CAN DO TO ENJOIN THE NEXT RULE. AND, YOU KNOW, MAYBE WE ARE BACK HERE. I HOPE THAT IS NOT THE CASE. HOPEFULLY THEY WILL GET THE MESSAGE AND MAKE SOME CHANGES TO THE RULES THAT ADDRESS THE REAL ISSUES.

BUT I THINK THAT THE INJUNCTION WE HAVE REQUESTED IS OF THESE TWO RULES AS THEY ARE CURRENTLY MADE.

THE COURT: OKAY.

MR. FISCHER: SO LET ME TALK A LITTLE MORE ABOUT THE PROCEDURAL VIOLATION OF THE APA. THE GOVERNMENT HAS ARGUED THAT THEY HAVE STATUTORY AUTHORITY TO WAIVE NOTICE AND COMMENT. WE ADDRESS THIS IN OUR BRIEFS. THE APA IS VERY CLEAR ABOUT THIS. SECTION 559 SAYS: SUBSEQUENT STATUTE MAY NOT HOLD -- MAY NOT BE HELD TO SUPERSEDE OR MODIFY THIS SUBCHAPTER, AND SEVERAL OTHERS, EXCEPT TO THE EXTENT IT DOES SO EXPRESSLY.

AND THE D.C. DISTRICT COURT IN COALITION FOR PARITY VERSUS SEBELIUS LOOKED AT THE VERY SAME AUTHORITY THAT THE AGENCIES ARE RELYING ON HERE, ANALYZED IT UNDER SECTION 549 OF THE APA, AND SAID IT

CLEARLY DOES NOT EXPRESSLY MODIFY THE REQUIREMENTS OF THE APA.

THE SECOND -- THE LANGUAGE THEY ARE RELYING ON IS SIMPLY A GENERAL GRANT THAT SAYS: THE SECRETARY MAY PROMULGATE ANY INTERIM FINAL RULES AS THE SECRETARY DETERMINES ARE APPROPRIATE TO CARRY OUT THIS PART.

NOTHING ABOUT WAIVING NOTICE AND COMMENT, NOTHING ABOUT PREEMPTING THE APA. GIVEN THE CLEAR REQUIREMENT IN THE APA THAT MODIFICATIONS HAVE TO BE DONE EXPRESSLY, WE THINK IT'S CLEAR THAT THAT DOES NOT GIVE THEM THE AUTHORITY THEY CLAIM IT DOES.

WE ALSO THINK IT IS FAIRLY CLEAR THEY DON'T HAVE GOOD CAUSE. THE GOOD CAUSE ARGUMENT, AS I UNDERSTAND, IS ESSENTIALLY, WELL, THERE IS A LOT OF LITIGATION GOING ON. WE WANT TO WRAP IT UP, SO WE WANT THESE RULES TO BE EFFECTIVE IMMEDIATELY.

NOW, IT IS INTERESTING, THEY HAVE ARGUED THAT MANY OF THE PLAINTIFFS IN THOSE CASES ARE PROTECTED BY INJUNCTIONS, WHICH IS TRUE. SO IF THE ARGUMENT IS -- THE ARGUMENT IS WE NEED TO PROTECT THESE PEOPLE IMMEDIATELY, WELL, BY THEIR OWN ADMISSION, MANY OF THEM ALREADY DO HAVE PROTECTION.

WE TALKED EXTENSIVELY IN OUR BRIEF ABOUT THE THIRD CIRCUIT'S DECISION IN UNITED STATES VERSUS

REYNOLDS BECAUSE IT SQUARELY REJECTS THE ARGUMENT THAT RESOLVING UNCERTAINTY IS AN ADEQUATE JUSTIFICATION FOR ISSUING IFRS. THE THIRD CIRCUIT THERE SAID VERY CLEARLY THAT THERE IS ALWAYS UNCERTAINTY IN THE RULEMAKING PROCESS, AND PARTICULARLY IF AN IFR IS ISSUED AS THIS ONE WAS, WITH A REQUEST FOR SUBSTANTIVE COMMENTS AND THE STATEMENT FROM THE AGENCY THAT THEY MAY BE MAKING FURTHER CHANGES TO THE RULE. THERE IS SIMPLY NO CERTAINTY THAT IS ACHIEVED AS A RESULT OF THAT.

AND FINALLY, I THINK THERE IS AN ARGUMENT THAT THEY MADE A FEW TIMES, WHICH IS THAT, WELL, IFR'S WERE ISSUED EARLIER IN APPLYING THE AFFORDABLE CARE ACT WOMEN'S HEALTH AMENDMENT, SO IT IS OKAY THIS TIME.

BUT I THINK IF THE COURT LOOKS BACK TO PRIESTS FOR LIFE, WHICH ADDRESSED THE PRIOR IFR THAT THEY ARE TALKING ABOUT, THE SPECIFIC IFR THAT THEY CITED TO YOU, WHICH IS AVAILABLE AT 79 FEDERAL REGISTER 51092, WAS ISSUED FOLLOWING THE WHEATON COLLEGE DECISION, WHICH CAME RIGHT AFTER HOBBY LOBBY.

ON THE SAME DAY, THE AGENCIES ISSUED A NOTICE OF PROPOSED RULEMAKING CALLED THE HOBBY LOBBY -- AND AN IFR THAT WAS BASED ON WHEATON COLLEGE. HERE IS WHAT THE WHEATON COLLEGE IFR SAID: THESE INTERIM FINAL REGULATIONS PROVIDED AN ALTERNATIVE PROCESS THAT AN ELIGIBLE ORGANIZATION MAY USE TO PROVIDE NOTICE OF ITS

RELIGIOUS OBJECTIONS TO PROVIDING CONTRACEPTIVE COVERAGE WHILE PRESERVING PARTICIPANTS' AND BENEFICIARIES' ACCESS TO COVERAGE OF THE FULL RANGE OF FDA-APPROVED CONTRACEPTIVES.

ALL THAT DID IS IT SAID, UNDER THE ACCOMMODATION BEFORE, YOU HAD TO PROVIDE NOTICE TO YOUR INSURANCE COMPANY OR YOUR THIRD-PARTY ADMINISTRATOR. THE COURT IN WHEATON COLLEGE ESSENTIALLY SAID, YOU WILL HAVE TO ALSO LET THEM PROVIDE NOTICE TO HHS, AND THEN YOU DO THE LEGWORK AND CONTACT THE THIRD-PARTY ADMINISTRATOR OR INSURANCE COMPANY.

SO ALL THIS REGULATION DID IS IT ESSENTIALLY IMPLEMENTED WHAT THE COURT DIRECTED. IT SAID, WE ARE GOING TO CREATE ANOTHER PROCESS WHERE YOU CAN SEND THE FORM TO US. THAT IS A FAR CRY FROM THE SWEEPING CHANGES THAT ARE AT ISSUE IN THIS CASE.

YOUR HONOR, I WOULD LIKE TO GET INTO THE SUBSTANTIVE APA DISCUSSION A LITTLE BIT BECAUSE I THINK THAT IS IN MANY WAYS THE MOST IMPORTANT -- YOU KNOW, ONE OF THE MOST IMPORTANT ISSUES IN THIS CASE.

YOUR HONOR HAD ASKED ABOUT CHEVRON DEFERENCE AND WHETHER THAT APPLIED HERE. CHEVRON DOES NOT APPLY EITHER TO THEIR INTERPRETATION OF THE AFFORDABLE CARE ACT OR TO THEIR INTERPRETATION OF RFRA.

WITH RESPECT TO RFRA, I THINK COUNSEL

CONCEDED EARLIER THAT -- THAT THEY DO NOT GET CHEVRON DEFERENCE UNDER RFRA, AND CERTAINLY IN THE HOBBY LOBBY DECISION, THERE WAS NOT EVEN A MENTION OF CHEVRON OR WHETHER THE GOVERNMENT'S INTERPRETATION OF RFRA WAS ENTITLED TO --

THE COURT: SO STEP ZERO ON RFRA.

MR. FISCHER: YES, IT'S A ZERO ON RFRA. AND ACTUALLY, I BELIEVE IT'S STEP ZERO ON THE ACA TOO.

AND I WOULD REFER TO --

THE COURT: SO -- WELL, WHY IT WOULD BE STEP 1 BUT YOU WOULD BE ARGUING THAT THEY HAVE TAKEN ULTRA VIRES ACTIONS UNDER STEP 1?

MR. FISCHER: I BELIEVE IT COULD BE FRANKLY ANY OF THE STEPS, I THINK. BUT I JUST WANT TO START AT STEP ZERO AND SAY THE SUPREME COURT DECISION IN KING VERSUS BURWELL I THINK IS A GOOD EXAMPLE. THAT WAS THE CASE INVOLVING THE LANGUAGE IN THE ACA ABOUT TAX CREDITS BEING AVAILABLE TO PEOPLE WHO PURCHASED HEALTH COVERAGE ON AN EXCHANGE RUN BY THE STATE. AND THE QUESTION WAS WHETHER THAT APPLIED TO THE HEALTHCARE.GOV OR BY THE FEDERAL GOVERNMENT.

CHIEF JUSTICE ROBERTS REJECTED THE ARGUMENT THAT CHEVRON DEFERENCE APPLIED, AND HIS REASONING WAS -- WAS THIS: THE TAX CREDITS ARE AMONG THE ACT'S KEY REFORMS INVOLVING BILLIONS OF DOLLARS IN

SPENDING EACH YEAR AND AFFECTING THE PRICE OF HEALTH INSURANCE FOR MILLIONS OF PEOPLE. WHETHER THOSE CREDITS ARE AVAILABLE UNDER FEDERAL EXCHANGES IS THUS A QUESTION OF DEEP ECONOMIC AND POLITICAL SIGNIFICANCE THAT IS CENTRAL TO THE STATUTORY SCHEME. HAD CONGRESS WISHED TO ASSIGN THAT QUESTION TO AN AGENCY, IT SURELY WOULD HAVE DONE SO EXPRESSLY. IT IS ESPECIALLY UNLIKELY THAT CONGRESS WOULD HAVE DELEGATED THIS DECISION TO THE IRS, WHICH HAS NO EXPERTISE IN CRAFTING HEALTH INSURANCE POLICY OF THIS SORT.

NOW HERE, THE STATUTE HAS A CLEAR DELEGATION OF AUTHORITY TO IDENTIFY APPROPRIATE PREVENTIVE SERVICES. THAT IS TO THE HEALTH RESOURCES AND SERVICE ADMINISTRATION. HRSA HAS SIGNIFICANT EXPERTISE ON PREVENTIVE MEDICINE, ON INCREASING ACCESS TO HEALTHCARE, ON PROMOTING HEALTHCARE FOR UNDERSERVED COMMUNITIES. THERE IS NO EXPERTISE THERE IN DEFINING EXEMPTIONS FOR EXISTING MANDATORY REQUIREMENTS.

IN FACT, THAT ACTUALLY RUNS COUNTER TO THEIR MISSION. THEIR MISSION IS TO INCREASE ACCESS TO HEALTHCARE. SO IT STRAINS CREDULITY TO SAY THAT CONGRESS WOULD HAVE DELEGATED TO HRSA THE RESPONSIBILITY TO INTERPRET THIS PROVISION IN A WAY THAT ALLOWED FOR SIGNIFICANT EXEMPTIONS.

REGARDLESS, IF WE DO GET INTO THE CHEVRON

FRAMEWORK, THE GOVERNMENT NEEDS TO IDENTIFY THE LANGUAGE IN THE ACA THAT THEY ARE INTERPRETING AND WHAT THEIR INTERPRETATION IS SO THE COURT CAN ASSESS WHETHER THEIR INTERPRETATION IS PRECLUDED BY THE LANGUAGE, AND IF NOT, WHETHER IT'S REASONABLE.

AS I READ THE GOVERNMENT'S ARGUMENTS, THEY REFER TO THE SECTION WHICH WE REFER TO. IT SAYS: A GROUP HEALTH PLAN AND HEALTH INSURANCE ISSUER OFFERING GROUP OR INDIVIDUAL HEALTH INSURANCE COVERAGE SHALL, AT A MINIMUM, PROVIDE COVERAGE FOR AND SHALL NOT IMPOSE ANY CAUTIONARY REQUIREMENTS FOR -- AND THEN SUBSECTION 4 IS: WITH RESPECT TO WOMEN, SUCH ADDITIONAL PREVENTIVE CARE AND SCREENINGS NOT DESCRIBED IN PARAGRAPH 1 AS PROVIDED FOR IN COMPREHENSIVE GUIDELINES SUPPORTED BY THE HRSA.

THE ONLY ARGUMENT I HAVE HEARD FROM THE GOVERNMENT AS TO HOW THEY ARE INTERPRETING THAT UNDER CHEVRON IS THAT SOMEHOW THE USE OF THE WORD "AS" BEFORE "PROVIDED FOR" IMPLIES THAT HRSA -- AND THEIR QUOTE IS: MAY DETERMINE NOT ONLY THE SERVICES COVERED BUT THE MANNER OR REACH OF THAT COVERAGE.

AND THEN THEY GO ON TO SAY: THE AGENCIES READ THE STATUTE TO AUTHORIZE THEM TO CRAFT OR MODIFY EXEMPTIONS FOR ANY CONTRACEPTIVE COVERAGE MANDATE AND THAT REASONABLE CONSTRUCTION MUST PREVAIL. AND THAT PUTS A LOT OF -- THE WORD "AS" IS DOING A LOT OF WORK

THERE. THAT IS THE INTERPRETATION THEY COME UP WITH.

HRSA HAS NO EXPERTISE IN THIS AREA AND THERE IS SIMPLY NO WAY THAT I CAN SEE THAT THAT LANGUAGE CAN REASONABLY BE READ TO SAY HRSA OR THE AGENCIES UNDER WHICH HRSA IS WORKING CAN CREATE THESE SIGNIFICANT CARVE-OUTS.

THE COURT: SORRY, GO ON.

MR. FISCHER: NO.

THE COURT: SO I ASKED THE GOVERNMENT -- THE DEFENSE -- YOU ARE BOTH THE GOVERNMENT -- WHETHER -- JUST TO TALK ME THROUGH THIS NOTION THAT THERE IS THE -- THE ACA SAYS TO HRSA: PROVIDES SOME GUIDELINES. THE GUIDELINES THAT ARE CREATED ON THE CONTRACEPTIVE MANDATE. AND THEN THE RULES, THE NEW IFR'S, ARE CREATED AS AN EXCEPTION TO THE GUIDELINES, SO IT'S AN AGENCY MODIFYING A GUIDELINE OR A RULE OF AN AGENCY.

AND I THINK THE RESPONSE OF THE DEFENDANTS WAS PERFECTLY FINE, IT HAPPENS ALL THE TIME. SO CAN YOU RESPOND TO THAT PARTICULAR POINT AND TELL ME -- IT SEEMS A LITTLE ODD, AND TELL ME WHETHER IT'S JUST ODD OR WHETHER THERE IS SOMETHING PROBLEMATIC ABOUT IT.

MR. FISCHER: WE BELIEVE IT'S SERIOUSLY PROBLEMATIC. THE AGENCY CANNOT MODIFY GUIDELINES IN A WAY THAT CONFLICTS WITH THE STATUTORY DIRECTION THAT

CREATED THOSE GUIDELINES, AND THE DELEGATION WAS TO HRSA AND IT WAS TO HRSA FOR A REASON, BECAUSE THEY HAVE EXPERTISE IN IDENTIFYING PREVENTIVE MEDICINE.

THERE HAS BEEN A LOT OF DISCUSSION ABOUT HOW CONTRACEPTIVE COVERAGE IS NOT SPECIFICALLY MENTIONED IN THE ACA. WELL, I DON'T THINK WE WANT CONGRESS TO IDENTIFY THE SPECIFIC PREVENTIVE CARE THAT INSURANCE COMPANIES MUST PROVIDE. CONGRESS, I BELIEVE, MADE A WISE DECISION THAT THAT DECISION WAS GOING TO BE DELEGATED TO HRSA, WHICH HAS EXPERTISE AND THEN COULD MODIFY THE SERVICES THAT IT RECOMMENDED ON AN AS-NEEDED BASIS, AS MEDICINE CHANGED, AS SCIENTIFIC ADVANCES MOVED US FORWARD.

SO THE IDEA THAT AN AGENCY CAN SIMPLY TAKE A GRANT OF AUTHORITY THAT IS FAIRLY CLEARLY LIMITED TOWARD IDENTIFYING THE SERVICES THAT HAVE TO BE PROVIDED AND BLOW THAT UP INTO, WELL, WE CAN CREATE ENTIRE EXEMPTIONS, BROAD EXEMPTIONS FROM THIS RULE THAT SAYS -- AND I REFER BACK TO THE PREFATORY LANGUAGE IN 42 U.S.C. 30GG-13, WHICH SAYS PROVIDERS OF HEALTH COVERAGE SHALL, AT A MINIMUM, PROVIDE COVERAGE AND SHALL NOT IMPOSE ANY COST SHARING REQUIREMENTS FOR. THAT LANGUAGE IS ABOUT AS MANDATORY AS YOU CAN GET.

AND THEN IT LISTS THE FOUR THINGS. AT THE VERY BOTTOM IS THE WOMEN'S HEALTH AMENDMENT. THE

GOVERNMENT SOMEHOW READS THE LANGUAGE IN THE WOMEN'S HEALTH AMENDMENT TO APPLY BACK TO THE MANDATORY LANGUAGE IN THE BEGINNING AND ALLOW HRSA, WHICH AGAIN, HAS NO EXPERTISE HERE, TO CREATE BROAD EXEMPTIONS FROM IT.

WE THINK THAT SIMPLY CAN'T BE SQUARED WITH LANGUAGE OF THE STATUTE, AND IN ADDITION, FLIES DIRECTLY IN THE FACE OF THE PURPOSE OF THE WOMEN'S HEALTH AMENDMENT, WHICH WAS INTENDED TO IMPROVE WOMEN'S ACCESS TO PREVENTIVE CARE.

THE GOVERNMENT ALSO RELIES A LOT ON THE EXISTENCE OF GRANDFATHER PLANS. I THINK YOUR HONOR DISCUSSED THAT. THERE IS VERY LITTLE EVIDENCE IN THE RECORD THAT GRANDFATHERED PLANS ARE CLAMORING FOR THE ABILITY TO CHANGE, AND THIS -- THE CONTRACEPTIVE MANDATE IS SOMEHOW BLOCKING THEM.

BUT ALSO, AS YOU HEARD FROM DR. CHUANG, THE NUMBER OF GRANDFATHER PLANS CONTINUES TO DECLINE. IT WAS LIMITED TO BEGIN WITH. AND THE FACT THAT CONGRESS MADE WHAT APPARENTLY WAS A NECESSARY COMPROMISE TO GET THE ACA PASSED DOES NOT UNDERMINE THE ARGUMENT THAT THE CONTRACEPTIVE COVERAGE HERE SERVES A COMPELLING AND IMPORTANT GOVERNMENT INTEREST.

I ALSO THINK IT IS IMPORTANT TO REMEMBER THAT THE ACA DOES NOT HAVE A CONSCIENCE CLAUSE. ONE WAS PROPOSED AND IT WAS REJECTED. THROUGHOUT THE RULES, THE

ARGUMENT THE GOVERNMENT MAKES IS, WELL, OTHER STATUTES HAVE THEM SO WE CAN RELY ON THAT HERE. THAT IS SIMPLY NOT THE CASE. YOU CAN'T TAKE LANGUAGE FROM ANOTHER STATUTE AND APPLY IT WHERE IT DOES NOT EXIST.

AND WHAT'S MORE IS THE FACT THAT CONGRESS REJECTED IT IS A PRETTY GOOD INDICATION THAT CONGRESS DOES NOT BELIEVE THERE IS AN IMPLICIT CONSCIENCE CLAUSE THAT IS ALREADY THERE.

NOW, IN THEIR BRIEFING, AND THE GOVERNMENT TO SOME EXTENT THE RULES SAID ALL OF THIS IS REQUIRED UNDER RFRA, THAT WE'RE ALL THIS -- EXCEPT FOR THE MORAL EXCEPTION, WHICH IS NOT A LAW REQUIRED UNDER RFRA.

AGAIN, THAT IS A MUCH BROADER READING OF RFRA THAN ANY COURT HAS EVER ADOPTED. AT THE VERY LEAST, I'M NOT AWARE OF ANY DECISION HOLDING THAT RFRA APPLIES TO PUBLICLY-TRADED COMPANIES. I THINK IN SOME WAYS THE IDEA THAT A PUBLICLY-TRADED COMPANY COULD ENGAGE IN THE FREE EXERCISE OF RELIGION IS A LITTLE QUESTIONABLE. CERTAINLY THE SUPREME COURT HAS NEVER HELD THAT.

AND FOR THE AGENCIES TO UNILATERALLY SAY WE THINK THIS IS WHAT RFRA MEANS I THINK GOES WELL BEYOND THE SCOPE OF THEIR AUTHORITY. THEY HAVE ALSO DECIDED APPARENTLY THAT THE CONTRACEPTIVE MANDATE DOES

NOT SERVE A COMPELLING INTEREST.

WELL, FIVE JUSTICES IN THE SUPREME COURT IN HOBBY LOBBY SEEM TO DISAGREE. THE FOUR CENTERS CLEARLY SAID THAT IT SERVES A COMPELLING INTEREST, AND JUSTICE KENNEDY DISCUSSED THE COMPELLING INTEREST, NEVER ACTUALLY SAID SPECIFICALLY "I BELIEVE IT SERVES A COMPELLING GOVERNMENT INTEREST," BUT MADE IT PRETTY CLEAR THAT THAT WAS HIS BELIEF. AND FRANKLY, THE MAJORITY IN HOBBY LOBBY NEVER EVEN QUESTIONED THAT. THEY JUST ASSUMED IT FOR PURPOSES OF THE OPINION.

SO THE IDEA THAT RFRA SOMEHOW REQUIRES WHAT THE GOVERNMENT IS DOING, THAT IT REQUIRES APPLYING THIS TO PUBLICLY-TRADED COMPANIES, THAT IT REQUIRES MAKING THE ACCOMMODATION PROCESS OPTIONAL IS NOT SUPPORTED BY ANY OF THE CASE LAW THAT IS RELEVANT HERE. AND IT'S NOT SUPPORTED BY A FAIR READING OF THE STATUTE.

AND I THINK TO SEE THAT THAT IS THE CASE, WE DON'T NEED TO LOOK ANY FURTHER THAN THE ZUBIK DECISION, WHERE THE SUPREME COURT CLEARLY STRUGGLED WITH APPLYING RFRA IN THE CONTEXT OF AN ENTITY WHO DID OBJECT TO THE ACCOMMODATION PROCESS. IF THE GOVERNMENT WAS CORRECT AND THIS WAS A SLAM DUNK UNDER RFRA, ZUBIK WOULD HAVE BEEN AN EASY DECISION FOR THE SUPREME COURT.

IT WAS NOT. ZUBIK EMPHASIZED THE NEED TO BALANCE WHAT IT SAW AS LEGITIMATE EXERCISE OF RELIGION

AND THE NEEDS OF WOMEN AND THE COMPELLING GOVERNMENT INTEREST IN SERVING AND PROVIDING ACCESS TO CARE -- WELL, ZUBIK DID NOT SPECIFICALLY FIND THAT IT WAS A COMPELLING INTEREST, BUT I THINK THE FACT THAT THAT DECISION CAME OUT THE WAY IT DID IS A SIGN -- IS A CLEAR INDICATION THAT RFRA SIMPLY DOES NOT SAY WHAT THE GOVERNMENT HERE BELIEVES IT SAYS.

I THINK -- I'M HAPPY TO COME BACK TO THE CONSTITUTIONAL CLAIMS. I WOULD ALSO LIKE TO GET INTO THE HARM THAT PENNSYLVANIA WILL SUFFER, BECAUSE I THINK THAT IS IMPORTANT AS WELL. IT GOES BOTH TO THE IRREPARABLE INJURY PRONG OF THE INJUNCTION AS WELL AS STANDING THAT THE COMMONWEALTH HAS IN THIS CASE.

THERE HAS BEEN A LOT OF QUESTIONING TODAY SUGGESTING, WELL, THE COMMONWEALTH CAN'T POINT TO ANY SPECIFIC EMPLOYER WHO IS GOING TO TAKE ADVANTAGE OR WHO HAS ANNOUNCED THEY ARE TAKING ADVANTAGE OF THIS. WELL --

THE COURT: WELL, ALSO, THEY CAN'T POINT TO ANY PARTICULAR WOMAN. SO TELL ME WHY -- GIVE ME A RESPONSE TO THAT.

MR. FISCHER: WELL, THAT IS A FUNCTION IN MANY RESPECTS OF THE WAY THE RULES ARE DRAFTED. THE RULES ARE DRAFTED SO THAT EMPLOYERS CAN DO THIS QUIETLY. THERE IS NO REQUIREMENT TO NOTIFY HHS. THERE'S NO

REQUIREMENT TO MAKE A PUBLIC ANNOUNCEMENT. THERE IS NOT EVEN A REQUIREMENT TO CLEARLY COMMUNICATE TO ALL PLAN MEMBERS WE ARE DROPPING YOUR CONTRACEPTION COVERAGE.

AN EMPLOYER CAN DO THIS BY SIMPLY INCLUDING IN THE SUMMARY OF BENEFITS OF COVERAGE THAT THEY PROVIDE ON AN ANNUAL BASIS, THAT WE ALL GET, AND PROBABLY MOST OF US DON'T NECESSARILY READ THAT THOROUGHLY. AS LONG AS SOMEWHERE IN THAT DOCUMENT THERE IS AN INDICATION THAT CONTRACEPTION COVERAGE IS NOT PROVIDED AND THAT DOCUMENT IS PROVIDED 30 DAYS PRIOR TO THE START OF THE PLAN YEAR, THAT SATISFIES THE NOTICE REQUIREMENTS.

SO THE IDEA THAT SOMEHOW WE WOULD KNOW ABOUT THIS, THAT IT WOULD BE WIDESPREAD KNOWLEDGE WHO IS OPTING OUT, IS NOT CONSISTENT WITH THE WAY THE RULES ARE WRITTEN. NOW, THEY COULD HAVE WRITTEN THE RULES IN SUCH A WAY THAT IT WOULD BE CLEAR HOW MANY COMPANIES ARE TAKING ADVANTAGE, HOW MANY WOMEN ARE AFFECTED. THEY COULD HAVE REQUIRED -- THIS IS HHS -- THEY COULD HAVE REQUIRED NOTICE TO STATE REGULATORS. THEY DID NOT.

AND HERE WE ARE IN A SITUATION WHERE IT IS EXTREMELY DIFFICULT FOR ANYONE TO ESTIMATE EXACTLY HOW MANY WOMEN ARE AFFECTED. IN FACT, THE GOVERNMENT CONCEDES THAT. THEY SAY THEY DON'T EVEN KNOW HOW MANY WOMEN ARE AFFECTED BY THE CURRENT ACCOMMODATION PROCESS.

THE ONLY NUMBERS THEY COME UP WITH ARE BASED ON THE COMPANIES THAT HAVE NOTIFIED HHS UNDER THAT SPECIFIC OPTION, AS WELL AS SOME COMPANIES THAT ARE SELF-INSURERS WHERE THE THIRD-PARTY ADMINISTRATOR HAS BEEN IN CONTACT WITH HHS.

NOW, DESPITE NOT FULLY KNOWING HOW MANY PEOPLE USE THE ACCOMMODATION, THEY DO TRY TO COME UP WITH ESTIMATES IN THE RULES AS TO HOW MANY WOMEN WILL BE AFFECTED. THEY ESTIMATE THAT OVER 1 MILLION INDIVIDUALS ARE COVERED BY PLANS THAT CURRENTLY USE THE ACCOMMODATION PROCESS. AND THEY GET THAT DOWN TO AN ESTIMATE OF ROUGHLY 32,000 WOMEN NATIONWIDE WHO MAY LOSE COVERAGE -- WHO WILL LOSE COVERAGE AS A RESULT OF THESE RULES.

NOW, WE BELIEVE THAT THERE ARE PROBLEMS WITH THE WAY THEY ESTIMATED THOSE NUMBERS, BUT REGARDLESS, THEIR OWN ESTIMATES TELL YOU THAT LARGE NUMBERS OF WOMEN WILL BE AFFECTED, AND THAT WILL INCLUDE LARGE NUMBERS OF WOMEN HERE IN PENNSYLVANIA. AS WE DETAIL IN OUR BRIEF, MANY OF THE PLAINTIFFS IN THESE CASES WERE PENNSYLVANIA ENTITIES.

YOU HAVE SEEN EVIDENCE OR YOU HAVE SEEN ARGUMENTS IN SOME OF THE AMICUS BRIEFS ABOUT HOW THIS RULE WILL AFFECT WOMEN IN DIFFERENT STATES ACROSS THE COUNTRY. I BELIEVE IN THE AMICUS BRIEFS SUBMITTED BY

THE OTHER STATES, THERE WAS AN ESTIMATE THAT OVER HALF A MILLION WOMEN IN PENNSYLVANIA WHO CURRENTLY RECEIVE EMPLOYER-SPONSORED COVERAGE WOULD BE ELIGIBLE FOR STATE-FUNDED PROGRAMS IF THEY LOST THEIR COVERAGE AND THEREFORE COULD WIND UP POSING A DIRECT COST TO THE STATES.

AND YOU HAVE ALSO HEARD TESTIMONY FROM OUR EXPERTS ABOUT THEIR EXPERIENCE WITH THE AFFORDABLE CARE ACT, WHAT THAT HAS MEANT TO PENNSYLVANIA WOMEN, AND THEREFORE WHAT THEY BELIEVE WILL HAPPEN IF WOMEN ARE DENIED COVERAGE.

SO BECAUSE OF THIS 30-DAY OPTION THAT ALLOWS AN EMPLOYER TO -- AN EMPLOYER OR ANY PLAN ENTITY, ANY PLAN SPONSOR TO MODIFY OR ELIMINATE ITS CONTRACEPTIVE BENEFITS AT THE BEGINNING OF A PLAN YEAR WITH ONLY 30 DAYS' NOTICE, THAT IS WHY WE BELIEVE AN INJUNCTION BY JANUARY 1ST IS IMPORTANT. JANUARY 1ST IS THE START OF THE PLAN YEAR FOR MANY EMPLOYERS, AND THEREFORE WE BELIEVE ON THAT DAY MANY WOMEN WILL BE AT A RISK OF LOSING THEIR COVERAGE.

PENNSYLVANIA IS ACTUALLY IN A UNIQUE SITUATION AS WELL, BECAUSE UNLIKE A LOT OF OTHER STATES, WE DO NOT HAVE A CONTRACEPTIVE PARITY STATUTE. SO WOMEN WHO ARE COVERED BY FULLY-INSURED PLANS THAT ARE NOT REGULATED UNDER ERISA DO NOT HAVE A FALLBACK OPTION

WHERE THERE IS A STATE LAW THAT WOULD REQUIRE THEIR EMPLOYER TO CONTINUE COVERING CONTRACEPTION. SO THE HARM IN PENNSYLVANIA WILL BE MORE SIGNIFICANT THAN IT IS IN SOME OTHER STATES LIKE NEW YORK AND MASSACHUSETTS, CALIFORNIA, WHERE THEY DO HAVE CONTRACEPTION PARITY STATUTES.

SO THE RESULT OF ALL OF THIS IS THAT WOMEN WILL LOSE COVERAGE, THERE WILL BE COSTS IMPOSED ON THE STATE BECAUSE SIGNIFICANT NUMBERS OF THESE WOMEN WILL BE ELIGIBLE FOR STATE-FUNDED PROGRAMS OR WILL GO TO CLINICS THAT RECEIVE STATE FUNDING, AND ULTIMATELY THE STATE AND OTHER ENTITIES WILL BE PAYING THOSE COSTS.

AGAIN, THAT IS NOT SOMETHING WE ARE JUST SPECULATING ABOUT. THERE IS EVIDENCE IN THE RECORD ABOUT HOW THOSE PROGRAMS WORK AND IT'S ALSO REFLECTED IN THE GOVERNMENT'S RULES. WHEN THEY ARGUE THAT THE RULES WILL NOT IMPOSE A SIGNIFICANT IMPACT ON WOMEN, ONE OF THE POINTS THEY MAKE IS, WELL, THERE ARE ALL THESE OTHER PROGRAMS OUT THERE, ALL THESE OTHER STATE-FUNDED PROGRAMS, STATE AND FEDERAL GOVERNMENT-FUNDED PROGRAMS THAT CAN PROVIDE COVERAGE, AND THEY POINT SPECIFICALLY TO TITLE 10 CLINICS.

SO EVEN THE GOVERNMENT ACKNOWLEDGES THAT THERE WILL BE A SHIFT FROM EMPLOYERS TO PUBLICLY-FUNDED PROGRAMS AS A RESULT OF THESE RULES.

FINALLY, YOUR HONOR, IN GETTING INTO PENNSYLVANIA ENTITIES THAT MAY TAKE ADVANTAGE OF THE EXEMPTION, WE HAVE INCLUDED IN EXHIBIT 20, WHICH IS IN THE RECORD, A SUBSET OF DOCUMENTS FROM A FOIA REQUEST THAT WAS A MADE OF THE GOVERNMENT, OF THE FEDERAL AGENCIES, AND WHAT THESE DOCUMENTS ARE ARE SOME OF THE NOTICES TO HHS AND SUBSEQUENT RESPONSES ABOUT ENTITIES, AND MOST OF THE ONES IN EXHIBIT 20 ARE PENNSYLVANIA ENTITIES, ENTITIES THAT WERE USING THE ACCOMMODATION PROCESS.

NOW, AS I SAID EARLIER, THE GOVERNMENT DOES NOT KNOW EVERYBODY WHO USES THE ACCOMMODATION PROCESS BECAUSE NOT EVERYBODY NOTIFIES THE GOVERNMENT, BUT HERE ARE SOME OF THE EXAMPLES OF PENNSYLVANIA ENTITIES THAT HAVE USED THE ACCOMMODATION PROCESS, WHICH AS A RESULT OF THESE RULES IS NOW OPTIONAL, AND IT'S CERTAINLY A REASONABLE INFERENCE THAT ENTITIES THAT HAVE A SINCERELY-HELD RELIGIOUS OBJECTION TO PROVIDING CONTRACEPTIVE COVERAGE WILL CHOOSE, IF GIVEN THE OPPORTUNITY, TO OPT OUT ENTIRELY RATHER THAN TO PARTICIPATE IN A PROCESS WHICH SOME ENTITIES HAVE ARGUED -- AND THIS HAS BEEN THE SUBJECT OF ZUBIK LITIGATION -- SOME ENTITIES HAVE ARGUED NEVERTHELESS STILL IMPOSES A SUBSTANTIAL BURDEN ON THEIR RELIGIOUS BELIEFS.

SO FOR ALL OF THOSE REASONS, WE THINK IT IS FAIRLY CLEAR THAT THE RULES VIOLATE THE APA. THEY ARE ARBITRARY AND CAPRICIOUS, THEY ARE INCONSISTENT WITH THE AFFORDABLE CARE ACT AND THE PROCESS THAT WAS FOLLOWED WAS NOT LEGITIMATE, AND BECAUSE OF THAT HARM, BECAUSE OF THAT ILLEGALITY, SUBSTANTIAL INJURY WILL OCCUR IN THE COMMONWEALTH.

I WANT TO RETURN TO JUST ONE ISSUE ON STANDING BEFORE I WILL CONCLUDE, BUT THE COURT ASKED EARLIER ABOUT THE EXTENT OF PENNSYLVANIA'S INJURY AND HOW, AS A STATE, PENNSYLVANIA CAN BRING THIS ACTION. WE THINK IT IS FAIRLY CLEAR THAT MASSACHUSETTS VS. EPA CONTROLS AND ALLOWS THE COMMONWEALTH TO BRING AN ACTION CHALLENGING THE DECISIONS HERE IN THE FEDERAL GOVERNMENT. THE COURT POINTED OUT THAT THAT WAS THE CASE INVOLVING INACTION RATHER THAN ACTION, BUT IN MANY WAYS THIS CASE, ALTHOUGH IT IS CHALLENGING THE SPECIFIC REGULATIONS THAT WERE ISSUED, ULTIMATELY IS ABOUT THE GOVERNMENT CHOOSING NOT TO ENFORCE THE REQUIREMENTS OF THE AFFORDABLE CARE ACT AND THE CONTRACEPTIVE MANDATE AGAINST ENTITIES THAT OBJECT. AS A RESULT OF THESE RULES, THOSE LAWS, THOSE REQUIREMENTS WILL NO LONGER BE ENFORCED.

WHAT IS MORE, I DON'T THINK THAT FOR STANDING ANALYSIS PURPOSES THERE IS A SIGNIFICANT

DIFFERENCE BETWEEN ACTION AND INACTION. EITHER WAY, PENNSYLVANIA'S HARMED, PENNSYLVANIA'S RESIDENTS ARE HARMED, THE COMMONWEALTH'S QUASI-SOVEREIGN INTEREST IN PROTECTING THE HEALTH AND SAFETY OF ITS RESIDENTS IS GOING TO BE HARMED, AND FOR ALL OF THOSE REASONS, WE BELIEVE THAT THE COMMONWEALTH DOES HAVE STANDING IN THIS CASE.

THE COURT: OKAY, I THINK YOUR COLLEAGUE WANTS YOU TO TELL ME ONE MORE THING.

MR. FISCHER: YOUR HONOR, I APOLOGIZE. I DO NOT BELIEVE I RESERVED ANY TIME FOR REBUTTAL. WOULD THAT BE POSSIBLE? IF I HAVE TIME LEFT --

THE COURT: THAT IS FINE.

MR. FISCHER: OKAY.

THE COURT: AS I SAID, IT'S ME AND YOU. THERE IS NO ONE HERE SO IT'S FINE. WE HAVE UNTIL 6 O'CLOCK SO LET'S --

MR. FISCHER: SO -- YEAH.

THE COURT: ARE YOU DONE NOW?

MR. FISCHER: I JUST HAVE ONE MORE --

THE COURT: GO AHEAD.

MR. FISCHER: ON THIS QUESTION OF WHETHER THE COMMONWEALTH WILL BE HARMED, IT REALLY COMES DOWN TO COMMON SENSE. WHAT THE GOVERNMENT IS SAYING IS THAT

DESPITE THESE SWEEPING NEW RULES THAT THEY ARGUE ARE SO IMPORTANT THAT THEY HAVE TO BE IMPLEMENTED IMMEDIATELY TO PROTECT PEOPLE THAT ARE SUFFERING, NEVERTHELESS, NOBODY IN PENNSYLVANIA IS GOING TO BE HARMED BECAUSE NO EMPLOYER IS GOING TO TAKE ADVANTAGE OF THEM.

NOW THAT JUST DEFIES LOGIC. IT IS FAIRLY CLEAR THAT THERE WILL BE WOMEN ACROSS THE COUNTRY AND IN PENNSYLVANIA, BASED ON THEIR OWN ESTIMATES, BASED ON PRIOR LITIGATION, BASED ON SOME OF THE DOCUMENTS IN THE RECORD, THERE WILL BE WOMEN WHO ARE HARMED. THAT WILL CAUSE HARM TO THE COMMONWEALTH, AND CLEARLY WE BELIEVE THAT THAT NOT ONLY GIVES US STANDING, BUT ALSO ESTABLISHES INJURY FOR PURPOSES OF OUR INJUNCTION.

THANK YOU, YOUR HONOR.

THE COURT: THANK YOU.

WHO WILL BE ARGUING ON BEHALF OF THE DEFENDANTS?

MR. DAVIS: I WILL, YOUR HONOR.

MAY I APPROACH, YOUR HONOR?

THE COURT: YOU MAY.

MR. DAVIS: IF YOUR HONOR WOULD INDULGE ME AT THE BEGINNING, I WOULD LIKE TO MAKE A RECORD ON CERTAIN EVIDENTIARY ISSUES. SPECIFICALLY WE WOULD LIKE TO MOVE TO STRIKE THE TESTIMONY OF DRS. WEISMAN, BUTTS AND CHUANG TO THE EXTENT THEY TESTIFIED ABOUT THE IMPACT

OF THE NEW RULES ON WOMEN'S ACCESS.

THE COURT: THE HORSE HAS LEFT THE BARN ON THAT. YOU HAD AN OPPORTUNITY, YOU HAD A LAWYER WHO WAS HANDLING THAT ISSUE. I RULED.

MR. DAVIS: YOUR HONOR, CERTAIN THINGS CAME UP THROUGH THE TESTIMONY AFTER THE OBJECTION WAS MADE THAT I'D JUST LIKE TO PUT ON THE RECORD, IF YOU DON'T MIND.

THE COURT: I RULED AGAINST YOU. I DO MIND. YOU DON'T GET TO HAVE A SECOND BITE AT THE APPLE.

GO AHEAD. THIS IS NOW THE CLOSING ARGUMENT PORTION OF THE PROCEEDING.

MR. DAVIS: OKAY. ON STANDING, YOUR HONOR, YOU HEARD FROM DRS. WEISMAN, BUTTS AND CHUANG THAT THEY ARE NOT AWARE OF A SINGLE INDIVIDUAL WHO WILL BE AFFECTED BY THE NEW RULES AND THEY ARE NOT AWARE OF A SINGLE EMPLOYER WHO WILL BE TAKING ADVANTAGE OF THE NEW RULES. I THINK IT WOULD BE EXTRAORDINARY TO GRANT AN INJUNCTION THAT WOULD NOT BENEFIT A SINGLE IDENTIFIABLE INDIVIDUAL. I THINK THAT TESTIMONY WAS VERY TELLING.

THE COURT: IF THEY HAD BEEN ABLE TO IDENTIFY ONE PERSON, WOULD YOUR RESPONSE HAVE BEEN DIFFERENT?

MR. DAVIS: YOUR HONOR, I THINK IT MIGHT HAVE BEEN DIFFERENT WITH RESPECT TO STANDING BUT NOT

WITH RESPECT TO IRREPARABLE INJURY. I THINK IRREPARABLE INJURY REQUIRES SOME SORT OF DAMAGE MORE THAN A MINOR AMOUNT, AND IT WOULD NOT BE DIFFERENT IN A SENSE -- WITH RESPECT TO STANDING, IN THE SENSE THAT THEY WOULD ALSO HAVE TO SHOW THAT THAT EMPLOYEE WOULD ACTUALLY QUALIFY FOR A STATE-FUNDED PROGRAM AND WOULD ACTUALLY GO SEEK COVERAGE FROM THAT STATE-FUNDED PROGRAM. SO IF THEY COULD SHOW ALL OF THAT, MAYBE IT WOULD CHANGE THE STANDING ANALYSIS.

THE COURT: WELL, LET'S FOCUS IN ON STANDING THEN.

SO I'M LOOKING AT FEDERAL REGISTER 82-197 AND THERE IS A SECTION, THE RELIGIOUS EXEMPTION. IT'S THE DISCUSSION OF THE PEOPLE WHO WOULD BE IMPACTED OR THE WOMEN WHO WOULD BE IMPACTED. IT SAYS: BASED ON OUR LIMITED INFORMATION FROM THE LITIGATION AND ACCOMMODATION NOTICES, WE EXPECT THAT THE OVERLAP IS SIGNIFICANT. NEVERTHELESS, IN ORDER TO ESTIMATE THE POSSIBLE EFFECTS OF THESE RULES WE ASSUME THERE IS NO OVERLAP BETWEEN THESE TWO NUMBERS AND THEREFORE -- AND HERE IS THE IMPORTANT PART -- THAT THESE INTERIM FINAL RULES WOULD AFFECT THE CONTRACEPTIVE COSTS OF APPROXIMATELY 31,700 WOMEN.

SO I THINK THAT YOUR RULES ALONE SUGGEST THAT -- WELL, THEY DON'T SUGGEST, THEY SAY THAT 31,700

WOMEN WILL BE AFFECTED. AM I READING THAT CORRECTLY?

MR. DAVIS: YOUR HONOR, THE RULES ESTIMATE THAT SOME WOMEN WILL BE AFFECTED BY THIS. THAT ESTIMATE STANDARD IS LOWER THAN THE CERTAINLY IMPENDING STANDARD NECESSARY TO SHOW STANDING. IN A COURTROOM, I THINK THE STANDARD IS CERTAINLY IMPENDING, REASONABLY CERTAIN, AND I THINK THAT IS WHAT THEY FAILED TO SHOW HERE. AND AGAIN, YOU'D THINK THAT --

THE COURT: SO INSTEAD OF STEPPING AWAY FROM MY QUESTION, ANSWER MY QUESTION. SO IN THE REGULATIONS THERE IS A STATEMENT IS THAT THESE INTERIM FINAL RULES WOULD AFFECT THE CONTRACEPTIVE COSTS OF APPROXIMATELY 31,700 WOMEN. IS THAT A CORRECT STATEMENT OF WHAT THE RULES SAY?

MR. DAVIS: YOUR HONOR, I DON'T HAVE THAT STATEMENT RIGHT IN FRONT OF ME. I ASSUME YOUR HONOR IS READING IT CORRECTLY.

THE COURT: SO GIVEN THE FACT THAT THE RULES THEMSELVES HAVE SAID 31,700 WOMEN WILL BE -- THE COST OF SEVEN -- 31,700 WOMEN WILL BE AFFECTED, HOW DOES THAT IMPACT HERE ON THE STANDING ANALYSIS?

MR. DAVIS: AGAIN, YOUR HONOR, IN THE CONTEXT OF THE RULES, THAT IS AN ESTIMATE. THAT IS NOT A BLANKET STATEMENT THAT 31,000 WOMEN ARE DEFINITELY GOING TO BE AFFECTED BY THESE RULES. I FUNDAMENTALLY

DISAGREE WITH THE IDEA THAT THAT IS AN IRONCLAD PREDICTION OF WHAT WILL HAPPEN. THAT IS AN ESTIMATE.

THE RULES IN OTHER PLACES SAY THAT THEY -- THAT IT'S -- THIS ENDEAVOR IS FRAUGHT WITH UNCERTAINTY, IT'S NOT CLEAR WHAT EFFECT THESE WILL HAVE, THAT MANY EMPLOYERS ARE ALREADY PROTECTED BY INJUNCTIONS. I DON'T THINK THERE IS ANY WAY TO READ THAT STATEMENT AS AN IRONCLAD PREDICTION THAT THIS IS WHAT WILL HAPPEN.

THE COURT: GO AHEAD.

MR. DAVIS: I WOULD ALSO LIKE TO -- YOU ALSO HEARD, ALSO ON THE STANDING QUESTION, YOUR HONOR, YOU HEARD FROM THE WITNESSES THAT ACCESS TO CONTRACEPTIVE COVERAGE HAS INCREASED IN THE YEAR AFTER THE AFFORDABLE CARE ACT, THAT NO LONGER ARE THEY BEING -- ARE DOCTORS BEING ASKED ABOUT COST-FREE CONTRACEPTION. I JUST WANTED TO POINT OUT THAT THIS NEW WORLD THAT THEY ARE TALKING ABOUT AFTER THE AFFORDABLE CARE ACT IS A WORLD WHERE EVERY KNOWN RELIGIOUS OBJECTOR WAS ALREADY EXEMPT. IT WAS ALREADY NOT PROVIDING CONTRACEPTIVE COVERAGE, SO IT'S NOT CLEAR THEN WHY THESE NEW RULES WOULD RETURN US BACK TO THE WORLD OF THE PRE-ACA ERA.

I'D ALSO LIKE TO RETURN TO WHAT WE TALKED ABOUT EARLIER THIS MORNING, YOUR HONOR, ON THE MORAL

OBJECTORS WHO COULD -- WHETHER OR NOT THERE IS A WAY TO POLICE SINCERITY IN THAT CONTEXT. JUST TO ELABORATE ON WHAT I SAID EARLIER, IT'S POSSIBLE FOR AN EMPLOYEE OF A COMPANY WHO BELIEVES THAT HER EMPLOYER IS IMPROPERLY ASSERTING A MORAL OBJECTION TO FILE A COMPLAINT UNDER ERISA WITH THE DEPARTMENT OF LABOR. LABOR HAS THE AUTHORITY TO ENFORCE UNDER ERISA.

LABOR ALSO HAS THE AUTHORITY TO REFER TO THE TREASURY DEPARTMENT, FOR IRS TO INVESTIGATE THE COMPANY FOR FAILING TO PAY EXCISE TAXES, IN OTHER WORDS FOR FAILING TO COMPLY WITH THE MANDATE. AND SINCE SINCERITY IS AN ELEMENT OF THE EXEMPTION, THAT WOULD BE A LIVE ENFORCEMENT ISSUE IN THIS CONTEXT.

AND I ALSO ADD THAT AN EMPLOYEE IN THAT CONTEXT WOULD CONCEIVABLY HAVE A TITLE VII REMEDY AVAILABLE AGAINST HER EMPLOYER.

I WOULD ALSO, ALTHOUGH I KNOW YOUR HONOR WAS NOT ENAMORED WITH THIS ARGUMENT, I WOULD JUST LIKE TO ADD JUST A COUPLE OF QUICK WORDS ON THE RICCI VERSUS DESTEFANO ARGUMENT. YOUR HONOR HAD EXPRESSED CONCERN THAT THAT CASE WAS NOT SUFFICIENTLY ON ALL FOURS WITH THIS CASE BECAUSE IT INVOLVED A CITY AND NOT THE FEDERAL GOVERNMENT FOR OTHER REASONS. IF IT GIVES YOU ANY SOLACE, YOUR HONOR, THERE ARE -- THERE IS AN ANALOGOUS PRINCIPLE IN THE CONTEXT OF CHEVRON DEFERENCE THAT MAY

BE CLOSER TO THIS CASE.

AND THERE IS A SUPREME COURT CASE CALLED SCIALABBA, S-C-I-A-L-A-B-B-A, VERSUS CUELLAR DE OSORIO, C-U-E-L-L-A-R D-E O-S-O-R-I-O, 134 S.CT 2191: WHEN AN AGENCY THUS RESOLVES STATUTORY TENSION, ORDINARY PRINCIPLES OF ADMINISTRATIVE DEFERENCE REQUIRE US TO DEFER.

ANOTHER CASE -- I WILL GIVE YOU THE CITE IN A SECOND -- SAYS THAT WHEN A STATUTORY SCHEME CONTAINS A FUNDAMENTAL AMBIGUITY ARISING FROM THE DIFFERENT MANDATES OF TWO PROVISIONS, IT IS APPROPRIATE TO LOOK TO THE IMPLEMENTING AGENCY'S EXPERT INTERPRETATION.

SO I THINK THAT MIGHT BE CLOSER TO WHAT YOUR HONOR WAS LOOKING FOR.

THE COURT: THAT IS BETTER.

MR. DAVIS: AND THAT CASE IS NATIONAL ASSOCIATION OF HOMEBUILDERS VERSUS DEFENDERS OF WILDLIFE. 551 U.S. 644-666.

THE COURT: SCIALABBA, WHAT YEAR WAS SCIALABBA?

MR. DAVIS: I NEGLECTED TO WRITE DOWN THE YEAR. I THOUGHT I HAD THAT.

ONE SECOND, YOUR HONOR. I WILL GET THAT FOR YOU.

THE COURT: OKAY.

MR. DAVIS: 2014.

THE COURT: 2014.

MR. DAVIS: YES.

THE COURT: OKAY. I WILL TAKE A LOOK AT THAT CASE.

MR. DAVIS: I WOULD LIKE TO RESPOND TO A FEW THINGS THAT MY COLLEAGUE ON THE OTHER SIDE JUST SAID. HE SUGGESTED THAT RECOGNITION OF MORAL OBJECTIONS IS UNPRECEDENTED, IF I HEARD HIM CORRECTLY. THAT IS NOT TRUE. MORAL OBJECTIONS HAVE BEEN STANDARD IN THE LAW FOR QUITE A LONG TIME. IN FACT, PENNSYLVANIA HAS ITS OWN CONSCIENCE CLAUSE PERMITTING MEDICAL PROFESSIONALS TO OPT OUT OF PROVIDING ABORTIONS, FOR EXAMPLE, AND THERE HAS BEEN THE CONSCIENCE CLAUSE EXEMPTING CONSCIENTIOUS OBJECTORS FROM THE DRAFT.

I WOULD ALSO LIKE TO ADDRESS THE KING VERSUS BURWELL ISSUE THAT CAME UP, YOUR HONOR, IN THE CONTEXT OF WHETHER OR NOT THE AGENCY'S INTERPRETATION IS ENTITLED TO -- OF THE AFFORDABLE CARE ACT IS ENTITLED TO CHEVRON DEFERENCE. YOUR HONOR, IN KING VERSUS BURWELL THE COURT HELD THAT WHETHER TAX CREDITS ARE AVAILABLE ON FEDERAL EXCHANGES IS A MAJOR QUESTION, THAT IT WOULD BE INCONCEIVABLE THAT CONGRESS WOULD HAVE DELEGATED THAT TO THE -- IMPLICITLY DELEGATED THAT TO THE AGENCIES.

SO KING WAS ABOUT IMPLICIT DELEGATIONS BUT THIS CASE IS ABOUT AN EXPLICIT DELEGATION OF AUTHORITY AT 42 U.S.C. 300GG-13(A)(4).

ANOTHER POINT I'D LIKE TO CLARIFY THAT CAME UP WAS THE QUESTION ABOUT WHETHER THE AGENCIES HAVE AUTHORITY TO CREATE EXEMPTIONS FROM THE GUIDELINES, WHICH WE DISCUSSED EARLIER. I JUST WANTED TO CLARIFY THAT THE EXEMPTIONS THEMSELVES ARE IN THE HRSA GUIDELINES, SO IT'S NOT LIKE THESE RULES ARE CREATING EXEMPTIONS TO HRSA'S GUIDELINES; THE GUIDELINES THEMSELVES SPELL OUT THE RELIGIOUS AND MORAL EXEMPTIONS.

AND THAT IS TRUE NOT ONLY OF THESE RULES OF THE GUIDELINES IN 2016, IT'S ALSO TRUE OF THE GUIDELINES IN 2011, WHEN THE LAST ADMINISTRATION DID THE RELIGIOUS EMPLOYER EXEMPTION. THE HRSA GUIDELINES THERE THEMSELVES INCORPORATED THE EXEMPTION, SO I DON'T THINK THIS QUESTION ABOUT WHETHER AGENCIES CAN CREATE EXCEPTIONS TO THE GUIDELINES IS REALLY PRESENTED HERE.

THERE WAS ALSO A REFERENCE TO ALL OF THE PENNSYLVANIA ENTITIES THAT ARE USING THE ACCOMMODATION. I JUST POINT OUT THERE, YOUR HONOR, THAT THERE IS NO INDICATION THAT ANY OF THOSE ENTITIES ARE GOING TO SWITCH FROM USING THE ACCOMMODATION TO USING THE EXEMPTION. IT MAY BE, LIKE FOR MANY ENTITIES, THAT THE ACCOMMODATION SATISFIES THEIR RELIGIOUS EXEMPTIONS AND

THEY WON'T SWITCH TO ANYTHING ELSE.

AND, FINALLY, YOUR HONOR, I THINK THIS POINT ABOUT HOW -- ON IRREPARABLE INJURY, ABOUT HOW THE EXCLUSION MUST BE CLEAR ON THE FACE OF THE PLAN DOCUMENT AND THAT IS WHY MAYBE THESE WITNESSES DID NOT KNOW ABOUT ANYONE WHO KNEW ABOUT ANYONE WHO WAS GOING TO LOSE CONTRACEPTIVE COVERAGE, WELL, THERE IS ALSO A REQUIREMENT THAT AN EMPLOYER WHO PLANS TO TAKE THIS EXEMPTION NOTIFY ITS EMPLOYEES 30 DAYS BEFOREHAND AND SEND OUT A PLAN DOCUMENT THAT -- WHERE THE EXCLUSION OF COVERAGE IS APPARENT FROM THE FACE OF THE PLAN DOCUMENT. AND WE HAVE HEARD NOTHING ABOUT ANY OF THOSE NOTICES BEING SENT OUT. NO WITNESS HAS TESTIFIED THAT THEY ARE AWARE OF ANY OF THOSE NOTICES. AND YOU WOULD THINK IF THIS IMPACT WAS GOING TO BE AS WIDESPREAD AS THE COMMONWEALTH SUGGESTS, WE WOULD HAVE HEARD SOME INKLING OF THAT. AND THE FACT IS THAT WE HAVE NOT.

SO I JUST -- THE LAST POINT I WOULD JUST LIKE TO MAKE, YOUR HONOR, IS THAT AGAIN, YOU ARE NOT WRITING ON A BLANK SLATE HERE. THERE IS A LOT OF WATER UNDER THE BRIDGE. THERE IS A LOT OF EXISTING PRELIMINARY INJUNCTIONS AND PERMANENT INJUNCTIONS OUT THERE THAT HAVE MEANT THAT THE STATE OF THE WORLD BEFORE THESE NEW RULES CAME OUT WERE THAT MOST, MAYBE EVEN ALL OF THE EMPLOYERS WHO OBJECTED TO PROVIDING CONTRACEPTIVE

COVERAGE WERE EXEMPT FROM THIS REQUIREMENT ALREADY. SO THERE IS NOT -- IT'S NOT CLEAR WHAT IMPACT AN INJUNCTION WOULD HAVE. AND IN THAT CIRCUMSTANCE, IT'S BLACK-LETTER LAW THAT THE AGENCY SHOULD STAY ITS HAND -- OR THE COURT SHOULD STAY ITS HAND. IT'S BLACK-LETTER LAW THAT THE COURT SHOULD STAY ITS HAND.

YOUR HONOR, ON ONE MORE ISSUE, ON THE APA, I JUST WOULD LIKE TO ADD THAT THIS CASE IS SUPPOSED TO BE LIMITED TO THE ADMINISTRATIVE RECORD, AND THAT WHILE I RECOGNIZE WHAT YOUR HONOR SAID ABOUT SOME OF THESE WITNESSES' TESTIMONY --

THE COURT: I DON'T THINK THAT IS THE CASE. IF YOU READ MY ORDER ON THE MOTION IN LIMINE, THAT IS NOT THE CASE.

MR. DAVIS: WELL --

THE COURT: DID YOU READ THE ORDER ON MOTION IN LIMINE?

MR. DAVIS: I DID, YOUR HONOR.

THE COURT: THEREFORE, THE CASE IS NOT SUPPOSED TO BE DECIDED ON THE ADMINISTRATIVE RECORD ONLY.

MR. DAVIS: YOUR HONOR, I'M RESPECTFULLY DISAGREEING WITH YOUR HONOR'S MOTION.

THE COURT: YOU CAN SAY THAT YOU BELIEVE THAT THAT IS THE CASE, BUT I DON'T THINK YOU CAN SAY

SUPPOSED TO, BECAUSE THERE IS AN ORDER OF THIS COURT WHICH PARTICULARLY DESCRIBES WHAT RECORD THIS DECISION IS BEING MADE ON. DO YOU UNDERSTAND THAT?

MR. DAVIS: FAIR ENOUGH, YOUR HONOR. I WILL PHRASE IT DIFFERENTLY. I BELIEVE THAT THIS CASE SHOULD BE DECIDED ON THE BASIS OF THE ADMINISTRATIVE RECORD. I DON'T BELIEVE THAT THE COURT'S RULING ON THE MOTION IN LIMINE WAS CORRECT. I THINK THAT THE WITNESS TESTIMONY IN THIS CASE WENT FAR BEYOND THE ADMINISTRATIVE RECORD. I THINK IT WENT INTO QUESTIONING THE CORRECTNESS AND WISDOM OF THE AGENCY'S DECISION. I THINK IT'S BLACK-LETTER LAW THAT THAT STUFF IS NOT PROPER.

THE COURT: MOVE ON. THAT WAS ON A MOTION IN LIMINE. WE ARE DOING THE CLOSING IN THIS CASE RIGHT NOW.

MR. DAVIS: YOUR HONOR, THAT IS ALL I HAVE, UNLESS YOU HAVE FURTHER QUESTIONS.

THE COURT: I HAVE NO FURTHER QUESTIONS. REBUTTAL.

MR. FISCHER: THANK YOU, YOUR HONOR. I WILL TRY TO KEEP THIS BRIEF.

THE DISCUSSION THAT WE ARE HAVING ABOUT THE MORAL EXEMPTION I THINK IS A GOOD METAPHOR FOR ALL THE PROBLEMS WITH BOTH RULES. THE FACT THAT WE ARE NOW

IN POSITION WHERE WE ARE HAVING A DEBATE ABOUT WHETHER THE DEPARTMENT OF LABOR SHOULD BE INVESTIGATING WHETHER EMPLOYERS' PROFESSED MORAL BELIEFS ARE SINCERE OR NOT, AND THEY FEEL AN EMPLOYEE DENIED CONTRACEPTIVE COVERAGE HAS TO FILE A TITLE VII CLAIM BECAUSE HER EMPLOYER, AS THE COURT HYPOTHESIZED, MAY DECIDE THAT HE OBJECTS TO WOMEN BEING IN THE WORKFORCE AND HE IS GOING TO DENY CONTRACEPTIVE COVERAGE AS A RESULT OF THAT. I THINK THAT IS A WORLD WE DON'T WANT TO BE IN.

THE RELIGIOUS FREEDOM RESTORATION ACT ADDRESSED THE TENSION INHERENT IN THAT ISSUE IN THE CONTEXT OF RELIGIOUS BELIEFS AND STRUCK A BALANCE WHERE COURTS GENERALLY DO NOT GET INTO THE SINCERITY OF BELIEFS, NOR SHOULD THEY. WHAT THEY CAN LOOK AT IS WHETHER THOSE BELIEFS OR THE EXERCISE OF THOSE BELIEFS IS SUBSTANTIALLY BURDENED BY GOVERNMENT PROGRAMS. THAT IS WHERE RFRA STRUCK THE BALANCE. WHAT WE HAVE NOW IS TWO RULES FROM THE GOVERNMENT THAT WOULD ESSENTIALLY UPSET THAT BALANCE AND PUT EMPLOYEES AT THE WHIM OF THE MORAL BELIEFS, WHATEVER THEY MAY BE, OF THEIR EMPLOYERS. AND I THINK THE GOVERNMENT IS SUGGESTING AT LEAST THAT AN EMPLOYER WHO HAD A MORAL BELIEF THAT WOMEN SHOULD NOT BE IN THE WORKFORCE, THAT THAT WOULD NOT BE A SINCERELY-HELD OR LEGITIMATE MORAL BELIEF. THERE IS NOTHING IN THE RULES THAT SAYS THAT. THERE IS NOTHING

IN THE RULES THAT LIMITS THE TYPES OF MORAL BELIEFS THAT AN ENTITY CAN PROFESS.

I WOULD LIKE TO THINK THAT HAD THIS GONE THROUGH THE RIGHT PROCESS, THERE WOULD HAVE BEEN SOME THOUGHT GIVEN TO THAT AND MAYBE THERE WOULD HAVE BEEN A DIFFERENT RESULT AND WE WOULD NOT HAVE THIS SWEEPING EXEMPTION, WE WOULD NOT HAVE THE PUBLICLY-TRADED COMPANY OPTION UNDER THE RELIGIOUS EXEMPTION RULE, AND WE WOULD NOT HAVE THE PROVISION MAKING THE ACCOMMODATION OPTIONAL. I THINK IN SOME WAYS THOSE ARE ALL THE RESULTS OF A FLAWED PROCESS AS I SAID THAT LED TO A FLAWED RESULT, BUT I ALSO THINK THAT BECAUSE THE RESULT IS SO FLAWED, IT IS IMPORTANT TO GET THAT ON THE RECORD AND MAKE CLEAR THAT IF WE ARE FORTUNATE, IF THE COURT DOES GRANT AN INJUNCTION AND THE GOVERNMENT GOES BACK TO THE DRAWING BOARD, ONE WOULD HOPE THAT THEY WOULD COME UP -- IF THEY DECIDE THERE'S A NEED FOR FURTHER RULE MAKING, ONE WOULD HOPE THAT THEY WOULD COME UP WITH A RULE THAT IS MUCH NARROWER THAN THIS, THAT DOES NOT ALLOW FOR SUCH SWEEPING OBJECTIONS, THAT IS MUCH MORE JUSTIFIABLE UNDER THE AFFORDABLE CARE ACT AND UNDER RFRA.

THE GOVERNMENT SAID -- TURNING BRIEFLY TO THE HARM, AGAIN, THE GOVERNMENT HAS SAID WELL, EVERY KNOWN RELIGIOUS OBJECTOR IS EXEMPT. NOW, THAT IS SIMPLY

NOT THE CASE.

RELIGIOUS -- MANY RELIGIOUS OBJECTORS ARE STILL OPERATING UNDER THE ACCOMMODATION PROCESS UNDER WHICH THEIR EMPLOYEES DO GET HEALTH COVERAGE. AND, IN FACT, EVEN IF YOU LOOK AT WHAT IS REFERRED TO AS THE ZUBIK INJUNCTION, THE ORDER FROM THE SUPREME COURT, THE COURT DID NOT SAY YOUR EMPLOYEES DO NOT GET COVERAGE. WHAT THEY SAID IS, HHS NOW KNOWS BY VIRTUE OF THIS LITIGATION YOU OBJECT, SO THEY CAN GO AHEAD AND ARRANGE FOR COVERAGE, AND THEY CAN'T FINE YOU FOR NOT PROVIDING THE NOTICE. NOW, SOME OF THOSE ENTITIES ARE COVERED BY CHURCH PLANS, WHICH IS A SIDE ISSUE, AND THEIR EMPLOYERS -- THEIR EMPLOYEES MAY NOT BE GETTING COVERAGE. BUT CERTAINLY TO STAY THAT ALL KNOWN RELIGIOUS OBJECTORS ARE EXEMPT IS NOT CONSISTENT WITH THE RECORD IN THIS CASE.

YOUR HONOR, THE GOVERNMENT COUNSEL HAS TALKED A LITTLE BIT ABOUT THE NEED TO DEFER TO THEIR INTERPRETATION AND CITED THE TWO CASES. IN THOSE CASES IT SOUNDS LIKE AT LEAST THERE WAS LEGITIMATE TENSION IN ONE OR AMBIGUITY IN ANOTHER THAT ALLOWED THE GOVERNMENT TO SAY WE ARE ADOPTING A REASONABLE INTERPRETATION. HERE THERE SIMPLY ISN'T. THERE'S NOT A BASIS FOR READING INTO THE WOMEN'S HEALTH AMENDMENT THIS BROAD AUTHORITY TO CARVE OUT EXEMPTIONS FROM WHAT IS A CLEAR

MANDATORY OBLIGATION THAT CONGRESS PASSED THAT THESE PLAN SPONSORS HAVE TO PROVIDE AND HAVE TO NOT IMPOSE COST SHARING REQUIREMENTS FOR THE NECESSARY PREVENTIVE MEDICINE AS DEFINED BY HRSA, THIS IDEA THAT HR -- THE GUIDELINES INCLUDE THE EXEMPTIONS. WELL, THE AGENCIES PROMULGATE THE EXEMPTIONS AND THEN THEY GIVE HRSA THE AUTHORITY, AND THEY APPEAR ON THE WEB PAGE. SO I DON'T THINK IT'S THE CASE THAT HRSA IS EXERCISING ITS INDEPENDENT AUTHORITY TO IMPLEMENT THESE GUIDELINES -- OR IMPLEMENT THESE EXCEPTIONS.

YOUR HONOR, LET'S RETURN TO THE THREE MOST PROBLEMATIC ASPECTS THAT I MENTIONED IN THE BEGINNING. THE MORAL EXEMPTION RULE IS SIMPLY NOT SUPPORTED BY THE RECORD. THIS EXPANSION OF PUBLICLY TRADED COMPANY IS NOT SUPPORTED. AND THE RENDERING OF THE ACCOMMODATION PROCESS OPTIONAL REALLY DOES THREATEN TO TAKE AWAY COVERAGE FOR MANY WOMEN WHO WORK FOR RELIGIOUS EMPLOYERS BUT WHO ARE NONETHELESS GETTING CONTRACEPTIVE COVERAGE TODAY.

AND WITH RESPECT TO ALL OF THESE IN SOME WAY, AT LEAST CERTAINLY THE MORAL EXEMPTION AND THE PUBLIC-TRADED COMPANY EXPANSION, THE GOVERNMENT'S RESPONSE IS, WELL, WE JUST DON'T THINK THAT MANY PEOPLE ARE GOING TO TAKE ADVANTAGE OF IT. THAT IN SOME WAYS IS KIND OF A PERFECT EXAMPLE OF ARBITRARY AND CAPRICIOUS

RULEMAKING. TO ALLOW FOR A SUCH SWEEPING EXEMPTION, BUT THEN TO SAY WE ARE DOING THIS BECAUSE WE DON'T ACTUALLY THINK THERE IS MUCH DEMAND FOR IT, WE DON'T THINK THERE IS MUCH NEED FOR IT, THAT IS SIMPLY NOT HOW THE AGENCY RULEMAKING PROCESS IS SUPPOSED TO WORK AND IT'S NOT THE KIND OF RESULT THAT IS ENTITLED TO DEFERENCE OR ENTITLED TO BE AFFIRMED BY A COURT.

AND FOR ALL OF THOSE REASONS WE BELIEVE THE RULES ARE ILLEGAL, THAT THEY WILL CAUSE IRREPARABLE HARM TO THE COMMONWEALTH, TO THE COMMONWEALTH'S RESIDENTS. PUBLIC INTEREST STRONGLY FAVORS AN INJUNCTION HERE, AND WE WOULD ASK THE COURT TO GRANT THE COMMONWEALTH'S MOTION. THANK YOU.

THE COURT: OKAY. AS I SAID AT THE BEGINNING OF THIS HEARING, I CONSIDERED ALL THE BRIEFINGS SUBMITTED BY THE PARTIES WITH RESPECT TO THIS PRELIMINARY INJUNCTION, INCLUDING THE COMMONWEALTH'S MOTION FOR PRELIMINARY INJUNCTION AND ITS SUPPORTING EXHIBITS, THE DEFENDANT'S RESPONSE IN OPPOSITION TO THE MOTION FOR PRELIMINARY INJUNCTION, AND THE COMMONWEALTH'S REPLY. I HAVE ALSO CONSIDERED THE ADMINISTRATIVE RECORD SUBMITTED BY THE DEFENDANTS. I ALSO WISH TO THANK THE AMICI FOR SUBMITTING THEIR THOUGHTFUL BRIEFS IN THIS CASE.

BASED ON THESE DOCUMENTS AND AS WELL AS

THE DOCUMENTS I HAVE RECEIVED AT TODAY'S HEARING, THE TESTIMONY I HAVE HEARD AT TODAY'S HEARING, AND THE ARGUMENT I HAVE HEARD, I WILL BE ABLE TO ISSUE AN OPINION IN THE TIME SCALE REQUESTED BY PENNSYLVANIA, WHICH IS PRIOR TO THE BEGINNING OF THE YEAR, AND WILL ENDEAVOR TO GET THAT OPINION OUT AS SOON AS POSSIBLE.

THANK YOU. ANYTHING ELSE?

MR. FISCHER: NOTHING FURTHER FROM THE COMMONWEALTH, YOUR HONOR.

MR. DAVIS: NOTHING FURTHER, YOUR HONOR.

MR. GOLDMAN: YOUR HONOR, I'M SORRY. YOU HAD SUGGESTED ON TUESDAY EVENING THAT YOU WANTED FINDINGS OF FACT AND CONCLUSIONS OF LAW.

THE COURT: BASED ON WHAT I HAVE READ AND WHAT I HAVE, I DON'T NEED YOU TO DO THAT. I WILL -- WE WILL BE ABLE TO DO THAT INTERNALLY. I THINK YOU WERE VERY CLEAR IN YOUR BRIEFS, AND I APPRECIATE THAT FROM ALL SIDES. SO TO THE EXTENT THAT MY PREVIOUS ORDER INDICATES A TIME FOR POST-HEARING BRIEFING AND POST-HEARING SUBMISSION OF FINDINGS OF FACT, I'M ABROGATING THAT PORTION IN MY ORDER. IT IS NOT NECESSARY THAT YOU DO THAT. SO INSTEAD OF HAVING TO GO HOME RIGHT NOW AND START WRITING, YOU CAN, I DON'T KNOW, GO AND HAVE A DRINK OR SOMETHING.

ALL COUNSEL: THANK YOU, YOUR HONOR.

(HEARING CONCLUDED.)

I CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

DATE OFFICIAL COURT REPORTER
SUZANNE R. WHITE

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EXHIBIT K

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA et al., Plaintiffs, v. DONALD J. TRUMP et al., Defendants.	**No. 2:17-cv-04540-WB**

DECLARATION OF KATHRYN KOST

I, Kathryn Kost, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by Plaintiffs in the above-captioned matter and, in support thereof, state as follows:

1. I am the Acting Vice President for Domestic Research at the Guttmacher Institute. I have worked for the Guttmacher Institute in a full-time or consulting capacity for nearly 30 years since joining the Institute as a Senior Research Associate in 1989. I received my BA in sociology from Reed College and my PhD in sociology from Princeton University, where I specialized in demography at the Office of Population Research.

2. The Guttmacher Institute is a private, independent, nonprofit, nonpartisan corporation that advances sexual and reproductive health and rights through an interrelated program of research, policy analysis, and public education. The Institute's overarching goal is to ensure quality sexual and reproductive health for all people worldwide by conducting research according to the highest standards of methodological rigor and promoting evidence-based policies. It produces a wide range of resources on topics pertaining to sexual and reproductive health and publishes two peer-reviewed journals. The information and analysis it generates on

reproductive health and rights issues are widely used and cited by researchers, policymakers, the media and advocates across the ideological spectrum.

3. Over the course of more than 30 years, I have designed, executed, and analyzed numerous quantitative and qualitative research studies in the field of reproductive health care, including those on contraceptive use and failure, unintended pregnancy, maternal and child health, and the impact on public health and fisc associated with particular reproductive health care policies or trends. My peer-reviewed research has been published in dozens of articles, including first-authored work in *Demography*, *Perspectives on Sexual and Reproductive Health*, *Contraception*, *Studies in Family Planning* and other public health, medical and demographic journals. My education, training, responsibilities and publications are set forth in greater detail in my curriculum vitae, a true and correct copy of which is attached as Exhibit A. I submit this declaration as an expert on reproductive health care, family planning, and unintended pregnancy, and the impact on individuals, families, and the public health from access to contraception and related care, or interference with that care, in the United States.

4. I understand that this lawsuit involves a challenge to the federal government's Final Rules ("Final Rules") regarding the Affordable Care Act's ("ACA") contraceptive coverage mandate. In my expert opinion, the Final Rules would compromise women's ability to obtain contraceptive methods, services and counseling and, in particular, to consistently use the best methods for them, thus putting them at heightened risk of unintended pregnancy.

Contraception Is Widely Used and the Majority of Women Rely on Numerous Contraceptive Methods for Decades of Their Lives

5. More than 99% of women aged 15–44 who have ever had sexual intercourse have used at least one contraceptive method; this is true across a variety of religious affiliations.[1] Some 61% of all women of reproductive age are currently using a contraceptive method.[2] Among women at risk of an unintended pregnancy (i.e., women aged 15–44 who have had sexual intercourse in the past three months, are not pregnant or trying to conceive, and are not sterile for noncontraceptive reasons), 90% are currently using a contraceptive method.[3]

6. A typical woman in the United States wishing to have two children will, on average, spend three decades—roughly 90% of her reproductive life—avoiding unintended pregnancy.[4]

7. Women and couples rely on a wide range of contraceptive methods: In 2014, 25% of female contraceptive users relied on oral contraceptives and 15% on condoms as their most effective method. That means that six in 10 contraceptive users relied on other methods: female or male sterilization; hormonal or copper intrauterine devices (IUDs); other hormonal methods including the injectable, the ring, the patch and the implant; and behavioral methods, such as withdrawal and fertility awareness methods.[5]

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[1] Daniels K, Mosher WD and Jones J, Contraceptive methods women have ever used: United States, 1982–2010, *National Health Statistics Reports*, 2013, No. 62, https://www.cdc.gov/nchs/products/nhsr.htm.
[2] Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012.
[3] Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012.
[4] Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*, New York: Guttmacher Institute, 2014, https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.
[5] Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012

8. Most women rely on multiple methods over the course of their reproductive lives, with 86% having used three or more methods by their early 40s.[6] Sometimes, women and couples may try out different methods to find one that they can use consistently or that minimizes side effects. Other times, they may switch from method to method—such as from condoms to oral contraceptives to sterilization—as their relationships, life circumstances and family goals evolve.

9. Many people use two or more methods at once: 17% of female contraceptive users did so the last time they had sex.[7] For example, they may use condoms to prevent STIs and an IUD for the most reliable prevention of pregnancy. Or they may use multiple methods simultaneously—for instance, condoms, withdrawal and oral contraceptives—to provide extra pregnancy protection.

Women Need Access to the Full Range of Contraceptive Options to Most Effectively Avoid Unintended Pregnancies

10. Using any method of contraception greatly reduces a woman's risk of unintended pregnancy. Sexually active couples using no method of contraception have a roughly 85% chance of experiencing a pregnancy in a one-year period, while the risk for those using a contraceptive method ranges from 0.05% to 28%.[8,9]

[6] Daniels K, Mosher WD and Jones J, Contraceptive methods women have ever used: United States, 1982–2010, *National Health Statistics Reports*, 2013, No. 62, https://www.cdc.gov/nchs/products/nhsr.htm.
[7] Kavanaugh ML and Jerman J, Concurrent multiple methods of contraception in the United States, poster presented at the North American Forum on Family Planning, Atlanta, Oct. 14–16, 2017.
[8] Sundaram A et al., Contraceptive failure in the United States: estimates from the 2006-2010 National Survey of Family Growth, *Perspectives on Sexual and Reproductive Health*, 2017, 49(1):7–16, https://www.guttmacher.org/journals/psrh/2017/02/contraceptive-failure-united-states-estimates-2006-2010-national-survey-family.
[9] Trussell J, Aiken A, "Contraceptive Efficacy" pp. 829–928. In Hatcher RA et al., eds., *Contraceptive Technology,* 21st ed., New York: Ayer Company Publishers, 2018.

11. All new contraceptive drugs and devices (just like other drugs and devices) must receive approval from the U.S. Food and Drug Administration (FDA) and must be shown to be safe and effective through rigorous scientific testing. Thus, the federal government itself provides the oversight to ensure that contraception is safe and effective in preventing pregnancy.

12. The government's effort to imply that there is doubt about whether contraception reduces the risk of unintended pregnancy is simply unfounded, as the data above illustrate. Though the Final Rules cite "conflicting evidence" for the effects of a contraceptive coverage requirement,[10] in the previous interim final rules, the government made positive arguments that contraceptive access did not reduce the risk of unintended pregnancy. This argument is flawed. For example, in the interim final rules the government argued, "In the longer term—from 1972 through 2002—while the percentage of sexually experienced women who had ever used some form of contraception rose to 98 percent, unintended pregnancy rates in the Unites States rose from 35.4 percent to 49 percent."[11]

13. However, the government's assertion in the interim final rules that unintended pregnancy rates rose between 1972 and 2002 was incorrect and based on faulty calculations and an inappropriate comparison. First, the numbers cited (35.4% and 49%) are the *percentage* of all pregnancies that were unintended, not the unintended pregnancy *rate*, which is the appropriate indicator for assessing trends in unintended pregnancy because it is not affected by changes in the incidence of *intended* pregnancy. Second, the 1972 figure includes only *births* (not all

[10] Department of the Treasury, Department of Labor and Department of Health and Human Services, Religious exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act, *Federal Register*, 83(221):57536–57590, https://www.gpo.gov/fdsys/pkg/FR-2018-11-15/pdf/2018-24512.pdf

[11] Department of the Treasury, Department of Labor and Department of Health and Human Services, Religious exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act, *Federal Register*, 82(197):47838–47862, https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-21852.pdf.

pregnancies), and then only those births that were to married women.[12] Births to unmarried women and all abortions are excluded; the proportion of both of these that were unintended were significantly higher, so excluding them results in an artificially low percentage. The 2002 figure, on the other hand, includes all pregnancies to all women. An appropriate comparison of rates based on pregnancies and on all women in the population shows a clear decline in the rate: In 1971, there were an estimated 2.041 million unintended pregnancies (including births and abortions, but excluding miscarriages),[13] and 43.6 million women of reproductive age (15–44),[14] for an unintended pregnancy rate (excluding miscarriages) of 47 per 1,000 women. By contrast, in 2011, the unintended pregnancy rate *including* miscarriages was 45 per 1,000.[15] Even when including miscarriages in the later rate, it is lower than the earlier rate; because miscarriages typically represent about 14% of all pregnancies,[16] excluding them from the 2011 figure for comparability would result in a rate of about 38 per 1,000, substantially lower than the 1971 rate.

14. Although using any method of contraception is more effective in preventing pregnancy than not using a method at all, having access to a *limited* set of methods is far different than being able to choose from among the full range of methods to find the *best* methods for a given point in a woman's life.

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[12] Weller RH and Heuser RL, Wanted and unwanted childbearing in the United States: 1968, 1969, and 1972 National Natality Surveys, *Vital and Health Statistics*, 1978, No. 32.
[13] Tietze C, Unintended pregnancies in the United States, 1970–1972, *Family Planning Perspectives,* 1979, 11(3):186–188.
[14] National Center for Health Statistics, Centers for Disease Control and Prevention, Population by age groups, race, and sex for 1960–1997, no date, https://www.cdc.gov/nchs/data/statab/pop6097.pdf.
[15] Finer LB and Zolna MR, Declines in unintended pregnancy in the United States, 2008–2011, *New England Journal of Medicine*, 2016, 374(9):843–852.
[16] Finer LB and Henshaw SK, Disparities in rates of unintended pregnancy in the United States, 1994 and 2001, *Perspectives on Sexual and Reproductive Health*, 2006, 38(2):90–96, https://www.guttmacher.org/journals/psrh/2006/disparities-rates-unintended-pregnancy-united-states-1994-and-2001.

15. One important consideration for most women in a choosing a contraceptive method is how well a method works for an individual woman to prevent pregnancy.[17] IUDs and implants, for example, are effective for years after they are inserted by a health care provider, and do not require women using them to think about contraception on a day-to-day basis.[18] By contrast, birth control pills must be taken every day, at approximately the same time. Nearly half of abortion patients who were users of birth control pills reported that they had forgotten to take their pills, and another quarter reported a lack of ready access to their pills (16% were away from their pills and 10% ran out).[19] Methods of contraception designed to be used during intercourse, such as condoms or spermicide, must be available, accessible, remembered, and used properly each time intercourse occurs.

16. Beyond effectiveness, there are many other features that people say are important to them when choosing a contraceptive method.[20] These include concerns about and past experience with side effects, drug interactions or hormones; affordability and accessibility; how frequently they expect to have sex; their perceived risk of HIV and other STIs; the ability to use the method confidentially or without needing to involve their partner; and potential effects on sexual enjoyment and spontaneity. For example, methods such as male condoms, fertility awareness and withdrawal require the active and effective participation of male partners. By contrast, methods

[17] Lessard LN et al., Contraceptive features preferred by women at high risk of unintended pregnancy, *Perspectives on Sexual and Reproductive Health*, 2012, 44(2):194–200.
[18] Winner B et al., Effectiveness of long-acting reversible contraception, *New England Journal of Medicine*, 366(21):1998–2007.
[19] Jones RK, Darroch JE and Henshaw SK, Contraceptive use among U.S. women having abortions in 2000–2001, *Perspectives on Sexual and Reproductive Health*, 2002, 34(6): 294–303, https://www.guttmacher.org/journals/psrh/2002/11/contraceptive-use-among-us-women-having-abortions-2000-2001.
[20] Lessard LN et al., Contraceptive features preferred by women at high risk of unintended pregnancy, *Perspectives on Sexual and Reproductive Health*, 2012, 44(2):194–200.

such as IUDs, implants, and oral contraceptives can be more reliably used by the woman alone in advance of intercourse.[21]

17. Being able to select the methods that best fulfill a woman's needs and priorities is an important way to ensure that she will be satisfied with her chosen methods. Women who are satisfied with their current contraceptive methods are more likely to use them consistently and correctly. For example, one study found that 30% of neutral or dissatisfied users had a temporal gap in use, compared with 12% of completely satisfied users.[22] Similarly, 35% of satisfied oral contraceptive users had skipped at least one pill in the past three months, compared with 48% of dissatisfied users.[23]

18. Consistent contraceptive in turn use helps women and couples prevent unwanted pregnancies and plan and space those they do want. The two-thirds of U.S. women (68%) at risk of unintended pregnancy who use contraceptives consistently and correctly throughout a year account for only 5% of all unintended pregnancies. In contrast, the 18% of women at risk who use contraceptives but do so inconsistently account for 41% of unintended pregnancies, and the 14% of women at risk who do not use contraceptives at all or have a gap in use of one month or longer account for 54% of unintended pregnancies.[24]

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[21] Bailey MJ, More power to the pill: the impact of contraceptive freedom on women's life cycle labor supply, *Quarterly Journal of Economics*, 2006, 121(1): 289–320, https://academic.oup.com/qje/article-abstract/121/1/289/1849021?redirectedFrom=fulltext.

[22] Guttmacher Institute, Improving contraceptive use in the United States, *In Brief*, New York: Guttmacher Institute, 2008, https://www.guttmacher.org/report/improving-contraceptive-use-united-states.

[23] Guttmacher Institute, Improving contraceptive use in the United States, *In Brief*, New York: Guttmacher Institute, 2008, https://www.guttmacher.org/report/improving-contraceptive-use-united-states.

[24] Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*, New York: Guttmacher Institute, 2014, https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

19. In summary, the ability to choose from among the full range of contraceptive methods encourages consistent and effective contraceptive use, thereby helping women to avoid unintended pregnancies and to time and space wanted pregnancies.

Access to Contraception Does Not Increase Adolescent Sexual Activity

20. Adolescent pregnancy has declined dramatically over the past several decades: In 2013, the U.S. pregnancy rate among 15–19-year-olds was at its lowest point in at least 80 years and had dropped to about one-third of a recent peak rate in 1990.[25] The adolescent birthrate has continued to fall sharply from 2013–2016, suggesting that the underlying pregnancy rates have likely declined even further.[26] Over these decades, adolescents' sexual activity has not increased—in fact, it has declined—while their contraceptive use has increased.

21. National data limited to adolescents attending high school document long-term increases from 1991–2015 in the share of students using contraception, and decreases over the same time period in the share of students who are sexually active.[27] Several studies have validated that contraceptive access reduces adolescent pregnancy without increasing sexual activity: The vast majority (86%) of the decline in adolescent pregnancy between 1995 and 2002 was the result of improvements in contraceptive use; only 14% could be attributed to a decrease in sexual activity.[28] Further, when examining these same two factors, all of the decline in the more recent

[25] Kost K, Maddow-Zimet I and Arpaia A, Pregnancies, *Births and Abortions Among Adolescents and Young Women in the United States, 2013: National and State Trends by Age, Race and Ethnicity*, New York: Guttmacher Institute, 2017, https://www.guttmacher.org/report/us-adolescent-pregnancy-trends-2013.
[26] Martin JA, Hamilton BE and Osterman MJK, Births in the United States, 2016, *NCHS Data Brief*, 2017, No. 287, https://www.cdc.gov/nchs/products/databriefs.htm.
[27] National Center for HIV/AIDS, Viral Hepatitis, TD, and TB Prevention, Centers for Disease Control and Prevention (CDC), *Trends in the Prevalence of Sexual Behaviors and HIV Testing National YRBS: 1991–2015,* Atlanta: CDC, no date, https://www.cdc.gov/healthyyouth/data/yrbs/pdf/trends/2015_us_sexual_trend_yrbs.pdf.
[28] Santelli JS et al., Explaining recent declines in adolescent pregnancy in the United States: the contribution of abstinence and improved contraceptive use, *American Journal of Public Health*, 2007, 97(1): 150–156, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1716232/.

2007–2012 period was attributable to better contraceptive use: More adolescents were using contraception, they were using more effective methods, and they were using them more consistently, while adolescent sexual activity did not change.[29]

22. Recent trends in adolescent contraceptive use buttress this point: During 2011–2015, 81% of adolescent girls used contraception the first time they had sex, up from 75% in 2002; the share of adolescent girls who were sexually active stayed stable.[30,31] Similarly, use of emergency contraception among sexually active female adolescents increased from 8% in 2002 to 22% in 2011–2013; there was no significant change in sexual activity during this time.[32] And in a 2010 review of seven randomized trials of emergency contraception, there was no increase in sexual activity (e.g., reported number of sexual partners or number of episodes of unprotected intercourse) in adolescents given advanced access to emergency contraception.[33]

23. Along the same lines, studies of the availability of contraception in high schools provide evidence that it does not lead to more sexual activity. Rather, while several studies of school-based health care centers that provide contraceptive methods have shown contraceptives' availability increases students' use of contraception,[34,35] other studies have not found any

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[29] Lindberg L, Santelli J and Desai S, Understanding the decline in adolescent fertility in the United States, 2007–2012, *Journal of Adolescent Health*, 2016, 59(5): 577–583, http://www.jahonline.org/article/S1054-139X(16)30172-0/fulltext.

[30] Martinez G, Copen CE and Abma JC, Teenagers in the United States: Sexual activity, contraceptive use, and childbearing, 2006–2010 National Survey of Family Growth, *Vital Health Statistics*, 2011, Series 23, No. 31, https://www.cdc.gov/nchs/products/series/series23.htm.

[31] Abma JC and Martinez G, Sexual activity and contraceptive use among teenagers in the United States, 2011–2015, *National Health Statistics Reports*, 2017, No. 104, https://www.cdc.gov/nchs/products/nhsr.htm.

[32] Martinez GM and Abma JC, Sexual activity, contraceptive use, and childbearing of teenagers aged 15–19 in the United States, *NCHS Data Brief*, 2015, No. 209, https://www.cdc.gov/nchs/products/databriefs.htm.

[33] Meyer JL, Gold MA and Haggerty CL, Advance provision of emergency contraception among adolescent and young adult women: a systematic review of literature, *Journal of Pediatric and Adolescent Gynecology,* 2011, 24(1):2–9, http://www.jpagonline.org/article/S1083-3188(10)00203-2/fulltext.

[34] Minguez M et al., Reproductive health impact of a school health center, *Journal of Adolescent Health*, 2015, 56(3): 338–344, https://www.ncbi.nlm.nih.gov/pubmed/25703321.

[35] Knopf FA et al., School-based health centers to advance health equity: a Community Guide systematic review, *American Journal of Preventive Medicine*, 2016, 51(1): 114-126, http://www.ajpmonline.org/article/S0749-3797(16)00035-0/fulltext.

associated increases in sexual activity.[36] And a recent review of studies of school-based condom availability programs found condom use increased the odds of students using condoms, while none increased sexual activity.[37]

Eliminating the Cost of Contraception Leads to Improved Contraceptive Use and Reduces Women's Risk of Unintended Pregnancy

24. Extensive empirical evidence demonstrates what common sense would predict: eliminating costs leads to more effective and continuous use of contraception. That is because cost can be a substantial barrier to contraceptive choice. The contraceptive methods that can be purchased over the counter at a neighborhood drugstore for a comparatively low cost—male condoms and spermicide—are far less effective than methods that require a prescription and a visit to a health care provider,[38] which have higher up-front costs.[39]

25. The most effective methods of contraception are long-acting reversible contraceptives (LARC), such as implants and IUDs. Even with discounts for volume, the cost of these devices exceeds $500, exclusive of costs relating to the insertion procedure,[40] and the total cost of initiating one of these methods generally exceeds $1,000.[41] To put that cost in perspective, beginning to use one of these devices costs nearly a month's salary for a woman working full

[36] Kirby D, *Emerging Answers 2007: Research Findings on Programs to Reduce Teen Pregnancy and Sexually Transmitted Diseases*, Washington, DC: The National Campaign to Prevent Teen and Unplanned Pregnancy, 2007, https://thenationalcampaign.org/sites/default/files/resource-primary-download/EA2007_full_0.pdf.
[37] Wang T et al., The effects of school-based condom availability programs (CAPs) on condom acquisition, use and sexual behavior: a systematic review, *AIDS and Behavior*, 2017, https://www.ncbi.nlm.nih.gov/pubmed/28625012.
[38] Trussell J, Aiken A, "Contraceptive Efficacy" pp. 829–928. In Hatcher RA et al., eds., *Contraceptive Technology,* 21st ed., New York: Ayer Company Publishers, 2018.
[39] Trussell J et al., Cost effectiveness of contraceptives in the United States, *Contraception*, 2009, 79(1):5–14.
[40] Armstrong E et al., *Intrauterine Devices and Implants: A Guide to Reimbursement*, 2015, https://www.nationalfamilyplanning.org/file/documents----reports/LARC_Report_2014_R5_forWeb.pdf.
[41] Eisenberg D et al., Cost as a barrier to long-acting reversible contraceptive (LARC) use in adolescents, *Journal of Adolescent Health*, 2013, 52(4):S59–S63, http://www.jahonline.org/article/S1054-139X(13)00054-2/fulltext.

time at the federal minimum wage of $7.25 an hour.[42] These costs are dissuasive for many women not covered by the contraceptive coverage guarantee; one pre-ACA study concluded that women who faced high out-of-pocket IUD costs were significantly less likely to obtain an IUD than women with access to the device at low or no out-of-pocket cost. And only 25% of women who requested an IUD had one placed after learning the associated costs.[43] Even oral contraceptives, which are twice as effective as condoms in practice, require a prescription and have monthly costs. And although some stores offer certain pill formulations at steep discounts, access to those cost savings can require a woman to change to a different formulation than the one prescribed by her clinician and increases her risk of adverse health effects.

26. The government acknowledges that without coverage, many methods would cost women $50 per month, or upwards of $600 per year, and in doing so, implies that such costs are a minimal burden. This is not true. For example, a national study found that about one-third of uninsured people and lower-income people in the United States would be unable to pay for an unexpected $500 medical bill, and roughly another third would have to borrow money or put it on a credit card and pay it back over time, with interest.[44]

27. Without insurance coverage to defray or eliminate the cost, the large up-front costs of the more-effective contraceptive methods put them out of reach for many women who want them, driving them to less expensive and less effective methods. In a study conducted prior to the contraceptive coverage guarantee, almost one-third of women reported that they would change

[42] 29 U.S.C. § 206(a)(1)(C). At 40 hours a week, that amounts to $290 a week, before any taxes or deductions.
[43] Gariepy AM et al., The impact of out-of-pocket expense on IUD utilization among women with private insurance, *Contraception*, 2011, 84(6):e39–e42, https://escholarship.org/uc/item/1dz6d3cx.
[44] DiJulio B et al., Data note: Americans' challenges with health care costs, 2017, https://www.kff.org/health-costs/poll-finding/data-note-americans-challenges-with-health-care-costs/?utm_campaign=KFF-2017-March-Polling-Beyond-The-ACA.

their contraceptive method if cost were not an issue.[45] This figure was particularly high among women relying on male condoms and other less effective methods such as withdrawal. A study conducted after the enactment of the ACA had similar findings: among women in the study who still lacked health insurance in 2015, 44% agreed that having insurance would help them to afford and use birth control and 44% agreed that it would allow them to choose a better method for them; 48% also agreed that it would be easier to use contraception consistently if they had coverage.[46] Among insured women who still had a copayment using a prescription method (e.g., those in grandfathered plans), 40% agreed that if the copayment were eliminated, they would be better able to afford and use birth control, 32% agreed this would help them choose a better method, and 30% agreed this would help them to use their methods of contraception more consistently. Other studies have found that uninsured women are less likely to use the most expensive (but most effective) contraceptive methods, such as IUDs, implants, and oral contraceptives,[47] and are more likely than insured women to report using no contraceptive method at all.[48,49]

28. Reducing financial barriers is critical to increasing access to effective contraception. Before the ACA provision went into effect, 28 states required private insurers that cover prescription drugs to provide coverage of most or all FDA-approved contraceptive drugs and

[45] Frost JJ and Darroch JE, Factors associated with contraceptive choice and inconsistent method use, United States, 2004, *Perspectives on Sexual and Reproductive Health,* 2008, 40(2):94–104, https://www.guttmacher.org/journals/psrh/2008/factors-associated-contraceptive-choice-and-inconsistent-method-use-united.

[46] Bearak JM and Jones RK, Did contraceptive use patterns change after the Affordable Care Act? A descriptive analysis, *Women's Health Issues*, 2017, 27(3):316–321, http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.

[47] Culwell KR and Feinglass J, The association of health insurance with use of prescription contraceptives, *Perspectives on Sexual and Reproductive Health,* 2007, 39(4):226–230.

[48] Culwell KR and Feinglass J, The association of health insurance with use of prescription contraceptives, *Perspectives on Sexual and Reproductive Health,* 2007, 39(4):226–230.

[49] Culwell KR and Feinglass J, Changes in prescription contraceptive use, 1995–2002: the effect of insurance coverage, *Obstetrics & Gynecology*, 2007, 110(6):1371–1378, https://www.ncbi.nlm.nih.gov/pubmed/18055734.

devices.[50] These programs gave women access at lower prices than if contraception were not covered, but (at the time) all states still allowed insurers to require cost-sharing. Experience from these states demonstrates that having insurance coverage matters.[51] Privately insured women living in states that required private insurers to cover prescription contraceptives were 64% more likely to use some contraceptive method during each month a sexual encounter was reported than women living in states with no such requirement, even after accounting for differences including education and income.[52]

29. Although these state policies reduced women's up-front costs, other actions to eliminate out-of-pocket costs entirely—which is what the federal contraceptive coverage guarantee does—have even greater potential to increase women's ability to use methods effectively. For example, when Kaiser Permanente Northern California eliminated patient cost-sharing requirements for IUDs, implants, and injectables in 2002, the use of these devices increased substantially, with IUD use more than doubling.[53] Another example comes from a study of more than 9,000 St. Louis-region women who were offered the reversible contraceptive method of their choice (i.e., any method other than sterilization) at no cost for two to three years, and were "read a brief

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[50] Guttmacher Institute, Insurance coverage of contraceptives, *State Policies in Brief (as of July 2012)*, 2012.
[51] The government argued in the interim final rules that the state mandates have not been effective, asserting that "Additional data indicates that, in 28 States where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall." The study the government relied on for this assertion was published in a law review rather than in a peer-reviewed scientific journal. [See New MJ, Analyzing the impact of state level contraception mandates on public health outcomes, *Ave Maria Law Review,* 2015, 13(2):345–369.] One basic flaw in this article is that, at the time, none of the state contraceptive coverage mandates eliminated out-of-pocket costs entirely, which is the major advance from the federal guarantee and the issue in this case. In addition, over the course of the period the article evaluated, contraceptive coverage quickly became the norm in the insurance industry—even in states without mandates—thus minimizing potential differences between states with laws and states without them. [Sonfield et al. U.S. insurance coverage of contraceptives and impact of contraceptive coverage mandates, 2002, *Perspectives on Sexual and Reproductive Health,* 2004, 36(2):72–79, https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/3607204.pdf.]
[52] Magnusson BM et al., Contraceptive insurance mandates and consistent contraceptive use among privately insured women, *Medical Care*, 2012, 50(7):562–568.
[53] Postlethwaite D et al., A comparison of contraceptive procurement pre- and post-benefit change, *Contraception*, 2007, 76(5): 360–365

script informing them of the effectiveness and safety of" IUDs and implants.[54] Three-quarters of those women chose long-acting methods (i.e., IUDs or implants), a level far higher than in the general population. Likewise, a Colorado study found that use of long-acting reversible contraceptive methods quadrupled when offered with no out-of-pocket costs along with other efforts to improve access.[55]

30. Government-funded programs to help low-income people afford family planning services provide further evidence that reducing or eliminating cost barriers to women's contraceptive choices has a dramatic impact on women's ability to choose and use the most effective forms of contraception. Each year, among the women who obtain contraceptive services from publicly funded reproductive health providers, 57% select hormone-based contraceptive methods, 18% use implants or IUDs, and 7% receive a tubal ligation.[56] It is estimated that without publicly supported access to these methods at low or no cost, nearly half (47%) of those women would switch to male condoms or other nonprescription methods, and 28% would use no contraception at all.[57]

[54] Peipert JF et al., *Preventing unintended pregnancies by providing no-cost contraception*, *Contraception*, 2012, 120(6):1291–1297.
[55] Ricketts S, Klinger G and Schwalberg G, Game change in Colorado: widespread use of long-acting reversible contraceptives and rapid decline in births among young, low-income women, *Perspectives on Sexual and Reproductive Health*, 2014, 46(3):125–132.
[56] Frost JJ and Finer LB, Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula, memo to interested parties, New York: Guttmacher Institute, June 23, 2017, https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf.
[57] Frost JJ and Finer LB, Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula, memo to interested parties, New York: Guttmacher Institute, June 23, 2017, https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf.

The ACA's Contraceptive Coverage Guarantee Has Had a Positive Impact

31. By ensuring coverage for a full range of contraceptive methods, services and counseling at no cost, the ACA's contraceptive coverage mandate has had its intended effect of removing cost barriers to obtaining contraception. Between fall 2012 and spring 2014 (during which time the coverage guarantee went into wide effect), the proportion of privately insured women who paid nothing out of pocket for the pill increased from 15% to 67%, with similar changes for injectable contraceptives, the vaginal ring and the IUD.[58] Similarly, another study found that since implementation of the ACA, the share of women of reproductive age (regardless of whether they were using contraception) who had out-of-pocket costs for oral contraceptives decreased from 21% in 2012 to just 4% in 2014.[59] These trends have translated into considerable savings for U.S. women: one study estimated that pill and IUD users saved an average of about $250 in copayments in 2013 alone because of the guarantee.[60]

32. Before the ACA, contraceptives accounted for between 30–44% of out-of-pocket health care spending for women.[61] Individual women themselves say that the ACA's contraceptive coverage guarantee is working for them. In a 2015 nationally representative survey of women aged 18–39, two-thirds of those who had health insurance and were using a hormonal contraceptive method reported having no copays; among those women, 80% agreed that paying nothing out of pocket helped them to afford and use their birth control, 71% agreed this helped

[58] Sonfield A et al. Impact of the federal contraceptive coverage guarantee on out-of-pocket payments for contraceptives: 2014 update, *Contraceptive*, 2015, 91(1):44–48.
[59] Sobel L, Salganicoff A and Rosenzweig C, *The Future of Contraceptive Coverage*, Kaiser Family Foundation (KFF) Issue Brief, Menlo Park, CA: KFF, 2017, https://www.kff.org/womens-health-policy/issue-brief/the-future-of-contraceptive-coverage/.
[60] Becker NV and Polsky D, Women saw large decrease in out-of-pocket spending for contraceptives after ACA mandate removed cost sharing, *Health Affairs*, 2015, 34(7):1204–1211.
[61] Becker NV and Polsky D, Women saw large decrease in out-of-pocket spending for contraceptives after ACA mandate removed cost sharing, *Health Affairs*, 2015, 34(7):1204–1211.

them use their birth control consistently, and 60% agreed that having no copayment helped them choose a better method for them.[62]

33. Demonstrating the population-level impact of the ACA's coverage provision (e.g., a change in unintended pregnancy rates) is complicated, because the provision affects only a subset of U.S. women, and because there are so many additional variables that affect women's pregnancy intentions, contraceptive use and ultimately the unintended pregnancy rate in the population. The evidence on whether the ACA's provision has affected contraceptive use at the population level is not definitive, but some studies suggest the guarantee has had an impact on contraceptive use, among those benefiting from the provision.

34. A study using claims data from 30,000 privately insured women in the Midwest found that the ACA's reduction in cost sharing was tied to a significant increase in the use of prescription methods from 2008 through 2014 (before and after the ACA provision went into effect), particularly long-acting methods.[63] Another study of health insurance claims from 635,000 privately insured women nationwide showed that rates of discontinuation and inconsistent use of contraception declined from 2010 to 2013 (again, before and after the ACA provision went into effect) among women using generic oral contraceptive pills after the contraceptive guarantee's implementation (among women using brand-name oral contraceptives, only the discontinuation rate declined).[64]

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[62] Bearak JM and Jones RK, Did contraceptive use patterns change after the Affordable Care Act? A descriptive analysis, *Women's Health Issues*, 2017, 27(3):316–321, http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.

[63] Carlin CS, Fertig AR and Down BE, Affordable Care Act's mandate eliminating contraceptive cost sharing influenced choices of women with employer coverage, *Health Affairs,* 2016, 35(9):1608–1615.

[64] Pace LE, Dusetzina SB and Keating NL, Early impact of the Affordable Care Act on oral contraceptive cost sharing, discontinuation, and nonadherence, *Health Affairs,* 2016, 35(9):1616–1624.

35. Two other studies, looking at the broader U.S. population, found no change in overall use of contraception or an overall switch from less-effective to more-effective methods among women at risk of unintended pregnancy before and after the guarantee's implementation.[65,66] However, both studies identified some positive trends among key groups. One of them found that between 2008 and 2014, among women aged 20–24 (the age group at highest risk for unintended pregnancy), LARC use more than doubled, from 7% to 19%, without a proportional decline in sterilization.[67] The other study showed that between 2012 and 2015, use of prescription contraceptive methods, and birth control pills in particular, increased among sexually inactive women, suggesting that more women were able to start a method before becoming sexually active or use a method such as the pill for noncontraceptive reasons after implementation of the contraceptive coverage guarantee.[68]

36. There is also considerable empirical data from controlled experiments to confirm that the concept of removing cost as a barrier to women's contraceptive use is a major factor in reducing their risk for unintended pregnancy, and the abortions and unplanned births that would otherwise follow. For example, a study of more than 9,000 St. Louis-region women who were offered the reversible contraceptive method of their choice at no cost found that the number of abortions performed at St. Louis Reproductive Health Services declined by 21%.[69] Study participants'

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[65] Bearak JM and Jones RK, Did contraceptive use patterns change after the Affordable Care Act? A descriptive analysis, *Women's Health Issues*, 2017, 27(3):316–321, http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.

[66] Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012.

[67] Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012.

[68] Bearak JM and Jones RK, Did contraceptive use patterns change after the Affordable Care Act? A descriptive analysis, *Women's Health Issues*, 2017, 27(3):316–321, http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.

[69] Peipert JF et al., *Preventing unintended pregnancies by providing no-cost contraception*, *Contraception*, 2012,

abortion rate was significantly lower than the rate in the surrounding St. Louis region, and less than half the national average.[70] Similarly, when access to both contraception and abortion increased in Iowa, the abortion rates actually declined.[71] Starting in 2006, the state expanded access to low- or no-cost family planning services through a Medicaid expansion and a privately funded initiative serving low-income women. Despite a simultaneous increase in access to abortion—the number of clinics offering abortions in the state actually doubled during the study period—the abortion rate dropped by over 20%.

Expanding Exemptions Would Harm Women

37. The Final Rules would make it more difficult, once again, for those receiving insurance coverage through companies or schools that use the exemption (i.e., employees, students and dependents) to access the methods of contraception that are most acceptable and effective for them. That, in turn, would increase those women's risk of unintended pregnancy and interfere with their ability to plan and space wanted pregnancies. These barriers could therefore have considerable negative health, social and economic impacts for those women and their families.

38. Allowing employers or schools to exclude all contraceptive methods, services and counseling from insurance plans—or to cover some contraceptive methods, services and information but not others—would prevent women from selecting and obtaining the methods of contraception that will work best for them. For example, Hobby Lobby objected to providing

120(6):1291–1297.

[70] Peipert JF et al., *Preventing unintended pregnancies by providing no-cost contraception*, *Contraception*, 2012, 120(6):1291–1297.

[71] Biggs MA, Did increasing use of highly effective contraception contribute to declining abortions in Iowa? *Contraception,* 2015, 91(2):167–173.

four specific contraceptive methods, including copper and hormonal IUDs, which are among the most effective forms of pregnancy prevention and also have among the highest up-front costs.

39. Allowing employers to restrict access to the full range of contraceptive methods and to approve coverage only for those they deem acceptable would place inappropriate constraints on women who depend on insurance to obtain the methods best suited to their needs. Moreover, in the absence of coverage, the financial cost of obtaining a method, and the fact that some methods have higher costs than others, would incentivize women to select methods that are inexpensive, rather than methods that are best suited to their needs and that they are therefore most likely to use consistently and effectively (see 10–19, above).

40. Excluding coverage for some or all contraceptive methods, services and counseling could deny women the ability to obtain contraceptive counseling and services from their desired provider at the same time they receive other primary and preventive care.[72,73] A woman going to her gynecologist for an annual examination, for example, may have to go to a different provider to be prescribed (or even discuss) contraception. This disjointed approach increases the time, effort and expense involved in getting needed contraception and interferes with her ability to obtain care from the provider of her choice.

41. Isolating contraceptive coverage in this way also would interfere with the ability of health care providers to treat women holistically. A woman's choice of contraception can be affected by her other medical conditions (e.g., diabetes, HIV, depression/mental health), and certain medications can significantly reduce the effectiveness of some methods of contraception, so a

[72] Leeman L, Medical barriers to effective contraception, *Obstetrics and Gynecology Clinics of North America,* 2007, 34(1):19–29.
[73] World Health Organization, Selected Practice Recommendations for Contraceptive Use, Third Ed., 2016, WHO: Geneva, Switzerland, http://apps.who.int/iris/bitstream/10665/252267/1/9789241565400-eng.pdf.

woman's chosen provider should be able to manage all health conditions and needs at the same time.[74,75]

42. To the extent that expanding the exemptions would burden women's contraceptive use in these ways, it would be harmful to women's health. Contraception allows women to avoid unintended pregnancies and to time and space wanted pregnancies, which has been demonstrated to improve women's health and that of their families. Specifically, pregnancies that occur too early in a woman's life or that are spaced too closely are associated with negative maternal health outcomes and/or adverse birth outcomes, including preterm birth, low birth weight, stillbirth, and early neonatal death.[76,77,78,79] Contraceptive use can also prevent preexisting health conditions from worsening and new health problems from occurring, because pregnancy can exacerbate existing health conditions such as diabetes, hypertension and heart disease.[80] Unintended pregnancy also affects women's mental health; notably, it is a risk factor for depression in adults.[81,82] For these reasons, the Centers for Disease Control and Prevention (CDC) included the development of and improved access to methods of family planning among

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[74] Centers for Disease Control and Prevention, *US Medical Eligibility Criteria for Contraceptive Use, 2016,* https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html.
[75] Centers for Disease Control and Prevention, U.S. medical eligibility criteria for contraceptive use, 2010, *Morbidity and Mortality Weekly Report,* May 28, 2010, Vol. 59, https://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf.
[76] Kavanaugh ML and Anderson RM, *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers,* New York: Guttmacher Institute, 2013, http://www.guttmacher.org/report/contraception-and-beyond-health-benefits-services-provided-family-planning-centers.
[77] Wendt A et al., Impact of increasing inter-pregnancy interval on maternal and infant health, Paediatric and Perinatal Epidemiology, 2012, 26(Suppl. 1):239–258.
[78] Conde-Agudelo A, Rosas-Bermúdez A and Kafury-Goeta AC, Birth spacing and risk of adverse perinatal outcomes: a meta-analysis, Journal of the American Medical Association, 2006, 295(15):1809–1823.
[79] Gipson JD, Koenig MA and Hindin MJ, The effects of unintended pregnancy on infant, child, and parental health: a review of the literature, *Studies in Family Planning,* 2008, 39(1):18–38.
[80] Lawrence HC, Testimony of American Congress of Obstetricians and Gynecologists, submitted to the Committee on Preventive Services for Women, Institute of Medicine, 2011, http://www.nationalacademies.org/hmd/~/media/8BA65BAF76894E9EB8C768C01C84380E.ashx.
[81] Herd P et al., The implications of unintended pregnancies for mental health in later life, *American Journal of Public Health,* 2016, 106(3):421–429.
[82] U.S. Preventive Services Task Force, Screening for depression in adults: recommendation statement, *American Family Physician,* 2016, 94(4):340A–340D, http://www.aafp.org/afp/2016/0815/od1.html.

the 10 great public health achievements of the 20th century.[83]

43. In the Final Rules, the government implies that there is debate about whether contraception may have negative health consequences that outweigh its benefits. In the previous interim final rules, the government implied that putative negative health consequences of contraception may outweigh its benefits. On the contrary, the government itself provides the oversight to ensure that the health benefits of contraception outweigh any potential negative consequences. Notably, the FDA's approval processes require that drugs and devices, including contraceptives, be proven safe and effective through rigorous controlled trials. In addition, the CDC publishes extensive recommendations to help clinicians and patients identify potential contraindications and decide which specific contraceptive methods are most appropriate for each patient's needs and health circumstances.[84,85] Medical experts, such as the American College of Obstetricians and Gynecologists, concur that contraception is safe and has clear health benefits that outweigh any potential risks.[86]

44. Expanding the exemptions to the contraceptive coverage requirement would also have negative social and economic consequences for women, families and society. By enabling them to reliably time and space wanted pregnancies, women's ability to obtain and effectively use contraception promotes their continued educational and professional advancement, contributing to the enhanced economic stability of women and their families.[87] Economic analyses have found

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[83] Centers for Disease Control and Prevention, Achievements in public health, 1900–1999: family planning, *Morbidity and Mortality Weekly Report,* 1999, 48(47): 1073–1080.
[84] Centers for Disease Control and Prevention, *US Medical Eligibility Criteria for Contraceptive Use, 2016,* https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html.
[85] Centers for Disease Control and Prevention, U.S. medical eligibility criteria for contraceptive use, 2010, *Morbidity and Mortality Weekly Report,* May 28, 2010, Vol. 59, https://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf.
[86] Brief of *Amici Curiae,* American College of Obstetricians and Gynecologists, Physicians for Reproductive Health, American Academy of Family Physicians, American Nurses Association, et al., *Zubik v. Burwell,* 2016, http://www.scotusblog.com/wp-content/uploads/2016/02/Docfoc.com-Amicus-Brief-Zubik-v.-Burwell.pdf.
[87] Sonfield A et al., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children,* New York: Guttmacher Institute, 2013, https://www.guttmacher.org/report/social-and-economic-benefits-

positive associations between women's ability to obtain and use oral contraceptives and their education, labor force participation, average earnings and a narrowing of the gender-based wage gap.[88] Moreover, the primary reasons women give for why they use and value contraception are social and economic: In a 2011 study, a majority of women reported that access to contraception had enabled them to take better care of themselves or their families (63%), support themselves financially (56%), stay in school or complete their education (51%), or get or keep a job or pursue a career (50%).[89]

45. The government contends that expanding the exemption would not impose any real harm, suggesting that the women most at risk for unintended pregnancy are not likely to be covered by employer-based group health plans or by student insurance sponsored by a college or university. That argument is misleading. Low-income women, women of color and women aged 18–24 are at disproportionately high risk for unintended pregnancy,[90] and millions of these women rely on private insurance coverage—particularly following implementation of the ACA. In fact, from 2013 to 2017, the proportion of women overall and of women below the poverty level who were uninsured dropped by more than one-third nationwide, declines driven by substantial increases in both Medicaid and private insurance coverage.[91] In addition, the ACA specifically expanded coverage for people aged 26 and younger, allowing them to remain covered as dependents on

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womens-ability-determine-whether-and-when-have-children.

[88] Sonfield A et al., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children,* New York: Guttmacher Institute, 2013, https://www.guttmacher.org/report/social-and-economic-benefits-womens-ability-determine-whether-and-when-have-children.

[89] Frost JJ and Lindberg LD, Reasons for using contraception: perspectives of U.S. women seeking care at specialized family planning clinics, 2012, *Contraception,* http://www.guttmacher.org/pubs/journals/j.contraception.2012.08.012.pdf.

[90] Finer LB and Zolna MR, Declines in unintended pregnancy in the United States, 2008–2011, *New England Journal of Medicine*, 2016, 374(9):843–852.

[91] Guttmacher Institute, Gains in insurance coverage for reproductive-age women at a crossroads, *News in Context,* Dec. 4, 2018, https://www.guttmacher.org/article/2018/12/gains-insurance-coverage-reproductive-age-women-crossroads.

their parents' plans, regardless of whether the young woman is working herself or attending college or university.

Medicaid, Title X and State Coverage Requirements Cannot Substitute for the Federal Contraceptive Coverage Guarantee

46. State and federal programs and laws—such as the Title X national family planning program, Medicaid, and state contraceptive coverage requirements—cannot replicate or replace the gains in access made by the contraceptive coverage guarantee. In the interim final rules, the government claimed that "[i]ndividuals who are unable to obtain contraception coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules…have other avenues for obtaining contraception…."[92]

47. Many women who have the benefit of the ACA's contraceptive coverage mandate are not eligible for free or subsidized care under Title X. Title X provides no-cost family planning services to people living at or below 100% of the federal poverty level ($12,060 for a single person in 2017),[93] and provides services on a sliding fee scale between 100% and 250% of poverty; women above 250% of poverty must pay the full cost of care. By contrast, the federal contraceptive coverage guarantee eliminates out-of-pocket costs for contraception regardless of income.

48. Funding for Title X has not increased sufficiently for the program even to keep up with the increasing number of women in need of publicly funded care;[94] therefore, Title X cannot

[92] Department of the Treasury, Department of Labor and Department of Health and Human Services, Religious exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act, *Federal Register*, 82(197):47838–47862, https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-21852.pdf.
[93] Office of the Assistant Secretary for Planning and Evaluation, U.S. federal poverty guidelines used to determine financial eligibility for certain federal programs, 2017, https://aspe.hhs.gov/poverty-guidelines.
[94] Women in need of publicly funded contraceptive services are defined as those women who a) are younger than 20

sustain additional beneficiaries as a result of the Final Rules. From 2010 to 2014, even as the number of women in need of publicly funded contraceptive care grew by 5%, representing an additional one million women in need,[95] Congress cut funding for Title X by 10%.[96] With its current resources, Title X is able to serve only one-fifth of the nationwide need for publicly funded contraceptive care.[97] Still, the government has proposed diverting already insufficient Title X funding to help cover the cost of care for any women affected by the Final Rules,[98] an action that would inevitably hurt patients who rely on publicly funded services.

49. Similarly, many women who would lose private insurance coverage of contraception under the federal government's expanded exemption would not be eligible for Medicaid. Eligibility for Medicaid varies widely from state to state, particularly in states that have not expanded Medicaid eligibility under the ACA. In almost all of those states, nondisabled, nonelderly childless adults do not qualify for Medicaid at any income level, and eligibility for parents is as low as 18% of the federal poverty level in Alabama and Texas.[99] Several of these states have expanded eligibility specifically for family planning services to people otherwise

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or are poor or low-income (i.e., have a family income less than 250% of the federal poverty level) and b) are sexually active and able to become pregnant but do not want to become pregnant. See Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update,* New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

[95] Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update,* New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

[96] Department of Health and Human Services, Office of Population Affairs, Funding history, 2017, https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html.

[97] Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update,* New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

[98] Department of Health and Human Services, Compliance with statutory program integrity requirements, *Federal Register*, 83(106):25502–25533, https://www.gpo.gov/fdsys/pkg/FR-2018-06-01/pdf/2018-11673.pdf.

[99] Kaiser Family Foundation, Medicaid income eligibility limits for adults as a percent of the federal poverty level, 2018, State Health Facts, https://www.kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level.

ineligible for full-benefit Medicaid; those income eligibility levels also vary considerably.[100,101] Again, by contrast, the federal contraceptive coverage guarantee applies regardless of income. And because the U.S. Supreme Court has ruled that states cannot be compelled by the federal government to expand Medicaid eligibility, the federal government cannot rely on Medicaid to fill in gaps in coverage that would result from expanding the exemption.

50. The federal government's assertion that Title X and Medicaid can replace or replicate the ACA's contraception coverage guarantee is additionally problematic given that the government itself is at the same time moving to undermine Title X and Medicaid. For example, the government's recent budget proposals have sought to exclude Planned Parenthood Federation of America and its affiliates from Title X, Medicaid and other federal programs,[102] and have called for massive cuts to Medicaid.[103] The Department of Health and Human Services has proposed sweeping changes to Title X regulations that would undermine quality of care and access to providers,[104] and it has encouraged states to revamp their Medicaid programs in ways that would restrict program eligibility (e.g., by imposing work requirements) and thereby interfere with coverage and care.[105] The administration has strongly backed similar congressional proposals for cutting and limiting access to Title X and Medicaid.

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[100] Guttmacher Institute, Medicaid family planning eligibility expansions, *State Laws and Policies (as of December 2018),* 2018, https://www.guttmacher.org/state-policy/explore/medicaid-family-planning-eligibility-expansions.
[101] Kaiser Family Foundation, Status of state action on the Medicaid expansion decision, 2018, State Health Facts, https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/.
[102] Hasstedt K, Beyond the rhetoric: the real-world impact of attacks on Planned Parenthood and Title X, *Guttmacher Policy Review,* 2017, 20:86–91, https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x.
[103] Luhby T, Not even the White House knows how much it's cutting Medicaid, *CNN,* May 24, 2017, http://money.cnn.com/2017/05/24/news/economy/medicaid-budget-trump/index.html.
[104] Department of Health and Human Services, Compliance with statutory program integrity requirements, *Federal Register*, 83(106):25502–25533, https://www.gpo.gov/fdsys/pkg/FR-2018-06-01/pdf/2018-11673.pdf.
[105] Sonfield A, Efforts to transform the nature of Medicaid could undermine access to reproductive health care, *Guttmacher Policy Review,* 2017, 20:97–102, https://www.guttmacher.org/gpr/2017/10/efforts-transform-nature-medicaid-could-undermine-access-reproductive-health-care.

51. In addition, proposed changes to Title X would make it even more unsuitable as a substitute for contraceptive coverage under the ACA. The recent proposed rule for Title X removes the requirement that the contraceptive methods offered by a Title X provider be "medically approved."[106] At the same time, the proposed rule seemingly opens the door to allow Title X funding to go to antiabortion counseling centers (also called "crisis pregnancy centers"), which do not offer the broad range of FDA-approved methods of contraception and may offer only abstinence-until-marriage counseling and fertility awareness–based methods. These proposed changes, if implemented, would shift the Title X program away from its mission of offering access to a broad range of family planning methods.[107]

52. Policymakers in many states have also restricted publicly funded family planning programs and providers, further undermining the ability of these programs to serve those affected by the expanded exemption.[108]

53. Neither can state-specific contraceptive coverage laws replicate or replace the increase in access to contraception provided by the ACA's contraceptive coverage guarantee. Twenty-one have no such laws at all.[109] Of the 29 states and the District of Columbia that do have contraceptive coverage requirements, only 10 currently bar copayments and deductibles for contraception (and another four states have new requirements not yet in effect). Additionally, the federal requirement limits the use of formularies and other administrative restrictions on women's use of contraceptive services and supplies, by making it clear that health plans may

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[106] Department of Health and Human Services, Compliance with statutory program integrity requirements, *Federal Register*, 83(106):25502–25533, https://www.gpo.gov/fdsys/pkg/FR-2018-06-01/pdf/2018-11673.pdf.
[107] Hasstedt K, A Domestic gag rule and more: the administration's proposed changes to Title X, *Health Affairs* Blog, June 18, 2018, https://www.guttmacher.org/article/2018/06/domestic-gag-rule-and-more-administrations-proposed-changes-title-x.
[108] Gold RB and Hasstedt K, Publicly funded family planning under unprecedented attack, *American Journal of Public Health,* 2017, 107(12):1895–1897, http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2017.304124.
[109] Guttmacher Institute, Insurance coverage of contraceptives, *State Laws and Policies (as of December 2018),* 2018, http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.

seek to influence a patient's choice only within a specific contraceptive method category (e.g., to favor one hormonal IUD over another) and not across methods (e.g., to favor the pill over the ring).[110] Few of the state laws include similar protections. Similarly, most of the state requirements do not specifically require coverage of all the distinct methods that the federal requirement encompasses. For example, only eight states currently require coverage of female sterilization, and few state laws make explicit distinctions between methods that some insurance plans have attempted to treat as interchangeable (such as hormonal versus copper IUDs, or the contraceptive patch versus the contraceptive ring).[111] Finally, state laws cannot regulate self-insured employers at all, and those employers account for 60% of all workers with employer-sponsored health coverage.[112]

State-Specific Impacts

54. The Final Rules would have public health and fiscal consequences in states across the country. If unable to access contraception coverage through their employer or university, some lower-income women who meet the strict income requirements of public programs would rely on publicly funded services to access this beneficial service. Many women who lose or lack contraceptive coverage because their employer or university objects, however, would not meet the strict income and eligibility requirements of public programs, and if as a result they are not using their preferred or the most effective methods for them, or if cost forces them to forgo

[110] Department of Labor, FAQs about Affordable Care Act implementation (part XXVI), May 11, 2015, https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf.
[111] Guttmacher Institute, Insurance coverage of contraceptives, *State Laws and Policies (as of December 2018),* 2018, http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.
[112] Claxton G et al., *Employer Health Benefits: 2017 Annual Survey,* Menlo Park, CA: Kaiser Family Foundation; and Chicago: Health Research & Educational Trust, 2017, https://www.kff.org/report-section/ehbs-2017-section-10-plan-funding/.

contraceptive use periodically or altogether, they would be at increased risk of unintended pregnancy. The costs of the resulting unintended pregnancies often then fall to the states because the federal government cannot or will not withstand these costs.

Pennsylvania

55. In Pennsylvania, some women impacted by the Final Rules would not qualify for Medicaid or Title X because they would not meet the income eligibility requirements for coverage or subsidized care under these programs.

56. For example, in Pennsylvania, childless adults and parents are only eligible for full-benefit Medicaid if they have incomes at or below 138% of the federal poverty level,[113] and individuals are eligible for coverage of family planning services specifically up to 220% of poverty.[114] This means that affected women who lose coverage as a result of the rules may not be eligible.

57. As a result, some women would be at increased risk of unintended pregnancy, either because they are not able to afford the methods that work best for them, or because cost would force them to forgo contraception use entirely.

58. Other women would be eligible for and rely on publicly funded family planning services through programs such as Medicaid and Title X. Those women could be denied the ability to obtain contraceptive counseling and services from their desired provider at the same time they receive other primary and preventive care, increasing the time, effort and expense involved in getting needed contraception. In addition, isolating contraceptive coverage in this way would

[113] Kaiser Family Foundation, Medicaid income eligibility limits for adults as a percent of the federal poverty level, 2018, State Health Facts, https://www.kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level.
[114] Guttmacher Institute, Medicaid family planning eligibility expansions, *State Laws and Policies (as of December 2018),* 2018, https://www.guttmacher.org/state-policy/explore/medicaid-family-planning-eligibility-expansions.

interfere with the ability of health care providers to manage all of a woman's health conditions and needs at the same time.

59. The increase in the number of women relying on publicly funded services would increase the strain on the state's family planning programs and providers, making it more difficult for them to meet the existing need for publicly funded care. In 2014, 746,000 women were in need of publicly funded family planning in Pennsylvania, and the state's family planning network was able to only meet 29% of this need.[115]

60. Another indicator of the existing unmet need for contraception in Pennsylvania is that substantial numbers of state residents experience unintended pregnancy each year. In 2010, 115,000 unintended pregnancies occurred among Pennsylvania residents, a rate of 47 per 1,000 women aged 15–44.[116]

61. Of those unintended pregnancies that ended in birth, 54% were paid for by Medicaid and other public insurance programs.[117] Unintended pregnancies cost the state approximately $248 million and the federal government approximately $479 million in 2010. The Final Rules are likely to increase the number of unintended pregnancies experienced by state residents, and thus to increase state and federal expenditures.

[115] Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update*, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.
[116] Kost K, *Unintended Pregnancy Rates at the State Level: Estimates for 2010 and Trends Since 2002*, New York: Guttmacher Institute, 2015, https://www.guttmacher.org/report/unintended-pregnancy-rates-state-level-estimates-2010-and-trends-2002.
[117] Sonfield A and Kost K, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, New York: Guttmacher Institute, 2015, https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy.

62. In conclusion, adding to the number of women at risk of unintended pregnancy by expanding the exemption is not in the public health or economic interest of Pennsylvania or its residents.

New Jersey

63. In New Jersey, some women impacted by the Final Rules would not qualify for Medicaid or Title X because they would not meet the income eligibility requirements for coverage or subsidized care under these programs.

64. For example, in New Jersey, childless adults and parents are only eligible for full-benefit Medicaid if they have incomes at or below 138% of the federal poverty level.[118] (New Jersey has not expanded Medicaid eligibility specifically for family planning services.) This means that affected women who lose coverage as a result of the rules may not be eligible.

65. As a result, some women would be at increased risk of unintended pregnancy, either because they are not able to afford the methods that work best for them, or because cost would force them to forgo contraception use entirely.

66. Other women would be eligible for and rely on publicly funded family planning services through programs such as Medicaid and Title X. Those women could be denied the ability to obtain contraceptive counseling and services from their desired provider at the same time they receive other primary and preventive care, increasing the time, effort and expense involved in getting needed contraception. In addition, isolating contraceptive coverage in this way would interfere with the ability of health care providers to manage all of a woman's health conditions and needs at the same time.

[118] Kaiser Family Foundation, Medicaid income eligibility limits for adults as a percent of the federal poverty level, 2018, State Health Facts, https://www.kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level.

67. The increase in the number of women relying on publicly funded services would increase the strain on the state's family planning programs and providers, making it more difficult for them to meet the existing need for publicly funded care. In 2014, 455,000 women were in need of publicly funded family planning in New Jersey, and the state's family planning network was able to only meet 22% of this need.[119]

68. Another indicator of the existing unmet need for contraception in New Jersey is that substantial numbers of state residents experience unintended pregnancy each year. In 2010, 97,000 unintended pregnancies occurred among New Jersey residents, a rate of 56 per 1,000 women aged 15–44.[120]

69. Of those unintended pregnancies that ended in birth, 52% were paid for by Medicaid and other public insurance programs.[121] Unintended pregnancies cost the state approximately $186 million and the federal government approximately $291 million in 2010. The Final Rules are likely to increase the number of unintended pregnancies experienced by state residents, and thus to increase state and federal expenditures.

70. In conclusion, adding to the number of women at risk of unintended pregnancy by expanding the exemption is not in the public health or economic interest of New Jersey or its residents.

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[119] Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update*, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

[120] Kost K, *Unintended Pregnancy Rates at the State Level: Estimates for 2010 and Trends Since 2002*, New York: Guttmacher Institute, 2015, https://www.guttmacher.org/report/unintended-pregnancy-rates-state-level-estimates-2010-and-trends-2002.

[121] Sonfield A and Kost K, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, New York: Guttmacher Institute, 2015, https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy.

Ample evidence demonstrates that the Final Rules would interfere with women's ability to identify and consistently use the contraceptive methods that would work best for them, thus putting them at heightened risk of unintended pregnancy and the health, social and economic harms that would result.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: December 14, 2018

By: Kathryn Kost
Acting Vice President for Domestic Research
The Guttmacher Institute

Kathryn Kost

The Guttmacher Institute · 125 Maiden Lane · New York, NY 10038
(212) 248-1111 · kkost@guttmacher.org

EDUCATION

Princeton University, Princeton, New Jersey
Ph.D., Sociology, 1990; Area of Specialization: Demography

Reed College, Portland, Oregon
Bachelor of Arts, Sociology, 1982

PROFESSIONAL EXPERIENCE

The Guttmacher Institute, New York, New York
Acting Vice President of Domestic Research 2018 - present
Director of Domestic Research 2016-2018
Principal Research Scientist 2015-2016
Senior Research Associate, 1989-1998, 2009-2014
Consultant, 2004-2009

Gynuity Health Projects, New York, New York
Consultant, 2009

Princeton University, Princeton, New Jersey
Teaching Assistant, Introductory Statistics (graduate-level), Woodrow Wilson School, 1986-1987

East-West Population Institute, Population Research Division, University of Hawaii, Honolulu, HI
Research Intern, 1987

Princeton University, Princeton, New Jersey
Teaching Assistant, Introductory Statistics (graduate-level), Woodrow Wilson School, 1986

National Academy of Sciences, Institute of Medicine, Washington, D.C.
Research Intern, Committee on Contraceptive Development, 1986

Princeton University, Princeton, New Jersey
NICHD Trainee, Office of Population Research, 1985-1989

American Health Foundation, New York, New York
Head of Data Management, Division of Child Health, 1983-1985

AREAS OF SPECIALIZATION

Sexual and Reproductive Health; Unintended Pregnancy and Childbearing; Pregnancy Surveillance and Statistics; Contraceptive Effectiveness.

PEER-REVIEWED PUBLICATIONS

Sundaram A, Vaughan B, Kost K, Bankole A, Finer LB, Singh S. (2017). Contraceptive failure in the United States: Estimates from the 2006-2010 National Survey of Family Growth. *Perspectives on Sexual and Reproductive Health, 49(1)*:7-16.

Kavanaugh MK, Kost K, Frohwirth L, Maddow-Zimet I. (2016). Parent's experience of unintended childbearing: A qualitative study of factors that mitigate or exacerbate effects. *Social Science and Medicine*, 174:133-141.

Lindberg LD, Kost K, Maddow-Zimet I. (2016). The role of men's childbearing intentions in father involvement. *Journal of Marriage and Family, 79(1)*:44-59.

Maddow-Zimet I, Lindberg LD, Kost K, and Lincoln A. (2016). Are pregnancy intentions associated with transitions into and out of marriage? *Perspectives on Sexual and Reproductive Health*, 48(1):35–43, DOI: 10.1363/ 48e8116

Vlassoff M, Diallo A, Philbin J, Kost K, Bankole A. (2016) Cost-effectiveness of two interventions for the prevention of postpartum hemorrhage in Senegal. *International Journal of Gynecology & Obstetrics* online, DOI:10.1016/ j.ijgo.2015.10.015

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Kost K, Maddow-Zimet I, Arpaia A., Pregnancies, Births and Abortions Among Adolescents and Young Women in the United States, 2013: National and State Trends by Age, Race and Ethnicity, New York: Guttmacher Institute, 2017.

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Kost K and Maddow-Zimet I, U.S. Teenage Pregnancies, Births and Abortions, 2011: State Trends by Age, Race and Ethnicity, New York: Guttmacher Institute, 2016.

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Kost K, Unintended Pregnancy Rates at the State Level: Estimates for 2002, 2004, 2006 and 2008, New York: Guttmacher Institute, 2013.

Kost K and Henshaw S, U.S. Teenage Pregnancies, Births and Abortions, 2008: State Trends by Age, Race and Ethnicity, New York: Guttmacher Institute, 2013.

Kost K and Henshaw S, U.S. Teenage Pregnancies, Births and Abortions, 2008: National Trends by Age, Race and Ethnicity, New York: Guttmacher Institute, 2012.

Kost K, Henshaw S and Carlin L, U.S. Teenage Pregnancies, Births and Abortions: National and State Trends and Trends by Race and Ethnicity, New York: Guttmacher Institute, 2010.

Henshaw SK and Kost K, Trends in the Characteristics of Women Obtaining Abortions, 1974 to 2004, New York: Guttmacher Institute, 2008.

OTHER PUBLICATONS

Curtin SC, Abma JC, Kost K. Pregnancy rates for U.S. women continue to drop: an update. NCHS Health E-stat, November 2015. Available at: http:/ / www.cdc.gov/ nchs/ data/ hestat/ pregnancy/ rates_1990_2010.

HONORS, AWARDS AND FELLOWSHIPS

East-West Center, University of Hawaii, Summer Fellowship (1987)

PROFESSIONAL ASSOCIATIONS

Population Association of America
American Sociological Association
PRAMS Steering Committee, New York City Department of Health & Mental Hygiene
Editorial Board, International Journal of Population Research
Full Fellow, Society of Family Planning
Member, Social Science and Population Studies Review Panel, National Institutes of Health (2012-2015)

EXHIBIT L

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, Plaintiff, v. DONALD J. TRUMP, *et al.*, Defendants.	**No. 2:17-cv-04540-WB**

DECLARATION OF CYNTHIA H. CHUANG, M.D., MSc[1]

I, Cynthia H. Chuang, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, I state as follows:

I. My Background and Experience

1. I am a practicing general internist, primary care provider, professor, and health services researcher, with a principal research interest in unintended pregnancy prevention and contraceptive decision-making in adult women.

A. *My Job, Educational Training and Academic Practice*

2. I work as a Professor of Medicine, Public Health Services, and Obstetrics and Gynecology in the Departments of Medicine, Public Health Sciences, and Obstetrics and Gynecology at the Pennsylvania State University College of Medicine, where I also serve as the Chief of the Division of General Internal Medicine, a division of over 70 physicians with clinical practice in primary care medicine, hospital medicine, palliative care, and post-acute care.

[1] I attach a true and correct copy of my curriculum vitae hereto as Exhibit 1.

3. I am also the Research Director of the Penn State K12 BIRCWH (Building Interdisciplinary Research Careers in Women's Health) Program.

4. I have been on faculty at the Penn State College of Medicine since 2004.

5. I earned a Bachelor of Science degree from the University of Michigan in 1992 and earned my Medical Degree from the New York University School of Medicine in 1997.

6. Thereafter, I completed my residency and chief residency in Internal Medicine at Temple University Hospital, in Philadelphia, Pennsylvania, in 2001.

7. I earned a Masters of Science in Epidemiology (MSc) from the Boston University School of Public Health in 2003 and completed my General Internal Medicine fellowship and residency in Preventive Medicine at Boston University School of Medicine, in 2004.

8. During my training, some of my most formative experiences were when I worked with patients in the areas of pregnancy prevention and contraceptive care at a family planning clinic in rural California; a primary care clinic at Temple University in North Philadelphia, Pennsylvania; and a women's health clinic at Boston Medical Center in Boston, Massachusetts.

9. Throughout my career, I have been an investigator on a number of studies and projects regarding contraception and reproductive health. For example, I was the Principal Investigator of a Patient-Centered Outcomes Research Institute (PCORI) contract to design and evaluate interventions aimed at assisting women with personalized contraceptive choices that best meet their individual needs (CD–1304–6117), and recipient of a National Institutes of Health (NIH) K23 career development award to study unintended pregnancy in women with chronic medical conditions. I am the Penn State site Principal Investigator for the PCORNet PaTH Clinical Data Research Network, a multi-institutional integrated research network in partnership with the University of Pittsburgh/University of Pittsburgh Medical Center, Temple University Health

System, Johns Hopkins University Health System, Geisinger Health System, and the University of Utah Health System.

10. I have authored over 70 scholarly publications, a significant portion of which focus on women's healthcare and preventive services. Among other topics, I have written about: reducing unintended pregnancies through reproductive planning and contraceptive action planning, contraceptive decision-making in women with and without chronic medical conditions, and the meaning of pregnancy intention.

11. Some of my recent articles include:

a. Snyder A, Weisman CS, Liu G, Leslie D, Chuang CH. The impact of the Affordable Care Act on contraceptive use and costs among privately insured women. *Women's Health Issues* 2018, 28(3): 219-223.

b. "Measuring Oral Contraceptive Adherence Using Self-Report Versus Pharmacy Claims Data," Contraception, 2017 Sep 04, Nelson HN, Borrero S, Lehman E, Velott DL, Chuang CH;

c. "How Do Pregnancy Intentions Affect Contraceptive Choices When Cost Is Not a Factor? A Study of Privately Insured Women," Contraception, 2015 Nov; 92(5):501-7, Weisman CS, Lehman EB, Legro RS, Velott DL, Chuang CH; and

d. "Making the Most of the Affordable Care Act's Contraceptive Coverage Mandate for Privately-Insured Women," Women's Health Issues, 2014 Sep-Oct; 24(5):465-8, Weisman CS, Chuang CH.

12. I have received multiple awards and recognitions for my academic work including delivering the 2017 Spring Dean's Lecture (Contraceptive Use: Before, During and After the Affordable Care Act). I received the Dean's Award for Innovation in Team Science in 2014, the

Department of Medicine Excellence in Mentoring Award in 2014 and the Junior Faculty Award for Excellence in Research in 2008. I have also received the Dean's Award for Excellence in Teaching in 2010 and 2014, and the Special Recognition for Education Leadership and Service Award on 2005.

B. ***My Medical Practice***

13. In addition to my academic work, I am also a clinician and maintain an active adult primary care practice in Hershey, Pennsylvania, in which a portion of my patients are women of child-bearing age.

14. My practice is focused on preventive medicine and chronic disease management.

15. For my female patients of child-bearing age, preventive medicine includes reproductive life planning, including the use of contraceptives.

16. For medical reasons, the ideal "spacing" between pregnancies is eighteen months, because there is a greater risk of poor birth outcomes, like low birthweight and preterm birth, if pregnancies are not properly spaced.

17. I routinely have conversations with my patients about spacing out their pregnancies due to their medical health and educational, work and economic goals. Indeed, the Centers for Disease Control and Prevention (CDC) recommends that doctors counsel their patients about issues of "reproductive life planning," including their life, financial and job goals.

18. These conversations routinely result in changes to patients' contraceptive care. Indeed, I have found that it is important to be flexible with respect to contraceptive care because patients' changing life situations will frequently call for changes in their contraceptive method choice.

19. Through my medical practice, I have found that the most important thing about

providing preventive contraceptive care is to counsel my patients to use the method of contraception that is best suited for their individual needs at their particular place in life.

20. My patients are generally highly insured and mostly white.

21. Some live in highly rural areas and drive long distances to see me.

22. I direct low-income patients without insurance to the Medicaid program (if eligible). I direct other uninsured or underinsured women without contraceptive coverage to seek care through Planned Parenthood, or another Federally Qualified Health Center (FQHC), where they may qualify for contraceptive coverage under Title X.

23. Some of my patients also work for and receive their health insurance through Catholic Schools and other institutions which might seek to eliminate contraceptive coverage through their employer-sponsored plans under the new religious and moral exemptions.

II. My Opinion on the Final Religious Exemption Rule and Final Moral Exemption Rule

24. I have reviewed both the final Religious Exemption Rule and the final Moral Exemption Rule (together, the "Final Exemption Rules"), as well as the amended Complaint filed by the Commonwealth of Pennsylvania in the above-captioned matter that challenges them.

25. Based upon my knowledge, education, training and experience, it is my professional opinion that the Final Exemption Rules will cause immediate and irreversible harm because they will cause women to lose preventive contraceptive care under their employer group health plans.

A. *Cost is a Barrier to Contraceptive Access*

26. It is my understanding, and it has been my experience, that cost is a barrier to access to contraceptives. This has been corroborated in research studies.

27. Prior to passage of the Affordable Care Act (the "Affordable Care Act" or "ACA"),

before preventive contraceptive care was provided at no out-of-pocket cost under the ACA's contraceptive mandate, I regularly counseled my patients about the cost related to their recommended contraceptive choices.

28. At that time, it was not unusual for my patients to reject the specific contraceptive I had recommended due to its cost; instead, they would request that I prescribe a less effective, but cheaper, method of contraception. Or they would forego use of contraception altogether.

29. Such requests were most frequent when I had recommended intrauterine Devices (IUDs) or contraceptive implants. IUDs and implants carried heavy cost-sharing responsibilities and, therefore, were most expensive to patients pre-ACA. But they are also a much more effective method of contraceptive care (<1% failure rate) than birth control pills (9% failure rate).

30. After the ACA passed and the contraceptive mandate was instituted, however, I saw that my patients were free to make contraceptive choices on the basis of their medical and personal needs and concerns, alone, without the burden of having to weigh the cost of the preferred medical choice. Put otherwise, post-ACA, the only concern has become what is best for the patient.

31. Since the ACA passed, no patient has contacted me to ask for a different, cheaper method of contraception than the one I had prescribed due to the cost under private insurance plans.

32. Furthermore, as a result of the ACA's contraceptive mandate, I have seen patients switch from a cheaper, less effective method to a more effective, expensive method that was better for their medical health and personal needs.

B. ***Because Patients Will Lose Contraceptive Coverage under the New Final Exemption Rules, They Will Make Less Medically Sound Contraceptive Choices and, Therefore, Will Be Harmed***

33. It is apparent, however, that under the new Final Exemption Rules this post-ACA focus on what is best for the patient will change.

34. This is so because, as a result of the Final Exemption Rules, some women will lose insurance coverage for preventive contraceptive care.

35. As a result, their costs for contraceptive care will rise.

36. Based upon my own experience and existing scientific and empirical information that I have reviewed and am aware of, under the new Final Exemption Rules, cost will, again, become a barrier to women's access to and use of the contraceptive that is medically recommended for them.

37. Many of these women who will no longer receive contraceptive coverage will not only face financial harm, but will also face medical harm.

38. This harm will manifest itself in the disruption of these patients' medical treatment, whether by substituting a less effective but cheaper method of contraception or by being forced to stop using contraceptives at all, due to financial reasons.

39. Some of these women will face unintended pregnancy and other adverse medical consequences.

C. ***The New Final Exemption Rules Are Not Based Upon Sound Scientific or Empirical Evidence***

40. It is also my opinion that the new Final Exemption Rules are not based upon sound scientific or empirical evidence.

41. The Final Exemption Rules indicate, among other things, that contraceptives are not effective in preventing unintended pregnancy. This is false.

42. This claim in the Final Exemption Rules is inconsistent with the weight of scientific and empirical authority.

43. Indeed, well-established research indicates that contraceptives are, in fact, effective preventing unintended pregnancy. To be sure, while various methods of contraception can be effective at preventing unintended pregnancy, some are more effective than others.

44. Several other statements in the Final Exemption Rules are also not scientifically credible.

45. The Final Exemption Rules state that some commenters criticized the 2011 IOM Report for citing studies that assert associative relationship between contraceptive use and decreases in unintended pregnancy, and not causal relationships. Establishing a causal relationship would be unethical and unrealistic. Studies of association have shown that women using specific contraceptive methods are less likely to become pregnant than women not using those methods. A causal relationship could only be established if a study were conducted where women were randomly assigned to receive a specific contraceptive method and compared with women who were randomly assigned to use no contraceptive method. Studies of association have provided the rationale for the knowledge that smoking causes lung cancer, HIV causes AIDS, and Pap smears reduce cervical cancer.

46. The Final Exemption Rules acknowledge commenters who report that hormonal contraceptives cause depression, citing one large study from Denmark. This report should not be evaluated in isolation, as other studies have found no consistent association between hormonal contraceptive use and depressive symptoms, while others have found hormonal contraception has reduced levels of depressive symptoms. These studies are difficult to conduct, since women who are receiving hormonal contraception must be enrolled in health care services, where they are more

likely to be screened and treated for depression.

47. The Final Exemption Rules acknowledge commenters who report that hormonal contraceptives may increase the risk of certain health conditions, such as venous thromboembolic disease (VTE) (i.e., deep venous thrombosis and pulmonary embolism). While it is true that the risk of VTE is increased with use of estrogen-containing hormonal contraception, pregnancy and the postpartum state increase VTE risk significantly more so. Thus, preventing unintended pregnancy is a more effective way to reduce risk of VTE than avoiding hormonal contraception.

48. Similarly, the Final Exemption Rules acknowledge commentators who expressed concern over the possible increased risk of certain cancers. There is conflicting evidence as to whether long-term hormonal contraceptive use may increase the risk of breast cancer, however there is strong evidence that hormonal contraception reduces the risk of ovarian and uterine cancer, and some evidence that it reduces the risk of colorectal cancer. The magnitude of the reductions in ovarian, uterine, and colorectal cancer greatly outweigh the potential increased risk in breast cancer.

49. For these reasons, I believe that an injunction of the Final Exemption Rules is necessary to prevent immediate and irreparable harm to women in Pennsylvania and around the Country, who will lose ongoing preventive care coverage under their group health plans due to the Final Exemption Rules.

I hereby affirm that the foregoing is true and correct based upon my knowledge, information and belief, and I make these statements subject to the penalty of perjury.

Date: 12/14/2018

By: _____
CYNTHIA H. CHUANG, M.D., MSc

EXHIBIT 1

Cynthia H. Chuang, MD MSc
Curriculum Vitae

Penn State College of Medicine/Milton S. Hershey Medical Center
500 University Drive, HO34
Hershey, PA 17033
Phone: (717) 531-8161
Fax: (717) 531-7726
Email: cchuang@pennstatehealth.psu.edu

Current Positions:

2016-present	Chief, Division of General Internal Medicine Pennsylvania State University College of Medicine; Hershey, PA
2015-present	Professor of Medicine, Public Health Sciences, and Obstetrics and Gynecology Pennsylvania State University College of Medicine; Hershey, PA (Appointment in Obstetrics and Gynecology added in 2018)
2012-present	Research Director, Penn State University Building Interdisciplinary Research Careers in Women's Health (BIRCWH) K12 Program

Previous Positions:

2014-2017	Co-Lead, Community Engagement and Research Core, Penn State Clinical and Translational Science Institute
2009-2015	Associate Director of Research, Division of General Internal Medicine, Penn State College of Medicine
2009-2015	Associate Professor of Medicine and Public Health Sciences Pennsylvania State University College of Medicine; Hershey, PA
2004-2009	Assistant Professor of Medicine and Public Health Sciences Pennsylvania State University College of Medicine; Hershey, PA

Education:

2003	MSc, Epidemiology Boston University School of Public Health, Boston, MA
1997	MD, New York University School of Medicine New York, NY
1992	BS, Cellular and Molecular Biology Graduated *cum laude*, Honors Program University of Michigan, Ann Arbor, MI

Post-Graduate Training:

2001-2004	Fellow, General Internal Medicine Boston University School of Medicine, Boston, MA
2001-2003	Resident, Preventive Medicine Boston University School of Medicine, Boston, MA
2000-2001	Chief Resident, Internal Medicine

Temple University Hospital, Philadelphia, PA

1997-2000 Resident, Internal Medicine
Temple University Hospital, Philadelphia, PA

Honors and Awards:

2018 Recipient, Penn State Hershey Medical Center Winter 2018 Inspire Award for Excellence

2017 Fellow, American College of Physicians

2017 Spring 2017 Dean's Lecturer: Contraceptive Use—Before, During, and After the Affordable Care Act. Penn State College of Medicine

2016 Penn State Hershey Leadership Academy for Excellence in Academic Medicine

2016 Patient Satisfaction Award—CG CAHPS Dean's List
Awarded for scoring in the 99th percentile for patient satisfaction nationwide.

2016 YWCA Tribute to Women of Excellence Award
The Tribute to Women of Excellence award honors women for their contributions to the workplace and community in Central Pennsylvania.
http://www.harrisburgmagazine.com/March-2016/YWCA-Greater-Harrisburgs-Class-of-2016-Women-of-Excellence/

2014 Dean's Award for Excellence in Teaching
Penn State College of Medicine

2014 Excellence in Mentoring Award
Department of Medicine, Penn State College of Medicine
This award recognizes a senior faculty member in the Department of Medicine for their work in encouraging and guiding the development of one of more junior faculty in their academic and clinical careers.

2014 Innovation in Team Science Award
Office of the Vice Dean for Research and Graduate Studies and Unified Campus Research Team, Penn State College of Medicine
This award recognizes scholarly inquiry and investigation related to education, educational processes, and dissemination and practical application of research results.

2012 Patient Satisfaction Award—CG CAHPS Dean's List
Awarded for scoring in the 99th percentile for patient satisfaction nationwide.

2010 Dean's Award for Excellence in Teaching
Penn State College of Medicine

2010 Educational Recognition Award
Department of Medicine, Penn State College of Medicine
This award honors the educational accomplishments of individual faculty within the Department based on consistent excellence in teaching

excellence in teaching.

2009	White Coat Ceremony, Keynote Speaker Penn State College of Medicine
2008	Junior Faculty Award for Excellence in Research Department of Medicine, Penn State College of Medicine
2006	Alpha Omega Alpha, Pennsylvania Eta Chapter
2005	Special Recognition for Education Leadership and Service Award Department of Medicine, Penn State College of Medicine *This award honors an individual who has contributed to the advancement of the educational mission of the Department in an exemplary manner.*
2004-2005	Junior Faculty Development Program graduate Penn State College of Medicine

Board Certification:

2000-present	American Board of Internal Medicine (recertification in 2010)
2004-2014	American Board of Preventive Medicine

Medical Licensure:

2000-present	Commonwealth of Pennsylvania (MD071211L)

Academic Appointments:

2018-present	Professor of Obstetrics and Gynecology Pennsylvania State College of Medicine, Hershey, PA
2015-present	Professor of Medicine and Public Health Sciences Pennsylvania State College of Medicine, Hershey, PA
2009-2015	Associate Professor of Medicine and Public Health Sciences Pennsylvania State College of Medicine, Hershey, PA
2004-2009	Assistant Professor of Medicine and Public Health Sciences Pennsylvania State College of Medicine, Hershey, PA
2001-2004	Clinical Fellow in Medicine Boston University School of Medicine, Boston, MA
2000-2001	Instructor of Medicine Temple University Hospital, Philadelphia, PA

Hospital Appointments:

2004-present	Medical Staff, Penn State Milton S. Hershey Medical Center, Hershey, PA
2001-2004	Medical Staff, Edith Nourse Rogers Veterans Memorial Hospital, Bedford, MA
2002-2003	Medical Staff, Boston Veterans Affairs Health System, Boston, MA
2000-2001	Medical Staff, Temple University Hospital, Philadelphia, PA

Grant Review Committees and Study Sections:

June 2016, Mar 2017, Nov 2017, Mar 2018, Nov 2018	Special Emphasis Panel, Fellowships (F31, F32): Risk, Prevention, and Health Behavior; ZRG1 F16-L (20) L

May 2017	Special Emphasis Panel, Centers for Disease Control and Prevention/National Center for Chronic Disease Prevention and Health Promotion: Understanding Provision of Confidential Sexual Health Services to Adolescents DP17-005:SIP17-005
May 2016, April 2017	Society of Family Planning Interdisciplinary Innovations Planning Grant Review Committee
January 2016	Special Emphasis Panel, Centers for Disease Control and Prevention/National Center for Chronic Disease Prevention and Health Promotion: Pregnancy Risk Assessment Monitoring System (PRAMS), Component A, RFA-DP-16-001
April 2015	Special Emphasis Panel, Centers for Disease Control and Prevention/National Center for Chronic Disease Prevention and Health Promotion: Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males DP15-007
June 2010, June 2011, March 2012	Ad hoc Reviewer, Population Science Subcommittee, Eunice Kennedy Shriver National Institute of Child Health and Human Development
March 2011	Special Emphasis Panel, Centers for Disease Control and Prevention/National Center for Chronic Disease Prevention and Health Promotion: Pregnancy Risk Assessment Monitoring System (PRAMS)
January 2009	Special Emphasis Panel, Centers for Disease Control and Prevention/National Center for Chronic Disease Prevention and Health Promotion Health Promotion and Disease Prevention Research Centers (PRCs)
2007	Special Emphasis Panel, Centers for Disease Control and Prevention/Office of Public Health Research: Improving Public Health Practice through Translation Research
2005	Special Emphasis Panel, Centers for Disease Control and Prevention/National Center for Chronic Disease Prevention and Health Promotion: Reproductive Health Research

Leadership Positions:

2018-present	Chair, Education Council, Department of Medicine
2016-present	Chief, Division of General Internal Medicine, Penn State College of Medicine
2015-present	Faculty Advisor, Penn State College of Medicine Medical Student for Choice (MSFC) Chapter
2012-present	Research Director, Penn State University Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program
2014-2017	Co-lead, Community Engagement and Research Core, Penn State Clinical and Translational Science Institute
2009-2015	Associate Director of Research, Division of General Internal Medicine, Penn State College of Medicine
2015	Meeting Co-Chair, 2nd Annual Penn State Women's Health Research Day, Penn State College of Medicine, Hershey, PA on April 28, 2015
2015	Meeting Co-Chair, Society of General Internal Medicine, Mid-Atlantic Regional Meeting. Held at the Hershey Lodge and Convention Center, Hershey, PA on March 13, 2015

2014-2015	PCORnet Patient & Consumer Engagement Task Force
2014	Co-Leader, Society of Family Planning Patient-Centered Research Priority Setting
2014	Meeting Chair, Inaugural Penn State Women's Health Research Day, Penn State College of Medicine, Hershey, PA on April 8, 2015
2004-2014	Faculty Advisor, Resident Research Forum Internal Medicine Residency Program, Penn State College of Medicine
2005-2013	Key Clinical Faculty, Internal Medicine Residency Program Penn State College of Medicine
2009-2010	Treasurer/Secretary, Society of General Internal Medicine, Mid-Atlantic Region
2008-2009	Membership Coordinator and Treasurer/Secretary Elect, Society of General Internal Medicine, Mid-Atlantic Region
2006	Meeting Chair, Society of General Internal Medicine, Mid-Atlantic Regional Meeting. Held at Penn State College of Medicine on March 10, 2006

Committee Service:

Penn State College of Medicine/Hershey Medical Center:

2018-present	Department of Medicine Education Council (Chair), Penn State College of Medicine
2018-present	Department of Medicine Executive Committee
2017-present	Support for Education Task Force, Penn State College of Medicine
2017-present	Population Health (PHX) Steering Committee, Penn State Health
2016-present	Department of Medicine Promotion and Tenure Committee
2018	Internal Medicine Residency Program Director Search Committee
2018	Search Committee Member: Associate Dean for Faculty and Professional Development
2017-2018	Funds Flow Advisory Committee, Penn State College of Medicine
2014-2017	Penn State Scientific Review Committee: • CTSI KL2 Scholar Applications 2017 • Small Grants for Qualitative Research Applications 2014, 2015 • CTSI Bridges to Translation 2015 • CTSI Novel Methodologies 2014
2016	Search Committee Member: Associate Dean for Faculty and Professional Development
2016	Internal Review Committee, Department of Medicine
2016	Penn State Hershey Physician Wellness Committee
2015	ACP East Region Abstract Competition Review Committee
2014	Search Committee Member: Associate Dean for Research Innovation
2014	Search Committee Member: Chair, Department of Psychiatry
2011-2012	Outpatient Quality Project: Improving Osteoporosis Screening in Ambulatory Care
2007-present	Division of General Internal Medicine Executive Committee
2005-2014	Internal Medicine Residency Selection Committee

2005-2014	Internal Medicine Residency Competency Committee
2005-2011	Medical Student Research Committee
2005-2010	Medical Student Candidate Interviewer
2010	Centers for Disease Control and Prevention Preconception Health & Health Care Initiative, Clinical Workgroup
2010	Search Committee Member: Associate Dean for Continuing Medical Education
2008-2010	Search Committee Member: Clinical Ethicist, Department of Humanities
2008-2009	Search Committee Chair, Behavioral Scientist, Div. of General Internal Medicine
2005-2006	Physician Satisfaction Task Force
2005-2006	Search Committee: Division Chief, General Internal Medicine
2005-2006	Planning Committee for Penn State College of Medicine's 8th Annual Women's Health: Ages & Stages Conference, April 2006
2005-2006	Task Force for Physician, Patient, and Society Course
2005	PACE (Patient Access & Care Efficiency) Processes of Care Committee

Fellowship:

2003-2004	Family Planning External Working Group Family Planning Program, Massachusetts Department of Public Health
2003-2004	Steering Committee, Massachusetts Emergency Contraception Network Massachusetts Department of Public Health
2001-2004	Chair, Subcommittee on Provider Education Massachusetts Emergency Contraception Network Massachusetts Department of Public Health

Residency/Chief Residency:

1999-2001	Internal Medicine Resident Admissions Committee Temple University Hospital, Philadelphia, PA
2000-2001	Internal Medicine Resident Review Committee Temple University Hospital, Philadelphia, PA

Medical School:

1996-1997	Regional coordinator for NY/NJ, Medical Students for Choice
2001-2004	Class representative, Student Council, NYU School of Medicine, New York, NY
2002-2003	Co-founder and co-president of Medical Students for Choice, NYU Chapter
2000-2001	Co-president of American Medical Women's Association, NYU student chapter
1994-1995	Secretary, Asian Students Union, NYU Chapter

Professional Societies:

2016-present	Association of Chiefs and Leaders in General Internal Medicine (ACLGIM)
2001-present	American College of Physicians (Fellow since 2017)
2001-present	Society of General Internal Medicine
2004-2007	American College of Preventive Medicine
2001-2004	Massachusetts Medical Society

Editorial Board

2009-2018	Women's Health Issues, Editorial Board

Ad-hoc Journal Peer Review

2004-present	Women's Health Issues (Editorial Board member since 2009)
2004-present	Journal of General Internal Medicine
2018	JAMA
2016	American Journal of Preventive Medicine
2015	Archives of Women's Mental Health
2014	BMC Pregnancy and Childbirth
2014	BMC Medical Informatics and Decision Making
2009-2013	Maternal and Child Health Journal
2013	Annals of Epidemiology
2012	Paediatric and Perinatal Epidemiology
2011, 2012	Diabetes Care
2012	Preventive Medicine
2010	Journal of Hospital Medicine
2010	Women and Health
2008	American Journal of Obstetrics and Gynecology
2008	Obstetrics and Gynecology
2008	Contraception
2007	Perspectives on Sexual and Reproductive Health
2005	Violence Against Women
2005	Journal of Pediatric and Adolescent Gynecology
2004	AIDS and Behavior
2004	Journal of American Medical Women's Association
2001	Annals of Internal Medicine

Teaching Activities:

Penn State Hershey Medical Center:

Fall 2017, 2018	Lecturer: Contraceptive Use Before, During, and After the Affordable Care Act PHS 531 Public Health Perspectives on Women's Health (Course Director: Jennifer McCall-Hosenfeld, MD, MSc)
Fall 2016, 2017	Lecturer: Intervention Studies in Health Services Research PHS 530: Introduction to Health Services Research (Course Co-Directors: Carol Weisman, PhD and Sara Baker, MSW, MPH)
2015, 2016, 2017, 2018	Co-Lecturer: Clinical Informatics and Big Data (with Tom Abendroth, MD) MS1 Course: Science of Health Systems (Course Director: Jed Gonzalo, MD, MS)
2011-2012, 2015-2016	Mentor, Junior Faculty Development Program The Junior Faculty Development Program provides a foundation for the success of junior faculty in the Penn State College of Medicine/Hershey Medical Center
Fall 2005-2013	Instructor: Clinical Breast Examination Internal Medicine Intern Course: Basic Clinical Skills
Fall 2012, 2013, 2014, 2015, 2016	Lecturer: Health Services Research MPH Course: PHS 519 Introduction to Patient-Oriented Research (Course Director: Tom Lloyd, PhD)

Spring 2014, Spring 2017	Recurring Seminar: Contraception Internal Medicine Residency Ambulatory Academic Half Day (Course Director: Andreas Achilleos, MD)
2004-2014	Preceptor, Internal Medicine Residents' Clinic (1-3 sessions/week) University Physicians Group, Penn State Hershey Medical Center
2005-2013	Facilitator, Problem Based Learning Endocrinology (ENDO 731 PBL), 2nd year medical students (Spring 2005, Spring 2009) Gastroenterology Section, 2nd year medical students (Nov-Dec 2005) Renal Section, 2nd year medical students (October 2007) CMBMP 712 PBL, 1st year medical students (January 2008, January 2013) Reproductive Medicine (REP 730 PBL), 2nd year medical students (Spring 2010) Evidence-Based Medicine (EBM I 713 PBL), 1st year medical students (February 2008, August 2012, Spring 2013) Evidence-Based Medicine (EBM II 723 PBL), 2nd year medical students (Fall 2010, Fall 2011, Fall 2012, Fall 2013)
Fall 2011, 2012	Lecture: Health in Rural America. MPH Course: PHS 571 Introduction to U.S. Health Services Organization and Delivery (Course Director: Wenke Hwang, PhD)
Fall 2010-2012	Lecture: Female Breast & Pelvic Examination Foundations of Clinical Medicine (FCM II 723) Course Director: Peter Lewis, MD
2004-2006	In-Patient Ward/Teaching Attending, 6 months Penn State Hershey Medical Center
Fellowship:	
2002-2004	Instructor, Integrative Problems, 2nd year medical students Boston University School of Medicine, Boston, MA
2002-2003	Preceptor, Internal Medicine Residents' Clinic Women's Health Clinic, Department of Veterans Affairs, Jamaica Plain, MA
2001-2002	Instructor, Introduction to Clinical Medicine Physical Examination Skills, 2nd year medical students Boston University School of Medicine, Boston, MA
Chief Residency:	
2000-2001	In-Patient Ward/Teaching Attending, 6 months Preceptor, Internal Medicine Residents' Clinic Temple University School of Medicine, Philadelphia, PA
2000	Instructor, Fundamentals of Clinical Care 201 History Taking, 2nd year medical students Temple University School of Medicine, Philadelphia, PA
2001	Instructor, Fundamentals of Clinical Care 202 Physical Examination Skills, 2nd year medical students Temple University School of Medicine, Philadelphia, PA
2000-2001	Instructor, Introduction to Clinical Medicine History Taking and Physical Examination Skills Temple University School of Podiatry, Philadelphia, PA

Clinical Activities:

Penn State Hershey Medical Center:

2010-present Primary Care Physician (1 session/week)

2004-2014 Preceptor, Internal Medicine Residents' Clinic (1-3 sessions/week)

2004-2006
2016 In-Patient Ward/Teaching Attending
- 2004-2006: six months per year
- 2016: 3 weeks per year

Fellowship:

2001-2004 Primary Care Clinician (1 session/week)
Ambulatory Care Clinic, Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA

2001-2004 Clinical Fellow (1 session/week)
Women's Health Group, Boston Medical Center, Boston, MA

Chief Residency:

2000-2001 In-patient Ward/Teaching Attending, 6 months
Temple University Hospital, Philadelphia, PA

Research Advisor/Mentorship Experience

Name Position and dates during mentorship	**Project/Product**	**Current Position**
Laura Shank, MD Medical student, PSCOM '05 2004-2006	Availability of emergency contraception at rural and urban pharmacies in Pennsylvania. *Contraception* 2006; 73(4): 382-385. --Selected as top medical student research project for presentation at 2005 Penn State College of Medicine Medical Student Research Symposium	Pediatrician, Wellspan Medical Group, York, PA
Jed Gonzalo, MD, MS Medical student, PSCOM '06 2004-present	Attending rounds and bedside case presentations: Medical student and medicine resident experiences and attitudes. *Teaching and Learning in Medicine* 2009;21(2):105-110	Associate Professor of Medicine and Public Health Sciences, Associate Dean for Health Systems Education, Penn State College of Medicine
Saima Zubair, MD Medical student, PSCOM '07 2005-2006	Determinants of reproductive counseling among women with chronic medical conditions. Best scientist abstract by a trainee award at 2006 Mid-Atlantic SGIM	Emergency Medicine physician, Methodist Hospital of Southern California
Gregory Pinkowsky, MD Medical student, PSCOM '08 2006-2010	Medicine versus Orthopaedic service for hospital management of hip fractures. *Clinical Orthopaedics and Related Research* 2010, 468(8): 2218-2223.	Orthopedic surgeon, Summit Medical Group, West Orange, NJ
Melissa (Goldstein) Accordino, MD, MS Medical student, PSCOM '09 2007-2010	Does medical student knowledge of anticoagulation differ by future intended practice? *Medical Teacher* 2010, 32(10): 857-859.	Assistant Professor of Medicine (hematology/oncology), Columbia University
Amanda Cattoi, MD Medical Student, PSCOM '11 2009-2012	Longitudinal association of intimate partner violence and depressive symptoms. *Mental Health in Family Medicine* 2012, 9(2): 107-114. Winner of the 2009 ACP Medical Student Abstract Competition	Family medicine physician, Altoona, PA

Kolapo Dasilva, MD Medical student, PSCOM '10 2008-2010	Effect of standardized electronic discharge instructions on post-discharge hospital utilization. *JGIM* 2011; 26(7): 718-723.	Emergency medicine physician, Charlottesville, VA
Hillary Darville Penn State undergraduate student (Biobehavioral Health) '11 Undergraduate thesis advisor 2010-2011	Honors Thesis: The right to emergency contraception: The reality behind knowledge, attitudes, and practices amongst college students in central Pennsylvania.	Product Development Associate, B Lab, Philadelphia, PA
Lara (Rosenwasser) Newman, MD Medical student, PSCOM '13 2009-2013	Barriers to colorectal cancer screening among women in rural Central Pennsylvania: primary care providers' perspective. *Rural and Remote Health* 2013, 13:2504.	Ophthalmologist, Hershey, PA
Michael Stengel Medical student, PSCOM '14 2010-2014	"What My Doctor Didn't Tell Me": Examining Health Care Provider Advice to Overweight and Obese Pregnant Women on Gestational Weight Gain and Physical Activity. *Women's Health Issues* 2012, 22(6): e535-e540. --Selected as top medical student research project for presentation at 2014 Penn State College of Medicine Medical Student Research Symposium	Emergency Medicine physician, WellSpan Health, Lancaster, PA
John Showalter, MD, MSIS Internal Medicine/Medical Informatics resident '11 2008-2011	Effect of standardized electronic discharge instructions on post-discharge hospital utilization. *JGIM* 2011; 26(7): 718-723.	Chief Medical Information Officer and Assistant Professor of Medicine, University of Mississippi Medical Center
Shahed Abbasi, MD Internal Medicine resident '15 2011-2012	Unintended pregnancy and postpartum depression among first time mothers. *Journal of Women's Health* 2013, 22: 412-416.	Internal Medicine physician, Rutgers New Jersey Medical School Faculty Practice, Newark, NJ
Michael MaCauley, MD Internal Medicine resident '12 2010-2012	The effect of a provider-enhanced clinical decision support tool for guiding venous thromboembolism pharmacoprophylaxis in 'low-risk' patients. *Hospital Practice* 2012, 40(3): 7-12.	Staff Physician, Lebanon VA, Lebanon, PA
Melissa Martenis, DO Internal Medicine resident '10 2008-2012	Contraception and abortion coverage: What do primary care physicians think? *Contraception* 2012; 86: 153-156.	Internal Medicine physician, Lancaster General Health, Lancaster, PA
Daphne Hernandez, PhD Assistant Professor of Human Development and Family Studies Penn State K12 BIRCWH Scholar 2010-2012	BIRCWH topic: Maternal health and healthy pregnancy behaviors, public assistance programs, and weight status in adult women	Associate Professor of Health and Human Performance, University of Houston
Jennifer Kraschnewski, MD, MPH Assistant Professor of Medicine Penn State KL2 CTSI Scholar 2012-2014	Kraschnewski J, Chuang CH, Poole ES, Peyton T, Blubaugh I, Pauli J, Feher A, Reddy M. Paging "Dr. Google": Does technology fill the gap created by the prenatal care visit structure? Journal of Medical Internet Research, 2014, 16(6):e147. Kraschnewski JL, Chuang CH, Downs DS, Weisman CS, McCamant EL, Baptiste-Roberts K, Zhu J, Kjerulff K. Association of prenatal physical activity and gestational weight gain: Results from the First Baby Study, Women's Health Issues, 2013, 23-4, 233-e238.	Associate Professor of Medicine and Public Health Sciences; Executive Director of Penn State PRO Wellness, Penn State College of Medicine, Hershey, PA
Esther Bowie, MD Assistant Professor of Ophthalmology Junior Faculty Development Program Mentee 2011-2012	Hereditary hemochromatosis (HFE) polymorphisms as risk factors for age-related macular degeneration • Funded award: 2011 Frontiers in Eye and Vision Research Award	Associate Professor of Ophthalmology
Jennifer Parkes Tinloy, MD Internal Medicine resident '13 2010-2013	Exercise during pregnancy and risk of late preterm birth, cesarean delivery, and hospitalizations. *Women's Health Issues* 2013.	Hospitalist, Kaiser Permanente, San Leandro, CA
Aminat Oluyemi, MD Gastroenterology fellow '13	Oluyemi AO, Welch AR, Yoo LJ, Lehman EB, McGarrity TJ, Chuang CH. Colorectal cancer screening in high-	Gastroenterologist, Carroll Health Group, Westminster,

2011-2013	risk groups in increasing, although current smokers fall behind. Cancer, 2014, 120(4): 2106-2113.	MD
Lisa Yoo, DO Internal Medicine resident '14 2011-2015	Yoo L, Oluyemi A, Welch A, Chuang C, Dye C, Moyer M, Ouyang A, Matthew A. Risk Factors for Aspiration Pneumonia in Ambulatory Endoscopy Patients. In AMERICAN JOURNAL OF GASTROENTEROLOGY, vol. 108, pp. S572-S572. --Winner of 2015 ACG Presidential Poster Award	Gastroenterologist, Lancaster General Health, Lancaster, PA
Poonam Mathur, DO, MPH Internal Medicine resident '14 2012-2015	Does doxycycline reduce the risk of Clostridium difficile infection in patients with cellulitis? • Top oral presentation at the Penn State College of Medicine Resident Research Day, May 2013 • Poster presentation at the Society of Medical Decision Making Meeting 2013	Assistant Professor of Medicine (Infectious Disease), University of Maryland, Baltimore, MD
Joslyn S. Kirby, MD Assistant Professor of Dermatology 2014-present	Co-Mentor AHRQ K08: Collaborative care clinics for hydradenitis supprativa management	Associate Professor of Dermatology, Penn State College of Medicine
Lauren J. Van Scoy, MD Assistant Professor of Medicine 2014-present	Co-Mentor, Parker B. Francis Fellow in Pulmonary Research Career Development Award Van Scoy LJ, Green MJ, Reading JM, Scott AM, Chuang CH, Levi BH. Can playing an end-of-life conversation game motivate people to engage in advance care planning? American Journal of Hospice & Palliative Medicine; 2016, DOI: 10.1177/1049909116656353. Van Scoy LJ, Reading J, Scott A, Green M, Chuang CH, Levi B. Exploring the topics discussed during a conversation card game about death and dying: a content analysis. Journal of Pain and Symptom Management 2016, DOI: 10.1016/j.jpainsymman.2016.03.021.	same
Lisa Callegari, MD, MPH Assistant Professor of Obstetrics and Gynecology, University of Washington	Steering Committee Member and Co-Mentor, VA Career Development Program	same
Timothy Deimling, MD Assistant Professor of Obstetrics and Gynecology Junior Faculty Development Program Mentee 2015-2016	Mentor, Penn State Hershey Junior Faculty Development Program Primary mentor for K23 award (pending)	same
Anne Dimmock, MPH Candidate	Thesis advisor: Development of a computable phenotype for idiopathic pulmonary fibrosis	Research Associate, Penn State College of Medicine
Ashley Snyder, MD, MS Fellow, General Internal Medicine 2015-2017	Snyder AH, Weisman CS, Liu G, Leslie D, Chuang CH. The impact of the Affordable Care Act on contraceptive use and costs among privately insured women. Contraception, 2017 – in press. Snyder AH, Zhang C, Liu G, Chuang CH, Sobota M. Internists underperform in provision of first line contraception. Oral presentation at the 2017 Society of General Internal Medicine Annual Meeting in Washington, DC	Assistant Professor of Medicine, Penn State College of Medicine
Julianne Lauring, MD Fellow, Maternal and Fetal Medicine 2015-2016	Lauring JR, Lehman EB, Deimling TA, Legro RS, Chuang CH. Combined hormonal contraception use in reproductive age women with contraindications to estrogen use. American Journal of Obstetrics and Gynecology, 2016.	Assistant Professor of Obstetrics and Gynecology, University of Massachusetts Medical School

Hallie Nelson Medical Student, PSCOM '19 2015-2019	Nelson HN, Borrero S, Lehman E, Velott DL, Chuang CH. Measuring oral contraceptive adherence using self-report versus pharmacy claims data. Contraception 2017.	same
Odessa Hamidi, MD Resident, Obstetrics & Gynecology 2016-2018	Hamidi O, Deimling T, Lehman E, Chuang CH. High self-efficacy is associated with prescription contraceptive use. Women's Health Issues 2018.	same
Joseph Needleman Medical Student, PSCOM '19 2016-2019	How do medical student attitudes about abortion differ by state?	same
Celeste Bailey, Laura Leuenberger, Elizabeth Thayer--PSCOM '18	Coverage Awareness and Contraceptive Choice: Factors Associated with New LARC Use in Privately Insured Women. Under review.	same
Dara Babinski, PhD Assistant Professor of Psychiatry BIRCWH Scholar 2015-2018	Contraceptive behavior among adult women with ADHD symptoms	same
Jennifer Jacobs, MD Resident, Internal Medicine 2017-present	Depression and contraceptive use	same

Research Support (on-going):

1 UL1 TR002014-01 (Sinoway) 09/01/2016-05/31/2021
NIH/NCATS
The Penn State Clinical and Translational Science Institute
In 2007 the Penn State CTSI was established. Over the past decade the Institute has developed into an active and visible entity within our University and the institutional home for clinical and translational research.
Role: Co-Investigator/Community Engagement Research Core

CDA 14-412 (Callegari) 08/01/2015-07/31/2020
VA Health Services Research & Development Career Development Program
Reproductive Planning for Women Veterans
Role: Steering Committee Member and Co-Mentor

CDRN-1306-04912 (McTigue, Hess) Phase 1: 03/15/2014-09/14/2015
Patient Centered Outcomes Research Institute (PCORI) Phase 2: 09/14/2015-03/12/2019
A PaTH Towards a Learning Health System in the Mid-Atlantic Region
The PCORI Clinical Data Research Networks (CDRNs) will develop the capacity to conduct randomized comparative effectiveness studies using data from clinical practice in a large, defined population. The PaTH network includes University of Pittsburgh Medical Center, Penn State College of Medicine, Temple University Hospital, and the Johns Hopkins University Health System. The University of Utah Health System and Geisinger Health System were newly added to the PaTH CDRN in Phase 2.
Role: Penn State Site Principal Investigator

Research Support (completed):

CD-1304-6117 (Chuang) 10/01/2013-08/31/2018
Patient Centered Outcomes Research Institute (PCORI)
Reducing Unintended Pregnancies through Reproductive Life Planning and Contraceptive Action Planning

The objective of this randomized controlled trial is to determine whether reproductive life planning, with or without contraceptive action planning, can help women formulate and achieve their reproductive goals compared with an information-only control group.
Role: Principal Investigator

2 K12 HD055882 (Weisman) 09/01/2012-07/31/2017 (NCE until 08/31/2018)
NIH/NICHD
Career Development Program in Women's Health Research at Penn State
The purpose of the Penn State BIRCWH program is to provide mentored research career development for junior faculty members, known as BIRCWH Scholars, who are conducting interdisciplinary research in women's health or on sex/gender differences in health.
Role: Co-Investigator/Research Director

No Number Assigned (Van Scoy) 07/01/2015-06/30/2018
Parker B. Francis Fellowship
Evaluating the impact of a conversation game on advance care planning activities
Role: Co-Mentor

0049450 (711300-3) (McTique) 4/1/2016-9/30/2017
PCORI
PCORnet Bariatric Study
The main goal of this PCORnet observational research study is to provide accurate estimates of the 1, 3, and 5 year benefits and risks of the three main surgical treatment options for severe obesity – Roux-en-y gastric bypass (RYGB), adjustable gastric banding (AGB), and vertical sleeve gastrectomy (VSG) – with a focus on the outcomes that have been shown to be most important to adults and adolescents with severe obesity – weight loss, improvement in diabetes, and risk of adverse events.
Role: Penn State Site Principal Investigator

No Grant # (Chuang) 6/1/2016 – 06/30/2017
PSU Pathway to Partnerships (P3) Stage 2
Neighborhood Effects on Health in Pennsylvania (2 projects)
We propose 2 Projects using the integrated EHR-contextual data source to better understand the influence of community and environmental factors on health: Project 1) Obesity and its Role in the Asthma Epidemic (Project Lead: Jennifer Kraschnewski, MD, MPH); and 2) Rural versus Urban Differences in Prevalence and Predictors of High-Risk Opioid Prescribing for Young Adult Patients (Project Lead: Shannon Monnat, PhD).
Role: Principal Investigator

1 U54 RR026071-01A2 (Sinoway) 6/1/2011-2/29/2016
NIH
The Penn State Clinical and Translational Science Institute
The goal of the Penn State CTSI is an engaged and responsive health science research and education enterprise that delivers on the promise of improved health.
Role: Community Engagement and Research Core Co-Leader

No Number Assigned (Chuang/Yapa) 05/26/2015-11/1/2015
Penn State College of Medicine Pathway to Partnership Stage One
Micro-geography of food and fitness for management and prevention of Type II diabetes
Role: Co-Principal Investigator $5,000

No Number Assigned (Chuang/Chi) 05/26/2015-11/1/2015

Penn State College of Medicine Pathway to Partnership Stage One
Population Health Research in the Era of Big Data
Role: Co-Principal Investigator $5,000

No Number Assigned (Chuang) 01/01/2013-12/31/2013; NCE until 08/31/2014
Penn State Clinical and Translational Science Institute/Community Engagement Research Core
Development of a Smartphone Intervention to Prevent Excessive Gestational Weight Gain
The purpose of this community-engaged project is to conduct focus groups with pregnant women in order to develop a smartphone intervention to prevent excessive gestational weight gain.
Role: Principal Investigator

No Number Assigned (Chuang & Weisman) 12/1/2009-11/30/2012
Rural Women's Health Care Project
Penn State Clinical and Translational Science Institute (CTSI) Pilot Project Grant
This project will involve semi-structured interviews with rural health providers in Central Pennsylvania to study barriers to preventive women's health care, as well as establish the Rural Women's Health Care Network.
Role: Co-Principal Investigator

5 K23 HD51634 (Chuang) 9/1/06-8/31/11
NIH/NICHD No Cost Extension until 8/31/12
Unintended Pregnancy in Women with Chronic Medical Conditions
This 5-year Mentored Patient-Oriented Career Development Award involves study of pregnancy intention, contraceptive use, and unintended pregnancy among women with the chronic conditions of diabetes, hypertension, and obesity using population-based samples and a focus-group study.
Role: Principal Investigator

No Number Assigned (Chuang & Kraschnewski) 07/1/11-06/30/12
Investigating Gestational Weight Gain
Association of Faculty and Friends
This qualitative study investigates the beliefs, attitudes, and habits of women who gained appropriate and excess weight during pregnancy.
Role: Co-Principal Investigator

Dean's Feasibility Grant (Chuang) 7/1/05-6/30/06
Penn State College of Medicine
Family Planning Behavior in Women with Chronic Medical Conditions
This 1-year project allows secondary database analysis of the 2004 Behavioral Risk Factor Surveillance System to examine childbearing intentions and contraceptive use in women with chronic medical conditions.
Role: Principal Investigator

No Number Assigned (Weisman) 6/1/04-5/31/08
Pennsylvania Department of Health
Central Pennsylvania Center of Excellence for Research on Pregnancy Outcomes
This 4-year project establishes a multi-institutional center of excellence in Central Pennsylvania to reduce disparities in adverse pregnancy outcomes through observational research and intervention research on women's preconceptional health. The project has a special emphasis on rural areas.
Role: Co-Investigator

Publications/Presentations:

Peer-Reviewed Publications:

1. Hamidi OP, Deimling T, Lehman E, Weisman C, Chuang C. High self-efficacy is associated with prescription contraceptive use. *Women's Health Issues*, 2018. https://doi.org/10.1016/j.whi.2018.04.006.

2. Snyder A, Weisman CS, Liu G, Leslie D, Chuang CH. The impact of the Affordable Care Act on contraceptive use and costs among privately insured women. *Women's Health Issues* 2018, 28(3): 219-223.

3. Toh S, Rasmussen-Torvik LJ, Harmata EE, Pardee R, Saizan R, Malanga E, Sturtevant JL, Horgan CE, Anau J, Janning CD, Wellman RD, Coley RY, Cook AJ, Courcoulas AP, Coleman KJ, Williams NA, McTigue KM, Arterburn D, and McClay J for the PCORnet Bariatric Study Collaborative. The National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study Cohort: Rationale, Methods, and Baseline Characteristics. JMIR Res Protoc 2017;6(12):e222. PMID: 29208590

4. McTigue KM, Hartelius EJ, Anderson TS, Allsup AP, Alston T, Chuang CH, Dillon S, Ford DE, Gunturi N, Hess R, Kirchner HL, Larson SL, Leon-Jhong AB, McCoy DR, Paranjape A, Uhrig JR, Waheed AA, Mitchell GR. Using a deliberative forum for engaging health system and health plan leaders to prioritize research topics. *European Journal for Person Centered Healthcare* 2018;6(2).

5. Nelson HN, Borrero S, Lehman E, Velott DL, Chuang CH. Measuring oral contraceptive adherence using self-report versus pharmacy claims data. *Contraception* 2017, 96: 453-459.

6. Scanlon DP, Wolf LJ, Chuang CH, Kraschnewski J, Lengerich EJ, McHale SM, Paul IM, Penrod J. A model for academic institution support for community-engaged research. *Journal of Clinical and Translational Science* 2017, doi:10.1017/cts.2017.295.

7. Van Scoy LJ, Scott AM, Reading J, Chuang CH, Chinchilli VM, Levi BL, Green MJ. From Theory to Practice: measuring end-of-life communication quality using multiple goals theory. *Patient Education and Counseling* 2017;100(5):909-918.

8. Schieffer KM, Chuang CH, Connor J, Pawelcyzk JA, Sekhar DL. Association of iron deficiency anemia with hearing loss in US adults. *JAMA Otolaryngology-Head & Neck Surgery* 2017, 143(4): 350-354. doi:10.1001/jamaoto.2016.3631. http://health.usnews.com/health-care/articles/2016-12-29/could-anemia-cause-hearing-loss

9. Sekhar DL, Kunselman AR, Chuang CH, Paul IM. Optimizing hemoglobin thresholds for detection of iron deficiency among reproductive age women in the United States. *Translational Research* 2017; 180:68-76.

10. Bhuva K, Kraschnewski JS, Lehman E, Chuang CH. Does body mass index or weight perception affect contraceptive use? *Contraception* 2017;95(1):59-64.

11. Van Scoy LJ, Green MJ, Reading JM, Scott AM, Chuang CH, Levi BH. Can playing an end-of-life conversation game motivate people to engage in advance care planning? *American Journal of Hospice & Palliative Medicine*; 2016, DOI: 10.1177/1049909116656353.

12. Van Scoy LJ, Reading J, Scott A, Green M, Chuang CH, Levi B. Exploring the topics discussed during a conversation card game about death and dying: a content analysis. *Journal of Pain and Symptom Management* 2016, DOI: 10.1016/j.jpainsymman.2016.03.021.

13. Phelan AL, Kunselman AR, Chuang CH, Raja-Khan NT, Legro RS. Exclusion of women of childbearing potential in clinical trials of type 2 diabetes medications: A review of protocol-based barriers to enrollment. *Diabetes Care* 2016 (April), dc152723.

14. Crites JS, Chuang C, Dimmock A, Hwang W, Johannes B, Paranjape A, Wu A. PROs in the Balance: Ethical Implications of Collecting Patient Reported Outcome Measures in the Electronic Health Record. *The American Journal of Bioethics*, Mar 11 2016 (online) Apr 1 2016 (print), in press.

15. Lauring JR, Lehman EB, Deimling TA, Legro RS, Chuang CH. Combined hormonal contraception use in reproductive age women with contraindications to estrogen use. *American Journal of Obstetrics and Gynecology*, 2016 Sep 1;215(3):330-e1.

16. Chuang CH, Mitchell JL, Velott DL, Legro RS, Lehman EB, Confer LN, Weisman CS. Women's awareness of their contraceptive benefits after the Patient Protection and Affordable Care Act. *American Journal of Public Health*, 2015 (November), 105:S713-S715. doi:10.2105/AJPH.2015.302829.

17. Chuang CH, Velott DL, Weisman CS, Sciamanna CN, Legro RS, Chinchilli VM, Moos M-K, Francis EB, Confer LN, Lehman EB, Armitage CJ. Reducing unintended pregnancies through web-based reproductive life planning and contraceptive action planning among privately insured women: Study protocol for the MyNewOptions randomized controlled trial. *Women's Health Issues*, 2015 (November-December), 92:501-507. http://dx.doi.org/10.1016/j.whi.2015.06.010.

18. Weisman CS, Lehman EB, Legro RS, Velott DL, Chuang CH. How do pregnancy intentions affect contraceptive choices when cost is not a factor? A study of privately-insured women. *Contraception*, 2015 (November), 92: 501-507.

19. Gonzalo JD, Kuperman EF, Chuang CH, Lehman EB, Glasser F, Abendroth T. Impact of an overnight internal medicine academic hospitalist program on patient outcomes. *Journal of General Internal Medicine*, 2015 (December), 30(12):1795-802. doi: 10.1007/s11606-015-3389-0. Epub 2015 May 20.

20. Sciamanna CN, Patel VA, Kraschnewski JL, Rovniak LS, Messina DA, Stuckey HL, Curry WJ, Chuang CH, Sherwood LL, Hess SL. A strength training program for primary care patients, central Pennsylvania, 2012. *Preventing Chronic Disease*, 2014, 11:130403.

21. Weisman CS, Chuang CH. Making the Most of the Affordable Care Act's Contraceptive Coverage Mandate for Privately-Insured Women. *Women's Health Issues*, 2014 (Sept-Oct); 24(5): 465-468.

22. Peyton T, Poole E, Reddy M, Kraschnewski J, Chuang C. "Every pregnancy is different": Designing mHealth interventions for the pregnancy ecology. Health & Community, DIS 2014, Vancouver, BC, Canada. http://dx.doi.org/10.1145/2598510.2598572

23. Kraschnewski J, Chuang CH, Poole ES, Peyton T, Blubaugh I, Pauli J, Feher A, Reddy M. Paging "Dr. Google": Does technology fill the gap created by the prenatal care visit structure? *Journal of Medical Internet Research*, 2014, 16(6):e147.

24. Kraschnewski JL, Chuang CH. "Eating for two": Excessive gestational weight gain and the need to change social norms. *Women's Health Issues*, 2014 (May-June); 24(3): e257-e259.

25. Amin W, Tsui F, Borromeo C, Chuang CH, Espino J, Ford D, Hwang W, Kapoor W, Lehmann H, Martich GD, Morton S, Paranjape A, Shirey W, Sorenson A, Becich M, Hess R and the PaTH network team. PaTH: Towards a learning health system in the Mid-Atlantic region. *Journal of the American Medical Informatics Association*, 2014, 21(4), 633-636. doi:10.1136/amiajnl-2014-002759.

26. Oluyemi AO, Welch AR, Yoo LJ, Lehman EB, McGarrity TJ, Chuang CH. Colorectal cancer screening in high-risk groups is increasing, although current smokers fall behind. *Cancer*, 2014, 120(4): 2106-2113.

27. Gonzalo JD, Wolpaw DR, Lehman E, Chuang CH. Patient-centered interprofessional collaborative care: Factors associated with bedside interprofessional rounds. *Journal of General Internal Medicine*, 2014, 29(7), 1040-1047. DOI: 10.1007/s11606-014-2817-x.

28. Chuang CH, Stengel MR, Hwang SW, Velott D, Kjerulff KH, Kraschnewski JL. Behaviors of overweight and obese women during pregnancy who achieve and exceed recommended gestational weight gain. *Obesity Research & Clinical Practice,* 2014, 1871. DOI: 10.1016/j.orcp.2013.12.254

29. Tinloy J,* Chuang CH, Zhu J, Pauli J, Kraschnewski JL, Kjerulff KH. Exercise during pregnancy and risk of late preterm birth, cesarean delivery, and hospitalizations. *Women's Health Issues*, 2014, 24(1): e99-e104. PMCID: PMC3913372.
Among Women's Health Issues' top 5 downloaded articles in 2014

30. McCall-Hosenfeld JS, Weisman CS, Perry AN, Hillemeier MM, Chuang CH. "I just keep my antennae out" - How Rural Primary Care Physicians (PCPs) Respond to Intimate Partner Violence (IPV). *Journal of Interpersonal Violence*, 2014, epub ahead of print: DOI: 10.1177/0886260513517299.

31. Colon-Gonzalez MC, McCall-Hosenfeld JS, Weisman CS, Hillemeier MM, Perry AN, Chuang CH "Someone's got to do it" – Primary care providers (PCPs) describe caring for rural women with mental health problems. *Mental Health in Family Medicine,* 2013, 10(4):191-202.

32. Maag R* and Chuang CH. Uncommon complications of heparin induced thrombocytopenia. *American Journal of Medicine*, 2013, 126(11):e5-6. .

33. Rosenwasser LA,* McCall-Hosenfeld JS, Weisman CS, Hillemeier MM, Perry AN, Chuang CH. Barriers to colorectal cancer screening among women in rural central Pennsylvania: Primary care physicians' perspective. *Rural and Remote Health*, 2013, 13: 2504. PMCID: PMC4050077.

34. Kraschnewski JL, Chuang CH, Downs DS, Weisman CS, McCamant EL, Baptiste-Roberts K, Zhu J, Kjerulff K. Association of prenatal physical activity and gestational weight gain: Results from the First Baby Study, *Women's Health Issues*, 2013, 23-4, 233-e238. PMCID: PMC3742311.

35. Abbasi S,* Chuang CH, Dagher R, Zhu J, Kjerulff K. Unintended pregnancy and postpartum depression among first time mothers. *Journal of Women's Health* 2013, 22(5): 412-416.

36. McCall-Hosenfeld JS, Chuang CH, Weisman CS. Prospective association of intimate partner violence (IPV) with receipt of clinical preventive services in women of reproductive age, *Women's Health Issues*, 2013; 23-2, e109-e116. PMCID: PMC3770472.

37. Kjerulff KH, Velott DL, Zhu J, Chuang CH, Hillemeier MM, Paul IM, Repke JT. Mode of first delivery and women's intentions for subsequent childbearing: Findings from the First Baby Study. *Paediatric and Perinatal Epidemiology* 2013, 27(1): 62-71.

38. Kraschnewski JL, Sciamanna CN, Stuckey HL, Chuang CH, Lehman EB, Hwang KO, Sherwood LL, Nembhard HB. A Silent Response to the Obesity Epidemic: Decline in U.S. Physician Weight Counseling. *Medical Care* 2013*,* 51(2):186-92. PMID: 23047128 (PMCID: In Progress)

39. Stengel MR,* Kraschnewski JL, Hwang SW, Kjerulff KH, Chuang CH. "What My Doctor Didn't Tell Me": Examining Health Care Provider Advice to Overweight and Obese Pregnant Women on Gestational Weight Gain and Physical Activity. *Women's Health Issues* 2012, 22(6): e535-e540. PMCID: PMC3490197
Most cited Women's Health Issues article on Scopus in 2014.

40. MaCauley M,* Showalter JW, Beck M, Chuang CH. The effect of a provider-enhanced clinical decision support tool for guiding venous thromboembolism pharmacoprophylaxis in 'low-risk' patients. *Hospital Practice* 2012, 40(3): 7-12. PMCID: PMC3761945.

41. Chuang CH, Cattoi AL,* McCall-Hosenfeld JS, Camacho F, Dyer AM, Weisman CS. Longitudinal association of intimate partner violence and depressive symptoms. *Mental Health in Family Medicine* 2012, 9(2): 107-114.

42. McCall-Hosenfeld JS, Weisman CS, Camacho F, Hillemeier MM, Chuang CH. Multi-Level Analysis of the Determinants of Receipt of Clinical Preventive Services Among Reproductive-Age Women, *Women's Health Issues* 2012; 22(3): e243-e251. PMCID: PMC3345071

43. Chuang CH, Martenis ME,* Parisi SM, Delano RE, Sobota M, Nothnagle M, Schwarz EB. Contraception and abortion coverage: What do primary care physicians think? *Contraception* 2012; 86: 153-156. PMCID: PMC3328663

44. Chuang CH, Hwang SW, McCall-Hosenfeld JS, Rosenwasser L, Hillemeier MM, Weisman CS. Primary care physicians' perceptions of barriers to preventive reproductive health care in rural communities. *Perspectives on Sexual and Reproductive Health* 2012; 44(2): 78-83. PMCID: PMC3706998

45. Parisi SM, Zikovich S, Chuang CH, Sobota M, Nothnagle M, Schwarz EB. Primary care physicians' perceptions of rates of unintended pregnancy. *Contraception* 2012; 86: 48-54. PMCID: PMC3708967

46. Domino SE, Bodurtha J, Nagel JD, and the BIRCWH Program Leadership. Interdisciplinary Research Career Development: Building Interdisciplinary Research Careers in Women's Health Program Best Practices. *Journal of Women's Health* 2011; 20(11): 1587-1601. PMCID: PMC3216063

47. Chuang CH, Hillemeier MM, Dyer AM, Weisman CS. The relationship between pregnancy intention and preconception health behaviors. *Preventive Medicine* 2011; 53: 85-88. PMCID: PMC3143280

48. Weisman CS, Hillemeier MM, Downs DS, Feinberg ME, Chuang CH, Botti JJ, Dyer AM. Improving women's preconceptional health: Long-term effects of the *Strong Healthy Women* behavior change intervention in the Central Pennsylvania Women's Health Study. *Women's Health Issues* 2011; 21(4): 265-271. PMCID: PMC3707004

49. Showalter JW,* Rafferty CM, Swallow NA, DaSilva KO,* Chuang CH. Effect of standardized electronic discharge instructions on post-discharge hospital utilization. *JGIM* 2011; 26(7): 718-723. PMCID: PMC3138594

50. Hillemeier MM, Weisman CS, Chuang CH, Downs DS, McCall-Hosenfeld J, Camacho F. Transition to overweight or obesity among women of reproductive age. *Journal of Women's Health* 2011; 20(5): 703-710. PMCID: PMC3096512

51. Chuang CH, Velott DL, Weisman CS. Exploring knowledge and attitudes related to pregnancy and preconception health in women with chronic medical conditions. *Maternal and Child Health Journal* 2010; 14(5): 713-719. PMCID: PMC2924436

52. Gonzalo JD,* Chuang CH, Huang G, Smith C. The return of bedside rounds: An educational intervention. *Journal of General Internal Medicine* 2010, 25(8): 782-8. PMCID: PMC2896611

53. Accordino MK,* Masters PA, Chuang CH. Does medical student knowledge of anticoagulation differ by future intended practice? *Medical Teacher* 2010, 32(10): 857-859. PMCID: PMC2946377

54. Chuang CH, Weisman CS, Hillemeier MM, Schwarz EB, Camacho FT, Dyer AM. Pregnancy Intention and Health Behaviors: Results from the Central Pennsylvania Women's Health Study (CePAWHS) Cohort. *Maternal and Child Health Journal* 2010; 14(4): 501-510. PMCID: PMC2896424

55. Weisman CS, Chuang CH, Scholle SH. Still piecing it together: Women's primary care. *Women's Health Issues* 2010 (July-August), 20(4):228-30.

56. Chuang CH, Pinkowsky GJ, Hollenbeak CS, Armstrong AD. Medicine versus Orthopaedic service for hospital management of hip fractures. *Clinical Orthopaedics and Related Research* 2010, 468(8): 2218-2223. PMCID: PMC2895834

57. Weisman CS, Hillemeier MM, Downs DS, Chuang CH, Dyer AM. Preconception predictors of weight gain during pregnancy: Prospective findings from the Central Pennsylvania Women's Health Study (CePAWHS). *Women's Health Issues* 2010;20:126-132. PMCID: PMC2908005

58. Weisman CS, Misra DP, Hillemeier MM, Downs DS, Chuang CH, Camacho FT, Dyer, AM. Preconception Predictors of Birth Outcomes: Prospective Findings from the Central Pennsylvania Women's Health Study. *Maternal and Child Health Journal* 2009; 15(7): 829-835. PMCID: PMC2939188

59. Chuang CH, Weisman CS, Hillemeier MM, Camacho FT, Dyer AM. Predicting pregnancy from pregnancy intentions: Prospective findings from the Central Pennsylvania Women's Health Study (CePAWHS). *Women's Health Issues* 2009;19:159-166. PMCID: PMC2758401

60. Gonzalo JD,* Masters PA, Simons RJ, Chuang CH. Attending rounds and bedside case presentations: Medical student and medicine resident experiences and attitudes. *Teaching and Learning in Medicine* 2009;21(2):105-110. PMCID: PMC2696474

61. Downs DS, Feinberg M, Hillemeier MM, Weisman CS, Chase GA, Chuang CH, Stauffer FL, Parrott R. Design of the Central Pennsylvania Women's Health Study (CePAWHS) Strong Healthy Women Intervention: Improving Preconceptional Health. *Maternal and Child Health Journal* 2009; 13(1):18-28. PMCID: PMC2696480

62. Hillemeier MM, Downs DS, Feinberg ME, Weisman CS, Chuang CH, Parrott R, Velott D, Francis LA, Baker SA, Dyer AM, Chinchilli VM. Improving Women's Preconceptional Health: Findings from a randomized trial of the Strong Healthy Woman intervention in the Central Pennsylvania Women's Health Study. *Women's Health Issues* 2008;18S:S87-S96. PMCID: PMC2744213

63. Chuang CH, Green MJ, Chase GA, Dyer AM, Ural SH, Weisman CS. Perceived risk of preterm and low birthweight birth in the Central Pennsylvania Women's Health Study. *American Journal of Obstetrics and Gynecology* 2008; 199:64.e1-64.e7. PMCID: PMC2696487

64. Weisman CS, Hillemeier MM, Chase GA, Misra DP, Chuang CH, Parrott R, Dyer AM. Women's perceived control of their birth outcomes in the Central Pennsylvania Women's Health Study (CePAWHS): Implications for the use of preconception care. *Women's Health Issues* 2008; 18(1): 17-25. PMCID: PMC2696461

65. Gee RE, Delli-Bovi LC, Chuang CH. Emergency contraception knowledge after a community education campaign. *Contraception* 2007; 76:366-371.

66. Chuang CH, Liebschutz JM, Cheng DM, Raj A, Samet JH. Substance use during sexual and physical assault in HIV-infected persons. *Violence and Victims* 2007; 22(2): 216-225.

67. Weisman CS, Hillemeier MM, Chase GA, Dyer AM, Baker SA, Feinberg M, Downs DS, Parrott RL, Cecil HK, Botti JJ, MacNeill C, Chuang CH, Yost B. Preconceptional Health: Risks of Adverse Pregnancy Outcomes by Reproductive Life Stage in the Central Pennsylvania Women's Health Study (CePAWHS). *Women's Health Issues* 2006; 16: 216-224.

68. Chuang CH and Shank L.* Availability of emergency contraception at rural and urban pharmacies in Pennsylvania. *Contraception* 2006; 73(4): 382-385.

69. Chuang CH, Liebschutz JM, Horton NJ, Samet JH. Association of violence victimization with inconsistent condom use in HIV-infected persons. *AIDS and Behavior* 2006; 10(2): 201-207.

70. Chuang CH and Freund KM. Emergency contraception: An intervention on primary care providers. *Contraception* 2005; 72(3): 182-186.

71. Chuang CH, Chase GA, Bensyl DM, Weisman CS. Contraceptive use by diabetic and obese women. *Women's Health Issues* 2005; 15(4): 167-173.

72. Liebschutz JM, Geier JL, Horton NJ, Chuang CH, Samet JH. Physical and sexual violence and health care utilization in HIV-infected persons with alcohol problems. *AIDS Care* 2005; 17(5): 566-578.

73. Chuang CH and Freund KM. Emergency contraception knowledge among women in a Boston community. *Contraception* 2005; 71(2): 157-160.

74. Chuang CH, Waldman LJ, Freund KM, Ash AS. Comparison of emergency contraception prescribing practices between Internal Medicine and other specialties. *Contraception* 2004; 69(1): 43-45.

75. Chuang CH and Liebschutz JM. Screening for intimate partner violence in the primary care setting: a critical review. *Journal of Clinical Outcomes Management* 2002; 9(10): 565-571.

76. Borgatta L, Murthy A, Chuang C, Beardsley L, Burnhill MS. Pregnancies diagnosed during Depo-Provera use. *Contraception* 2002; 66(3): 169-172.

Peer-Reviewed Conference Papers:

1. Peyton T*, Poole E, Reddy M, Kraschnewski J, Chuang C. (Accepted) "Every Pregnancy is different": Designing mHealth for the pregnancy ecology. In Proc. Of ACM Conf. on Designing Interactive Systems 2014 (DIS 2014). Vancouver, Canada. June 21-25, 2014.

Non-Peer-Reviewed Publications:

1. Kern LM, Chuang C, Berlin C, Ward L. Institutional champions for General Internal Medicine. *SGIM Forum* 2010, 33(10): 1, 13-14.

2. Chuang CH, Weisman CS. Pregnancy intention and health behaviors: The Central Pennsylvania Women's Health Study Cohort. IFAVA: The Scientific Newsletter. May 2010, No. 45.

Book Chapters:

1. Sherwood L* and Chuang CH. Osteoporosis. In Williams R, Kahan S, Eds., *In a Page Ambulatory Medicine*: Lippincott Williams and Wilkins, 2007.

2. Sherwood L* and Chuang CH. Hirsuitism. In Williams R, Kahan S, Eds., *In a Page Ambulatory Medicine*: Lippincott Williams and Wilkins, 2007.

3. Shah P* and Chuang CH. Cancer Screening. In Williams R, Kahan S, Eds., *In a Page Ambulatory Medicine*: Lippincott Williams and Wilkins, 2007.

4. Mohammed S* and Chuang CH. Screening and Prevention of Coronary Artery Disease. In Williams R, Kahan S, Eds., *In a Page Ambulatory Medicine*: Lippincott Williams and Wilkins, 2007.

5. Chuang CH, Emergency Contraception. In: Carr PL, Ricciotti HA, Freund KM, Kahan S, Eds. *In a Page OB/GYN and Women's Health*: Blackwell Publishing, 2004.

6. Chuang CH, Domestic Violence. In: Carr PL, Ricciotti HA, Freund KM, Kahan S, Eds. *In a Page OB/GYN and Women's Health*: Blackwell Publishing, 2004.

*Indicates trainee

Master's Thesis:

Chuang CH. Association of physical and sexual abuse with high-risk sexual behavior in HIV-infected persons with alcohol problems. May 2003

Peer-Reviewed Abstracts Presented at National Meetings (from past 5 years):

Nelson HN, Borrero S, Lehman E, Velott DL, Chuang CH. Measuring oral contraceptive adherence using self-report versus pharmacy claims data. Poster presentation by Ms. Nelson at the 2017 Annual Congress on Women's Health in Washington, DC in April 2017.

Bailey CV, Leuenberger LA, Thayer EG, Lehman EB, Chuang CH. Coverage Awareness and Contraceptive Choice: Factors Associated with New LARC Use in Privately Insured Women. Poster presentation by Ms. Bailey, Leuenberger, and Thayer at the 2017 Annual Congress on Women's Health in Washington, DC in April 2017.

Chuang CH, Weisman CS, Velott D, Lehman D, Moos MK, Sciamanna C, Legro RS, Armitage C, Chinchilli V. Main findings from the MyNewOptions Study: A randomized controlled trial of a web-based reproductive life planning intervention. Poster presented at the 2017 Society of General Internal Medicine Annual Meeting in Washington, D.C. in April 2017.

Snyder AH, Zhang C, Liu G, Chuang CH, Sobota M. Internists underperform in provision of first line contraception. Oral presentation by Dr. Snyder at the 2017 Society of General Internal Medicine Annual Meeting in Washington, DC

Hamidi O, Deimling T, Weisman C, Lehman E, Chuang CH. High self-efficacy correlates with use of long-active reversible contraceptives. ePoster presentation by Dr. Hamidi at the 2017 American Congress of Obstetrics and Gynecology (ACOG) Annual Clinical and Scientific Meeting in San Diego, CA in May 2017.

Confer K, Garber J, McCullough J, Chuang CH, McTigue K, Kraschnewski J. You've got mail: Using e-mail to recruit a representative cohort for a healthy lifestyles research study. Poster presentation by Ms. Confer at the American Public Health Association Annual Meeting in Denver, CO in November 2016.

Dimmock AEF, Danoff SK, Lindell KO, Cordova FC, Gibson KF, Lehmann H, Chuang CH, Bascom R. Impact of IPF on Executive functioning: A cross-sectional analysis. Poster presentation by Ms. Dimmock at the International Colloquium on Lung and Airway Fibrosis (ICLAF) in Dublin, Ireland in September 2016.

Dimmock AEF, Green MJ, Cordova FC, Danoff SK, Gibson KF, Lehmann H, Chuang CH, Bascom R, Lindell KO. Variable advance care planning in patients in the PaTH IPF cohort.
Poster presentation by Ms. Dimmock at the International Colloquium on Lung and Airway Fibrosis (ICLAF) in Dublin, Ireland in September 2016.

Snyder A, Weisman CS, Liu G, Leslie D, Chuang CH. Effect of the contraceptive mandate of the Affordable Care Act on insertion rates and out-of-pocket cost for the intrauterine device. Poster presentation at the Penn State Department of Medicine and Public Health Sciences Research Day in April 2016 and the 2016 Society of General Internal Medicine Annual Meeting in Hollywood, FL in April 2016.

Lauring JR, Lehman EB, Deimling TA, Legro RS, Chuang CH. Use of estrogen-containing contraception among reproductive age women with medical contraindications. Oral presentation at the 2016 Society of General Internal Medicine Annual Meeting in Hollywood, FL in April 2016.

Paranjape A, McTigue KM, Becich M, Bennett WL, Chuang CH, Clark JM, Ford DE, Herring SJ, Kraschnewski J, Sciamanna C, Hess R. Can secure electronic messaging serve as an efficient participant recruitment tool? The PaTH experience. Poster presentation by Dr. Paranjape at the 2016 Society of General Internal Medicine Annual Meeting in Hollywood, FL in April 2016.

Van Scoy LJ, Reading J, Scott AM, Chuang CH, Levi BH, Green MJ. Towards the best end-of-life conversation possible: Describing a data-driven approach to maximizing conversation quality and content during a conversation game. Submitted to the 2016 American Thoracic Society Meeting.

Dimmock AEF, Bascom R, Cordova F, Lindell KO, Gibson K, Chuang C, Danoff SK. Using a Clinical Data Research Network-Derived Idiopathic Pulmonary Fibrosis Cohort to Estimate Recruitment Bias in Clinical Pharmaceutical Trials. Submitted to the 2016 American Thoracic Society Meeting.

Dimmock AEF, Johannes BL, Danoff SK, Lindell KO, Gibson K, McCullough J, Cordova F, Dobi CD, Gauvey-Kern ME, Mahler B, Uhrig J, Carns JE, Chuang C, Bascom R. A multi-platform recruitment approach to establishing an idiopathic pulmonary fibrosis cohort for patient-centered research. Poster presentation (by Ms. Dimmock) at the 2016 American Thoracic Society Meeting in San Diego, CA, May 2016.

Ahmad TA, Liu G, Alagona P, Chuang C, Foy AJ, Bokhari SM, Leslie D. Association between statin exposure and diabetes incidence in a nationwide claims database. Oral abstract presentation (by Dr. Ahmad) at the American Heart Association Scientific Session in Orlando, FL, November 2015. Circulation 2015; 132:A16008.

Yoo L, Welch Am, McGarrity T, Mathew A, Chuang C, Liu G, Leslie D. Risk factors for aspiration pneumonia in ambulatory endoscopy patients utilizing Marketscan data. Poster presentation (by Dr. Yoo) at the American College of Gastroenterology's 80th Annual Meeting, in Honolulu, HI, October 2015. Winner of the 2015 ACG Presidential Poster Award.

Chuang CH, Mitchell J, Velott D, Sciamanna CN, Legro RS, Lehman E, Confer L, Weisman CS. Women's awareness of their contraceptive benefits after the Affordable Care Act. Oral presentation at the Society of General Internal Medicine Annual Meeting in Toronto, Canada in April 2015 and poster presentation at the Society of General Internal Medicine Mid-Atlantic Regional Meeting in Hershey, PA in March 2015 (Winner, Best Faculty Research Poster) and North American Forum on Family Planning in November 2015 in Chicago, IL.

Gonzalo JD, Kuperman EF, Chuang CH, Glasser F, Lehman EB, Abendroth T. Impact of an Overnight Internal Medicine Academic Hospitalist Program on Patient Outcomes. Poster presentation (by Dr. Gonzalo) at the Society of General Internal Medicine Annual Meeting in Toronto, Canada, April 2015.

Dimmock AEF, Chuang CH, Bhattacharjee S, Meck DS, Bascom R. Evaluation of a Computable Phenotype for Identification of Patients with Idiopathic Pulmonary Fibrosis. Am J Resp Crit Care Med 2015. Poster presentation at the 2015 American Thoracic Society (ATS) Annual Meeting in Denver, CO, May 2015.

Peyton T, Poole E, Kraschnewski J, Reddy M, Chuang CH. Information, sharing and support in pregnancy: Addressing needs for mHealth design. Poster presentation (by Ms. Peyton) at the 17th Association for Computing Machinery (ACM) Conference on Computer Supported Cooperative Work and Social Computing (CSCW 2014) conference in Baltimore, MD, February 2014.

Chuang CH, Kraschnewski J, Stengel M, Hwang S, Velott D, Kjerulff K. Behaviors of pregnant women who achieve and exceed recommended gestational weight gain. Poster presentation at the Women's Health 2013: The 21st Annual Congress in Washington, DC in March 2013 and the Society of General Internal Medicine Annual Meeting in Denver, CO, April 2013

Chuang CH, Zhu J, Kjerulff K. Pregnancy intention and ambivalence in obese and non-obese women. Poster presentation at the Women's Health 2013: The 21st Annual Congress in Washington, DC in March 2013 and the Society of General Internal Medicine Annual Meeting in Denver, CO, April 2013

Colon-Gonzalez M, McCall-Hosenfeld JS, Chuang CH, Hillemeier MM, Weisman CS. "Someone's got to do it": Primary care providers (PCPs) describe caring for rural women with mental health problems. Poster presentation (by Dr. Colon-Gonzalez) at the Society of General Internal Medicine Mid-Atlantic Regional Meeting in Philadelphia, PA, March 2013 and Society of Teachers of Family Medicine Annual Spring Conference in Baltimore, MD, May 2013

Lectures/Workshops:

December 2017	Panel Presentation: *Leaning In… Addressing Women's Leadership Growth within General Internal Medicine* 2017 Association of Chiefs and Leaders in General Internal Medicine (ACLGIM) Annual Summit, Paradise Valley, AZ
December 2017	Panel Presentation: *Exploring Critical Contributions to Access beyond Provision* Medical Students for Choice, Philadelphia, PA
May 2017	Panel Presentation: *Translational research use cases for Integrative Analyses of EHR data with behavioral, socio-demographic, environmental and other types of data* Penn State CTSI Informatics Panel, Penn State College of Medicine, Hershey, PA
May 2017	2017 Spring Dean's Lecture: *Contraceptive Use: Before, During and After the Affordable Care Act* Penn State College of Medicine, Hershey, PA
April 2017	Workshop: *How to "Do" Patient-Centered Family Planning Counseling: New Approaches to Assessing Pregnancy Intention and Conducting Contraceptive Counseling* Co-Faculty: Sonya Borrero, MD (University of Pittsburgh), Lisa Callegari, MD (University of Washington) 2017 Society of General Internal Medicine Annual Meeting, Washington, D.C.
December 2016	Panel Presentation: *Engaging Special Populations in the Research Process* Moderator Penn State CTSI Bench to Bedside and Beyond (B3) Seminar Series
December 2016	Lecture: *The MyNewOptions Study* Health Services and Behavioral Research Seminar Series Penn State College of Medicine, Hershey, PA

November 2016	Panel Presentation: *Stop, collaborate and listen: learning how to engage patients in reproductive health care improvement efforts* North American Forum on Family Planning, Denver, CO
October 2016	Keynote Presentation: *A Journey through the Career of a Primary Care Provider* Primary Care Day Penn State College of Medicine, Hershey, PA
May 2016	Medical Grand Rounds: *Clinical Updates in General Internal Medicine* Penn State Hershey Medical Center, Hershey, PA
November 2015	Panel Presentation: *Patient-Centered Outcomes Research* Society of Family Planning Career Development Seminar North American Forum on Family Planning, Chicago, IL
October 2015	Panel Presentation: *Reproductive Health and Patient-Centered Outcomes Research* Planned Parenthood Associates: Patient-Centered Outcomes Research & Reproductive Health Summit, New York, NY
October 2015	Panel Presentation: *Reproductive Health and Patient-Centered Outcomes Research* 2015 Patient-Centered Outcomes Research Institute: Progress in Building a Patient-Centered Comparative Clinical Effectiveness Research Community; Washington, D.C.
May 2015	Panel Discussion: *Pragmatic and Patient-Centered: Clinical Trials Done Differently* Society of General Internal Medicine 38th Annual Meeting, Toronto, ON
March 2015	Panel Discussion (Moderator): *PCORnet in the Mid-Atlantic Region: The PaTH and NYC Clinical Data Research Networks* 2015 Mid Atlantic Regional Society of General Internal Medicine Meeting: Building the SGIM Neighborhood: Communication, Collaboration and Creativity to Enhance the Future of Generalism
February 2015	Panel Presentation: *Voices of Experience* Getting to Know PCORI: From Application to Closeout Atlanta, GA
May 2014	Presentation: *PCORI, PCORnet, and the PaTH Mid-Atlantic Clinical Data Research Network* Penn State College of Medicine Departments of Medicine & Surgery Research Day, Hershey, PA
April 2014	Lecture: *Applying for PCORI Funding* Health Services Research Colloquium, Department of Health Policy and Administration Penn State University, University Park, PA
April 2014	Lecture: *Osteoporosis Update: Prevention, Screening, and Treatment*

	National Public Health Week Lecture Series Penn State College of Medicine Mini-Medical School, Hershey, PA
March 2014	Lecture: *Osteoporosis Update: Prevention, Screening, and Treatment* Penn State College of Medicine Mini-Medical School, Hershey, PA
March 2014	Workshop: *Jumpstart Your Research: Identifying Opportunities with Secondary Dataset Analyses* Mid-Atlantic Society of General Internal Medicine Meeting, New York, NY Co-Faculty: Dr. Jennifer Kraschnewski
February 2014	Lecture: *Applying for PCORI Funding* Penn State College of Medicine Department of Public Health Sciences Seminar Series, Hershey, PA
January 2014	Seminar: *Applying for PCORI Funding* Penn State College of Medicine K Seminar Series, Hershey, PA
March 2013	Seminar: *How to Write a Successful K Award Application* Penn State College of Medicine K Seminar Series, Hershey, PA
August 2011	Medical Grand Rounds: *Update in Women's Health* Penn State Hershey Medical Center, Hershey, PA
March 2010	Medical Grand Rounds: *The Mammography Controversy* Temple University Hospital, Philadelphia, PA
March 2010	Lecture: *Update in Pap Smear Guidelines* General Internal Medicine conference Temple University Hospital, Philadelphia, PA
May 2009	Workshop: *Contraception in Women with Chronic Medical Conditions* Society of General Internal Medicine Annual Meeting, Miami, FL Co-Faculty: Dr. Bimla Schwarz, Dr. Mindy Sobota, Dr. Sara Levin
October 2008	Seminar: *How to Write a Successful K Award Application* Penn State College of Medicine K Seminar Series, Hershey, PA
May 2006	Medical Grand Rounds: *Update in Contraception/Reproductive Health* Penn State Hershey Medical Center, Hershey, PA
April 2005	Lecture: *Emergency Contraception* Penn State College of Medicine's 7th Annual Women's Health: Ages & Stages Conference, Grantville, PA
May 2004	Lecture: *Emergency Contraception* Springfield SouthWest Health Center, Springfield, MA
April 2004	Lecture: *Emergency Contraception* Lowell Community Health Center, Lowell, MA

April 2004	Lecture: *Emergency Contraception* Greater New Bedford Community Health Center, New Bedford, MA
April 2004	Lecture: *Emergency Contraception* Martha Eliot Health Center, Jamaica Plain, MA
December 2003	Lecture: *Emergency Contraception* Chelsea Health Center, Chelsea, MA
October 2003	Lecture/Discussion: *Emergency Contraception* Medical Students for Choice Regional Conference Boston University School of Medicine, Boston, MA
July 2003	CE lecture: *Emergency Contraception* Northeastern University School of Pharmacy, Boston, MA
June 2003	Lecture: *Emergency Contraception* Brookside Health Center, Jamaica Plain, MA
June 2003	Lecture: *Emergency Contraception* Southern Jamaica Plain Health Center, Jamaica Plain, MA
March 2003	Discussion: *Current Clinical Guidelines for Emergency Contraception* At the Massachusetts Emergency Contraception Network and Health Care of Southeastern Massachusetts, Inc. conference: Emergency Contraception: A Multidisciplinary Approach to Improving Access. Brockton, MA
December 2002	Family Medicine Grand Rounds: *Emergency Contraception* Boston Medical Center, Boston, MA
December 2002	Medical Grand Rounds: *Emergency Contraception* Lowell General Hospital, Lowell, MA
December 2002	CME lecture: *Emergency Contraception* Neighborhood Health Plan, Boston, MA
November 2002	General Internal Medicine Grand Rounds: *Emergency Contraception* Boston Medical Center, Boston, MA
November 2002	Discussion: *Current Clinical Guidelines for Emergency Contraception* At the Massachusetts Emergency Contraception Network and Massachusetts Public Health Association conference: Emergency Contraception: A Multidisciplinary Approach to Improving Access Boston, MA
November 2002	*Preventing Unintended Pregnancy: Emergency Contraception* At the Reproductive Options Education Consortium for Nursing conference: Caring for the Woman with an Unintended Pregnancy: Teaching What Nurses Need to Know, Charlestown, MA

November 2002	*Emergency Contraception and New Contraceptive Methods* Medical Students for Choice Regional Conference Harvard Medical School, Boston, MA
October 2002	Medical Grand Rounds: *Emergency Contraception* Quincy Medical Center, Quincy, MA
October 2002	CME lecture: *Emergency Contraception* Harrington Memorial Hospital, Harrington, MA
August 2002	Medical Grand Rounds: *Emergency Contraception* Cambridge Hospital, Cambridge, MA
April 2002	Workshop Co-Moderator: *Domestic Violence* American College of Physicians Annual Session, Philadelphia, PA

Legislative and Other Testimony:

December 2017	Testimony as expert witness in Commonwealth of Pennsylvania vs. Donald Trump (No. 2:17-cv-04540-WB) in U.S. District Court for the Eastern District of Pennsylvania: Declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania to prevent execution of the Religious Exemption Rule and Morale Exemption Rule intended to limit contraceptive coverage as mandated by the Affordable Care Act.
October 2016	Statement before the Pennsylvania Medical Society (Reference Committee D) in support of Resolution 16-404: Comprehensive Women's Reproductive Health Care
May 2007	Testimony before the Health and Human Services Committee, Pennsylvania House of Representatives: Mandating availability of Emergency Contraception in Pennsylvania Emergency Departments
December 2005	Statement for Press Conference in support of House Bill 2217: The Access to Legal Pharmaceuticals Bill
June 2003	Testimony before the Health Care Committee, Massachusetts State House: Mandating availability of Emergency Contraception in Massachusetts Emergency Departments
March 2003	Briefing of Massachusetts State House Legislators on bill for emergency contraception use in emergency departments and collective pharmacy agreements

EXHIBIT M

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, Plaintiff, v. DONALD J. TRUMP, *et al.*, Defendants.	**No. 2:17-cv-04540-WB**

DECLARATION OF CAROL S. WEISMAN, Ph.D.[1]

I, Carol S. Weisman, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, I state as follows:

I. My Background and Experience

1. I am originally from Pittsburgh, Pennsylvania and, since 2003, I have served as a Distinguished Professor of Public Health Sciences, Obstetrics and Gynecology, and Health Policy and Administration at the Pennsylvania State University College of Medicine. Since 2009, I have also served at the Associate Dean for Faculty Affairs at the College of Medicine. I am also a faculty associate at the Penn State Population Research Institute.

2. My area of academic specialization is women's healthcare, with a focus on preventive services, including contraceptives and family planning.

3. I earned a Bachelor of Arts degree, with High Honors, in Sociology and Anthropology from Wellesley College in 1969, and a Ph.D. in Social Relations (Sociology) from Johns Hopkins University in 1973.

[1] I attach a true and correct copy of my curriculum vitae hereto as Exhibit 1.

4. Prior to working at the Penn State College of Medicine, I taught doctoral courses, conducted research, and authored scholarly articles at two schools of public health.

5. From 1974 until 1997, I worked at Johns Hopkins University in Baltimore, Maryland, as an Assistant Professor at the School of Health Services (1974-1978), an Assistant Professor in the School of Hygiene and Public Health (1974-1981), an Associate Professor in the School of Hygiene and Public Health (1981-1988) and, from 1988 until 1997, as a Professor in the Department of Health Policy and Management in the School of Hygiene and Public Health.

6. In my 23 years at Johns Hopkins, I held several leadership roles. I served as the Director of the MHS Program in Health Finance and Management (1988-1992), the Director of the Doctoral Program in Health Care Organization and Financing (1992-1994) and the Associate Chair for Health Services Research (1997).

7. From 1997 until 2002, I served as a Professor in the Department of Health Management and Policy at the University of Michigan School of Public Health. I had a joint appointment in the Department of Obstetrics and Gynecology at the University of Michigan Medical School, and was the Founding Director of the Interdepartmental Concentration in Reproductive and Women's Health at the University of Michigan School of Public Health.

8. Throughout my career, I have published over 175 scholarly articles, books, books chapters, monographs, and reports in the area of women's healthcare, including on the following topics:

a. access to health care services and systems for women of reproductive age;

b. contraceptive decision processes;

c. contraceptive counseling in managed care and preventing unintended pregnancy in adults;

d. contraceptive action planning among privately insured women; and

e. contraceptive choices and cost.

9. In addition, I have been an investigator and lead investigator, on more than 40 studies and projects, many regarding women's healthcare. Most recently, I was a co-investigator on the project, "Reducing Unintended Pregnancies through Reproductive Life Planning and Contraceptive Action Planning," PCORI CD-1304-6117, 2013-2017.

10. I have also lectured and made almost 75 presentations throughout the country, in connection with my academic work, at various schools and professional organizations. My recent presentations include:

a. "The Affordable Care Act and Women's Preventive Services: The 2011 IOM Report," keynote lecture as Distinguished Professor in Women's Health, Society of General Internal Medicine 35th annual meeting, Orlando, FL, May 10, 2012;

b. "The Patient Protection and Affordable Care Act's Implications for Women's Health Care," invited seminar at the Pennsylvania Department of Health, Harrisburg PA, May 27, 2014; and

c. "Implications of Proposed Changes to the Affordable Care Act for Women's Reproductive Health Care," invited panelist for The Future of Reproductive Health Policy, Penn State College of Medicine, March 9, 2017.

11. Throughout my career, I have received accolades and recognitions. For example, in 1997, I received the National Award for Excellence in Women's Health Research from the National Association of Professionals in Women's Health; in 2008, I received the Leader in the Field Award from the Family Health Council of Central Pennsylvania; and, in 2012, I received the award of Distinguished Professor in Women's Health from the Society of General Internal

Medicine.

12. I also participate, and have participated, in a variety of professional activities. Among them, I have been on the Editorial Board of *Women's Health Issues* since 1990, serving as Editor-in-Chief (2003-2006) and Associate Editor (1995-2002 and 2007-present), and have been a Full Fellow of the Society of Family Planning since 2016. Since 1988, I have been a member of AcademyHealth, a professional organization dedicated to advancing the fields of health services research and health policy.

II. My Service on the Institute of Medicine Committee Convened by the U.S. Department of Health and Human Services, and the Committee's Report

13. Throughout my career, I have been engaged as a consultant to numerous governmental and academic institutions.

A. *My Service on the Institute of Medicine Committee on Preventive Services for Women*

14. From 2010 to 2011, I served as one of only sixteen invited members of the Institute of Medicine Committee on Preventive Services for Women (the "Committee").

15. This Committee was convened at the request of the United States Department of Health and Human Services ("HHS") to identify existing gaps in women's preventive care and to recommend services and screenings that HHS should consider to fill those gaps.

16. The sixteen experts on the Committee had backgrounds in preventive care, disease prevention, women's health issues, and other areas.

B. *Committee Recommends FDA-Approved Contraception, Sterilization Procedures, and Patient Education and Counseling as Part of Women's Preventive Care*

17. In 2011 the Committee issued its report, titled, *Clinical Preventive Services for Women: Closing the Gaps* (National Academies Press, 2011) (the "Report").

18. The Report made specific recommendations to the Health Resources and

Services Administration ("HRSA"), a department of HHS, regarding evidence-based preventive services to be incorporated in the guidelines promulgated pursuant to the Affordable Care Act, 42 U.S.C. § 18001 *et seq.* (2010) (the "Affordable Care Act" or "ACA").

19. The Committee found that contraceptives are preventive medical services because they prevent unintended pregnancies and that contraceptives should be included in the list of recommended preventive services for women under the ACA, specifically, the "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *See* Ex. B, Report at 109-10.

i. Reducing Unintended Pregnancies

20. In making this finding, the Committee relied on evidence that "contraception and contraceptive counseling" are "effective at reducing unintended pregnancies" and observed that "[n]umerous health professional associations recommend" that such family planning services be included as part of standard preventive care for women. *Id.* at 109.

21. In making this recommendation, the Committee considered recommendations from the American Academy of Pediatrics, the Society of Ado20lescent Medicine, the American Medical Association, the American Public Health Association, the American College of Obstetricians and Gynecologists, and the Association of Women's Health, Obstetric and Neonatal Nurses. *Id.* at 109-10.

22. But the Committee's recommendation was based on a review of the evidence, including the prevalence of unintended pregnancy in the United States.

23. As the Committee stated in its Report, in 2001, an estimated "49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time

of conception." *Id.* at 102 (internal citations omitted).

24. The Committee found that these "unintended" pregnancies disproportionately impact the most vulnerable: Although one in every 20 American women has an unintended pregnancy each year, unintended pregnancy is "more likely among women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group." *Id.*

25. Furthermore, the Committee reported that unintended pregnancies are more likely than intended pregnancies to result in abortions; specifically, "[i]n 2001, 42 percent of [] unintended pregnancies [in the United States] ended in abortion." *Id.*

26. The Committee also concluded that evidence proved that women carrying babies to term are less likely to follow best health practices when their pregnancies were unintended.

27. According to the Institute Committee on Unintended Pregnancy, "women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy." *Id.* at 103.

28. Women facing unintended pregnancies are also more likely to be "depressed during pregnancy, and to experience domestic violence during pregnancy." *Id.*

29. The Committee also considered evidence that the "odds of preterm birth and low birth weight among unintended pregnancies ending in live births" was "significantly increased …. compared with pregnancies that were intended." *Id.*

30. Importantly, the Committee determined that contraceptives are effective in preventing unintended pregnancies, citing evidence of contraceptive effectiveness from the Food and Drug Administration and from Contraceptive Technology. *Id*. at 105.

31. The Committee also noted that "greater use of contraception within the population

is associated with lower unintended pregnancy and abortion rates nationally." *Id.* at 105.

32. In making this determination, the Committee relied on a study showing that, as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, their rates of unintended pregnancy and abortion both declined. *Id.*

33. The Committee also considered other studies that showed increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a "decline in teen pregnancies" and, conversely, that "periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use." *Id.*

ii. Minimizing Health Risks, Promoting Recommended Spacing, and Recognizing Additional Health Benefits Unrelated to Preventing Unintended Pregnancy

34. While all pregnancies carry inherent health risks, the Committee also considered that some women have serious medical conditions for which pregnancy is strictly contraindicated or inadvisable.

35. The Committee considered, for example, that "women with serious medical conditions such as pulmonary hypertension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and … Marfan Syndrome," are advised against becoming pregnant. *Id.*

36. The Committee also considered that the use of contraceptives also promotes medically recommended "spacing" between pregnancies. *Id.*

37. The Committee found that such spacing is important because there is an "increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy)" and "[s]hort interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small for gestational age births." *Id.*

38. The Committee also considered the risks and benefits of contraception and

recognized that contraceptives have other significant health benefits unrelated to preventing unintended pregnancy, including "treatment of menstrual disorders, acne or hirsutism, and pelvic pain," and that long-term use of oral contraceptives has been shown to "reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases." *Id.* at 105 and 107.

iii. Recognizing the Need for Family Planning Services and that Cost is a Barrier

39. The evidence reviewed by the Committee demonstrated that, as of 2008, there were still "approximately 36 million U.S. women of reproductive age (usually defined as ages 15 to 44 years)" who were "estimated to be in need of family planning services because they were sexually active, able to get pregnant, and not trying to get pregnant." *Id.* at 103.

40. Citing a Kaiser Permanente study that found "when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods," the Committee recognized that cost is a meaningful barrier to contraceptive access and found that "[d]espite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years." *Id.* at 109.

41. For these and the other reasons set forth in the Report, the Committee recommended that "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity" be included in women's preventive care. *Id.* at 109-10.

42. The Committee's recommendation was based upon reaching consensus following consideration of evidence presented by its members and a variety of professionals and

academics.

III. My Opinion on the final Religious Exemption Rule and final Moral Exemption Rule

43. I have reviewed both the final Religious Exemption Rule and the final Moral Exemption Rule promulgated by the Defendants (the "final Exemption Rules"), as well as the amended Complaint filed by the Commonwealth of Pennsylvania in this matter that challenges them.

44. In addition to my relevant background and experience set forth above, by virtue of being one of the sixteen members of the Institute of Medicine Committee on Preventive Services for Women, I have direct knowledge regarding the Report, promulgated by the HRSA pursuant to the Affordable Care Act, which gave rise to the ACA's original guidelines regarding contraceptives as a preventive service.

45. Based upon my knowledge, education, training and experience, it is my professional opinion that the final Exemption Rules will cause immediate and irreversible harm because they will cause women to lose contraceptive care under their employer group health plans.

46. As set forth above and credited by the Committee, cost to patients has been shown to be a barrier to access to contraceptive care. Women are more likely to use contraceptives – and use them properly and consistently – if they have no cost-sharing responsibilities.

47. Conversely, when women are required to shoulder financial responsibility for preventive care, they are less likely to seek preventive care.

48. Several studies conducted after the ACA went into effect have shown that women are paying less for contraception and that they are using more effective contraceptive methods as a result of having contraceptive coverage under ACA.

49. A study we conducted at Penn State using national health claims data for privately insured women showed a post-ACA decrease in out-of-pocket contraceptive costs and an increase in uptake of long-acting reversible contraceptives, the most effective contraceptives on the market (Snyder AH, Weisman CS, Liu G, Leslie D, Chuang CH. The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women. *Women's Health Issues* 28(3):219-223, 2018.

50. For these reasons, some women who lose contraceptive coverage through their employers as a result of the final Exemption Rules, will choose a less effective contraceptive option for their medical needs, will use contraception inconsistently, or will discontinue using contraceptives entirely.

51. This, in turn, will have irreparable negative physical and mental health impacts on women, including disruptions in ongoing medical treatment and/or unintended pregnancies.

52. It is also my opinion that the new final Exemption Rules are not based upon sound scientific or empirical evidence.

53. The final Exemption Rules indicate, among other things, that contraceptives are not effective in preventing unintended pregnancy, that they are harmful to women's health, and that they promote promiscuity.

54. These representations conflict with peer-reviewed and medically-accepted data, and are not credible.

55. For these reasons, I believe that an injunction of the final Exemption Rules is necessary to prevent immediate and irreparable harm to women in Pennsylvania and around the Country, who will lose ongoing preventive care coverage under their group health plan due to the final Exemption Rules.

I hereby affirm that the foregoing is true and correct based upon my knowledge, information and belief, and I make these statements subject to the penalty of perjury.

Date: 12/17/2018

By: Carol S. Weisman
CAROL S. WEISMAN, Ph.D

EXHIBIT 1

CURRICULUM VITAE

Carol S. Weisman, Ph.D.

OFFICE ADDRESS

Department of Public Health Sciences
Pennsylvania State University College of Medicine
90 Hope Drive, A210
Hershey, PA 17033-0855
Telephone: 717-531-6690
Fax: 717-531-0839
E-mail: cweisman@psu.edu

PLACE OF BIRTH

Pittsburgh, Pennsylvania

EDUCATION

B.A., Wellesley College, Sociology and Anthropology, 1969

Ph.D., Johns Hopkins University, Social Relations (Sociology), 1973

CURRENT POSITIONS

Distinguished Professor of Public Health Sciences, Obstetrics and Gynecology, and Health Policy and Administration, Pennsylvania State University College of Medicine, 2003 – present

Associate Dean for Faculty Affairs, Pennsylvania State University College of Medicine, 2009 – present

Faculty Associate, Penn State Population Research Institute

PREVIOUS POSITIONS

1997-2002 Professor, Department of Health Management and Policy, Founding Director of the Interdepartmental Concentration in Reproductive and Women's Health, University of Michigan School of Public Health, Ann Arbor, MI; Joint appointment in Department of Obstetrics and Gynecology, University of Michigan Medical School

1988-1997 Professor, Department of Health Policy and Management, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD
Associate Chair for Health Services Research, 1997
Director, Doctoral Program in Health Care Organization and Financing, 1992-1994
Director, MHS Program in Health Finance and Management, 1988-1992

1981-1988 Associate Professor, School of Hygiene and Public Health, Johns Hopkins University

1974-1981 Assistant Professor, School of Hygiene and Public Health, Johns Hopkins University

1974-1978 Assistant Professor, School of Health Services, Johns Hopkins University

1973-1974 Assistant Professor, Department of Sociology, University of Maryland, College Park, MD

1972-1973 Associate Research Scientist, Office of Health Manpower Studies, School of Health Services, Johns Hopkins University

AWARDS AND HONORS

B.A. with High Honors and Durant Scholar, Wellesley College, 1969

Woodrow Wilson Fellow, 1969

NIMH Pre-Doctoral Research Fellow, 1970-72

Delta Omega, 1988

Fellow of the Association for Health Services Research, 1997

National Award for Excellence in Women's Health Research, National Association of Professionals in Women's Health, 1997

Leader in the Field Award, Family Health Council of Central Pennsylvania, 2008

Distinguished Professor in Women's Health, Society of General Internal Medicine 35th annual meeting, 2012

PROFESSIONAL ACTIVITIES

Associate Editor, *Women's Health Issues*, 2007- present; Editor-in-Chief 2003 - 2006 (Associate Editor, 1995-2002; member of the Editorial Board since 1990)

Full Fellow, Society of Family Planning, 2016 – present

Member, Abortion Facility Standards Initiative Advisory Committee, Advancing New Standards in Reproductive Health (ANSIRH), University of California, San Francisco. 2015 - 2017

Member, Well Woman Visits Advisory Committee, National Women's Law Center and Brigham and Women's Hospital, 2013- 2015

Member, National Maternal Health Initiative, Women's Health Work Group, Maternal and Child Health Bureau, HRSA, 2012-2013

Member, Institute of Medicine (IOM) Committee on Preventive Services for Women, 2010 - 2011

Member, Research and Project Development Subcommittee, AAMC Group on Faculty Affairs, 2010 – 2012

Member, Women's Health Steering Committee, National Committee for Quality Assurance, 2009 – 2011

Co-chair, Maternity Care Measure Development Work Group, American Medical Association, 2009 - 2010

Member, AHRQ Expert Group on Women's Health, 2009 - 2010

Member, CDC Select Panel on Preconception Care, 2005 -2006

Member, The Standards of Care Project Advisory Board, National Health Law Program, 2005 – 2010

Member, Advisory Committee, Jacobs Institute of Women's Health at George Washington University, 2006 - 2007

Chair, Board of Directors, AcademyHealth, 2007 (Board Member, 2004-2007; Vice-Chair, 2006)

Member, Women's Health Research Coalition Advisory Committee, Society for Women's Health Research, 2004 – 2006

Member, Board of Governors, Jacobs Institute of Women's Health, 1998-2004

Member, Advisory Board to Pfizer Women's Health, U.S. Pharmaceuticals, 1998-2003

Co-chair, Women's Health Measurement Advisory Panel, National Committee for Quality Assurance, 1997-2003

Family Planning Service Delivery Improvement Research, Technical Experts meetings, The Urban Institute, 2003

Association of Professors of Gynecology and Obstetrics, Women's Health Education Retreat invited panel to develop competencies for medical students, June 13-15, 2003

Member, Steering Committee, Women's Health Research Coalition, Society for Women's Health Research, 1999-2003

Co-Chair, Jacobs Institute of Women's Health Expert Panel on Menopause Counseling, 1999-2000

Chair, Advisory Committee on Academic Rank, University of Michigan School of Public Health, 1999-2001

Member, Advisory Committee on Labor Standards and Human Rights, University of Michigan, 1999-2000

Member, Advisory Panel on Cardiovascular Health for Women, Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), 2000-2002

Member, Women's Health Report Card National Advisory Committee, 1998-2003

Chair, Advisory Committee to "Women's Health and Managed Care" project of The Jacobs Institute of Women's Health, 1996-1998

Member, Advisory Committee to "Improving Women's Health: Mid-Life and Beyond" project of the Women's Research and Education Institute, 1997

Member of the Affiliate Medical Committee of Planned Parenthood of Maryland, 1993 - 1997

Member of the Council for Quality Health Care, Maryland Hospital Association, 1993 - 1996

Member, *Johns Hopkins Women's Health* Editorial Advisory Board, 1993-1995

President of the Faculty Senate and member of the Advisory Board, Johns Hopkins University School of Hygiene and Public Health, 1992-1995

Member of the Editorial Board, *American Sociological Review*, 1992-94

Member, Interdivisional Collaboration and Restructuring strategic study group of the Committee for the 21st Century, Johns Hopkins University, 1993

Member, Scientific Advisory Board, Center for VDT and Health Research, Johns Hopkins University School of Hygiene and Public Health, 1992-1995

Member of the Norplant Consortium of the Baltimore City Health Department, 1992-1993

Member, Provost's Committee on the Status of Women, Johns Hopkins University, 1991- 1993; Co-Chair, Academic Issues Subcommittee, 1991- 1993

Associate Editor, *Journal of Health and Social Behavior*, l989-91

Member, Public Interest Investment Advisory Committee, Johns Hopkins University, l986-87

Reviewer, BOSTID Research Program of the National Research Council, Washington, D.C., 1987
Advisor, Maryland Hospital Association, Task Force on Nursing Issues, l986-87

Member, Advisory Committee to the National Survey of Worksite Health Promotion Activities, Office of Disease Prevention and Health Promotion, l985-86

Reviewer, Health Services Research and Development Service, Veterans Administration Central Office, Washington, D.C., 1984

Member, Review Panel, Health Care Financing Administration, Preventive Services Demonstrations, 1984-85

Member, Advisory Panel on Data Needs for the Institute of Medicine Study of Nursing, Institute of Medicine, Washington, D.C., April 1981

Member, Board of Directors, Planned Parenthood of Maryland, 1978-1984

PROFESSIONAL MEMBERSHIPS

AcademyHealth, 1988-present

SELECTED CONSULTING

Member, NCQA Maternal Health Measurement Advisory Panel, 2013-2014

Consultant, Women’s Health, National Committee for Quality Assurance, 2009 – 2011

Consultant, RAND-Magee Women’s Health Initiative, 2003

Consultant, Women’s Health Program, AHRQ, 2001-2003

Consultant, Office on Women’s Health, Department of Health and Human Services, 1999-2000

Consultant, Maternal and Child Health Bureau, HRSA, 1999-2000

Consultant on the National Survey of Women's Health, conducted by Louis Harris & Associates for The Commonwealth Fund, 1992-1993

Consultant to the Panel on Screening for Alzheimer's Disease and Related Disorders, Agency for Health Care Policy and Research, 1992-1993

Consultant to the University of Rochester School of Nursing, Enhanced Professional Practice Model for Nursing Project, l989-1993

Member, Advisory Group for the 1990 Followup Survey of Young Men, The Urban Institute, 1990, 1994

Consultant to Robert Wood Johnson University Hospital, Robert Wood Johnson Foundation/Pew Trust project on strengthening hospital nursing, 1989

Consultant to the State of New Jersey Department of Higher Education on issues in nursing education, l988

Consultant to Survey Research Associates, Inc., Baltimore, Maryland, on NHLBI-funded survey of physicians' preventive practices related to lung disease, 1985-89

Consultant to Study of Anticipated Nursing Turnover, University of Arizona, College of Nursing, Tucson, Arizona, 1983-85

Member of Advisory Committee on Multi-Institutional Arrangements and Methodology Task Force, Joint Commission on Accreditation of Hospitals, Chicago, Illinois, 1982-84

Consultant to Sisters of Mercy Health Corporation, Farmington Hills, Michigan, 1982

SELECTED PROJECTS

Co-investigator, “Reducing Unintended Pregnancies through Reproductive Life Planning and Contraceptive Action Planning,” PCORI CD-1304-6117, 2013-2017

Principal Investigator, “Career Development Program in Women’s Health Research at Penn State,” NIH BIRCWH (Building Interdisciplinary Research Careers in Women’s Health) Program, Grant Number K12 HD055882, 2007-2017

Co-leader, Community Engagement and Research Core, Penn State CTSI, NIH UL1RR033184, 2011 - 2014

Principal Investigator, “National Children’s Study,” Subcontract with the University of Pittsburgh (Grant from NIH), 2007-2011

Principal Investigator, “Central Pennsylvania Center of Excellence for Research on Pregnancy Outcomes,” Grant Number 4100020719 from the Pennsylvania Department of Health, 2004-2008

Co-investigator, “Single Home Visits to Improve Health Outcomes,” HRSA Grant No. 1 R40MC06630-01-00, 2006-2009

Co-investigator, “Analysis of HEDIS Data to Investigate Gender Differences in Quality of Care for Cardiovascular Disease and Its Risk Factors,” Subcontract with the National Committee for Quality Assurance (Grant from AHRQ), 2005-2007

Co-investigator, “Impact of Practice Structure on the Quality of Care for Women Veterans,” Subcontract with the Greater Los Angeles VA (Grant from US Department of Veterans Affairs), 2005-2007

Co-investigator, “Survival Strategies of Health Care Safety Net Providers,” Grant from the Blue Cross Blue Shield of Michigan Foundation, 2001-2004

Principal Investigator, “Comparing the OWH National Centers of Excellence in Women’s Health (CoE) Program to the VA Specialized Women’s Health Centers,” Contract No. 02TO2012301D, U.S. Department of Health and Human Services, Office on Women’s Health, 2002-2003

Principal Investigator, “Developing a Short-form MoM Survey: Management of Menopause,” Subcontract with the National Committee for Quality Assurance, 2002-2003

Principal Investigator, “Measurement of Women’s Satisfaction with Primary Care,” AHRQ Grant No. R01 HS10237, 2000-2002

Evaluation Director, “National Center of Excellence in Women’s Health,” Contract No. 282-97-0071, U.S. Department of Health and Human Services, Office on Women’s Health, 1997-2002

Principal Investigator, “Contraceptive Counseling in Managed Care,” Project under the ASPH/CDC/ATSDR Cooperative Agreement, 1999-2001

Principal Investigator, “Women’s Health Services Survey Development,” Subcontract with Johns Hopkins Women’s and Children’s Health Policy Center, Maternal and Child Health Bureau, DHHS, 1998-2001

Co-investigator, “Gender Analysis of CAHPS,” AHCPR Reference No. 99R302869 with Jacobs Institute of Women’s Health, 1999-2000

Principal Investigator, Robert Wood Johnson Foundation Investigator Award in Health Policy Research, "Toward a Women's Health Policy: Exploring Gender Issues in U.S. Health Care," 1994-1998

Principal Investigator, "Catholic Health Systems and Reproductive Health Services," Grant No. 95-1810 from The Henry J. Kaiser Family Foundation, 1996-1997

Principal Investigator, "Study of Women's Health Centers," Grant No. 94-54 from The Commonwealth Fund, 1994-1995

Investigator, "Improving Cervical Cancer Screening in Hospital Settings," Grant No. 1 R03 CA59205 from the National Cancer Institute, 1993-1994

Investigator, "Accuracy of Substituted Judgments in Terminal Illness," Grant No. 1 R01 NR03045 from the National Center for Nursing Research, 1993-1995

Principal Investigator, "Evaluation of The Commonwealth Fund's Graduate Program in Nursing and Management," Grant No. 93-25 from The Commonwealth Fund, 1992-1993

Investigator, "Youth Mental Health Services Research Center," Grant No. 1 P50 MH50204 from the National Institute of Mental Health, 1992-1997

Co-Principal Investigator, "Trials to Promote Behavior Change to Prevent HIV Spread," Cooperative Agreement with the National Institute of Mental Health, 1990-1995

Co-Principal Investigator, "Condom Use to Prevent STDs Including AIDS in Baltimore," Grant No. 1 R01 AI29508 from the National Institute for Allergy and Infectious Diseases, 1989-l994

Principal Investigator, "Adolescent Women's Contraceptive Decision Making," Grant No. 1 R01 HD22275 from the National Institute of Child Health and Human Development, l987-91

Co-Principal Investigator, "A Model for Reorganizing Nursing Resources," Grant No. NR02091 from the National Center for Nursing Research, l989-l992

Co-Investigator, "Comparison of Rates of Medicaid versus Non-Medicaid Malpractice Claims," Grant Number 14042 from the Robert Wood Johnson Foundation, l989

Co-Investigator, "Fertility-Related Behavior in STD Clinic Clients," Grant No. 1 R01 HD24802 from the National Institute of Child Health and Human Development, l988-91

Investigator, "Study of Barriers to Curriculum Change in Medical Education," Grant from the PEW Foundation to the University of Rochester and Johns Hopkins University, l987-89

Co-Principal Investigator, "Early Detection of Cervical Cancer Among Elderly Women," Grant No. 1 R01 CA36569 from the National Cancer Institute, 1984-87

Principal Investigator, "Fertility-Control Services: Provider Influences," Grant No. 1 R01 HD17135 from the National Institute of Child Health and Human Development, 1983-86

Investigator, "JHU/BCH Residency Training in General Internal Medicine," Grant No. 5D28PE13163 from the Division of Medicine, Bureau of Health Professions, HRA, 1978-84

Co-Investigator, "U.S. Health Personnel Abroad: Needs and Opportunities," Contract with U.S.A.I.D., 1981-82

Principal Investigator, "Gender and Physician Specialty Distribution," Grant No. 1 R03 HS04299 from the National Center for Health Services Research, OASH, 1981-1982

Investigator, "Modeling the Graduate Medical Education System," Contract No. HRA-232-78-0161 with Division of Medicine, Bureau of Health Professions, HRA, 1979-80

Investigator, "Oncology Center Surveys of Consumers and Providers," Grant No. CA20333 from the National Cancer Institute, 1978-80

Principal Investigator, "Job Satisfaction and Turnover among Hospital Nurses," Grant No. 1 R01 NU00568 from the Division of Nursing, Bureau of Health Professions, HRA, 1977-79

Principal Investigator, "Organizational Determinants and Consequences of Job Satisfaction Among Hospital Nurses: A Pilot Study," American Nurses' Foundation Grant No. 2-76-067, 1976-77

Project Director, "Career Patterns of Unaccepted Applicants to Medical School," NIH Contract No. 72-4407, 1972-74

SELECTED PRESENTATIONS

Levine DM, Weisman CS. "Career Decisions of Unaccepted Applicants to Medical School," Paper presented at the Research in Medical Education Conference, Association of American Medical Colleges, Chicago, Illinois, November 1974.

Weisman CS, Morlock LL, Sack DG, Levine DM. "Sex Differences in Response to a Blocked Career Pathway among Unaccepted Medical School Applicants," Paper presented at the 70th Annual Meeting of the American Sociological Association, San Francisco, CA, August 27, 1975.

Weisman CS, Alexander CS. "Determinants of Hospital Staff Nurses' Job Satisfaction," Presentation at the University of Iowa Health Services Research and Development Center, April 1978.

Weisman CS, Levine DM, Steinwachs, DM. "Convergence of Male and Female Physician Career Patterns: Evidence of Specialty Choices and Graduate Experiences for Seven Cohorts," Paper presented at the Annual Meeting of the American Sociological Association, New York, August 31, 1980.

Steinwachs DM, Elzinga DJ, Levine DM, Parker R, Salkever D, Weisman C. "Changing Patterns of Graduate Medical Education: Analyzing Recent Trends and Projecting Their Impact," Paper presented at the Annual Meeting of the American Public Health Association, Medical Care Section, Detroit, Michigan, October 1980.

Celentano DD, Weisman CS, Shapiro S. "Cancer Preventive Screening Behavior Among Elderly Women," Paper presented at the Annual Meeting of the American Public Health Association, Gerontological Health Section, Detroit, Michigan, October 1980.

Weisman CS. "Recruitment, Retention, and Responsibility: What Research Tells Us About Hospital Nursing," Keynote Address at the Seventh Annual Conference of the National Association of Nurse Recruiters, Philadelphia, PA, July 31, 1981.

Dear MR, Weisman CS, O'Keefe S. "Organization of Nursing for Staff Retention," Paper presented at the Health Administration Section at the Annual Meeting of the American Public Health Association, Montreal, Canada, 1982.

Weisman CS. "Managing Organizations in the Presence of Stress: Human Resource Problems," Presentation at the Public Health and Preventive Medicine Conference, Johns Hopkins University School of Hygiene and Public Health, April 18, 1983.

Celentano DD, Weisman CS, Rosenshein NB, Enterline JP, Klassen AC. "Case-Control Study of Risk Factors for Cervical Cancer," Presentation at the 113th Annual Meeting of the American Public Health Association, Epidemiology Contributed Papers Session, November 20, 1985.

Weisman CS. "Communication between Women and Their Health Care Providers: Research Findings and Unanswered Questions," Invited paper presented at the National Conference on Women's Health, National Institutes of Health, June 18, 1986.

Weisman CS, Teitelbaum MA. "The Work-Family Role System and Physician Productivity," Paper presented at the 81st Annual Meeting of the American Sociological Association, New York, August 31, 1986.

Celentano DD, Weisman CS, Klassen AC. "Duration of Relative Protection of Pap Testing for Cervical Cancer," Paper presented at the 114th Annual Meeting of the American Public Health Association, Las Vegas, Nevada, October 1, 1986.

Weisman CS. "Research Linking Work Environment, Provider Satisfaction, and Quality of Care," Invited presentation at the Department of Psychology, University of Stockholm, Stockholm, Sweden, September 1, 1987.

Weisman CS, Teitelbaum MA, Celentano DD. "Physicians' Practice Changes in Response to Malpractice Litigation," Paper presented at the 115th Annual Meeting of the American Public Health Association, New Orleans, Louisiana, October 20, l987.

Weisman CS. "The Requirement of Work Shifts in Job Redesign," Invited presentation at the State-of-the-Science Invitational Conference: Nursing Resources and the Delivery of Patient Care, National Institutes of Health, National Center for Nursing Research, February 19, 1988.

Weisman CS, Teitelbaum MA, Nathanson CA, Ensminger M. "AIDS Knowledge, Perceived Risk, and Prevention in Adolescent Clients of a Family Planning Clinic," Paper presented at the 116th Annual Meeting of the American Public Health Association, Boston, Massachusetts, November 14, 1988.

Weisman CS, Nathanson CA, Ensminger M, Robinson JC, Plichta S. "Consistency of Condom Use by Adolescent Clients of a Family Planning Clinic," Paper presented at the 118th Annual Meeting of the American Public Health Association, New York, New York, October 2, 1990.

Weisman CS, "Nursing Practice Models: Research on Patient Outcomes," Invited paper presented at the National Center for Nursing Research Conference on Patient Outcomes Research, Rockville, MD, September 11, 1991.

Weisman CS, "The Women's Health Agenda," Invited presentation at the Maryland ACE/NIP Annual Conference, Goucher College, June 12, 1992.

Weisman CS, Plichta SB, Tirado D, Dana KH. "Norplant Adoption: Comparison of Early Norplant Adopters and Oral Contraceptive Users in a Family Planning Clinic in Baltimore," Paper presented at the Annual Meeting of the American Public Health Association, Washington, D.C., November 11, 1992.

Weisman CS. "Contraceptive Decision Processes," Invited Paper presented at the NICHD Workshop on Negotiating the Paths to Parenthood, NIH, February 9, 1993.

Weisman CS and Cassard SD. "Health Consequences of Exclusion or Under-representation of Women in Clinical Studies," Workshop presentation to the Institute of Medicine Committee on the Legal and Ethical Issues Relating to the Inclusion of Women in Clinical Studies, Georgetown University, Washington, D.C., March 24, 1993.

Zenilman J and Weisman CS. "Condom Use to Prevent STDs Including AIDS in Baltimore," Presentation at the Behavioral Research on the Role of Condoms in Reproductive Health conference, NIH, May 10-12, 1993.

Weisman CS. "The Commonwealth Fund's Survey of Women's Health: Analysis of Health Care Utilization Patterns," Presented at the American Psychological Association's Conference on Psychosocial and Behavioral Factors in Women's Health: Creating an Agenda for the 21st Century, Washington, D.C., May 13, 1994.

Weisman CS and Cassard SD. "Women's Health Care: Physician Use Patterns," Presented at the 122nd Annual Meeting of The American Public Health Association, Washington, D.C., October 31, 1994.

Weisman CS, Curbow BC, Khoury AJ. "The National Survey of Women's Health Centers: Current Models of Women-Centered Care," Invited paper presented at the 12th Annual Meeting of the Association for Health Services Research and the Foundation for Health Services Research, Chicago, IL, June 5, 1995.

Conference Chair, "Women's Health and Managed Care: Balancing Cost, Access, and Quality," The Jacobs Institute of Women's Health, Washington, D.C., July 17, 1995.

Weisman CS. "Providers for Women's Health Care," A Woman's Journey, Johns Hopkins Medical Institutions, Baltimore, MD, October 14, 1995.

Weisman CS. "Women's Health Centers and Managed Care," Presented at the 123rd Annual Meeting of the American Public Health Association, San Diego, CA, October 31, 1995.

Weisman CS. "Women's Health Centers: Past, Present, and Prospects," Invited paper presented at "An Unfinished Revolution: Changes and Challenges in Women's Health Care," Mary Baldwin College, Staunton, Virginia, April 29, 1996.

Weisman CS. "Women's Health Centers and Managed Care," Paper presented at A Women's Health Conference, American Psychological Association, Washington, D.C., September 19, 1996.

Weisman CS. "Women's Care-Seeking Patterns: Preferences and Implications," Paper presented at A Women's Health Conference, American Psychological Association, Washington, D.C., September 19, 1996.

Weisman CS. "The Development of Women's Health Centers," Invited paper presented at the Fourth Annual Pitts Memorial Lectureship on Issues in Medical Ethics: "Women's Health Issues," Medical University of South Carolina, Charleston, S.C., November 8, 1996.

Weisman CS. "The Growth of Managed Care and Women's Health," Panel on Industry Investment in Women's Health, 25th Anniversary Meeting of the Society for Menstrual Cycle Research, Chicago, IL, June 7, 1997.

Weisman CS. "Multiple Pathways of Entry into the Health Care System for Women," Presented at the Scientific Advisory Meeting, "Toward a Women's Health Outcomes Research Agenda," Society for the Advancement of Women's Health Research," Washington, D.C., October 21, 1997.

Weisman CS. "Women's Health Centers," Keynote address at the 6th Annual Primary Health Care of Women conference, University of Michigan Medical School, Ann Arbor, Michigan, December 4, 1997.

Weisman CS. "The Gap Between Quality Initiatives and Outcomes Measures," Capitol Hill Briefing Series on Women's Health, Healthcare Leadership Council and the Society for the Advancement of Women's Health Research, U.S. Capitol, Washington, D.C., March 19, 1998.

Weisman CS. "Two Centuries of Women's Health Activism," invited presentation at The History and Future of Women's Health, PHS Office on Women's Health, Washington, D.C., June 11, 1998.

Weisman CS. "The Health Care Delivery System and Perinatal and Women's Health," paper presented at the Fifth Women's Policy Research Conference, Institute for Women's Policy Research and George Washington University, Washington, D.C., June 13, 1998.

Weisman CS. "The History and Strategies of U.S. Women's Health Movements," lecture in the "Women's Health: Historical Perspectives and Policy Dilemmas" lecture series, University of Michigan, Ann Arbor, Michigan, November 4, 1998.

Weisman CS, et al. "Affiliations between Catholic and Non-Catholic Health Care Organizations and Availability of Reproductive Health Services," paper presented at the 126th annual meeting of the American Public Health Association, Washington, D.C., November 17, 1998.

Weisman CS, Henderson JT. "Women's Health Plans and Patterns of Care: Access, Preventive Services, and Satisfaction," paper presented in the panel on "What's Next in Women's Health: Coverage, Access and Quality" at the 16th Annual Meeting of the Association for Health Services Research, Chicago, IL, June 28, 1999.

Weisman CS. "The Quality of Care for Women: Toward a Research Agenda," paper prepared for the Agency for Health Care Policy and Research meeting on Defining a Women's Health Services Research Agenda, Rockville, MD, September 24, 1999.

Weisman CS. "Quality in Women's Health Care: Multiple Perspectives and Measurement Issues." Keynote address at the 12th Annual Executive Summit on Women's Health, National Association for Women's Health, Philadelphia, PA, October 25, 1999.

Weisman CS. "Quality in Women's Health Care: HEDIS Measures." Keynote presentation at the Fourth Annual Nurse-Midwifery Business Institute, Ann Arbor, MI, October 27, 1999.

Weisman CS. "Women's Health and Public Policy." Presentation to the Health Chairs Project of the National Conference of State Legislatures, Washington, D.C., December 3, 1999.

Weisman CS. "Disparities in Women's Health." Presentation at the Michigan State Medical Society Conference, "Women's Health: A Lifetime of Care," Novi, MI, April 14, 2000.

Weisman CS. "Women's Health Quality Measures in Managed Care." Presentation at the Jacobs Institute of Women's Health Breakfast Seminar, Capitol Hilton, Washington, D.C., June 21, 2000.

Henderson JT, Weisman CS. "Women's Patterns of Physician Use: A Life Stage Perspective." Paper presented at the annual meeting of the Population Association of America, Washington, D.C., March 29, 2001.

Weisman CS. "Consensus Guidelines for Menopause Counseling." Presentation at the 10th Annual Primary Health Care of Women Conference, University of Michigan Medical School, Ann Arbor, MI, November 30, 2001.

Weisman CS. "What's Hot in Women's Health Research and Policy?" Presentation at the Penn State Women's Leadership Conference, State College, PA, April 8-9, 2004.

Weisman CS. "The Status of Women's Health Research." Invited talk, Penn State College of Health and Human Development, State College, PA, March 28, 2005.

Weisman CS. "CePAWHS: Central Pennsylvania Women's Health Study." Invited talk, Expecting Something Better: A Conference to Optimize Maternal Health Care, Washington, D.C., May 18, 2005.

Hillemeier MM, Weisman CS, Chase GA et al. "Preconceptional Health and Health Care Use in the Central Pennsylvania Women's Health Study (CePAWHS): Implications for Preconceptional Health Care," Annual Research Meeting of AcademyHealth, Seattle, WA, June 25, 2006.

Hillemeier MM, Weisman CS. "Predictors of Mental Health Status among Rural Women of Reproductive Age: Findings from the CePAWHS Study," National Rural Women's Health Conference, San Antonio, TX, November 17, 2006.

Weisman CS, Hillemeier MM, Botti J, Baker SA. "Improving Health and Wellness for Women and Their Families: The Central Pennsylvania Women's Health Study," Invited talk, Regional Symposium on Health Care and Quality of Life, Penn State Harrisburg, March 2, 2007.

Weisman CS. Guest Panelist on "Research, Data, and Evaluation Panel," Central Region Health Equity Summit, Pennsylvania Department of Health, Harrisburg, PA, March 6, 2007.

Weisman CS. "The Central Pennsylvania Women's Health Study," CDC Select Panel Meeting, Atlanta, GA, May 16, 2007.

Weisman CS. "CDC's 2006 Recommendations for Preconception Care: Changing the Paradigm from Prenatal Care to Preconception Care?" Policy Roundtable Moderator, AcademyHealth 2007 Annual Research Meeting, Orlando, FL, June 4, 2007.

Chuang CH, Weisman CS, Hillemeier MM, Baker SA. "Central Pennsylvania Women's Health Study: *Strong Healthy Women* Intervention," Webinar sponsored by HRSA and the CDC Preconception Health Initiative, November 18, 2010.

Weisman CS. "CePAWHS Prevention Intervention," Pennsylvania Department of Health Quarterly Epidemiology Meeting, Hershey, PA, April 5, 2011.

Weisman CS, Hillemeier MM. "Improving Women's Preconceptional Health: Long-term Effects of the *Strong Healthy Women* Behavior Change Intervention in the Central Pennsylvania Women's Health Study," Invited presentation at the 3rd National Summit on Preconception Health and Health Care, Tampa/St. Petersburg, FL, June 14, 2011.

Weisman CS. "Women's Clinical Preventive Services: The 2011 IOM Report." Invited presentation at ParaGard® IOM Summit, Teva Pharmaceuticals, North Wales, PA, November 9, 2011.

Weisman CS. "The Affordable Care Act and Women's Preventive Services: The 2011 IOM Report." Keynote lecture as Distinguished Professor in Women's Health, Society of General Internal Medicine 35th annual meeting, Orlando, FL, May 10, 2012.

Weisman CS. "The Patient Protection and Affordable Care Act's Implications for Women's Health Care." Invited seminar at the Pennsylvania Department of Health, Harrisburg PA, May 27, 2014.

Weisman CS. "Research on Women's Health Care and Policy." Keynote address at 2nd Annual BIRCWH Northwest Women's Health and Sex/Gender Differences Research Conference, Oregon Health and Science University, Portland, OR, May 22, 2015.

Weisman CS. "Implications of Proposed Changes to the Affordable Care Act for Women's Reproductive Health Care." Invited panelist for The Future of Reproductive Health Policy, Penn State College of Medicine, March 9, 2017.

Weisman CS. "Access to Reproductive Services." Panelist for Women's Health Care: Do You Know What's at Stake? Penn State College of Medicine, October 17, 2017.

TESTIMONY

Weisman CS. Testimony on behalf of the American Public Health Association before the Task Force on Opportunities for Research on Women's Health, National Institutes of Health, June 12, 1991.

Weisman CS. Expert Witness on contraceptive coverage. United States District Court for the Eastern District of Pennsylvania, Commonwealth of Pennsylvania v. Donald J. Trump, et al., Case No. 2:17-cv-04540-WB, December 14, 2017.

REPORTS

Weisman CS. Organizational Determinants and Consequences of Job Satisfaction among Hospital Nurses: A Pilot Study. Report to the American Nurses' Foundation, May 1977.

Weisman CS, Alexander CS, Chase GA. Job Satisfaction and Turnover among Hospital Nurses. Final Report to the Division of Nursing, Bureau of Health Professions, HRA, November 1979.

Weisman CS. Gender and Physician Specialty Distribution. Final Report to the National Center for Health Services Research, OASH, June 1982.

Beyers M and Weisman CS. Review of Nursing Standards for Multihospital Systems Project. Report to the Joint Commission on Accreditation of Hospitals, January 1984.

Weisman CS. Fertility-Control Services: Provider Influences. Final Report to the National Institute of Child Health and Human Development, March 1986.

Weisman CS. Shift Work and Nursing. Report prepared under contract for the Office of Technology Assessment, U.S. Congress, December 3, 1989.

Weisman CS. Evaluation of The Commonwealth Fund's Graduate Program in Nursing and Management. Final Report to The Commonwealth Fund, February 28, 1993.

Weisman CS, Curbow B, Khoury AJ. Study of Women's Health Centers. Final Report to The Commonwealth Fund, December 31, 1995.

Weisman CS, Curbow B, Khoury AJ. Case Studies of Women's Health Centers: Innovations and Issues in Women-Centered Care. Report to The Commonwealth Fund, August 1, 1996.

Weisman CS, Khoury AJ, Sharpe VA, Cassirer C, Morlock LL. Affiliations between Catholic and Non-Catholic Health Care Providers and the Availability of Reproductive Health Services: Is There a Common Ground? Report to The Henry J. Kaiser Family Foundation, Menlo Park, CA, 1997.

Jacobs Institute of Women's Health Expert Panel on Menopause Counseling. Guidelines for Counseling Women on the Management of Menopause. Jacobs Institute of Women's Health, Washington, D.C., 2000 (Panel co-chair).

Institute of Medicine Committee on Preventive Services for Women. *Clinical Preventive Services for Women: Closing the Gaps*. Washington, D.C.: National Academies Press, 2011.

BOOKS, BOOK CHAPTERS, MONOGRAPHS

Crain RL, **Weisman CS**. *Discrimination, Personality and Achievement: A Survey of Northern Blacks*. New York: Academic Press, 1972.
aLevine DM, **Weisman CS**. Career Patterns of Unaccepted Applicants to Medical School: A Case Study of Levine DM, **Weisman CS**. Career Patterns of Unaccepted Applicants to Medical School: A Case Study of Reactions to a Blocked Career Pathway. DHEW Publication No. (HRA) 75-29, October 1974.

Amick BC, **Weisman CS**, Smith MJ. The implications of technological change for worker health: the role of the job redesign model in public health. In HW Hendrick and O Brown Jr. (Editors), *Human Factors in Organizational Design and Management*, North-Holland: Elsevier Science Publishers, 1984.

Longo DR, Chase GA, Ahlgren LA, Roberts JS, **Weisman CS**. Compliance of multihospital systems with standards of the Joint Commission on Accreditation of Hospitals. In Bradford H. Gray (Editor), *For-Profit Enterprise in Health Care*, Washington, D.C.: National Academy of Sciences, 1986.

Weisman CS. Nursing practice models: research on patient outcomes. Pp. 112-120 in *Patient Outcomes Research: Examining the Effectiveness of Nursing Practice*, DHHS, NIH Publication No. 93-3411, 1992.

Weisman CS, Cassard SD. Health consequences of exclusion or underrepresentation of women in clinical studies. Pp. 35-40 in AC Mastrioianni, R Faden, and D Federman (Editors), *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies, Vol. 2*, Washington, D.C.: National Academy Press, 1994.

Gordon DL, **Weisman CS**, Cassard S, Wong R. Reorganizing hospital nursing resources: a self-managed unit model. In Kathleen Kelly (Editor), *Health Care Work Redesign*, Series on Nursing Administration Vol. VII, Thousand Oaks, CA: Sage Publications, 1995.

Weisman CS. Women's use of health care. Chapter 1 in Marilyn M. Falik and Karen Scott Collins (Editors), *Women's Health: The Commonwealth Fund Survey*. Baltimore, MD: Johns Hopkins University Press, 1996.

Weisman CS, Curbow B, Khoury AJ. Case Studies of Women's Health Centers: Innovations and Issues in Women-Centered Care. The Commonwealth Fund, New York, N.Y., 1997.

Weisman CS. *Women's Health Care: Activist Traditions and Institutional Change*, Baltimore MD: Johns Hopkins University Press, 1998.

Weisman CS, Poole V. Health care services and systems for women of reproductive age. Pp. 25-40 in H. Grason, J. Hutchins, and G. Silver (Editors), *Charting a Course for the Future of Women's and Perinatal Health, Volume II: Reviews of Key Issues*, Baltimore: Women's and Children's Health Policy Center, Johns Hopkins School of Public Health, 1999.

Weisman CS. Women's health in perspective. Chapter 1 in Vicki L. Seltzer and Warren H. Pearse (Editors), *Women's Primary Care: Office Practice and Procedures*, 2nd edition, New York: Mc-Graw-Hill, 2000.

Weisman CS. Breast cancer policymaking. PP. 213-243 in A.S. Kasper and S.J. Ferguson (Editors), *Breast Cancer: The Social Construction of an Illness*, New York: St. Martin's Press, 2000.

Hillemeier MM, **Weisman CS**, Chase GA, Romer M. Preterm and low birthweight outcomes among rural women: the importance of preconception physical and mental health status. In Coward RT, Davis LA, Gold CH, et al. (Editors), *Rural Women's Health: Mental, Behavioral, and Physical Issues.* New York: Springer Publishing, 2006.

JOURNAL ARTICLES

Levine DM, **Weisman CS**, Seidel HM. Career decisions of unaccepted applicants to medical school. *Journal of the American Medical Association*, 232, June 15, 1975.

Weisman CS, Morlock LL, Sack DG, Levine DM. Sex differences in response to a blocked career pathway among unaccepted medical school applicants. *Sociology of Work and Occupations* 3(2):187-208, 1976.

Weisman CS, Levine DM, Sack DG, Morlock LL. Unaccepted applicants to medical school as a health resource. *Medical Care* 14(6):512-525, 1976.

Weisman CS, Levine DM, Steinwachs DM, Chase GA. Male and female physician career patterns: specialty choices and graduate training." *Journal of Medical Education* 55(Oct.):813-825, 1980.

Weisman CS, Alexander CS, Chase GA. Job satisfaction among hospital nurses: a longitudinal study. *Health Services Research* 15(4):341-364, 1980.

Alexander CS, **Weisman CS**, Chase GA. Evaluating primary nursing in hospitals: examination of effects on nursing staff. *Medical Care* 19(1):80-89, 1981.

Weisman CS, Alexander CS, Chase GA. Determinants of hospital staff nurse turnover. *Medical Care* 19(4):431-443, 1981.

Weisman CS, Dear MR, Alexander CS, Chase GA. Employment patterns among newly hired hospital staff nurses: comparison of nursing graduates and experienced nurses." *Nursing Research* 30(3):188-191, 1981.

Weisman CS, Alexander CS, Morlock LL. Hospital decision making: what is nursing's role?" *Journal of Nursing Administration* 11(9):31-36, 1981.

Vaughn WP, Waalkes TP, Lundhal S, Shapiro S, White P, Celentano D, **Weisman CS**, Hughes R, Elwood T. The Frederick Cancer Project. *Maryland State Medical Journal*, March 1982.

Alexander CS, **Weisman CS**, Chase GA. Determinants of staff nurses' perceptions of autonomy within different clinical contexts. *Nursing Research* 31(1):48-52, 1982.

Weisman CS. Recruit From within: hospital nurse retention in the 1980s. *Journal of Nursing Administration* 12(5):24-31, 1982.

Steinwachs DM, Levine DM, Elzinga DJ, Salkever DS, Parker RD, **Weisman CS**. Changing patterns of graduate medical education: analyzing recent trends and projecting their impact. *New England Journal of Medicine* 306(1):10-14, 1982.

Dear MR, **Weisman CS**, Alexander CS, Chase GA. The effect of the intensive care nursing role on job satisfaction and turnover. *Heart and Lung: The Journal of Critical Care* 11(6):560-565, 1982.

Dear MR, Celentano DD, **Weisman CS**, Keen MF. Evaluating a hospital nursing internship. *Journal of Nursing Administration* 12(11):16-20, 1982.

Celentano DD, Shapiro S, **Weisman CS**. Cancer preventive screening behavior among elderly women. *Preventive Medicine* 11(4):454-463, 1982.

Baker TD, **Weisman CS**, Piwoz E. U.S. physicians in international health: report of a current survey. *Journal of the American Medical Association* 251(4):502-504, 1984.

Dear MR, **Weisman CS**. ICU nurses aren't so stressed after all: what can we learn from them? *Cardiothoracic Nurse*, January 1984.

Weisman CS. Gender composition of medical schools and specialty choices of graduates. *Journal of Medical Education* 59(4):347-349, 1984.

Baker TD, **Weisman CS**, Piwoz E. United States health professionals in international health work. *American Journal of Public Health* 74(5):438-441, 1984.

Dear MR, **Weisman CS**, O'Keefe S. Evaluation of a contract model for professional nursing practice. *Health Care Management Review* 10(2):65-77, 1985.

Weisman CS, Teitelbaum MA. Physician gender and the physician-patient relationship: recent evidence and relevant questions. *Social Science and Medicine* 20(11):1119-1127, 1985.

Weisman CS, Nathanson CA. Professional satisfaction and client outcomes: a comparative organizational analysis. *Medical Care* 23(10):1179-1192, 1985.

Weisman CS, Nathanson CA, Teitelbaum MA, Chase GA, King TM. Abortion attitudes and performance among male and female obstetrician-gynecologists. *Family Planning Perspectives* 18(2):67-73, 1986.

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Last updated: 10/2018

EXHIBIT N

Women's Health Issues 28-3 (2018) 219–223

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WOMEN'S HEALTH ISSUES

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Policy Matters

The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women

Ashley H. Snyder, MD, MSc [a,*], Carol S. Weisman, PhD [b,c], Guodong Liu, PhD [b], Douglas Leslie, PhD [b], Cynthia H. Chuang, MD, MSc [a,b]

[a] Division of General Internal Medicine, Penn State College of Medicine, Hershey, Pennsylvania
[b] Department of Public Health Sciences, Penn State College of Medicine, Hershey, Pennsylvania
[c] Department of Obstetrics and Gynecology, Penn State College of Medicine, Hershey, Pennsylvania

Article history: Received 20 September 2017; Received in revised form 19 January 2018; Accepted 22 January 2018

A B S T R A C T

Objectives: The Affordable Care Act (ACA) contraceptive coverage mandate issued in August 2012 requires most private health insurance plans to cover all U.S. Food and Drug Administration-approved contraceptive methods without cost sharing. We evaluate the impact of this policy on out-of-pocket costs and use of long-acting reversible contraceptives (LARCs) and other prescription methods through 2014.

Methods: Data from Truven Health MarketScan were used to examine out-of-pocket costs and contraceptive use patterns for all reversible prescription contraceptives before and after the implementation of the contraceptive mandate for privately insured women ages 13 to 45. Costs were estimated by combining copayment, coinsurance, and deductible payments for both contraception and insertion fees for LARCs. Contraceptive use rates were examined and multivariable logistic regression analysis of LARC insertions before and after the ACA was conducted.

Results: Out-of-pocket costs for all reversible contraceptives, including LARCs, decreased sharply after the ACA contraceptive mandate. The greatest proportion of women in each year was oral contraceptive users (24.3%-26.1%). Rates of new LARC insertions increased significantly after the ACA, when controlling for cohort year, age group, geographic region, and rural versus urban setting (adjusted odds ratio, 1.03; 95% confidence interval, 1.02-1.04).

Conclusions: Our study adds to the current literature with the inclusion of 2014 data and confirms previous findings of a post-ACA decrease in out-of-pocket contraceptive costs. In addition, there was a small but statistically significant increase in LARC insertions after the ACA. This finding indicates the importance of reduced cost sharing for increasing use of the most effective contraceptives.

Long-acting reversible contraceptives (LARCs), which include the intrauterine device (IUD) and contraceptive implant, are highly effective forms of prescription contraception. LARCs have become more affordable to insured women as a result of the contraceptive coverage mandate of the Affordable Care Act (ACA), which took effect in August 2012. The mandate requires most private health insurance plans to cover all U.S. Food and Drug Administration-approved contraceptive methods without cost-sharing (Henry J. Kaiser Family Foundation, 2015; U.S. Department of Health and Human Services, 2016). Before the ACA, the greater upfront out-of-pocket costs of LARCs likely discouraged women from choosing them over less effective prescription birth control methods with lower upfront costs (Chuang et al., 2015). Nevertheless, LARC use increased from 2.4% of all contraceptive users in 2002 to 14.3% in 2014, according to the National Survey of Family Growth (Daniels, Daugherty, Jones, & Mosher, 2015; Guttmacher Institute, 2014; Kavanaugh & Jerman, 2018; Xu, Macaluso, Ouyang, Kulczycki, & Grosse, 2012).

Several studies have examined the effect of the ACA contraceptive coverage mandate on out-of-pocket costs for contraception (Bearak, Finer, Jerman, & Kavanaugh, 2016; Becker & Polsky, 2015; Finer, Sonfield, & Jones, 2014; Sonfield, Tapales, Jones, & Finer, 2015), and all show decreasing out-of-pocket costs to women after 2012. Other studies have examined both out-of-pocket costs and types of contraception women use after

* Correspondence to: Ashley H. Snyder, MD, MSc, 500 University Drive, HO34; Division of General Internal Medicine; Hershey, PA 17033, USA. Phone: (717) 531-8161.
E-mail address: asnyder6@pennstatehealth.psu.edu (A.H. Snyder).

1049-3867/$ - see front matter © 2018 Jacobs Institute of Women's Health. Published by Elsevier Inc.
https://doi.org/10.1016/j.whi.2018.01.005

the ACA. Using claims data from a regional health plan, Carlin, Fertig, and Dowd (2016) found that reduced cost sharing was associated with increased use of prescription contraceptives, including LARCs, among Midwestern women. Using a national health claims database, Law et al. (2016) found a steep decline in out-of-pocket costs for LARCs after the ACA contraceptive provision and an increase in IUD claims from 1.2% in 2011, to 1.3% in 2012, to 1.6% in 2013. Pace, Dusetzina, and Keating (2016) found that the proportion of claims without cost-sharing for IUDs and implants increased over time but found no significant increase in LARC uptake post-ACA implementation as of 2013. Using survey data, Bearak and Jones (2017) observed no changes in patterns of contraceptive use between two time points: fall of 2012 (pre-ACA) and spring of 2015 (post-ACA).

In this study, we examine the out-of-pocket costs for prescription contraception and contraceptive use patterns between 2006 and 2014 using a large national database of health claims for privately insured women. This is the first study, to our knowledge, with post-ACA claims data through 2014. We hypothesize that the post-ACA out-of-pocket costs for prescription contraception will be decreased and that the use of LARCs will increase.

Materials and Methods

Data Source and Inclusion Criteria

Data are from the Truven Health Analytics MarketScan database, which consists of reimbursed health care claims for employees, retirees, and their dependents from more than 250 employers and health plans from all 50 states and the District of Columbia. Individuals included in the database are covered under commercial (private) insurance plans. This large, national database includes an annual population of more than 50 million people and captures administrative claims with data from inpatient visits, outpatient visits, and pharmacy claims deidentified at the patient level. This study was approved by the Penn State College of Medicine Institutional Review Board.

We conducted a retrospective cohort analysis to examine claims and out-of-pocket costs for prescription contraceptive methods used by women before and after implementation of the ACA contraceptive mandate in August 2012. We consider 2013 as the first post-ACA year because it is the first benefits year in which contraceptive coverage without cost-sharing would have been implemented. Study cohorts were created for each calendar year between 2006 and 2014 (the most recent year for which data are available) that included women ages 13 to 45 who had continuous medical and pharmacy coverage during that year. We were unable to identify whether women belonged to employer groups that were exempt from the contraceptive mandate.

Measures of Contraceptive Use

Contraceptive claims were identified using Healthcare Common Procedure Coding System (HCPCS), *International Classification of Diseases*, 9th edition (ICD-9), National Drug Code, and Current Procedural Terminology (CPT)-4 codes. IUD insertions were identified using ICD-9 codes V25.11 and 69.7, CPT-4 code 58300, or HCPCS codes J7300, J7301, J7302, S4981, and S4989. Implant insertions were identified using ICD-9 code V25.5, CPT-4 code 11981, and HCPCS codes J7306 and J7307. Because the CPT-4 code for implant insertion is not contraceptive specific, the CPT-4 code was combined with the contraceptive-specific ICD-9 and HCPCS codes to ensure only the capture of contraceptive implant insertions. The LARC insertion rate was defined as the percent of women in each cohort year who had a LARC insertion claim. The LARC insertion rate does not represent the total proportion of contraceptors using LARC methods during that year, because some LARC users will have had their LARC inserted in previous years. The LARC insertion rate is not comparable with the LARC use rate reported based on surveys such as the National Survey of Family Growth, which include both insured and uninsured women and self-reported contraceptive use.

For non-LARC methods, pharmacy claims were searched for oral contraceptive pills, patches, injection, and the contraceptive ring. Injections were additionally identified using procedure codes. Women with pharmacy claims for more than one type of non-LARC method in a calendar year were coded as using the method that was in use for the longest period of time in that year. Use rates of non-LARC methods were defined as the percent of women using each of the contraceptive methods during each cohort year. Nonprescription contraceptive methods could not be accounted for because they do not generate claims.

Measures of Contraceptive Costs

Individual out-of-pocket costs for each type of contraception were estimated by combining copayment, coinsurance, and deductible payments for both contraception and insertion fees (in the case of LARCs). Costs for LARCs are reported as out-of-pocket cost for insertion (including device and insertion fees). Oral contraceptives, patches, and rings are reported as cost per 28-day supply obtained (e.g., a pack of contraceptive pills). Injection is reported as cost per injection. All costs were adjusted for inflation to 2015 dollars using the Consumer Price Index.

Measures of Covariates

Contraceptive choices are influenced by other variables in addition to cost (Weisman, Lehman, Legro, Velott, & Chuang, 2015), but covariates available for this analysis are limited. The MarketScan database includes limited information on the patient, and key sociodemographic variables such as educational level, race/ethnicity, and marital status are not available. We were able to control for age group, with age groups defined as 13 to 17, 18 to 25, 26 to 35, and 36 to 45 years. Geographic region was included as a covariate to account for possible variations in prescribing patterns; region is precoded in the dataset as northeast, north central, south, and west. Finally, urban versus rural residence, which is measured in the dataset based on the Metropolitan Statistical Area, was included because the availability of providers for LARCs is likely to be higher in urban areas.

Statistical Analysis

For each study year, we report the mean and median out-of-pocket costs for each contraceptive method in 2015 dollars, using the medical care component of the Consumer Price Index. For method use, we report the IUD and implant insertion rates and percent of women using oral contraceptives, injections, ring, and patch in each study year. To test whether the trend in LARC use can be attributed to the ACA, we estimate the likelihood of LARC insertion post-ACA implementation compared with pre-ACA

Table 1
Characteristics of Sample of Privately Insured Reproductive-age Women, by Study Year (Percentages)

Year	Base n (Millions)	Age (y)				Region*				Rural Residence†
		13-17	18-25	26-35	36-45	Northeast	North Central	South	West	
2006	3.88	17	18	27	38	12	23	48	17	16
2007	4.44	17	18	27	38	11	24	47	18	17
2008	5.68	17	18	28	37	14	26	43	16	15
2009	5.86	16	19	29	37	11	28	43	17	14
2010	6.31	16	19	29	36	14	26	40	20	14
2011	7.13	16	22	28	35	16	24	40	19	15
2012	7.32	15	23	28	34	16	24	38	20	15
2013	6.26	15	24	27	34	17	22	36	22	15
2014	6.47	15	24	27	34	19	20	40	18	15

Note: Percentages for each category may not sum to 100% owing to rounding.
Data Source: Truven Health Analytics MarketScan.
* Region is a predefined variable in the database.
† Urban versus rural residence is determined by the Metropolitan Statistical Area.

using multivariable logistic regression adjusting for covariates and year (to account for secular trends). Statistical analyses were performed using SAS version 9.4 (SAS, Inc, Cary, NC).

Results

Table 1 describes the characteristics of the study sample, which consists of more than 3 million women in each study year. The sample size changes year to year because of changes in the number of employers and health plans that contribute data to MarketScan, or because of changes in the number of enrollees. The sample distribution by age, region, and urban versus rural residence is similar over time, with one exception: the greater proportion of women ages 18 to 25 after 2010 could reflect increased dependent coverage under ACA.

Table 2 shows the mean and median out-of-pocket costs for each prescription contraceptive method in each study year. After the ACA contraceptive coverage mandate (2013-2014), the mean out-of-pocket cost for all types of contraception decreased sharply. Similarly, the median out-of-pocket cost for all types of prescription contraception decreased to $0. In 2014 (data not shown), 91.5% of IUD recipients and 87.1% of implant recipients paid $0 out of pocket.

Table 3 shows the trend in prescription contraceptive use over successive cohort years. Each year, the greatest proportion of women was oral contraceptive users (about 1 in 4 women each year). The IUD insertion rate was 0.6% in 2006 and increased steadily over time to 2.0% in 2014. The contraceptive implant insertion rate was less than 0.1% in 2006 and increased to 0.4% in 2014.

Table 4 shows that there was a statistically significant increased odds of LARC insertion (adjusted odds ratio, 1.03; 95% confidence interval, 1.02-1.04) after the contraceptive mandate was implemented, when adjusting for covariates. There was a statistically significant 14% increased odds of LARC insertion with each subsequent year from 2006 to 2014. Compared with the oldest age group, girls 13 to 17 years old were significantly less likely to have a LARC insertion, whereas women aged 18 to 25 and 26 to 35 had increased odds of LARC insertions. Women living in the Northeast had decreased odds of LARC insertions, whereas women in the South and West had increased odds of LARC insertions compared with women living in the North central region. There was no difference in LARC insertion for women in rural versus urban areas.

Discussion

This study confirms prior studies showing a dramatic decrease in out-of-pocket costs for prescription contraceptive methods, including LARCs, after the ACA contraceptive coverage mandate was implemented. This study extends this finding using national claims data for privately insured women through 2014. Although most women had no out-of-pocket costs for LARCs after 2012, the mean cost for an IUD was still between $17 and $22. These post-2012 costs may be attributable to grandfathered plans, employers with religious exemptions to the contraceptive

Table 2
Mean and Median Out-of-Pocket Costs by Contraceptive Type, 2006-2014 (Dollars)

Year	Oral Contraceptive		Injection		Ring		IUD		Implant		Patch	
	Mean	Median	Mean	Median	Mean	Median	Mean	Median	Mean	Median	Mean	Median
2006	31	18	13	8	60	18	78	23	50	46	25	18
2007	24	16	13	9	62	29	79	29	107	72	24	16
2008	20	14	11	6	80	43	74	27	87	27	23	16
2009	19	13	11	6	70	39	80	26	91	26	20	15
2010	18	12	11	6	88	44	94	25	98	25	20	15
2011	17	12	12	6	64	35	101	23	103	23	19	13
2012	15	10	11	6	82	34	114	21	139	38	18	12
2013	6	0	5	1	35	0	22	0	31	0	9	0
2014	5	0	4	0	7	0	17	0	24	0	8	0

Note: Dollars are adjusted for inflation to 2015 dollars using the medical care component of the Consumer Price Index. Intrauterine device (IUD) and implant cost presented as out-of-pocket cost in dollars per insertion. Injection cost is presented as out-of-pocket cost in dollars per injection. Cost for other methods (oral contraceptive, ring, and patch) presented as out-of-pocket cost per 28-day supply obtained.

Table 3
Contraceptive Use by Year, 2006-2014 (Percent of Women Ages 13-45)

Year	Oral Contraceptive	Injection	Ring	IUD Insertions	Implant Insertions	Patch
2006	24.8	2.3	1.3	0.6	<0.1	<0.1
2007	24.3	2.3	1.5	0.8	<0.1	<0.1
2008	25.2	2.3	1.7	1.2	0.1	<0.1
2009	26.1	1.4	2.3	1.3	0.1	<0.1
2010	25.3	1.4	2.4	1.3	0.1	<0.1
2011	25.7	2.4	1.8	1.4	0.2	<0.1
2012	25.6	2.5	1.8	1.5	0.2	<0.1
2013	25.5	1.8	1.7	1.8	0.3	<0.1
2014	26.1	1.9	1.7	2.0	0.4	<0.1

Abbreviation: IUD, intrauterine device.

mandate, noncompliance with the ACA contraceptive mandate, or failure to cover all types of LARCs (Tschann & Soon, 2015). Currently, the future of contraceptive coverage without cost-sharing is uncertain. If more health plans were to become exempt from coverage, out-of-pocket spending for contraception would be expected to increase.

The rate of new LARC insertions increased over the study period, with a statistically significant 3% increased odds of insertion after implementation of the ACA contraceptive coverage requirement. A 3% increase across the millions of privately insured reproductive-age women nationally is highly significant from a population perspective. This finding is promising and suggests that the removal of the cost barrier to IUDs and implants has increased their rate of adoption after the ACA.

As noted, the 2013 plan year is the first year in which the ACA contraceptive coverage benefit would have been in effect for most privately insured women, and to date we have claims data only through 2014. Because many privately insured women were not aware of the ACA contraceptive coverage benefit during this timeframe (Chuang et al., 2015), their contraceptive choices might not yet have changed despite having no-cost coverage. Cost could be a leading indicator in that, once more women experience no-cost coverage for their contraceptive prescriptions, their behavior with regard to contraceptive choices could change.

A limitation of this study is that the MarketScan claims database does not include all private insurers, and it does not include those covered by Medicaid or the uninsured. This limitation made it difficult to make meaningful comparisons with National Survey of Family Growth data, which are based on nationally representative surveys that include Medicaid patients and uninsured women. Because this is a claims database, we cannot account for all relevant covariates, or for the use of nonprescription contraceptive methods, or for prescription methods obtained for which a claim was not generated (e.g., in family planning or school-based clinics). In addition, we could not account for ongoing LARC use by women who obtained the method in a year outside of our period of observation. This limitation underestimates LARC use for each year. Strengths of this database include its large size and national scope over many years, including 2 full years after the ACA mandate implementation.

Table 4
Adjusted Odds of LARC (IUD or Implant) Insertion

	Adjusted OR (95% CI)
Post-ACA	1.03 (1.02–1.04)
Pre-ACA	Reference
Cohort year (1 year increments, 2006–2014)	1.14 (1.13–1.14)
Age group (y)	
13-17	0.37 (0.37–0.38)
18-25	1.63 (1.62–1.64)
26-35	2.24 (2.23–2.26)
36-45	Reference
U.S. region	
Northeast	0.90 (0.89–0.90)
North Central	Reference
South	1.04 (1.04–1.05)
West	1.20 (1.19–1.21)
Urban residence	1.00 (1.00–1.00)
Rural residence	Reference

Abbreviations: ACA, Affordable Care Act; CI, confidence interval; IUD, intrauterine device; LARC, long-acting reversible contraceptive; OR, odds ratio.
Note: Hosmer and Lemeshow goodness-of-fit test χ^2 statistic 3545.9 ($p < .0001$).

Conclusions

The ACA contraceptive mandate has dramatically reduced out-of-pocket costs for prescription contraceptives including LARCs. After the ACA, there was a small but statistically significant increase in LARC insertions.

Implications for Practice and/or Policy

Increased LARC insertions after the ACA in this database of privately insured women is an important finding that indicates the importance of reduced cost-sharing for increasing use of the most effective contraceptives and preventing unintended pregnancy.

Acknowledgments

This research was funded by the Robert E. Dye, MD, Professorship at the Penn State College of Medicine and by the Penn State Center for Women's Health Research.

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Author Descriptions

Ashley H. Snyder, MD, MSc, is a general internist with a clinical focus in outpatient primary care and with research interests in reproductive women's health and health policy.

Carol S. Weisman, PhD, is a sociologist and health services researcher with principal interests in women's health and in the organization and quality of women's health care.

Guodong Liu, PhD, is a computer scientist and bioinformatician with extensive research experience in data mining and knowledge discovery over large electronic medical records and large administrative claims databases.

Douglas Leslie, PhD, is a health economist with considerable experience in the fields of health economics, health services research, and pharmacoeconomics who has worked extensively with large administrative claims databases.

Cynthia H. Chuang, MD, MSc, is Professor of Medicine and Public Health Sciences, and Chief of the Division of General Internal Medicine at Penn State College of Medicine. Her research focuses on reproductive health care for adult women.

EXHIBIT O

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, Plaintiff, v. DONALD J. TRUMP, *et al.*, Defendants.	**No. 2:17-cv-04540-WB**

DECLARATION OF SAMANTHA F. BUTTS, M.D., MSCE[1]

I, Samantha F. Butts, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, I state as follows:

I. My Background and Experience

1. I am a doctor, teacher, and clinical researcher in the area of women's reproductive health. Of the time I spend working, I spend approximately 15% on education and administration, 10%-15% on clinical research, and 70%-75% on patient care.

A. *My Education, Licensure and Board Certifications*

2. I earned a Bachelor of Arts degree, *cum laude*, from Harvard University, in 1994, and a Medical Degree from the Harvard University School of Medicine, in 1998.

3. I completed both my residency in Obstetrics and Gynecology (1998-2002) and a Fellowship in Reproductive Endocrinology and Infertility (2002-2005) at the Hospital of the University of Pennsylvania.

4. After that, I earned a Masters of Science in Epidemiology (MSCE) from the

[1] I attach a true and correct copy of my curriculum vitae hereto as Exhibit A.

University of Pennsylvania School of Medicine in 2006.

5. I have been licensed to practice medicine in Pennsylvania since 2001.

6. I have also been certified by the American Board of Obstetrics and Gynecology with a specialty in Obstetrics and Gynecology since 2006 and subspecialty in Reproductive Endocrinology & Infertility since 2009.

B. ***My Teaching, Research and Additional Qualifications***

7. I have held a faculty position at the University of Pennsylvania School of Medicine since 2005.

8. I started as an Assistant Professor and, since 2014, I have served as an Associate Professor of Obstetrics and Gynecology, in the Division of Reproductive Endocrinology and Infertility (REI). From 2014-2016, I was honored to serve as the Ombudsman for the Students at the University of Pennsylvania School of Medicine, Perelman School of Medicine.

9. As an AssociateProfessor of Obstetrics and Gynecology, I am actively involved in the clinical training of medical students, residents and fellows. I participate in didactic education programs and mentor resident-driven clinical research projects.

10. I also developed the first comprehensive reproductive endocrinology and infertility curriculum for trainees at the Hospital of the University of Pennsylvania and supervise resident training in reproductive endocrinology and infertility. In 2011, my achievements in resident education were recognized with a National Faculty Teaching Award from the American College of Obstetricians and Gynecologists and the Council on Resident Education in Obstetrics and Gynecology.

11. I also spend a meaningful amount of my time acting as a clinical researcher.

12. In this capacity, I serve and have served as an investigator and principal

investigator on a number of studies and projects regarding women's healthcare, many of which have been fully funded by grants. For example, I was one of the first people to receive a National Institute of Health training grant as part of the NIH's National Training Program in Reproduction (NIH T32 grant), and I was the inaugural recipient of the New Investigator Award from the Center of Excellence in Environmental Toxicology at the University of Pennsylvania.

13. I have published more than 100 scholarly articles, abstracts, research publications, reviews, book chapters, and committee reports related to women's reproductive healthcare. Among these, I have researched and written peer-reviewed articles about treating hormonal disorders, such as polycystic ovary syndrome, using contraceptives as a first-line medication. *See, e.g., Polycystic Ovary Syndrome: How Best to Manage?*, Consultant, 46:745-749, (2006) and *Abnormal Uterine Bleeding*, NMS Series for Independent Study: Obstetrics and Gynecology, Chap. 23, (6th. Ed. 2008).

14. I am often engaged to consult and collaborate with academic and private institutions. Recently, for example, as a member of the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice (ACOG Committee), I was asked to develop an opinion regarding treatment of Primary Ovarian Insufficiency. In connection with my work on this issue, the ACOG Committee published an opinion in May of 2017 recommending that contraceptives be considered among the options to provide as hormone replacement therapy to treat Primary Ovarian Insufficiency. *See* Opinion 698, *Hormone Therapy for Primary Ovarian Insufficiency*, Obstetrics and Gynecology, 129(5): 963-964 (May 2017).

15. In connection with my work, I have lectured throughout the country, by invitation, about reproductive health. For example, at the 2016 Women in Statistics Conference in Charlotte, North Carolina, I delivered a presentation called "Reproductive Decision Making

and Your Career: Embracing Biology, Debunking Myths, and Gaining Control."

16. I have also organized and moderated multiple scientific meetings throughout my career, including annual meetings of the American Society of Reproductive Medicine.

17. I have held various professional appointments, as well. Among these, I have been a Member of the Center for Research on Reproduction and Women's Health since 2005; an Associate Scholar for the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania since 2006; and a Member of the Center for Excellence in Environmental Toxicology, Endocrine Disruptors Core, since 2008.

18. I also maintain memberships in a number of professional, academic, and scientific societies, both nationally and internationally, including the American Society for Reproductive Medicine (since 2002), the Society for Reproductive Endocrinology and Infertility (since 2002), the American College of Obstetricians and Gynecologists (since 1998) and the Endocrine Society (since 2012). I have received many professional accolades, awards, and honor society memberships throughout my career.

C. *My Medical Practice*

19. In addition to my academic work, I maintain an active medical practice and, in 2017, was listed as one of *Philadelphia Magazine*'s "Top Doctors".

20. Since 2005, I have served as an Attending Physician in the Department of Obstetrics and Gynecology, and also in the Reproductive Surgical Facility at the Hospital of the University of Pennsylvania.

21. Last year I saw and treated approximately 1,500 to 2,000 patients.

22. Some of my patients travel thousands of miles for the specialty medical treatment I can provide at Penn Medicine.

23. But in many ways, my medical practice reflects the reality that the Hospital of the University of Pennsylvania is also the community hospital of West Philadelphia.

24. In addition to specialty patients and residents of West Philadelphia, I also treat many members of the academic community at at the University of Pennsylvania.

25. My clinical expertise includes reproductive endocrinology, with a focus on managing hormonal disorders such as polycystic ovary syndrome, primary ovarian insufficiency/premature ovarian failure, amenorrhea, dysmenorrhea/chronic pelvic pain, and abnormal uterine bleeding, as well as in infertility, in vitro fertilization, and reproductive surgery.

26. Many of these medical conditions and disorders are common among women.

27. As part of my practice, I regularly prescribe contraceptives for both contraceptive and non-contraceptive purposes.

II. Benefits of Contraceptive Use

A. *Contraceptives Are Effective and Approved for Uses Other Than Preventing Pregnancy*

28. Contraceptives are effective, and approved, to be used as medication for purposes other than preventing pregnancy. Indeed, I regularly use all kinds of contraceptives for non-contraceptive uses, including for the treatment of life-threatening problems.

29. For example, contraceptives are the standard first-line of care for a number of hormonal, and other, disorders, including poly-cystic ovarian syndrome, primary ovarian insufficiency/premature ovarian failure, amenorrhea, dysmenorrhea/chronic pelvic pain, and abnormal uterine bleeding.

30. These conditions greatly impact the quality of life of the many women who suffer from them. In fact, about 10% percent of all women have irregular periods caused by poly-cystic

ovarian syndrome or other hormonal disorders which can significantly harm well-being and quality of life. Extreme cases of heavy menstrual bleeding due to hormonal or anatomic problems of the uterus that I see and treat can at times be life-threatening.

31. I frequently use contraceptives to treat these conditions in my own medical practice and, in fact, prescribe "birth control pills" more for these other purposes than to prevent pregnancy given the population of patients who make up my practice.

32. Throughout my career, I have been required to perform non-operative blood transfusions for at least 50 women due to loss of blood caused by heavy periods and acute menstrual bleeding that can cause anemia.

33. In 2009, the FDA approved use of the Mirena Inter-Uterine Device (IUD) to treat women with heavy bleeding and hemophilia. Among my patients who use the Mirena IUD, the vast majority (90%-95%) use it for purposes other than birth control.

34. The hormonal and other disorders I treat inflict direct and indirect personal and financial costs upon the women who suffer from them; they prevent women from participating fully in the workplace and, more broadly in society.

35. Contraceptives are a cost-effective and clinically proven way to treat these often debilitating disorders.

B. *Contraceptives Are Effective in Preventing Unintended and Ill-Advised Pregnancies, and Their Use Causes Other Long-Term Health Benefits*

36. Contraceptives also play an important role in preventing unintended pregnancy.

37. For some women, this treatment is not optional – it is necessary to prevent serious illness and even death.

38. There are multiple high risk conditions for which pregnancy is relative or absolutely contraindicated. These conditions include cardiac problems and history of stroke.

39. For survivors of breast cancer, pregnancy hormones can cause serious medical harm until the patient is well into remission.

40. Contraceptives help patients avoid unintended pregnancies in such situations; they prevent medical harm and save lives.

41. Contraceptives use also carries long-term health benefits for women.

42. For instance, it has been shown that long-term users of the standard oral contraceptive pill (at least 5-10 years of usage) are 50-80% less likely to develop ovarian or uterine cancer.

III. My Opinion on the "Religious Exemption Rule" and "Moral Exemption Rule"

43. I have reviewed both the "Religious Exemption Rule" and the "Moral Exemption Rule" (together, the "Rules"), as well as the Complaint filed by the Commonwealth of Pennsylvania in the above-captioned matter that challenges them.

44. Based upon my knowledge, education, training and experience, it is my professional opinion that the Rules will cause immediate and irreversible harm because they will cause women to lose preventive contraceptive care under their employer group health plans.

A. *Cost is a Barrier to Contraceptive Access*

45. It is my understanding, and it has been my experience, that cost is a barrier to patient access to contraceptives.

46. Prior to passage of the Affordable Care Act (the "Affordable Care Act" or "ACA"), before preventative contraceptive care was provided at no additional cost under the ACA's contraceptive mandate, I regularly counseled my patients about the cost related to their recommended contraceptive choices.

47. I would estimate that, prior to the ACA, about 10-20% of the patients for whom I

had prescribed contraceptives would come back from the pharmacy without filling their prescriptions; they would, instead, request that I prescribe a less effective, but cheaper, method of contraception. Or they would forego use of contraception altogether.

48. Such requests were most frequent when I had prescribed an IUD because, pre-ACA, IUDs were one of the most expensive forms of contraception for patients. But they are also a much more effective method of contraceptive care than are birth control pills.

49. And, for therapeutic reasons, some patients cannot take estrogen birth control pills, at all.

50. After the ACA passed and the contraceptive mandate was instituted, however, I saw that my patients were free to make contraceptive choices on the basis of their medical needs and concerns, alone, without the burden of having to weigh the cost of the preferred medical choice. Post-ACA, the only concern has been what is best for the patient.

51. As a result, I have seen my patients making more medically informed contraceptive choices and have not had the experience of patients rejecting the contraceptives I prescribed due to their cost under private insurance plans.

C. *Because Patients Will Lose Contraceptive Coverage under the New Rules, They Will Make Less Medically Sound Contraceptive Choices and, Therefore, Will Be Harmed*

52. It is apparent, however, that under the new Rules this post-ACA focus on what is best for the patient will change.

53. This is so because, as a result of the Rules, some women will lose insurance coverage for preventative contraceptive care.

54. As a result, their cost for contraceptive care will rise.

55. Based upon my own experience and existing scientific and empirical information that I have reviewed and am aware of, under the new Rules, cost will, again, become a barrier to

women's access to and use of the contraceptive that is medically recommended for them.

56. Many of these women who will no longer receive contraceptive coverage will not only face financial harm, but will also face medical harm.

57. This harm will manifest itself in the disruption of these patients' medical treatment, whether by substituting a less effective but cheaper method of contraception or by being forced to stop using contraceptives at all, due to financial reasons.

58. Some of these women will face unintended pregnancy and other adverse medical consequences.

D. ***The New Rules Are Not Based Upon Sound Scientific or Empirical Evidence***

59. It is also my opinion that the new Rules are not based upon sound scientific or empirical evidence.

60. The Rules indicate, among other things, that contraceptives are not effective in preventing unintended pregnancy, that they are harmful to women's health, and that they promote promiscuity. This is false.

61. These representations conflict with peer-reviewed and medically-accepted data, and are not credible.

62. For these reasons, I believe that an injunction of the Rules is necessary to prevent immediate and irreparable harm to women in Pennsylvania and around the Country, who will otherwise lose ongoing preventive care coverage under their group health plans due to the Rules.

I hereby affirm that the foregoing is true and correct based upon my knowledge, information and belief, and I make these statements subject to the penalty of perjury.

Date: 10/25/17

By: _____
SAMANTHA F. BUTTS, M.D., MSCE

EXHIBIT A

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Samantha F. Butts, MD, MSCE

Address: Penn Fertility Care
Center for Reproductive Medicine and Surgery
University of Pennsylvania Medical Center
3701 Market Street, 8th Floor
Philadelphia, PA 19104 US

Education:

1994	BA	Harvard University, Cambridge MA (History and Science-cum laude)
1998	MD	Harvard University School of Medicine, Boston, MA
2006	MSCE	University of Pennsylvania School of Medicine, Philadelphia, PA

Postgraduate Training and Fellowship Appointments:

1998-2002	Resident in Obstetrics and Gynecology, The Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania
2002-2005	Fellow in Reproductive Endocrinology and Infertility, The Hospital of the University of Pennsylvania, Philadelphia, PA

Faculty Appointments:

2005-2014	Assistant Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine
2014-present	Associate Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine

Hospital and/or Administrative Appointments:

2005-present	Attending Physician, Department of Obstetrics and Gynecology, Division of REI, Hospital of the University of Pennsylvania, Philadelphia, PA
2005-present	Attending Physician, Reproductive Surgical Facility, Hospital of the University of Pennsylvania, Philadelphia, PA
2014-2016	Ombudsman for the Students at the University of Pennsylvania School of Medicine, Perelman School of Medicine

Other Appointments:

2005-Present	Member, Center for Research on Reproduction and Women's Health
2006-present	Associate Scholar, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania
2008-present	Member, Center for Excellence in Environmental Toxicology, Endocrine Disruptors Core

Specialty Certification:

2006	American Board of Obstetrics and Gynecology
2009	American Board of Obstetrics and Gynecology, subspecialty board of Reproductive Endocrinology & Infertility

Licensure:

2001-Present	Pennsylvania - MD074255-L

Awards, Honors and Membership in Honorary Societies:

2003	National Institutes of Health Post-Doctoral Research Training Grant (T32)
2004-2006	National Institutes of Health Contraception and Infertility Loan Repayment Program Award
2004	The Stewart Scholarship for Research in Public Health awarded by the Association of Reproductive Health Professionals
2005	The Emily B. Hartshorne Mudd Award for Contributions to Family Health
2006	AAMC Early Career Women Faculty Professional Development Seminar
2009	Philadelphia Magazine's Best Physicians Age 40 and Under
2009	Center for Excellence in Environmental Toxicology New Investigator Award
2010-2012	National Institutes of Health Contraception and Infertility Loan Repayment Program Award (renewal)
2011	National Faculty Award, The American College of Obstetricians and Gynecologists and The Council on Resident Education in Obstetrics and Gynecology
2011	Invitation to attend the White House Business Leaders' Briefing, sponsored by the White House Business Council and Business Forward, December 7th, 2011
2011	American Association of Obstetricians and Gynecologists Foundation James W. Kennedy Award to attend The American Gynecological and Obstetrical Society Meeting
2011	Faculty Teaching Award for Excellence in Resident Education, Department of Obstetrics and Gynecology
2012	The Network Journal's "40 Under 40" Achievement Award
2014	SREI Strategic Planning Retreat

2014	Mentor to Dr. Nyia Noel, Recipient of 2014 Resident Research Award for Excellence in Research for "*Risk Factors for Hospital Readmissions for Patients Undergoing Benign Gynecologic Surgery*"
2015	ASRM Access to Care Reproductive Summit, Invited Participant
2016	NIH Study Section, Integrative and Clinical Endocrinology and Reproduction -- Ad Hoc Member
2017	Dr. Edward S. Cooper Wharton Leadership Training Program
2017	Philadelphia Magazine's Top Doctors

Memberships in Professional and Scientific Societies and Other Professional Activities:

International:

2012-Present The Endocrine Society

- Member, Advocacy and Public Outreach Core Committee, 2014-2016

National:

1998-Present American College of Obstetricians and Gynecologists

- Fellow, 2006-present
- Chair, Gynecologic Practice Subcommittee on Reproductive Endocrinology, 2014-2017
- Member, Committee on Gynecologic Practice, Subcommittee on Reproductive Endocrinology, 2011-2017
- Ex-Officio Member, Committee on Gynecologic Practice, 2014-2017

2002-Present American Society for Reproductive Medicine

- ASRM Practice Committee, ACOG Representative, 2014-2017
- Society for Assisted Reproductive Technologies-Clinical Outcomes Reporting System Research Committee, 2012-2016
- Health Disparities Special Interest Group, 2009-present
- Environment and Reproduction Special Interest Group, 2010-present
- Reviewer, E-learn Modules for Continuing Education Committee 2016
- Nutrition Special Interest Group, 2012-present
- Poster Prize Award Committee ASRM Annual Meeting 2011 and 2013

2002-Present Society for Reproductive Endocrinology and Infertility

2007-2012 National Medical Association

2011-2014 Pacific Coast Reproductive Society

Editorial Positions:

2008-present	Ad Hoc Editorial Board/Abstract Grading Committee, American Society of Reproductive Medicine
2008-Present	Peer Reviewer, Human Reproduction Journal

2008-Present	Peer Reviewer, Fertility and Sterility Journal
2008-Present	Peer Reviewer, Consultant Journal
2011-Present	Peer Reviewer American Journal of Obstetrics and Gynecology
2011-Present	Peer Reviewer, Journal of Clinical Endocrinology and Metabolism
2013-Present	Peer Reviewer, Journal of the American Medical Association (JAMA)
2017-present	Editorial Board, Journal of Clinical Endocrinology and Metabolism

Academic and Institutional Committees:

2002-2003	Mudd Professorship Suite for Women's Health Research
2004-2005	Advisor to the Obstetrics and Gynecology Resident Journal Club
2006-present	Director, Research in Progress Meetings for Division of Infertility and Reproductive Endocrinology
2007-2009	Chair, Information Technology Committee -- Women's Health Clinical Research Center
2012-2013	Selection Committee, Medical Student Research Paper Prize Awards, Perelman School of Medicine
2013-present	MSCE Comprehensive Exam Committee, Center for Clinical Epidemiology and Biostatistics
2013	Ad Hoc Reviewer, University Research Foundation Review Committee
2014-present	Faculty Coordinator, Grand Rounds, Department of Obstetrics and Gynecology
2014-2015	Member of the Committee to Review the Department of Orthopedic Surgery, Hospital of the University of Pennsylvania
2014-present	Member, University of Pennsylvania Provost's Academic Planning and Budget Committee – *This committee provides advice on academic policies and procedures, interdisciplinary and cross-school efforts, strategic planning issues, research support and regulations, budgetary issues, and such matters as faculty and minority gender equity, early retirement, and personnel benefits. It also advises the Provost on school and center external review recommendations and proposed new academic degrees and new research institutes*
2017-present	Member, Search Committee for the Senior Vice Dean for Medical Education, Perelman School of Medicine
2017-present	Ad Hoc Reviewer, Penn Presbyterian Harrison Award Committee
2017-present	Unit Based Care Leadership Committee – This committee of physicians and nurses oversees quality initiatives for gynecologic surgical patients at the Hospital of the University of Pennsylvania

Major Academic and Clinical Teaching Responsibilities:

2004	Eritrean Fistula Project: United Nations Population Fund-Sponsored Clinical Mission to Eritrea to Treat Birth-Related Fistulas and Investigate Causes of Secondary Amenorrhea

2004-Present	Lecturer for BSTA 510 a course for the Biostatics Graduate School Curriculum, Center for Clinical Epidemiology and Biostatics, University of Pennsylvania
2005-Present	Faculty in the Reproduction Module for First Year Medical Students
2005-Present	Mentor, Residents and Fellows in Ob/Gyn Research
2005-2008	Advisor and Lecturer, Ob/Gyn Medical Student Interest Group, Eritrean Fistula Project, 2008
2005-Present	Clinical Instructor, Students, Resident, Fellows in Ambulatory, OR and In-Patient Settings
2006-Present	Faculty in Reproductive Epidemiology Course, Center for Clinical Epidemiology and Biostatics
2006-Present	Mentor, Clinical Epidemiology Master's Students with Theses in Reproduction
2006-Present	Faculty, Obstetrics and Gynecology Core Clerkship Didactics -- Lecturer on Ectopic Pregnancy, Eight Lectures per Year
2007-2008	Faculty Advisor, Recipient of FOCUS Medical Student Fellowship in Women's Health
2007-Present	Education Committee, Department of Obstetrics and Gynecology
2007-Present	Director, Medical Student Elective in Reproductive Endocrinology and Infertility
2007	"Obesity, Weight Loss and Reproductive Outcomes: Characterizing the Impact on Adults and the Risks to their Offspring", Grand Rounds for the Division of Medical Endocrinology, University of Pennsylvania Medical School, Philadelphia, PA
2009-2010	"Maternal and Child Health and the Provision of Infertility Treatments: An Ethical Debate", Guest Faculty Lecture for Healthcare Ethics: Policy, Management and Law, Columbia University School of Public Health, New York, NY
2009-present	Invited Faculty, Case Presentation Series for Underrepresented Minority Students in preparation for OB/Gyn Clerkship, Perelman School of Medicine
2010-Present	Director, Resident Education in Infertility and Reproductive Endocrinology
2010-Present	Faculty Coordinator, Resident Preoperative Conference
2010-Present	Faculty, Penn Academy for Reproductive Science: An outreach program that educates female high school students in Philadelphia about reproductive science and women's health through workshops, lectures, and hands-on lab experience
2010	"Disparities in Assisted Reproductive Technologies: Do They Exist, and Could Endocrine Disruptors Play a Role?", Grand Rounds, Division of Endocrinology, Department of Internal Medicine, University of Pennsylvania Medical School, Philadelphia, PA
2011, 2017	Mentor, STEER Summer Undergraduate Environmental Health Scholar Program, Center for Excellence in Environmental Toxicology

2011	Guest Faculty, Obstetrical Society of Philadelphia Annual Resident Education Day
2011-Present	Didactic Lecturer, Department of Family Practice on Infertility and Reproductive Endocrine Topics
2011	Lecturer, "Polycystic Ovary Syndrome" Department of Student Health
2012-2013	Mentor, Research Rotation, Pharmacology Graduate Program
2012-2013	Invited Faculty, Roundtable Discussion with Students on Careers and Training in Obstetrics and Gynecology, Harvard Medical School
2013	Faculty Coordinator and Presenter at "Nutrition and Pregnancy", a Patient Oriented Educational Seminar Addressing Nutritional Guidelines before and Early in Pregnancy. Perelman School of Medicine, University of Pennsylvania
2013	"Primary Ovarian Insufficiency", Grand Rounds for the Division of Medical Endocrinology, University of Pennsylvania Medical School, Philadelphia, PA
2013-present	Mentor, University of Pennsylvania Summer Pre-Med Enrichment Program for Minority Undergraduate Students sponsored by the Center of Excellence for Diversity in Health Education and Research (COE) and the School of Medicine
2014	Faculty, Center of Excellence for Diversity in Health Education and Research Annual Meeting, One on One mentoring of Junior Faculty, June 3, 2014
2014-present	Faculty Mentor for OB/Gyn Resident Research Projects of Nyia Noel, Joan Price, Lilli Zimmerman, Sevelle Holder

Lectures by Invitation:

Sep, 2004	"Premature Ovarian Aging and Infertility", The Steward Award Presentation at the Association of Reproductive Health Professionals Annual Meeting, Washington, DC
Feb, 2005	"Novel Approaches to the Understanding of Premature Ovarian Aging", Grand Rounds, department of Obstetrics and Gynecology, Meharry Medical College, Nashville, TN
Jul, 2005	"Assisted Reproductive Technologies Update: Recent Trends in Success and Emerging Challenges Concerning Outcomes", National Medical Association Annual Convention and Scientific Assembly, New York, NY
Oct, 2005	"Telomere Length and Telomerase Activity in Developing Follicles: Correlation with Premature Ovarian Aging and Outcomes in IVF", Special Research Presentations Session at the 61st Annual Meeting of the American Society for Reproductive Medicine, New Orleans, LA
Jan, 2008	"The Obesity Epidemic and Reproduction: Insights on Maternal, Fetal and Childhood Risks", Grand Rounds, Department of Obstetrics and Gynecology, Emory University School of Medicine, Atlanta, GA

Aug, 2008	"The Northeast Consortium for Minority Faculty Development: A Collaborative Approach among New Jersey Medical School, the University of Pennsylvania School of Medicine, Mount Sinai School of Medicine and Albert Einstein College of Medicine of Yeshiva University", AAMC Group on Faculty Affairs Professional Development Conference, Pittsburgh, PA
May, 2009	"Early Ovarian Aging: Defining Populations at Risk", Annual Retreat, Center for Research on Reproduction and Women's Health, Philadelphia, PA
Jul, 2009	"Environmental Reproductive Toxicants", National Medical Association Annual Convention and Scientific Assembly, Las Vegas, NV
Mar, 2010	"Reproductive Aging Update: Investigating Novel Markers of Senescence and Threats to Ovarian Reserve", Grand Rounds, Department of Obstetrics and Gynecology, Lankenau Hospital/Main Line Health, Bryn Mawr, PA
May, 2010	"Disparities in Assisted Reproductive Technology Outcomes and Access to Infertility Treatment", Grand Rounds, Department of Obstetrics and Gynecology and Women's Health, Albert Einstein College of Medicine of Yeshiva University and Montefiore Medical Center, Bronx, NY
Mar, 2011	"Disparities in Reproductive Outcomes: Exploring the Impact of Nutrition", The Annual Hunger Conference in Delaware County, Chester PA
Apr, 2011	"Reproductive Outcomes in ART: Exploring the Impact of Race and Ethnicity", Pacific Coast Reproductive Society Annual Meeting, Palm Springs, CA
Apr, 2011	"Environmental Toxins and Gametes", Pacific Coast Reproductive Society Annual Meeting, Palm Springs, CA
Jul, 2011	"Obstetrics and Gynecology: How I Got there and What's in Store for the Specialty", National Youth Leadership Forum on Medicine, Villanova University, Villanova, PA
Sep, 2011	"From the First Nine Months to the Rest of Your Life: The Role of Maternal Nutrition and Environment on Fetal Growth and Adult Disease Risk", Grand Rounds Drexel University College of Medicine, Philadelphia, PA
Aug, 2012	"Smoking and Genetic Variation in Metabolism of Environmental Chemicals: A Model for Environmental Reproductive Toxicology", The 45th Annual Meeting of the Society for the Study of Reproduction, Pennsylvania State University, State College, PA
Sep, 2012	"In Vitro Fertilization (IVF): Methods to Prevent Multiple Births", OptumHealth Conference, Philadelphia, PA
Oct, 2012	"Smoking, Genetic Variation, and Reproductive Aging: Exploring Links in a Population Based Cohort", Grand Rounds, Department of Obstetrics and Gynecology, Massachusetts General Hospital, Harvard Medical School, Boston, MA

Oct, 2012	"Infertility 2012: Current Evaluations, Treatments and Controversies", National Association of Nurse Practitioners in Women's Health Annual Conference, Orlando, Florida.
Oct, 2012	"Premature Ovarian Insufficiency", Roundtable Discussion, Annual Meeting of the American Society for Reproductive Medicine, San Diego, CA
Feb, 2013	"Ancestry, Geography, and Reproductive Health: How Race, Ethnicity, and Environment Impact Outcomes Across the Lifecourse", Grand Rounds, Department of Obstetrics and Gynecology, Lehigh Valley Hospital, Allentown, PA
Mar, 2013	"Roe After 40: The Ethics of Fertility and Reproduction: A Fresh Look", Panel Discussion, University of Pennsylvania Law School, Philadelphia, PA
Mar, 2013	"Reproductive Health, Nutrition, and the Environment: Exploring the Impact of Exposures Across the Female Lifecourse", Grand Rounds, Department of Obstetrics and Gynecology, University of Washington School of Medicine, Seattle, WA
Jul, 2013	"State Mandated Coverage for Infertility: Current and Future Impact on Treatment Outcomes and Reproductive Potential", Grand Rounds, Department of Obstetrics and Gynecology, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA
Aug, 2013	"Reproductive Functioning and Potential Across the Female Lifespan: Considering the Impact of Ethnicity and Race", Grand Rounds, Department of Obstetrics and Gynecology, Maimonides Medical Center, Brooklyn, NY
Oct, 2013	"The Environment and Reproduction", The American Gynecological Club Annual Meeting, Philadelphia, PA
Oct, 2013	"Ovarian Function after Gastric Bypass Surgery", Annual Meeting of the Androgen-Excess and Polycystic Ovary Syndrome Society, Newport, RI
Oct, 2013	"Vasomotor Symptoms and Alternatives to Hormonal Therapy", Roundtable discussion at the IFFS/ASRM 2013 Conjoint Meeting, Boston, MA
Mar, 2014	"Reproductive Aging and the Environment: Dissecting Interactions between Chemical Exposures, Race, and Genetic Background", Women's Health Research Seminar Series, Washington University, St. Louis, MO
Mar, 2014	"The Environment and Human Reproductive Health", Web based lecture sponsored by The Health Resources and Services Administration/Maternal and Child Health Bureau, Philadelphia, PA
Apr, 2014	"The Road Less Traveled: Triplets Reflect on Service, Mentorship, and their Professional Journeys", The Annual Helen O. Dickens Commemorative Lecture in Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Mar, 2015	"Female Fertility - The Reproductive Endocrinologist's Perspective", at Fertility and Family Building: Medical, Psychosocial, and Financial Issues sponsored by the Penn Forum for Women Faculty, Philadelphia, PA
Oct, 2016	"Reproductive Decision Making and Your Career: Embracing Biology, Debunking Myths, and Gaining Control", Women in Statistics Conference, Charlotte, NC
Nov, 2016	"Current Practice in Ambulatory Gynecologic Surgery: A Case Based Approach", 7th Annual Peri-operative Conference, Penn Presbyterian Medical Center, Philadelphia, Pennsylvania

Organizing Roles in Scientific Meetings:

Oct, 2008	Moderator, Oral Abstract Session, American Society of Reproductive Medicine Annual Meeting San Francisco, California
Mar, 2009	Moderator, Reproductive Biology Oral Abstract Session, Society for Gynecologic Investigation Annual Meeting Glasgow, Scotland UK
Aug, 2010	Program Co-Chair, Reproductive Endocrinology and Infertility Session, Obstetrics and Gynecology Section, National Medical Association Annual Convention and Scientific Assembly Orlando, FL
Jul, 2011	Moderator, Abstract Session, Obstetrics and Gynecology Section, National Medical Association Annual Convention and Scientific Assembly Washington, DC
Jul, 2011	Program Co-Chair, Reproductive Endocrinology and Infertility Session, Obstetrics and Gynecology Section, National Medical Association Annual Convention and Scientific Assembly Washington, DC
Oct, 2012	Moderator, Reproductive Biology Oral Abstract Session, American Society of Reproductive Medicine Annual Meeting San Diego, CA
Sep, 2013	Steering Committee, Mid-Atlantic Center for Children's Health and the Environment Conference on Environmental Health for Obstetricians and Gynecologists Washington, DC
Oct, 2013	Moderator, Reproductive Endocrinology and Infertility Fellows Research Abstract Session, Conjoint Meeting of the International Federation of Fertility Societies and the American Society for Reproductive Medicine Boston, MA
Oct, 2014	Moderator, Reproductive Biology Oral Abstract Session, American Society of Reproductive Medicine Annual Meeting Honolulu, HI

Oct, 2015	Moderator, Oral Abstract Session, American Society of Reproductive Medicine Annual Meeting Baltimore, MD
Aug, 2016	Faculty Representative for Perelman School of Medicine Office of Inclusion and Diversity at the National Medical Association Annual Meeting Los Angeles, CA
Apr, 2017	Faculty Representative for Perelman School of Medicine Office of Inclusion and Diversity at the American Medical Women's Association Annual Meeting San Francisco, CA

Grants:

Past:

Maternal Vitamin D Status and Outcomes in Pregnancy, Penn Presbyterian Harrison Fund, 7/2015-6/2016 (Samantha Butts, MD MSCE, PI: David Seifer MD, Andrea Kelly MD MSCE, Co-Investigator. The main goal of this investigation is to evaluate the association between preconception vitamin D status and fertility treatment outcomes in women with polycystic ovary syndrome and with unexplained infertility), $50,000/annual direct costs, 2% effort.

Prenatal Environmental Exposures and Reproductive Hormone Concentrations (PERCH), SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE, R21-ES-023883-01, 4/2014-3/2016 (Sathyanarayana, PI: Butts, Co-Investigator), $11,842/annual direct costs, 5% effort (PERCH aims to examine the relationship between phthalate and BPA exposures in relation to hormone concentrations and subsequent infant reproductive outcomes.)

Basser Research Center for BRCA 1&2, University of Pennsylvania, 7/2012-6/2014 (Domchek, PI), $8,992/annual direct costs, 5% effort (Role in grant: investigator. The major goal of this project is to examine symptoms and risks in women after risk reducing bilateral salpingoophorectomy (BRCA1/2) carriers.)

Department of Health & Human Services, Center of Excellence for Diversity in Health Education and the Health Resources and Services Administration, D34-HP-24459, 7/2012-6/2013 (Jerry Johnson, PI), $45,048/annual direct costs, 5% effort (Role in grant: Scholar. The main goal of this project is to support scholarly activity related to research efforts and career development.)

Penn Center for Study of Epigenetics in Reproduction (Pilot Study), NIH/NICHD, U54-HD-068157, 5/2011-3/2015 (M.Bartolomei/C.Coutifaris, PI), $78,889/annual direct costs, 10% effort (Role in grant: Pilot Study PI. The major goal of this project is to test the association between preconception and mid-gestation levels of endocrine disruptors and micronutrients and reproductive outcomes.)

Center of Excellence in Environmental Toxicology (CEET)
NIH/NIEHS (ARRA), 3P30ES013508-04S1, 9/2009-3/2010 (Trevor Penning, PhD, PI), $25,000/annual direct costs, 10% effort (Role in grant: Pilot PI)

Center of Excellence in Environmental Toxicology (CEET), NIH/NIEHS, 5P30ES013508-04 , 1/2008-12/2009 (Trevor Penning, PI), $22,616/annual direct costs, 15% effort (Role in grant: Pilot PI)

Macy Foundation Scholar Award, Macy Foundation, 8/2007-7/2008 (Samantha Butts, MD MSCE, PI), $25,000/annual direct costs, 10% effort (Role in grant: PI)

Telomere Homeostasis in Granulosa Cells: A Novel Molecular Approach to Reproductive Senescence, The McCabe Fund, 7/2007-6/2010 (Samantha Butts, MD MSCE, PI), $23,416/annual direct costs, 10% effort (Role in grant: PI)

Improvements in Reproductive Status Following Bariatric Surgery, American Society for Bariatric Surgery , 7/2007-6/2009 (Kelly Allison, PhD, PI), $25,000/annual direct costs, 10% effort (Role in grant: Co-Investigator)

Markers of Senescence in Granulosa Cells: Relationship to Ovarian Reserve and Outcomes in In Vitro Fertilization, University Research Foundation , 3/2006-2/2007 (Samantha Butts, MD, PI), $25,000/annual direct costs, 10% effort (Role in grant: Principal Investigator)

Building Interdisciplinary Research Careers In Women's Health (BIRCWH K12), NIH/NICHD, K12 HD043459-, 1/2006-3/2008 (Strauss/Freeman, PI), $92,392/annual direct costs, 75% effort (Role in grant: K12 Scholar)

Oxidative Stress and the Human Egg: Correlation of Telomere Length and Telomerase Activity in Developing Follicles with Outcomes in IVF, NIH T32 Grant, 7/2004-6/2005 (Kurt Barnhart, MD, MSCE, PI), 70% effort (Role in grant: investigator)

Bibliography:

Research Publications, peer reviewed (print or other media):

1. Torigian DA, Siegelman ES, Terhune KP, **Butts SF**, Blasco L, Shlansky-Goldberg RD: Case report: MRI of uterine necrosis after uterine embolization for treatment of uterine leiomyomata. Amer J Roentgenology 184(2):555-59, 2005. PMCID: 15671379

2. Wrotniak BH, Shults J, **Butts S**, Stettler N: Gestational weight gain and risk of overweight in the offspring at age seven years in a multicenter, multiethnic cohort study. Amer J Clin Nutrit 87(6):1818-24, June 2008. PMCID: 18541573

3. **Butts S**, Riethman HR, Ratcliffe S, Coutifaris C, Shaunik A, Barnhart K: Correlation of telomere length and telomerase activity with primary ovarian insufficiency. J Clin Endocrinol Metabol 94(12):4835-34, December 2009. PMCID: 19864453

4. **Butts SF**, Gibson E, Sammel SD, Shaunik A, Rudick B, Barnhart KT: Race, socioeconomic status and response to methotrexate treatment of ectopic pregnancy in an urban population. Fertil Steril 94(7):2789-92, December 2010. PMCID: 20674907

5. Shlansky-Goldberg R, Coryell L, Stavropoulos SW, Trerotola SO, Mondschein J, Beshara M, **Butts SF**, Sondheimer S, Tureck RW, Rosen M: Outcomes following fibroid expulsion after uterine artery embolization. J Vasc Interv Radiol 22: 1586-1593, 2011. PMCID: 22024118

6. **Butts SF**, Freeman EW, Sammel MD, Queen K, Lin H, Rebbeck T: The joint effect of smoking and gene variants involved in sex steroid metabolism on hot flashes in late reproductive age women. J Clin Endocrinol Metabol 97 (6): E1032-E1042, June 2012. PMCID: 22466345

7. **Butts SF**, Ratcliffe S, Dokras A, Seifer DB: Diagnosis and treatment of diminished ovarian reserve in ART cycles of women up to age 40: The role of insurance mandates. Fertil Steril 99:382-88, February 2013. PMCID: 409153

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5. "Think about your health men; Because making babies is men's work too" The Plain Dealer Cleveland Newspaper April 2009.

6. "When parents can't conceive" Interview with MetroKids newspaper January 2010.

7. "When to see a fertility specialist" Interview for University of Pennsylvania Health System Women's Health Newsletter December 2011.

8. "Menopause: Smokers have more hot flashes, genes can play an additional role too, study finds" Interview with WebMD Health News May 2012.

9. "Doctors' group sounds warning on freezing eggs to buy time on your biological clock" Interview with NBC News Health/Today.com December 2013.

10. "Smoking Can Speed Menopause for Some Women" Interview with NBC News.com February 2014.

11. Sister 2 Sister Magazine: "Motherhood on Reserve: Why Some Women Have Decided to Freeze Their Eggs" Interview with Sister 2 Sister Magazine February 2014.

12. "The Age Your Fertility Really Begins To Decline -- And Why You Shouldn't Freak Out" Interview with The Huffington Post, February 2014.

13. "Sisters, triplets, colleagues in medicine" Interview with WHYY (Philadelphia PBS affiliate), June 2014.

14. "How Fear Fuels the Business of Egg Freezing" Interview with The Washington Post, March 2015.

15. "Three Steps to Freezing Your Eggs" Interview on The Dr. Oz Show, October 2015.

16. "Should You Take an at-Home Fertility Test?" Interview with New York Magazine.com, April 2016.

17. "Age at Menopause: Do Chemical Exposures Play a Role?" Expert interview with Environmental Health Perspectives, July 2017 (Vol 125, issue 6, DOI:10.1289/EHP2093).

EXHIBIT P

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, Plaintiff, v. DONALD J. TRUMP *et al.* Defendants.	**NO. 2:17-cv-04540-WB**

DECLARATION OF SETH A. MENDELSOHN

I, Seth A. Mendelsohn, declare and state as follows:

1. I am the Executive Deputy Insurance Commissioner for the Pennsylvania Department of Insurance (the "Department"). In this capacity I oversee, *inter alia*, the Office of Insurance Product Regulation and Administration, including the Bureau of Life, Accident and Health Insurance.

2. The Department is the primary regulator for all health insurance products sold in the Commonwealth of Pennsylvania.

3. Insurance providers are subject to a complex set of federal and state laws and regulations, and federal and state agencies have distinct but overlapping responsibilities in regulating these entities.

4. For instance, the federal Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq.* (ERISA), governs most employee health care coverage and other benefit plans offered by private employers. ERISA preempts certain state laws relating to the regulation of insurance.

5. As a result of the preemption provisions of ERISA, the Department does not regulate self-funded health care coverage plans offered by private employers, which are plans established and maintained by an employer or by an employee organization for which the employer or employee organization bears the direct financial risk for the cost of claims for health care benefits. These plans are subject to ERISA and are regulated primarily by the U.S. Department of Labor.

6. The Department does regulate fully-insured employer group health insurance policies. These are health plans that an employer group purchases from an insurer, for which the insurer assumes the direct financial risk for the cost of claims for health care benefits.

7. In addition, the Department regulates health insurance policies offered in the individual market.

8. I am familiar with the Affordable Care Act's requirement that group health plans and health insurance issuers offering group or individual health insurance coverage cover preventive health services, including FDA-approved methods of contraception, without any cost-sharing requirements (the "Contraceptive Care Mandate").

9. The Contraceptive Care Mandate applies both to ERISA-regulated plans as well as almost all insured group and individual health insurance plans that are regulated by the Department.

10. More than 2.5 million women in Pennsylvania could benefit from the Contraceptive Care Mandate. This total includes women who receive insurance through their employer or through a spouse or other family member's employer, along with those who purchase insurance for themselves and their families through the individual market.

11. The Department estimates that the women in Pennsylvania who have benefited from the Contraceptive Care Mandate have saved over $250 million annually as a result.

12. Many states have enacted laws requiring insurers that cover prescription drugs to provide coverage for any Food and Drug Administration-approved contraceptive. These statutes are commonly referred to as "contraceptive parity" laws.

13. Pennsylvania, however, does not have a "contraceptive parity" statute. As a result, employers offering Department-regulated plans that opt out of the ACA's Contraceptive Care Mandate will not be subject to any requirement to provide contraceptives to their employees and beneficiaries. Thus, women in plans provided by these employers will not receive contraceptive coverage through these plans.

14. Similarly, employers offering plans that are subject to ERISA that opt out of the Contraceptive Care Mandate will also not be subject to any requirement to provide contraception to their employees and beneficiaries.

15. The Department anticipates that women who lose contraceptive coverage through employer plans – whether the plan of their own employer or that of another family member – may seek contraceptive coverage from other sources, including state-funded programs, or face the financial burden of paying for the full cost of contraceptives themselves.

16. Further, insofar as the Final Rules[1] effectively expand the universe of employers that may claim a contraceptive coverage exemption, even more women may be denied access to contraceptive coverage.

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[1] "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act", 83 Fed. Reg. 57536 et seq. (Nov. 15, 2018) and "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act", 83 Fed. Reg. 57592 et seq. (Nov. 15, 2018) (the "Final Rules").

17. Moreover, because the Final Rules contemplate that individuals, covered by employer plans that provide contraceptive care, may nevertheless opt out of the ACA's Contraceptive Care Mandate, and, in so doing, effectively deny contraceptive care to all of the individual's female dependents covered by the same plan, still more women may be denied access to contraceptive coverage.

18. In any case, whether it is the employer's choice or the individual's choice or the choice of the individual as to whom a woman is a dependent, women who have access to affordable employer-based coverage but who lose contraceptive coverage as a result of the Final Rules will be unable to purchase individual coverage on the marketplace with any applicable premium tax credit and cost sharing reductions. Again, the Department anticipates that women put in this position may seek contraceptive coverage from other sources, including state-funded programs, or face the financial burden of paying for the full cost of contraceptives themselves.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Seth A. Mendelsohn

SETH A. MENDELSOHN

Dated: December 12, 2018

EXHIBIT Q

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, Plaintiff, v. DONALD J. TRUMP *et al.* Defendants.	**NO. 2:17-cv-04540-WB**

DECLARATION OF LEESA ALLEN

I, Leesa Allen, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, I state as follows:

I. Background

1. I serve as the Acting Executive Deputy Secretary for the Pennsylvania Department of Human Services ("DHS" or "the Department"). Before assuming my current position, I was the Deputy Secretary for Medical Assistance Programs at DHS. I have worked for the Department of Public Welfare, now DHS, since 1993, serving in various roles within the Office of Medical Assistance Programs since 2000. I was most recently the Deputy Secretary for Medical Assistance Programs, the Executive Medicaid Director, Chief of Staff, and Director of the Bureau of Policy. In my current role, I oversee all of the Department's operations and report directly to the Acting Secretary of DHS, who serves as a member of the Governor's cabinet.

2. DHS is responsible for administering a variety of services and benefits to residents of Pennsylvania, including health care services, support for individuals with

disabilities, child support enforcement, treatment for substance use disorder, and services for children and families.

II. Pennsylvania's Medical Assistance Program

3. DHS's Office of Medical Assistance Programs has primary responsibility for overseeing Commonwealth programs that offer health benefits to Pennsylvania residents. Those programs include the Medicaid program, known as Medical Assistance in Pennsylvania. In my prior role as Deputy Secretary for Medical Assistance Programs, I oversaw the Office of Medical Assistance Programs.

4. Medicaid is a program jointly funded by the states and the federal government that makes health care available to low-income individuals and families. States have responsibility for administering Medicaid, but are subject to federal oversight.

5. Medicaid is funded according to a formula under which the federal government contributes a specific amount for every dollar spent by Pennsylvania. If additional Pennsylvanians enroll in the Medical Assistance program, the federal and state government will both spend more on the program, thereby shifting costs from the private to the public sector.

6. As of August 2017, there were 2,869,246 Pennsylvanians enrolled in the Medical Assistance program. For the period April 1, 2016, through March 31, 2017, a total of $28.8 billion in state and federal funding was spent on Medical Assistance. Of that amount, $11.2 billion was provided by the Commonwealth, and the remainder was provided by the federal government.

7. Eligibility for Medical Assistance is based primarily on income level. The Affordable Care Act expanded Medicaid eligibility so that individuals and families with incomes up to 138% of the federal poverty limit would generally be eligible for the program. However, in

National Federation of Independent Business v. Sebelius, 567 U.S. 519 (2012), the Supreme Court ruled that states could not be required to expand Medicaid under the ACA, and therefore the expansion was rendered optional.

8. Governor Tom Wolf elected to expand the Medical Assistance program in 2015, so that individuals and families in Pennsylvania with incomes up to 138% of the federal poverty limit are eligible for the program. Over 700,000 Pennsylvanians have enrolled in the Medical Assistance program as a result of the expansion.

9. For women who are pregnant, Medical Assistance eligibility requirements are different. Pregnant women are eligible if they have incomes at or below 215% of the federal poverty limit. In 2017, 215% of the federal poverty limit is $25,929 for an individual and $52,890 for a family of 4.

10. Medical Assistance provides beneficiaries with a variety of contraception options. In November 2016, DHS announced that it was making changes to its payment policies to hospitals to encourage the use of long-acting reversible contraception (LARC), which includes intrauterine devices and birth control implants.

11. Although LARCs are more effective than other methods of contraception and save money in the long run, they can have high upfront costs. By changing its fee-for-service payment policies for hospital providers for these costs, DHS has made it easier for women to use LARCs.

12. Over half of all unplanned pregnancies occur within two years of delivery of a child. For this reason, the Commonwealth encourages the use of LARCs as post-partum contraception to reduce the rate of such unplanned pregnancies.

13. In addition, Medical Assistance offers specific benefits for eligible pregnant women Those benefits include full scope medical benefits, as well as other benefits including proper prenatal care and early detection and treatment of health problems.

III. Pennsylvania's Family Planning Services Program

14. DHS also administers Pennsylvania's Family Planning Services program. The Family Planning Services program provides family planning benefits to individuals who are not eligible for full Medical Assistance benefits but satisfy other conditions. The Family Planning Services program receives federal and state Medicaid funds.

15. The Family Planning Services program was launched in 2008 as the SelectPlan for Women. Originally, it operated pursuant to a "Section 1115 waiver" granted by the U.S. Secretary of Health and Human Services. Section 1115 waivers free states from certain requirements of the Medicaid program so they can implement demonstration projects using federal and state Medicaid funds. Section 1115 waivers must be renewed every 5 years.

16. In 2015, the SelectPlan for Women Program authorized under the Section 1115 Waiver was transitioned to the Family Planning Services program authorized under the Medicaid State Plan. Under a provision of the ACA, states were provided the option to provide family planning and family planning-related services to individuals with incomes at or below 215% of the federal poverty limit who would not otherwise be eligible for Medicaid. With the transition, the program began to provide family planning and family planning-related services to men as well. As a result of this new authority, the Commonwealth no longer needs to seek a waiver from the Department of Health and Human Services every five years.

17. The Family Planning Services program is open to individuals and families with incomes at or below 215% of the federal poverty limit. Pregnant women (who would be eligible for Medical Assistance) are not eligible.

18. In August 2017, 17,333 individuals were enrolled in the Family Planning Services program.

19. Women and men who are employed and who receive health insurance through their employer may participate in Family Planning Services, provided they satisfy the eligibility criteria, and many beneficiaries of the program are employed. However, individuals who receive coverage for family planning services through their employer or from another source are not eligible for the program. Therefore, those participants in Family Planning Services who are employed either do not receive health coverage from their employers or receive coverage that does not include family planning services.

20. Because the Family Planning Services program is funded under Medicaid, total spending on the program depends on enrollment. If more individuals participate in the program, federal and state spending increase.

21. The Family Planning Services program provides contraceptive benefits, including coverage for birth control pills and LARCs. The program also provides a variety of other benefits, including pregnancy counseling, HIV and STD testing and treatment, and male and female sterilization.

22. These services are provided to beneficiaries without copays, deductibles, or other cost-sharing arrangements.

23. It is not unreasonable to expect that women who do not receive contraceptive care from their employers or private insurance will turn to government-funded programs,

such as Medical Assistance, to the extent they are eligible for these programs. Therefore, some eligible women who require contraceptive care but who work for employers that choose to opt out under the new exemption rules will likely seek out other coverage options, including the Commonwealth-funded programs discussed above.

IV. The Administration's Executive Orders

24. I am generally familiar with the Affordable Care Act's Contraceptive Care Mandate, which requires non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for FDA-approved methods of contraception without imposing cost-sharing requirements.

25. I understand that the Administration issued two rules on October 6, 2017, that expanded the exemptions from the Contraceptive Care Mandate. Under these rules, covered entities may opt out of complying with the mandate on the basis of a sincerely held moral or religious conviction.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Teresa M. Allen

Dated: October 27, 2017

EXHIBIT R

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, Plaintiff, v. DONALD J. TRUMP *et al.* Defendants.	**NO. 2:17-cv-04540-WB**

DECLARATION OF DAYLE STEINBERG

I, Dayle Steinberg, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, state as follows:

1. I am the CEO of Planned Parenthood Southeastern Pennsylvania. Planned Parenthood is one of the nation's largest providers of health care to women, men, and teenagers.

2. Nationwide, Planned Parenthood operates more than 600 health centers providing a variety of health services, including family planning services. Each year, 2.4 million women, men, and young people visit a Planned Parenthood health center to obtain services or information. Approximately 75% of these patients seek services to prevent unintended pregnancy.

3. Planned Parenthood Southeastern Pennsylvania provides services in Chester, Delaware, Montgomery, and Philadelphia Counties. We operate 8 health centers in the area and, in fiscal year 2016, provided services to 36,779 women, men, and teens in these centers.

I. The Title X Program Provides Federal Grants for Family Planning Services

4. Title X of the Public Health Service Act[1] provides grants to both public and private agencies for family planning services. Specifically, Title X authorizes grant money "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services."

5. Title X grants are awarded through a competitive process. They fund services provided by state and local health departments, hospitals, university health centers, and non-profit agencies. The Title X program is overseen by the Office of Population Affairs of the U.S. Department of Health and Human Services (HHS-OPA) oversees the Title X grant program.

6. Since 2010, Title X funding has decreased by $31 million, nationally. In 2010, the nationwide program received $317.5 million; in 2017, it received $286.5 million.[2] In addition, there are frequent efforts by some in Congress to eliminate funding for the program entirely.

7. In Pennsylvania, Title X grant money is provided directly to four private, non-profit, regional Family Health Councils. They are: AccessMatters (formerly the Family Planning Council) in Philadelphia; Adagio Health in Pittsburgh, Maternal and Family Health Services, Inc. in Wilkes Barre, and the Family Health Council of Central Pennsylvania in Camp Hill. The Alliance of Pennsylvania Councils supports and coordinates the efforts of the four Family Health Councils.

8. These four Family Health Councils also receive funding from the Commonwealth of Pennsylvania as well as local sources. For instance, in the fiscal year ending June 30, 2016, AccessMatters received approximately $8.2 million in federal funding and $3.9 million in state

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[1] 42 U.S.C. § 300 *et seq*.

[2] National Family Planning & Reproductive Health Association, Title X Budget & Appropriations, *available at* https://www.nationalfamilyplanning.org/title-x_budget-appropriations.

and local funding. The vast majority of this $3.9 million was provided by the Pennsylvania Department of Health and the Pennsylvania Department of Human Services.[3]

II. Pennsylvania's Family Planning Clinics

9. These four Family Health Councils in turn provide funding to a variety of organizations in Pennsylvania. These organizations operate clinic-based health centers throughout the Commonwealth.

10. As of December 2016, there were 162 facilities in Pennsylvania receiving Title X funding. Each county in Pennsylvania has at least one such clinic.

11. These clinics provide women and men with access to a variety of family planning services. These services include contraception, HIV and STD testing, counseling services, pregnancy testing, certain infertility services, and breast and cancer screening. They are important to the citizens of Pennsylvania and to the overall health of Pennsylvania, as a whole.

12. Although facilities that receive Title X grants are typically referred to as "Title X clinics," they actually receive funding from a variety of sources and only a small part through Title X. In fact, Title X accounts for less than one-fifth of their revenue.

13. According to the 2016 Title X Family Planning Annual Report[4] (at ES-3), the top three sources of revenue for Title X clinics nationwide were Medicaid and CHIP (the Children's Health Insurance Program) (39% of revenue); Title X (19%); and state government funding (10%).

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[3] AccessMatters, *Consolidated Financial Statements and Supplemental Information, Years Ended June 30, 2016, and 2015*, at 4, *available at* http://www.govwiki.info/pdfs/Non-Profit/PA%20Accessmatters%202016.pdf.

[4] Department of Health and Human Services Office of Population Affairs, *Title X Family Planning Annual Report, 2016 National Summary* (August 2017), *available at* https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.

14. Title X acts as "the payer of last resort" for these clinics. In other words, each clinic can only use Title X funds to pay for services if no other source of funding is available. This includes funding from the Commonwealth or other federal funding. As a result, many of our patients receive services that are funded by multiple sources.

15. For this reason – and to ensure that clinic patients can receive the best possible care – Title X clinics work to educate patients about available government health programs and help patients enroll in programs for which they are eligible.

16. In Pennsylvania, these programs include Medical Assistance (Medicaid) and the Family Planning Service Program, both of which received Commonwealth funding. Title X clinics will assist patients who are eligible for (but not enrolled in) these programs with the necessary paperwork so that they can be enrolled. Doing so not only ensures that the patient has all the coverage for which she is eligible for, but it allows the clinic to save Title X and Commonwealth grant money.

17. While the priority of the Family Health Councils is to assist low income families, each Title X clinic in Pennsylvania provides family planning services to any individual seeking *services*, regardless of income or insurance status. Family planning services are provided based on a sliding scale fee structure depending on the individual/family income level.

18. According to the 2016 Annual Report (at B-3), in 2016, family planning services through Title X grants were provided to 198,825 Pennsylvania residents.

19. Of these recipients of care, 73% had some form of insurance. Among this 73%, 46% had insurance through Medicaid or another government-funded program (vs. 37% nationwide) and 27% had private insurance (vs. 18% nationwide) (2016 Annual Report at B-7).

20. Many Title X patients are currently employed or have a family member who is currently employed. Many of these patients receive insurance through their employer or their family member's employer.

21. In some cases, Title X clinics are reimbursed by the insurance company; however, private insurance often does not provide sufficient coverage. Thus, while 18% of all Title X users nationwide have private insurance, private sources of funding account for only 10% of clinic revenue (2016 National Report at B-7).

III. The Effects of the Contraceptive Care Mandate

22. I understand that the Administration has issued new regulations that will make it easier for employers and others to opt out of the Affordable Care Act's contraceptive mandate.

23. My colleagues at Planned Parenthood Southeastern Pennsylvania and I are very concerned that this action will lead to an increase in the number of employers in Pennsylvania that do not provide their employees with adequate insurance coverage for contraceptive care.

24. Women who need contraceptive care but whose employers refuse to provide coverage for it will be forced to get care elsewhere. Many of these women will seek assistance from government programs.

25. In fact, for many low-income women in this situation, a government-funded program will be the only viable option for obtaining contraceptive care.

26. Therefore, we expect that many women in Pennsylvania who lose their contraceptive coverage will seek care from one of the 162 Title X clinics in the Commonwealth.

27. Some of these women will likely be eligible for either Medical Assistance (Medicaid) or Pennsylvania's Family Planning Services program. If they seek care at a Title X clinic in Pennsylvania, the clinic will help them enroll in either program.

28. Low-income women who seek services from a Title X clinic and are not eligible for these programs will receive contraceptive care funded by other sources. In most instances, their care will be funded through Title X and funding provided by the Commonwealth of Pennsylvania.

29. We expect that the new exemptions from the Contraceptive Care Mandate will lead to an increase in the number of women who get contraception through Medicaid and Family Planning Services, as well as an increase in the number of women who obtain contraception from Title X clinics paid for by federal and state funding.

30. We are also concerned that some women who lose their coverage will stop using contraception altogether. Women who stop using contraception are more likely to have unplanned pregnancies and to require additional medical attention. According to an analysis of 2010 data by the Guttmacher Institute, 68% of unplanned births are paid for by public insurance programs, including Medicaid, while 38% of planned births are paid for by these programs.[5]

31. As I explained above, meeting this increased need will require additional state funds.

32. For all these reasons, I believe that the new exemptions to the contraceptive mandate will have a negative effect on the health of Pennsylvania women; that they will increase the number of women who receive contraceptive coverage through Medical Assistance and Family Planning Services; and that they will impose additional economic and other burdens on Title X clinics across the Commonwealth.

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[5] Guttmacher Institute, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010* (Feb. 2015), *available at* https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Dayle Steinberg

Dated: October 31, 2017

EXHIBIT S

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, and STATE OF NEW JERSEY Plaintiffs, v. DONALD J. TRUMP, *et al.* Defendants.	**Civil Action No: 2:17-cv-04540-WB**

DECLARATION OF SARAH ADELMAN

I, Sarah Adelman, declare and state as follows:

1. I serve as Deputy Commissioner of the New Jersey Department of Human Services. In this capacity I oversee the Division of Medical Assistance and Health Services ("DMAHS").

2. DMAHS administers New Jersey's $17 billion state- and federally- funded Medicaid and Children's Health Insurance Programs (collectively referred to as "NJ FamilyCare") that provide health coverage for certain low to moderate income residents. Through its programs, DMAHS serves more than 1.7 million people in New Jersey.

3. NJ FamilyCare provides comprehensive medical coverage and family planning services to its beneficiaries.

4. New Jersey also has Title X family planning clinics within the state that are not affiliated with DMAHS.

5. Medicaid is a program jointly funded by the states and the federal government that makes health care available to low-income individuals and families. States have responsibility for administering Medicaid, but are subject to federal oversight.

6. Medicaid is funded according to a formula under which the federal government contributes a specific amount for every dollar spent by New Jersey. If additional New Jerseyans enroll in the Medical Assistance program, the federal and state government will both spend more on the program, thereby shifting costs from the private to the public sector.

7. As of October 2018, there were 1,747,375 NJ FamilyCare beneficiaries in New Jersey. For State fiscal year 2018, a total of approximately $16,267,000,000 in state and federal funding was spent on NJ FamilyCare. Of that amount, roughly $9,843,000,000 was provided by the federal government, and $6,424,000,000 was provided by New Jersey.

8. For fiscal year 2018, DMAHS's estimated cost to provide contraceptive and family planning coverage through NJ FamilyCare was approximately $15 million, with the federal government covering 90% of that cost.

9. Eligibility for NJ FamilyCare is based primarily on income level. The Affordable Care Act expanded Medicaid eligibility so that individuals and families with incomes up to 138% of the federal poverty level would generally be eligible for the program. However, in National Federation of Independent Business v. Sebelius, 567 U.S. 519 (2012), the Supreme Court ruled that states could not be required to expand Medicaid under the Affordable Care Act, and therefore the expansion was rendered optional.

10. New Jersey elected to expand Medicaid in January 2014, so that single adults, childless couples, parents, and caretakers with incomes up to 138% of the federal poverty limit

are eligible for the program. Over 500,000 of these individuals have enrolled in NJ FamilyCare since its expansion.

11. For women who are pregnant, NJ FamilyCare has expanded income-based eligibility so that pregnant women are eligible if they have incomes at or below 205% of the federal poverty level. At present, 205% of the federal poverty level is $4,302 per month for a family of four.

12. DMAHS is planning the 2019 rollout of a family planning benefit program called Plan First for individuals with income ranging from 133% to 205% of the federal poverty level.

13. DMAHS projects that there will be 10,000 to 12,000 Plan First participants in the first year of the program, and between 31,000 to 55,000 participants by the fifth program year.

14. DMAHS designed the Plan First program to allow pregnant women to transition seamlessly into the Plan First program after the 60-day postpartum period and to allow Plan First beneficiaries who become pregnant to easily transition to a DMAHS program ensuring early prenatal treatment. The eligibility standards for Plan First will mirror the current NJ FamilyCare requirements for pregnant women.

15. NJ FamilyCare provides beneficiaries with a variety of contraception options, and there is no co-pay for family planning preventive services.

16. Among those options is long-acting reversible contraception ("LARC"), which includes intrauterine devices and birth control implants. While NJ FamilyCare has always covered LARC devices in an outpatient setting or as part of a bundled inpatient payment, it began to allow providers to bill separately for devices and insertion in the immediate postpartum period (defined as within 10 minutes after delivery of the placenta) in July 2018. In addition, the Plan First program will provide for access to LARCs for additional individuals in 2019.

17. New Jersey recognizes the importance of allowing members who wish to utilize LARC devices to have free and open access to them to reduce the rate of unplanned pregnancies. Although LARCs can have high upfront costs, they are not associated with compliance issues that can cause failures with other comparable methods of birth control, and as such are more effective than most other methods of contraception and would likely result in better outcomes and better long-term savings to the State when compared to other contraceptive methods.

18. LARCs facilitate optimal "birth spacing," defined as a minimum 18 month interval between pregnancies. Without birth spacing, babies are more likely to be premature, of low birthweight, small for their gestational age, and, consequently, more likely to face long-term health problems and higher mortality rates. In 2017, the prematurity rate in New Jersey was one in eleven babies.[1]

19. DMAHS anticipates that some women, particularly low-income women, who lose contraceptive coverage through their employer's plans may seek contraceptive coverage from other sources, such as NJ FamilyCare, Plan First, and Title X. This will result in additional costs to New Jersey, which will be forced to absorb additional costs presently borne by private insurers.

20. Other women who lose their contraceptive benefits may forego contraceptive use entirely, which would result in increased numbers of unintended pregnancies and a dramatic increase in costs to State-funded programs designed to ensure the health of women and infants.

21. The loss of employer-sponsored health insurance coverage for contraception can be expected to disproportionately impact New Jersey's women of color. In 2015, 28% of New

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[1] March of Dimes, *A Profile of Prematurity in New Jersey, available at* https://www.marchofdimes.org/peristats/tools/prematurityprofile.aspx?reg=34.

Jersey pregnancies were unplanned, including 53.1% among non-Hispanic black women and 31.8% among Hispanic women.[2]

22. I am generally familiar with the Affordable Care Act's Contraceptive Care Mandate, which requires non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for FDA-approved methods of contraception without imposing cost-sharing requirements.

23. I understand that the Administration has issued rules that expanded the exemptions from the Contraceptive Care Mandate. Under these rules, covered entities may opt out of complying with the mandate on the basis of a sincerely held moral or religious conviction.

24. The expanded exemptions are expected to result in greater financial expenditures by both the State of New Jersey and women in New Jersey on contraceptive coverage and on healthcare generally for women and infants.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Sarah Adelman

Dated: 12/7/18

[2] The Centers for Disease Control and Prevention and New Jersey Department of Health, *Pregnancy Risk Assessment Monitoring Report on Pregnancy Intention 2012-2015, available at* https://www.nj.gov/health/fhs/maternalchild/documents/NJ%20Pregnancy%20Intention%20Topic%20Report%202012-2015.pdf.

EXHIBIT T

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA, and STATE OF NEW JERSEY, Plaintiffs, v. DONALD J. TRUMP, *et al.* Defendants.	**Civil Action No: 2:17-cv-04540-WB**

DECLARATION OF PHILIP GENNACE

I, Philip Gennace, declare and state as follows:

1. I am the Assistant Commissioner of Life and Health in the New Jersey Department of Banking and Insurance ("DOBI"). In this capacity, I oversee, *inter alia*, the licensing and oversight of health insurance regulated by the State of New Jersey. I make this affidavit based on my personal knowledge and information provided to me in my official capacity.

2. DOBI is the primary regulator for all fully-insured health insurance plans sold in the State of New Jersey.

3. Insurance carriers are subject to a complex set of federal and state laws and regulations, and federal and state agencies have distinct but overlapping responsibilities in regulating these entities.

4. For instance, the federal Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001, *et seq.* ("ERISA"), governs most employee benefit plans offered by private employers, including private employers' self-funded employee health benefit plans. ERISA

preempts most state laws relating to such plans.

5. As a result of the preemption provisions of ERISA, DOBI does not regulate self-funded health coverage plans offered by private employers, which are plans established and maintained by an employer or by an employee organization for which the employer or employee organization bears the direct financial risk for the costs of claims for health care benefits. These plans are subject to ERISA and are regulated primarily by the U.S. Department of Labor, and are often colloquially referred to as "ERISA plans."

6. DOBI does regulate fully-insured employer group health plans issued in the State. These are health plans that an employer group purchases from an insurer, for which the insurer assumes the direct financial risk for the cost of claims for health care benefits.

7. In addition, DOBI regulates health insurance policies offered in the individual market.

8. I am familiar with the Affordable Care Act's (ACA) requirement that group health plans and health insurance issuers offering group or individual health insurance coverage cover preventive health services, including FDA-approved methods of contraception, without any cost-sharing requirement (the "Contraceptive Care Mandate").

9. The Contraceptive Care Mandate applies both to non-grandfathered ERISA-regulated plans, as well as almost all insured group and individual health insurance plans that are regulated by DOBI.

10. In addition, New Jersey law requires employers who offer fully-insured plans to provide coverage for expenses incurred in the purchase of prescription female contraceptives to the same extent as any other outpatient prescription drug under the policy ("New Jersey

Mandate").[1]

11. Unlike the ACA's Contraceptive Care Mandate, however, the New Jersey Mandate does not require insurers to cover women's contraceptive services without cost sharing. Also, the ACA contraceptive mandate covers all FDA-approved female contraceptive methods. By contrast, the New Jersey mandate covers only those methods which are obtained via prescription (not those that are available over the counter or through an inpatient or out-patient procedure).

12. In addition, a religious employer (defined as a church, association or convention of churches, or an elementary or secondary school controlled, operated, or principally supported by a church) is statutorily entitled to an exclusion from the New Jersey Mandate if the required coverage conflicts with the employer's *bona fide* religious beliefs and practices. The exemption is not available for prescription drugs that may act as contraceptives but are prescribed for a particular user for medical reasons other than contraception. Also, the exemption is not available for prescription female contraceptives that are necessary to preserve the life or health of an insured.

13. Approximately 3,434,000 New Jersey residents who have health coverage are covered by employer plans that are self-funded.[2] Under ERISA, such plans offered by private employers are exempt from state regulation, including the New Jersey Mandate.

14. Private employers offering self-funded plans that opt out of the Contraceptive Care

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[1] *See* N.J.S.A. 17B:27A-7.12 (for individual health benefits plans); N.J.S.A. 17B:26-2.1y (for individual health insurers); N.J.S.A. 17:48A-7bb (for medical service corporations); N.J.S.A. 17:48-6ee (for hospital service corporations) and N.J.SA. 17:48E-35.29 (for health service corporations); N.J.S.A. 17:48F-13.2 (for prepaid prescription service organizations); N.J.S.A. 26:2J-4.30 (for health maintenance organizations); N.J.S.A. 17B:27A-19.15 (for small employer health benefits plans); N.J.S.A. 52:14-17.29j (for the State Health Benefits Plan); and N.J.S.A. 17B:27:46.1ee (for group health insurers).

[2] This includes residents covered under New Jersey's state health benefits programs, as well as self-funded plans offered by private employers.

Mandate under the newly expanded exemptions will not be subject to any federal or state requirement to provide contraception to their employees and beneficiaries. Thus, women in plans provided by these employers will not receive contraceptive coverage through these plans.

15. Upon information and belief, a number of these newly-exempted employers are expected to be New Jersey employers. As a result, those newly-exempted entities that offer self-funded plans, or that are church-affiliated schools eligible for New Jersey's religious exemption,[3] would no longer have an obligation to provide any contraceptive coverage for their employees and their employees' female dependents.

16. Moreover, because the ACA's Contraceptive Care Mandate is broader than the New Jersey Mandate and prohibits cost sharing, even employees and female dependents of newly-exempt employers who offer fully-insured plans subject to the New Jersey Mandate will lose coverage for certain contraceptive methods and be subject to cost sharing that was previously prohibited.

17. Therefore, many New Jersey women are likely to lose the medical coverage for contraceptive care to which they are otherwise entitled under the ACA.

18. DOBI anticipates that some women who lose contraceptive coverage through their employer's plans, particularly low-income women, will seek contraceptive coverage from other sources, including state-funded programs, such as the New Jersey Prescription Assistance Program, Medicaid, and Title X clinics. Women who do not seek outside funding or who seek it but do not qualify for financial assistance likely will face substantial additional costs. Among

[3] Churches and associations and conventions of churches have been exempted from the ACA's Contraceptive Care Mandate since 2011. *See* 76 Fed. Reg. 46621-01 (Aug. 3, 2011). However, unlike Defendants' broad new religious exemption, the 2011 exemption was not applicable to most church-affiliated schools.

these women, some likely will forgo regular contraceptive use or use cheaper, less effective contraceptive methods, resulting in more unintended pregnancies.

19. Women who lose their contraceptive coverage obtained through their employers' plans, even if they are in plans that remain subject to the New Jersey Mandate, likely will in many cases face copays and deductibles when attempting to obtain necessary contraceptive coverage. These financial constraints likely will cause some women to change their preferred choice of contraceptive method, fail to consistently maintain their use of contraceptives, or forgo contraceptive use entirely, which will result in more unintended pregnancies.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

PHILIP GENNACE

Dated: 12/12/18

EXHIBIT U

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY, Plaintiffs, v. DONALD J. TRUMP, *et al.* Defendants.	**Civil Action No: 2:17-cv-04540-WB**

DECLARATION OF ELIZABETH COULTER

I, Elizabeth Coulter, declare and state as follows:

1. I serve as Deputy Director of the Office of Women's Health ("OWH") within the New Jersey Department of Health ("DOH"). I make this affidavit based on my personal knowledge and information provided to me in my official capacity.

2. DOH's priority is to strengthen New Jersey's health system by investing in population health, promoting equity, and achieving better health outcomes for all residents. DOH is committed to providing access to high quality, affordable, culturally competent, and trauma-informed care, as well as reducing and eliminating disparities in health outcomes across all healthcare services.

3. OWH is charged with eradicating health disparities and fostering women's equity and equality in healthcare and health outcomes. The office works closely with local, state, and federal government agencies, as well as private-sector partners, to oversee programs and services that, among other things, provide family planning and reproductive healthcare and provide science-backed sexual and reproductive health information and education.

I. New Jersey's Family Planning Clinics

4. The non-profit New Jersey Family Planning League ("NJFPL") has ten sub-grantee agencies that provide health services, including family planning services, through 47 service sites ("Family Planning Clinics") covering all 21 counties in the state.

5. New Jersey's Family Planning Clinics provide women and men with access to family planning services. These services include contraceptive services and counseling, HIV and STD testing, pregnancy testing, certain infertility services, and breast and cervical cancer screening. The Family Planning Clinics are integral to the family planning provider supply in New Jersey. Indeed, in 2017, NJFPL provided family planning and reproductive health care services to 99,844 New Jersey residents, including 89,945 female patients.

a. Funding to New Jersey's Family Planning Clinics

6. DOH awards family planning funds within New Jersey. These funds are aggregated from the following sources: Social Services Block Grant ("SSBG") funds, Maternal and Child Health ("MCH") Block Grant funds (administered within DOH's Maternal and Child Health Division), the State of New Jersey's budgeted family planning funds. DOH has awarded these funds to NJFPL.

7. OWH sets the programmatic, data reporting, and budget priorities with the NJFPL through the annual grant application process and oversees those priorities through quarterly reporting requirements.

8. In addition to receiving DOH-awarded funding, NJFPL receives funds from patient service revenues (which include Medicaid, private insurance, and patient self-pay) and from federal Title X grants, as the sole New Jersey grantee.[1]

[1] Although the Family Planning Clinics are sometimes colloquially referred to as "Title X clinics," Title X accounts for only about one-quarter of NJFPL's funding.

9. Title X of the Public Health Service Act[2] provides federal grants to both public and private agencies for family planning services. Specifically, Title X authorizes grant money "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services."

10. Since 2010, Title X funding has decreased by $31 million, nationally. In 2010, the nationwide program received $317.5 million; in 2017, it received $286.5 million.[3] In addition, there are frequent efforts by some in Congress to eliminate funding for the program entirely.

11. According to the 2016 Title X Family Planning Annual Report, the top three sources of revenue for Family Planning Clinics nationwide were Medicaid and CHIP (the Children's Health Insurance Program) (39% of revenue); Title X (19%); and state government funding (10%).[4]

12. OWH is not involved with the application for or administration of federal Title X funds.

b. Provision of Services and Payment at New Jersey's Family Planning Clinics

13. NJFPL's mission is to provide high quality comprehensive family planning and accompanying preventative reproductive health care to every person seeking services. All patients, regardless of income or insurance coverage, are offered a full range of contraceptive methods and services.

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[2] 42 U.S.C. § 300, *et seq.*

[3] National Family Planning & Reproductive Health Association Title X Budget & Appropriations, *available at* https://www.nationalfamilyplanning.org/title-x_budget-appropriations.

[4] Department of Health and Human Services Office of Population Affairs, *Title X Family Planning Annual Report, 2016 National Summary* (August 2017), *available at* https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.

14. Family Planning Clinics bill private insurance or Medicaid if the patient presents such coverage. If the patient does not present coverage, family planning services are provided based on a sliding fee scale depending on the individual/family income level.

15. In 2017, NJFPL provided family planning and reproductive health care services to 99,844 New Jersey residents, including 89,945 female patients.

16. In 2017, approximately 51.9% of NJFPL patients had some form of insurance coverage (35.5% had insurance coverage through Medicaid or another government-funded program and 16.4% had private insurance coverage).

17. Many Family Planning Clinic patients are currently employed or have a family member who is currently employed. Many of these patients receive insurance through their employer or as dependents on coverage provided by their family member's employer.

18. In some cases, Family Planning Clinics are reimbursed by a patient's insurance plan, however, private insurance may not provide sufficient coverage. Thus, while 18% of all such clinic users nationwide have private insurance, private third-party sources of funding account for only 10% of clinic revenue (2016 National Report at B-7).

II. The Effects of the New Exemption Rules

19. The Affordable Care Act ("ACA"), together with its implementing regulations, requires coverage for all FDA-approved methods of contraception. As a result, New Jersey women have enjoyed widespread contraceptive coverage beyond that required by New Jersey's state contraceptive coverage requirement

20. I understand that the Trump Administration has issued new regulations ("Exemption Rules") that will make it easier for employers and others to opt out of the Affordable Care Act's contraceptive mandate.

21. My colleagues at DOH and I are very concerned that the Exemption Rules will reduce access to family planning care for New Jerseyans because there will be an increase in the number of New Jersey employers that do not provide their employees with adequate insurance coverage for contraceptive care.

22. Women whose employers opt out of providing contraceptive coverage face a dilemma: forego using contraception or find a way to pay for contraception without insurance coverage. This decision will be most challenging for lower income women. Without private insurance coverage and without the means to pay for contraception out of pocket, many such women will turn to assistance from government funded contraceptive care to prevent pregnancy.

23. Women who lose coverage for contraceptive care and therefore seek publicly-funded services at a Family Planning Clinic, rather than pay out of pocket for contraceptives, are more likely to be high need, lower-income patients. Many such women would likely utilize the Family Planning Clinics' sliding fee scale, drawing more heavily on the limited public funds for reproductive services.

24. In fact, for many low-income women in this situation, government-funded care will be the only viable option for obtaining contraceptive care.

25. Therefore, we expect that many women in New Jersey who lose their contraceptive coverage will seek care from one of the 47 New Jersey Family Planning Clinics. In order to ensure continued access to the most effective (and most expensive) forms of contraception, limited public funds, *state funds in particular,* would need to be expended.

26. Notably, the most effective methods of contraception are typically the most expensive.

27. If the increased need for contraceptive care were to exceed capacity without accompanying increases to funding, service reductions would be likely -- with clinic closures, decreased clinic hours of operation, and staff reductions as potential outcomes.

28. We are also concerned that New Jersey women who lose coverage (as a result of their employers opting out of the ACA's contraceptive mandate) will stop using contraception altogether. Women who stop using or never use contraception are more likely to have unplanned pregnancies and to require additional medical attention. According the Guttmacher Institute, 68% of unplanned births are paid for by public insurance programs, including Medicaid, while 38% of planned births are paid for by these programs. In New Jersey in 2010, the federal and state governments spent a combined $477.1 million on unintended births; of this, $186.1 million was paid by the State.[5]

29. Because women experiencing unintended pregnancies are less likely to receive timely prenatal care (or any prenatal care at all), access to contraception is vital to New Jersey's efforts to reduce both infant and maternal mortality. Lack of access to prenatal care yields poor outcomes for mother and baby.

30. Pregnancy carries significant risk, especially in New Jersey. Currently, New Jersey is ranked 45th worst nationally in maternal mortality, and the maternal mortality rate for black women is more than double the national average.[6] New Jersey women are more likely than women in other states to suffer injury and death related to pregnancy. Many costs associated with New

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[5] Guttmacher Institute, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010* (Feb. 2015), *available at* https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy.

[6] United Health Foundation, America's Health Rankings, *2018 Health of Women and Children Report, New Jersey in 2018*, *available at* https://www.americashealthrankings.org/explore/health-of-women-and-children/measure/overall_mch/state/NJ.

Jersey's high rate of maternal mortality are paid for using public funding. Planned pregnancies, through the use of contraception, are essential to curbing the tide of maternal mortality and morbidity in the State.

31. Other negative outcomes associated with unintended pregnancy include reduced likelihood of breastfeeding, increased risk of maternal depression, and increased risk of physical violence during pregnancy, in addition to severe limitations on participation in the economy.

32. Children born from unintended pregnancies are more likely to experience poor mental and physical health during childhood and, as teenagers, are more likely to experience lower rates of educational attainment and higher rates of behavioral issues. Many of these outcomes lead to conditions and circumstances for which social supports are publicly funded.

33. For all these reasons, I believe that the Exemption Rules to the contraceptive coverage mandate will have a negative effect on the health of New Jersey women; that they will increase the number of women who receive contraceptive coverage through NJFPL; and that they will impose additional economic and other burdens on the State.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Elizabeth Coulter

Dated: 12/12/2018

EXHIBIT V

	A	B	C	D	E	F	G	H	I	J
1	**Case**	**Plaintiffs**	**Type: For-profit (F), Nonprofit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)**	**Number of Employees/Students**	**Document employee number located within**	**Are students/employees counted in final total?**	**If not counted, explanation why**	**Number counted towards final total**	**Total employees (minus HoW/IA and SICPs)**	**Total students at relevant universities**
2	Am. Pulverizer Co. v. U.S. Dep't of Health and Human Servs., No. 6:12-cv-03459, 2012 WL 6951316 (W.D. Mo. Dec. 20, 2012);		F	175 employees	Complaint	Yes		175	175	
3	American Family Association v. Sebelius, 1:13-cv 00032-SA-DAS (N.D. Miss. Feb. 20, 2013)		N	135 employees	Complaint	Yes		135	135	
4	Annex Med., Inc. v. Burwell, No. 13-1118, 2013 WL 1276025 (8th Cir. Feb. 1, 2013)		F	18 employees	Complaint	Yes		18	18	
5	Archdiocese of St. Louis v. Burwell, No. 4:13-cv-02300 (E.D. MO), No. 14-3016 (8th Cir.)	Archdiocese of St. Louis	H	7,800 employees/staff	Complaint	No	Diocese self-insured plan (see Brandt v Burwell note below	0	0	
6		Catholic Charities of St. Louis	C	1600 employees	Complaint	No	same	0	0	
7	Armstrong v. Burwell, No. 1:13-cv-00563-RBJ (D. Colo. Sept. 17, 2013); gov't appeal dismissed Sept. 4, 2014 (10th Cir. order);		F	730 employees	Complaint	Yes		730	730	
8	Association of Christian Schools International v. Burwell, No. 1:14-cv-2966 (D. Colo.), No. 14-1492 (10th Cir.)	Association of Christian Schools International	N	140 employees	Complaint	Yes		140	140	
9		Samaritan Ministries International	N	133 employees	Complaint	Yes		133	133	
10		Taylor University	N	1,900 Students; 641 Employees	Complaint	Students = no; employees = yes	Complaint does not state that they offer a student health plan; therefore students not counted	641	641	0
11		Indiana Wesleyan University	N	15,000 students; 3,565 employees (1,018 FT and 2,547 PT)	Complaint	Students = no; employees = partial	Complaint does not state that they offer a student health plan; therefore students not counted. Complaint states that 890 employees enroll in the plan. Because other entities usually provide the overall number of employees, not the number enrolled in the plan, and in the IFR we estimate 62% of all employees are in plans, this number is upscaled to 890/62%=1435.	1,435	1,435	0
12	Autocam Corp. v. Burwell, 730 F.3d 618 (6th Cir. Sept. 17, 2013),	Autocam	F	478 employees	Complaint	Yes		478	478	
13		Autocam Medical	F	183 employees	Complaint	Yes		183	183	
14	Ave Maria Foundation v. Burwell, No. 2:13-cv-15198 (E.D. Mich.), Nos. 14-1310 (6th Cir.)	The Ave Maria Foundation	N	51 employees	Estimated number based on online information	Yes		51	51	
15		Ave Maria Communications	N	19 employees	Form W-3 filing	Yes		19	19	
16		Domino's Farms Petting Farm	N	18 employees	Form W-3 filing	Yes		18	18	
17		Rhodora J. Donahue Academy, Inc.	N	26 employees	Website	Yes		26	26	
18		Thomas More Law Center	N	14 employees	Form W-3 filing	Yes		14	14	
19	Ave Maria School of Law v. Burwell, No. 2:13-cv-00795 (M.D. Fl.), Nos. 14-15777 (11th Cir.)		N	68 employees	Complaint	Employees = yes; students = no	Complaint does not state that they offer a sudent health plan; therefore students not counted	68	68	0
20	Ave Maria University v. Burwell, No. 2:13-cv-00630 (M.D. Fla.), Nos. 14-15780 (11th Cir.)		N	150 employees	Complaint	Employees = yes; students = no	Complaint does not state that they offer a student health plan, therefore students not counted	150	150	0
21	Barron Indus., Inc. v. Burwell, No. 1:13-cv-01330-KBJ (D.D.C. Sept. 25, 2013);		F	56 employees	Complaint	Yes		56	56	
22	Beckwith Elec. Co. v. Burwell, No. 8:16-cv-1944 (M.D. Fla.)		F	126 employees	Complaint	Yes		126	126	
23	Belmont Abbey College v. Sebelius, et al., No. 1:11-cv-01989 (D.D.C. Nov. 10, 2011)		N	1,600 students; 305 employees	Complaint	Yes		1,600 students; 305 employees	305	1,600
24	Bick Holdings, Inc. v. Burwell, No. 4:13-cv-00462-AGF (E.D. Mo. Apr. 1, 2013);		F	196 employees	Complaint	Yes		196	196	
25	Brandt v. Burwell, No. 2:14-cv-00681 (W.D. Pa.), Nos. 14-3663, 14-4087 (3d Cir.)	Diocese of Greensburg	H	3,100 employees; 5,000 other participants in plan (this is a high number- it includes employees from other Dioceses)	Complaint	No	Diocese self-insured plan; Government argued that these and all similar Catholic diocese-sponsored self-insured plans and entities participating in such plans that are litigants represented by Jones Day likely qualify to be church plans exempt from ERISA. See, e.g., Doc. # 23, 2:14-cv-00681-AJS (W.D. Pa.). We cannot force such plan TPAs to offer contraceptive payments, and it is likely the churches will tell them not to, and the TPAs will not make the offers.	0	0	
26		Catholic Charities	C	18 employees	Complaint	No	Diocese self-insured plan	0	0	
27		St. John School	C	13 employees	Complaint	No	Diocese self-insured plan	0	0	

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28	Briscoe v. Burwell, No. 1:13-cv-00285-WYD-BNB (D. Colo. Sept. 6, 2013); gov't appeal dismissed Sept. 4, 2014 (10th Cir. order);	Briscoe owns all plaintiff organizations involved: Continuum Health Partnerships, Inc./ Mountain States Health Properties, LLC/ Continuum Health Management, LLC/ CH-Greeley, LLC	F	200 employees	Complaint	Yes		200	200	
29	Catholic Benefits Association LCA v. Burwell (*CBA I*), No. 5:14-cv-00240 (W.D. Okla.), Catholic Benefits Association LCA v. Burwell (CBA II), No. 5:14-cv-00685 (W.D. Okla.),Nos. 14-6171, 14-6163, 15-6029, 15-6037, 15-6139, 16-6030, 16-6217 (10th Cir.)	Catholic Benefits Associatoin	N	Unknown	N/A	To estimate the number in CBA plans that may be effected, 10,000 used.	CBA does not carry its own insurance	0	10,000	
30		Catholic Insurance Company	N	Unknown	N/A	No	CBA owns CIC, so we assume CIC also does not offer insurance	0	0	
31		Archdiocese of Baltimore	H	5, 500 participants	Complaint	No	Diocese self-insured plan	0	0	
32		Cathedral Foundation (AKA Catholic Review Media)	C	32 employees	Complaint	No	Diocese self-insured plan	0	0	
33		Archdiocese of Oklahoma City- Complaint lists Mount St. Mary, St. Ann, and Office of Catholic Schools as sub-ministries	H	Unknown (see St. Ann, Mount St. Mary and Office of Catholic Schools below)		No	Diocese self-insured plan	0		
34		St. Ann	C	78 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
35		Mount St. Mary	C	Unknown		No	Diocese self-insured plan	0	0	
36		Office of Catholic Schools	C				Disocese self-insured plan	0	0	
37		Villa St. Francis Catholic Care Center	N	100 participants	Complaint	Yes		100	100	
38		Goodwill Publishers	N	140 employees	Complaint	Yes		140	140	
39		Catholic Charities Oklahoma City	C	103 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
40		All Saints	C	Unknown		No	Diocese self-insured plan	0	0	
41		Catholic Charities and Family Services, Diocese of Norwich	N	69 employees	Second Complaint	Yes		69	69	
42	Catholic Charities of the Archdioceses of Philadelphia	Catholic Social Services	C	626 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
43	v. Burwell, No. 2:14-cv-3096 (E.D. Pa.), No. 14-3126 (3d Cir.)	St. Francis Homes for Boys	C	227 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
44		St. Edmund's Home for Children	C	226 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
45		Don Guanella Village	C	413 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
46		Divine Providence Village	C	667 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
47		St. Gabriel's System	C	458 emplyees	Form W-3 filing	No	Diocese self-insured plan	0	0	
48		Catholic Community Services	C	92	Form W-3 filing	No	Diocese self-insured plan	0	0	
49		Nutritional Development Services	C	64	Form W-3 filing	No	Diocese self-insured plan	0	0	
50		Villa St. Martha	C	117 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
51		St. Monica Manor	C	356 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
52		St. John Neumann Nursing Home	C	360 Employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
53		Immaculate Mary Home	C	490 Employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
54		St. Francis Country House	C	488 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
55		St. Martha Manor	C	272 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
56		St. Mary Manor	C	339 employees	Form W-3 filing	No	Disocese self-insured plan	0	0	
57		St. John Vianney Center	C	84 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
58		Catholic Clinical Consultants	C	19	Form W-3 filing	No	Diocese self-insured plan	0	0	
59	Catholic Diocese of Beaumont v. Burwell, No. 1:13-cv-00709 (E.D. Tex.), No. 14-40212 (5th Cir.)	Diocese	H	950 employees; 232 staff at schools	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust- a self insured church plan	0	0	
60		Catholic Charities of Southeast Texas, Inc.	C	18 employees	Complaint		Offers coverage through Christian Brothers Employee Benefit Trust- a self insured church plan	0	0	
61	Catholic Diocese of Biloxi v. Burwell, No. 1:14-cv-00146 (S.D. Miss.)	Diocese of Jackson	H	900 employees	Complaint	No	Diocese self-insured plan	0	0	
62		Catholic Charities	C	140 employees	Complaint	No	Diocese self-insured plan	0	0	
63		Vicksburg	C	70 employees	Website	No	Diocese self-insured plan	0	0	
64		St Joseph	C	85 employees	Website	No	Diocese self-insured plan	0	0	
65		Diocese of Biloxi	H	600 employees	Complaint	No	Diocese self-insured plan	0	0	
66		De L'epee Deaf Center	C	5 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
67		Catholic Social & Community Services Inc.	C	20 employees	Form W-3 filing	no	Diocese self-insured plan	0	0	
68		Resurrection Catholic and Sacred Heart	C	200 employees	Complaint	No	Diocese self-insured plan	0	0	

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69		St. Dominic-Jackson Memorial Hospital and affiliated locations and programs	G	2,200 employees	Complaint	No	Self-insured plan sponsored by Catholic affiliated hospital; grandfathered and already omits contraceptives, so could retain grandfathered status or pursue church plan status to continue omitting.	0	0	
70	Conlon, Bishop of Catholic Diocese of Joliet v. Sebelius, 1:12-cv-03932 (N.D. Ill. May 21, 2012)	Diocese of Joliet	H	At least 1,570 employees	Complaint	No	Diocese self-insured plan	0	0	
71		Catholic Charities of Joliet	C	240 employees	Complaint	No	Diocese self-insured plan	0	0	
72		Diocese of Springfield	H	2585 employees	Complaint	No	Diocese self-insured plan	0	0	
73		Catholic Charities of Springfield	C	200 employees	Complaint	No	Diocese self-insured plan	0	0	
74		Catholic Charities of Chicago	N	2700 employees	Complaint	Yes	Self-funded welfare benefit plan but not sure if church plan	2,700	2,700	
75	Catholic Diocese of Nashville v. Burwell, No. 3:13-cv	Diocese of Nashville	H	1200 employees	Complaint	No	House of Worship, fully insured	0	0	
76	1303 (M.D. Tenn.), No. 13-6640 (6th Cir.)	Catholic Charities	N	115 employees	Complaint	Yes		115	115	
77		Aquinas College	N	16 employees	Website	employees: yes; students: no	Website/news reports indicate recent drastic downsizing of workforce; students not counted because complaint does not allege a student plan	16	16	0
78		Camp Marymount	N	75 employees	Complaint	Yes		75	75	
79		MQA	N	85 employees	Complaint	Yes		85	85	
80		St. Mary Villa	N	50 employees	Complaint	Yes		50	50	
81		Dominican Sisters	H	23 employees		No	Religious order	0	0	
82	Catholic Diocese of Peoria v. Sebelius, 1:12-cv-01276 JES-BGC (C.D. Ill. August 9, 2012)		H	Unknown		No	Diocese self-insured plan (court order, 2013 WL 74240), and grandfathered	0	0	
83	Catholic Health Care System v. Burwell, No. 1:12-cv-02542 (E.D.N.Y.), No. 14-427 (2d Cir.); **PACER**	Archdiocese of New York	H	10,000 employees	Complaint	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F.Supp.2d at 242	0	0	
84		ArchCare	C	4,000 employees	Complaint	No	Catholic hospital self-insured plan?	0	0	
85		Catholic Health Services of Long Island	C	17,000 employees	Complaint	No	Catholic hospital self-insured plan	0	0	
86		The Diocese of Rockville Centre	H	2,000 employees	Complaint	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F.Supp.2d at 242	0	0	
87		Monsignor Farrel High School	C	73 employees	Website	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F.Supp.2d at 242	0	0	
88		Cardinal Spellman High School	C	100 employees	Complaint	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F.Supp.2d at 242	0	0	
89	Christian & Missionary Alliance Foundation, Inc., No. 2:14-cv-00580 (M.D. FL.), Nos. 15-11437, 15-11635 (11th Cir.)	CMA d/b/a Shell Point Retirement Center		1247 employees	Form W-3 filing	Yes		1,247	1,247	
90		Alliance Community for Retirement Living		344 employees	Form W-3 filing	Yes		344	344	
91		Alliance Home of Carlisle		219 employees	Form W-3 filing	Yes		219	219	
92		Town and Country Manor		365 employees	Form W-3 filing	Yes		365	365	
93		Simpson University		815 employees	Complaint	employees: yes; students: no	Complaint does not seek relief for any student plan	815	815	0
94		Crown College		114 employees	Form W-3 filing; student enrollment: https://www.crown.edu/about/quick-facts/ ("nearly 1,300 students")	Yes		1,275 students; 114 employees	114	1,275
95	Christian Employers Alliance v. Burwell, No. 3:16-cv-309 (D.N.D.)	Christian Employers Alliance		Unknown		No	No claim was made for CEA plans, and no list of members beyond TBC and TIC	0	0	
96		Trinity Bible College		249 employees	Form W-3 filing	employees: yes; students: no	complaint does not mention student plan	249	249	
97		Treasure Island Coins		9 staff	Website	Yes		9	9	
98	Colorado Christian Univ. v. Burwell, No. 1:13-cv-02105 (D. Colo.), No. 14-1329 (10th Cir.)	Colorado Christian University		5,300 students; 680 employees	Complaint	Yes		5,300 students; 680 employees	680	5,300
99	Conestoga Wood Specialties Corp. v. Burwell (Burwell v. Hobby Lobby Stores, Inc.), No. 13-356 (U.S. June 30, 2014);	Conestoga Wood Specialties Corp. (Individual operators of Conestoga Wood Specialities Corporation are the three other named plaintiffs)		950 employees	Complaint	Yes		950	950	

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100	Diocese of Cheyenne v. Burwell, No. 2:14-cv-00021 (D. Wyo.), No. 14-8040 (10th Cir.)	Diocese of Cheyenne		16 employees plus over 100 teachers	Complaint	No	Diocese self-insured plan	0	0	
101		Catholic Charities		6 employees	Complaint	No	Diocese self-insured plan	0	0	
102		St. Anthony School		41 employees	Complaint	No	Diocese self-insured plan	0	0	
103		St. Joseph's Home		130 employees, 62 orphan children	Complaint	No	Diocese self-insured plan	0	0	
104		JPIICS		20	Complaint	No	Diocese self-insured plan	0	0	
105		Wyoming Catholic College		32 employees	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust- a self insured church plan	0	0	0
106	Diocese of Fort Wayne-South Bend Inc. v. Burwell, No. 1:12-cv-00159 (N.D. Ind.), No. 14-1431 (7th Cir.)	Diocese of Fort Wayne South Bend		2,741 employees	Complaint	No	Diocese self-insured plan; also grandfathered	0	0	
107		Catholic Charities		39 employees	Complaint	No	Diocese self-insured plan	0	0	
108		St Anne Home		310 employees	Complaint	Yes	Self-insured plan, but not sure if it is a church plan	310	310	
109		University of St Francis		2,300 students, 413 employees	Complaint	employees: yes; students: no	No student plan discussed; Employees are offered a self-insured health plan, but not sure it is a church plan, so included	413	413	0
110		Our Sunday Visitor		300 employees	Complaint	Yes	Self-insured plan, but not sure if it is a church plan	300	300	
111		Specialty Physicians		342 employees	Complaint	Yes		342	342	
112		Franciscan Alliance		18,000 employees	Complaint	Partial	All but 1,733 employees are on a church plan exempt from ERISA. See: https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf (Only employees in Illinois are in BCBS plans and there are 1733 of those employees according to complaint)	1,733	1,733	
113	Doboszenski & Sons, Inc. v. Burwell, No. 0:13-cv-03148-JNE-FLN (D. Minn. Nov. 11, 2013);			32 employees	Complaint	Yes		32	32	
114	Dobson v. Burwell, No. 1:13-cv-03326 (D. Colo.), No. 14-1233 (10th Cir.)			28 employees	Complaint	Yes		28	28	
115	Domino's Farms Corporation v. Sebelius et al., No. 12 cv-15488 (E.D. Mich. Dec. 20, 2012)			89 employees	Complaint	Yes		89	89	
116	Dordt Coll. v. Burwell, No. 5:13-cv-04100 (N.D. Iowa, Western Divison), No. 14-2726 (8th Cir.)	Dordt College		1,400 students, 280 employees	Complaint	Yes		1,400 students, 280 employees	280	1,400
117		Cornerstone University		2,923 students, 294 employees	Complaint	employees: yes; students: no	No student plan discussed	294	294	0
118	East Texas Baptist Univ. v. Burwell, No. 4:12-cv-03009 (S.D. Tex.), No. 14-20112 (5th Cir.)	Houston Baptist University		2,589 students, 416 employees	Complaint	No	Self-insured church plan	0	0	0
119		East Texas Baptist Univeristy		1,290 students, 283 employees	Complaint	Yes		1,290 students, 283 employees	283	1,290
120		Westminster Theological Seminary (Intervenor)		60 FT, 65 PT employees, 620 students	Complaint in intervention	employees: yes; students: no	complaint does not mention student plan	125	125	0
121	Eden Foods, Inc. v. Burwell, No. 13-1677 (6th Cir. June 28, 2013),			128 employees	Complaint	Yes		128	128	
122	Eternal Word Television Network, Inc. v. Burwell, No. 1:13-cv-00521 (S.D. AL), No. 14-12696 (11th Cir.)			350 employees	Complaint	Yes		350	350	
123	Fellowship of Catholic University Students v. Burwell No. 1:13-cv-03263-MSK-KMT (D. Colo. Apr. 23, 2014)			450 employees	Complaint	No	Case resolved on basis that plaintiff is integrated auxilary	0	0	
124	Feltl & Co., Inc. v. Burwell, No. 13-CV-2635 DWF/JJK (D. Minn. Nov. 8, 2013);	Complaint lists two owners of the company as individual plaintiffs		4 employees	Website	Yes		4	4	
125	Franciscan University v. Sebelius, 2:12–CV–440 (S.D. Ohio)			Unknown	Complaint	No	Sued while grandfathered and then dropped student plan. With no additional suit, no apparent affect from rule.	0	0	0
126	Geneva College v. Burwell, No. 2:12-cv-00207 (W.D. Pa.), Nos. 13-3536, 14-1374 (3rd. Cir.)	Geneva College		1,850 students, 350 employees	Complaint	Yes		1,850 students, 350 employees	350	1,850
127		Seneca Hardwood Lumber		22 employees	Complaint	No	Permanent injunction shields from previous rule	0	0	
128	Gilardi v. U.S. Dep't of Health and Human Servs.,	Freshway Foods		340 employees	Complaint	Yes		340	340	
129	No. 13-5069, 2013 WL 5854246 (D.C. Cir. Nov. 1,	Freshway Logistics		55 employees	Complaint	Yes		55	55	
130	Grace Schools v. Burwell, No. 3:12-cv-00459 (N.D. Ind.), No. 14-1430 (7th Cir.)	Grace College and Seminary		2,700 students, 457 employees	Complaint	Yes		2,700 students, 457 employees	457	2,700
131		Biola University		6,222 students, 856 employees	Complaint	Yes		6,222 students, 856 employees	856	6,222

	A	B	C	D	E	F	G	H	I	J
1	**Case**	**Plaintiffs**	**Type: For-profit (F), Nonprofit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)**	**Number of Employees/Students**	**Document employee number located within**	**Are students/employees counted in final total?**	**If not counted, explanation why**	**Number counted towards final total**	**Total employees (minus HoW/IA and SICPs)**	**Total students at relevant universities**
132	Grote Indus. LLC v. Burwell, No. 13-1077, 2013 WL 5960692 (7th Cir. Nov. 8, 2013), cert. denied sub nom. Burwell v. Korte, No. 13-937 (U.S. July 1, 2014);			1,148 employees	Complaint	Yes		1,148	1,148	
133	Hall v. Burwell, No. 0:13-cv-00295-JRT-LIB (D. Minn. Apr. 2, 2013);			Approximately 50 employees	Complaint and online news reports	Yes		50	50	
134	Hartenbower v. U.S. Dep't of Health and Human	Hart Electric		54 employees (including owners)	Complaint	Yes		54	54	
135	Servs., No. 1:13-cv-02253 (N.D. Ill. Apr. 18, 2013);	H.I. Hart		7 employees	Complaint	Yes		7	7	
136	Hastings Chrysler Center, Inc. v. Burwell, No. 0:14-cv-00265-PAM-JJG (D. Minn. May 28, 2014);			60 employees	Complaint	Yes		60	60	
137	Hobby Lobby Stores, Inc., et al. v. Sebelius, et al., No:	Hobby Lobby		13,240 employees	Complaint	Yes		13,240	13,240	
138	CIV-12-1000-HE (W.D. Okla. Oct. 2, 2012); Burwell	Mardel		372 employees	Complaint	Yes		372	372	
139	Holland v. U.S. Dep't of Health and Human Servs, No. 13-15487 (S.D. W. Va. July 15, 2014);			150 employees	Complaint	Yes		150	150	
140	Infrastructure Alternatives, Inc. v. Burwell, No. 1:13-cv-00031-RJJ (W.D. Mich. Sept. 30, 2013)			70 employees	Complaint	Yes		70	70	
141	Insight for Living Ministries v. Burwell, No. 4:14-cv-675 (E.D. Tex.), No. 15-40031 (5th Cir.)			108 employees	Form W-3 filing	Yes		108	108	
142	Johnson Welded Prods. v. Burwell, No. 1:16-cv-557 (D.D.C.)			421 employees (including Lilli Johnson)	Complaint	Yes		421	421	
143	Korte v. Burwell, No. 12-3841, 2013 WL 5960692 (7th Cir. Nov. 8, 2013), cert. denied No. 13-937 (U.S. July 1, 2014);			90 employees	Complaint	Yes		90	90	
144	Legatus v. Burwell, No. 2:12-cv-12061-RHC-MJH	Legatus		69 employees	Complaint	Yes		69	69	
145	(E.D. Mich. Dec. 20, 2013)	Weignartz Supply Company, W&P Management LLC, and subsidiaries		170 employees	Complaint	Yes		170	170	
146	Lindsay v. U.S. Dep't of Health and Human Servs., No. 13-cv-1210 (N.D. Ill. Mar. 20, 2013);			70 employees	Complaint	Yes		70	70	
147	Little Sisters of the Poor Home for the Aged v. Burwell, No. 1:13-cv-2611 (D. Colo.), No. 13-1540 (10th Cir.)	Christian Brothers Employee Benefit Trust (Little Sisters uses Christian Brothers Employee Benefit Trust, and Christian Brothers Services is the TPA for the Christian Brothers Employee Benefit Trust)		5,000 employees	Complaint	No	Self-insured church plan	0	0	
148	Louisiana Coll. v. Burwell, No. 1:12-cv-00463 (W.D. La.), No. 14-31167 (5th Cir.)			1,450 students, 260 employees	Complaint	No	Self-insured church plan	0	0	0
149	March for Life v. Burwell, No. 1:14-cv-1149 (D.D.C.), No. 15-5301 (D.C. Cir.)			2 employees covered in plan; less than 10 overall		No	All employees must/do oppose the coverage; therefore not counting as affected by rules	0	0	
150	Media Research Center v. Sebelius, No. 1:14-CV-379 (E.D. Virginia)			114 employees	Complaint	Yes		114	114	
151	Mersino Mgmt. Co. v. Burwell, No. 13-1944 (6th Cir. July 9, 2014)			110 employees	Complaint	Yes		110	110	
152	Michigan Catholic Conf. v. Burwell, No. 1:13-cv-	Michigan Catholic Charities		6,429 employees	Complaint	No	Self-insured church plan	0	0	
153	1247 (W.D. Mich.), No. 13-2723 (6th Cir.)	Catholic Charities		55 employees	Complaint	No	Self-insured church plan	0	0	
154	Midwest Fastener Corp. v. Burwell, No. 1:13-cv-01337-ESH (D.D.C. Oct. 16, 2013);			187 employees	Complaint	Yes		187	187	
155	MK Chambers Co. v. Dep't of Health and Human Servs., No. 13-cv-11379 (E.D. Mich. Nov. 21, 2014)			106 employees	Business profile on manta.org	Yes		106	106	
156	Nagle, Christopher, et al. v. Kathleen Sebelius, et al.; No. 2:13-cv-12036-VAR-DRG (E.D. Mich. May 10, 2013) (AKA "*M&N Plastics*")			109 employees	Complaint	Yes		109	109	
157	Newland v. Burwell, 881 F. Supp. 2d 1287 (D. Colo. July 27, 2012), affirmed on appeal, No. 12-1380 (10th Cir. Oct. 3, 2013)			Unknown		No	Permanent injunction	0		
158	O'Brien v. U.S. Dep't of Health & Human Servs., No. 12-3357 (8th Cir. Nov. 28, 2012)			87 employees	Complaint	Yes		87	87	
159	Ozinga v. Burwell, No. 1:13-cv-3292 (N.D. Ill.), No. 15-3648 (7th Cir.)			675+ employees	Complaint	Partial	Only 110 obtain insurance through the plan that would be affected by the exemption. This is upscaled to 110/62%=178	178	178	
160	Persico v. Burwell, No. 1:13-cv-0303 (W.D. Pa.),	Cathllice Diocese of Erie		1,500 employees	Complaint	No	Diocese self-insured plan	0	0	
161	Nos. 14-1376 (3d Cir.);	St Martin Center		61 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
162	formerly Most Reverend Donald W. Trautman, Bishop	Prince of Peace Center		20 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
163	of the Roman Catholic Diocese of Erie, et al., v. Sebelius; No. 1:12-cv-00123-SPB (W.D. Pa. May 30,	Erie Catholic Preparatory School		80 employees	Complaint	No	Diocese self-insured plan	0	0	
164	Priests for Life, No. 1:13-cv-01261 (D.D.C.), No. 13-5368 (D.C. Cir.)			60 employees	Website	Yes		60	60	

	A	B	C	D	E	F	G	H	I	J
1	**Case**	**Plaintiffs**	**Type: For-profit (F), Nonprofit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)**	**Number of Employees/Students**	**Document employee number located within**	**Are students/employees counted in final total?**	**If not counted, explanation why**	**Number counted towards final total**	**Total employees (minus HoW/IA and SICPs)**	**Total students at relevant universities**
165	Randy Reed Auto. Inc. v. Burwell, No. 5:13-cv-6117-SJ-ODS (W.D. Mo. Dec. 3, 2013);			approximately 179 employees	Complaint	Yes		179	179	
166	Reaching Souls Int'l, Inc. v. Burwell, No. 5:13-cv-01092 (W.D. Okla.), No. 14-6028 (10th Cir.)			78,000 participants (pastors, employees, and their families)	Complaint	No	Self insured church plan	0	0	
167	Real Alternatives, Inc. v. Burwell, No. 1:15-cv-105 (M.D. Pa.), No. 16-1275 (3d Cir.)			3 employees	Complaint	No	All employees must/do oppose the coverage; therefore not counting as affected by rules	0	0	
168	Right to Life of Michigan v. Kathleen Sebelius; No. 1:13-CV-01202 (W.D. Mich. Nov. 22, 2013)			43 employees	Complaint	No	All employees must/do oppose the coverage; therefore not counting as affected by rules	0	0	
169	Roman Catholic Archbishop of Washington v. Burwell, No. 1:13-cv-01441 (D.D.C.), Nos. 13-5371, 14-5021 (D.C. Cir.)	Cathloic University		7,000 students, 1,766 employees	Complain	Yes		7,000 students, 1,766 employees	1,766	7,000
170		Archdiocese of Washington		2,100 eligible employees, 1,200 teachers/employees at schools	Complaint	No	Diocese self-insured plan	0	0	
171		Thomas Aquinas College		370 students, 78 eligible employees	Complaint	No	Church plan and complaint does not state that it offers student insurance	0	0	0
172		Consortium of Catholic Academies		119 employees	Complaint	No	Diocese self-insured plan	0	0	
173		Archbishop Carroll		70 employees	Complaint	No	Diocese self-insured plan	0	0	
174		Don Bosco		51 employees	Complaint	No	Diocese self-insured plan	0	0	
175		Cathloic Information Center		9 employees	Complaint	No	Diocese self-insured plan	0	0	
176		Mary of Nazareth		44 employees	Complaint	No	Diocese self-insured plan	0	0	
177		Catholic Charities		890 employees	Complaint	No	Diocese self-insured plan	0	0	
178		Victory Housing		184 employees	Complaint	No	Diocese self-insured plan	0	0	
179	Roman Catholic Archdiocese of Atlanta v. Burwell, No. 1:12-cv-03489 (N.D. Ga.), Nos. 14-12890, 14-13239 (11th Cir.)	Roman Catholic Archdiocese of Atlanta		9,800 students, 4,200 employees	Complaint	No	Diocese self-insured plan	0	0	
180		Catholic Charities		75 employees	Complaint	No	Diocese self-insured plan	0	0	
181		CENG		200 employees	Complaint	No	Diocese self-insured plan	0	0	
182		Diocese of Savannah		5,000 students; hundreds of employees	Complaint	No	Diocese self-insured plan	0	0	
183	Roman Catholic Diocese of Dallas v. Sebelius, No. 3:12-cv-01589-B (N.D. Tex.)			900 teachers/staff, 100+ employees	Complaint	No	Diocese self-insured plan	0	0	
184	School of the Ozarks v. Rightchoice Managed Care, Inc., No. 6:13-cv-03157 (W.D. Mo.), No. 15-1330 (8th Cir.)			1,442 students, 601 employees	Students - online; employees - Form w3 Filing	Employees only	Complaint does not say they offer a student plan	601	601	
185	Sharpe Holdings, Inc. v. Burwell, No. 2:12-cv-92 (E.D. Mo.) and CNS Intl Ministries, No. 14-1507 (8th Cir.)	Sharpe		50 employees	2dam complaint and Linked in	Yes		50	50	
186		Ozark		51 employees	2dam complaint and Linked in	Yes		51	51	
187		CNS International Ministries		204 employees	Form W-3 filing	Yes		204	204	
188		NIS Financial		49 employees	2dam Complaint	Yes		49	49	
189		CNS Corp		49 employees	2dam Complaint	Yes		49	49	
190		Heartland Christian College		12 employees	Form W-3 filing	Employees only	Complaint does not say they offer a student plan	12	12	0
191	Sioux Chief Mfg. Co. v. Burwell, No. 13-0036-CV-W-ODS (W.D. Mo. Feb. 28, 2013);			370 employees	Complaint	Yes		370	370	
192	SMA, LLC v. Burwell, No. 0:13-cv-01375-ADM-LIB (D. Minn. July 8, 2013);			35 employees	Complaint	Yes		35	35	
193	Southern Nazarene Univ. v. Burwell, No. 5:13-cv-1015 (W.D. Okla.), No. 14-6026 (10th Cir.)	Southern Nazarene University		2,100 students, 505 employees	Complaint	Yes		2,100 students, 505 employees	505	2,100
194		OK Weselan University		1,220 students, 557 employees	Complaint	Employees only	Complaint does not say they offer a student plan	557 employees	557	0
195		OK Baptist University		1,900 students, 328 employees	Complaint	Yes		1,900 students, 328 employees	328	1,900
196		Mid America Christian University		1,447 stuendts, 298 employees	Complaint	No	Mid America Christian Univ is on Guidestone, a self-insured church plan	0	0	0
197	Stewart v. Burwell, No. 1:13-cv-01879 (D.D.C. Apr. 3, 2014);	Encompass Develop, Design & Construct, LLC		43 employees	Complaint	Yes		43	43	
198	Stinson Electric, Inc. v. Burwell, No. 14-00830-PJS-JJG (D. Minn. April 30, 2014);			19 employees	Business profile on manta.org	Yes		19	19	
199	The C.W. Zumbiel Co. v. Burwell, No. 1:13-cv-01611 (D.D.C. Nov. 27, 2013);			350 employees	Complaint	Yes		350	350	
200	The Criswell College v. Sebelius, No. 3:12-cv-04404-N (N.D. Tex.)			322 students, 50 employees	Complaint	Employees only	Complaint does not say they offer a student plan	50	50	
201	The QC Grp., Inc., v. Burwell, No. 0:13-cv-01726-JRT-SER (D. Minn. Sept. 11, 2013);			62 employees	Complaint	Yes		62	62	
202	Thomas G. Wenski v. Kathleen Sebelius; No. 12-cv-23820-Graham/Goodman (S.D. Fla. Nov. 7, 2012)	Archdiocese of Miami		Unknown		No	House of worship	0	0	
203		Catholic Health Services		2,000 employees	Complaint	Yes		2,000	2,000	
204		Catholic Hospice		610 employees	Form W-3 filing	Yes		610	610	

	A	B	C	D	E	F	G	H	I	J
1	**Case**	**Plaintiffs**	**Type: For-profit (F), Nonprofit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)**	**Number of Employees/Students**	**Document employee number located within**	**Are students/employees counted in final total?**	**If not counted, explanation why**	**Number counted towards final total**	**Total employees (minus HoW/IA and SICPs)**	**Total students at relevant universities**
205		St. Thomas University		Unknown		No	Lawsuit mentions St. Thomas University but asserts no claims for its health plans	0	0	0
206	Tonn & Blank Constr. v. Burwell, No. 1:12-cv-00325-JD-RBC (N.D. Ind. Apr. 1, 2013);			60 employees	Complaint	Yes		60	60	
207	Trijicon, Inc. v. Burwell, No. 1:13-cv-1207 (D.D.C.)			469 employees	Complaint	Yes		469	469	
208	Tyndale House Publishers, Inc. v. Burwell, 904 F. Supp. 2d 106 (D.D.C. Nov. 16, 2012);			260 employees	Complaint	Yes		260	260	
209	Union University v. Burwell, No. 1:14-cv-1079 (W.D. Tenn.)			2,829 students, 1,116 employees	Students - online; employees - Form w3 Filing	Employees only	Complaint does not say they offer a student plan	1,116 employees	1,116	0
210	Univ of Dallas v. Burwell, No. 4:12-cv-00314 (N.D. Tex.), No. 14-10241 (5th Cir.), Nos. 14-10661 (5th Cir.)	Roman Catholic Diocese of Fort Worth		6,500 students, 2,000 employees	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust- a self insured church plan	0	0	
211		University of Dallas		2,600 students, 725 employees	Complaint	Yes		2,600 students, 725 employees	725	2,600
212		Catholic Charities		332 employees	Complaint	Yes		332	332	
213		Our Lady Of Victory Catholic School		23 employees	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust- a self insured church plan	0	0	
214	Univ. of Notre Dame v. Burwell, No. 3:13-cv-1276 (N.D. Ind.), No. 13-3853 (7th Cir.)			11,500 students, 5,000 employees	Complaint	yes		11,500 students, 5,000 employees	5,000	11,500
215	Valley Forge Christian College of the Assemblies of God v. Burwell; No. 14-4622 (E.D. Pa. Aug. 14, 2014)			Unknown	Complaint	No	Plaintiff voluntarily dismissed suit; our understanding is they were satisfied with previous accommodation	0	0	0
216	Weingartz Supply Co. v. Burwell, No. 2:12-cv-12061 (E.D. Mich.), No. 14-1183 (6th Cir.)			170 employees	DC Ruling	Yes		170	170	
217	Wheaton College v. Burwell, No. 1:13-cv-08910 (N.D. Ill.), No. 14-2396 (7th Cir.)			870 Employees	Complaint	Yes	Note: Students not counted because complaint states that Wheaton dropped student coverage	870	870	0
218	Williams v. Burwell, No. 1:13-cv-01699 (D.D.C. Nov. 19, 2013);			3 employees	Complaint	Yes		3	3	
219	Willis Law v. Burwell, No. 1:13-cv-01124-CKK (D.D.C. Aug. 23, 2013);			15 employees	Complaint	Yes		15	15	
220	Yep v. Seblius, No. 1:12-cv-6756 (N.D. Ill.), Triune Health Group, Inc. v. Burwell, No. 1:12-cv-06756 (N.D. Ill.); No. 13-1478 (7th Cir.)			4 employees	Website	Yes		4	4	
221	Zubik v. Burwell, No. 2:13-cv-1459 (W.D. Pa.), Nos. 14-1377 (3d Cir.)	Diocese		140+ full-time employees	Complaint	No	Diocese self-insured plan	0	0	
222		Catholic Charities		115 employees	Complaint	No	Diocese self-insured plan	0	0	
223		Catholic Cemeteries		207 employees	Complaint	No	Diocese self-insured plan. Cemeteries was covered by the diocese's previous self-insured plan the Catholic Employers Benefits Plan; the new complaint says that CEBS was converted to the Catholic Benefits Trust, and Cemeteries are omitted as co-plaintiffs.	0	0	
224								Total	64,352	46,737
225										7% of students use university sponsored plans http://www.gao.gov/new.items/d08389.pdf
226								Total	64,352	3,272
227									employees in affected plans	students in affected plans

EXHIBIT W

DRAFT: INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been pub icly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated distributed or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the fu l extent of the law.

Notification from Elig ble Organizations to HHS Regarding Religious Objections to Providing Contraceptive Coverage

Redacted

				Eligible Organization Information					Plan Information			
Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in Litigation? (Yes or No) (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
Redacted	8/26/2014	E-mail	Cummins-Al ison Corp and Cummins Illinois Inc.	Redacted	Other	No	Plan B Ella Mirena Copper IUDs	Redacted	Other	self-insured	Redacted
	9/8/2014	E-mail	Loyola University		Non-profit	No	All		Other	Fully insured	
									Other	Fully insured	
									Other	Fully insured	
	9/10/2014	E-mail	Valley Forge Christian College		Non-profit	Yes	Ulipristal (aka E la) Levonorgestrel (aka Plan B Plan B One-Step Next Choice) Intrauterine Devices (of any type) Abortion services except to save the life of the mother		Other	Fully insured	
									Other	self-insured	
	9/19/2014	E-mail	Sisters of the Order of St. Dominic of Grand Rapids (Dominican Sisters)		Non-Profit	No	All		Other	Fully insured	
	9/19/2014	E-mail	Continuant		Other	No	Emergency Contraceptives & IUD's		Other	Fully Insured	
									Other	Fully Insured	
	10/ /2014	E-mail	Management Analysis and Ut lization Inc.		Other	No	"All abortifacient coverages such as but not limited to morning after and week after services"		Other	Both	
									Other	Both	
									Other	self-insured	
	10/6/2014	E-mail	Holy Ghost Preparatory School		Non-profit	No	All		Other	Fully insured	
	10/9/2014	Ma l	The Catholic Diocese of Memphis in Tennessee		Non-profit				Church Plan	self-insured	
	10/9/2014	Ma l	Belhaven University		Non-profit		All		Other	self-insured	
									Other	self-insured	
									Other	self-insured	
	10/10/2014	E-mail	Bingaman and Son Lumber Inc. PO Box 247 1195 Creek Mountain Rd Kreamer PA 17833		Other		Plan B Ella Mirena Paraguard		Other	Fully insured	
									Other	Fully Insured	

Notifications

	M	N	O	P	Q	R	S	T	U	V	W
1											
2											
3											
4											
5	Service Provider Information								Action Taken		
6	Contact Information for Issuer (enter N/A if none)	Name of TPA (enter N/A if none)	Contact Information for TPA (enter N/A if none)	Original Information or updated Information?	For updated information, date the information is effective	For updated information, summary of changes	For fu ly insured plans, date letter sent to Issuer by HHS	For self-insured plan, date notification forwarded to DOL	For for-profit organizations, date letter sent to organization (see instruction #1 above)	Notes	
7	Redacted	Redacted	Redacted	Original	N/A	Redacted					
8				Original	N/A						
9				Original	N/A						
10				Original	N/A						
11				Original	N/A						
12				Original	N/A						
13				Original	N/A						
14				Original	N/A						
15				Original	N/A						
16				Original	N/A						
17				Original	N/A						
18				Original	N/A						
19				Original	N/A						
20				Original	N/A						
21				Original	N/A						
22				Original	N/A						
23				Original	N/A						
24				Original	N/A						
25				Original	N/A						

Notifications

	A	B	C	D	E	F	G	H	I	J	K	L
5				Eligible Organization Information					Plan Information			
6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in Litigation? (Yes or No) (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
26	Redacted				Redacted				Redacted	Other	Fully insured	Redacted
27		10/15/2014	E-mail	Loyola University		Non-profit	No	All		Other	Fully insured	
28										Other	Fully insured	
29										Other	Fully insured	
30		10/16/2014	Litigation	Wheaton College		Non-profit	Yes	"Abortion-causing drugs abortion procedures and related services but has no religious objection to providing coverage for contraceptive drugs and devices that prevent conception (as opposed to interfering with the continued survival of a human embryo). Specifica ly identifies Plan B ella and certain unspecified IUDs as drugs and devices to which it has religious objections."		Other	self-insured	
31										Other	self-insured	
32										Student	Fully insured	
33		10/20/2014	Ma l	Carithers-Wallace-Courtenay LLC		Other						
34		10/29/2014	Email	Contract Packaging Inc.		Other		Plan B E la Next Choice		Other		
35		11/5/2014	Ma l	Avesta Homes LLC		Other		All		Other	Fully Insured	
36		11/1 /2014	E-mail	Kent Manufacturing Company		Other						
37		11/14/2014	Ma l	Dakota Tube Inc		Other						
38		11/18/2014	E-mail	Oral Roberts University		Non-profit		EC Plan B One-step (the morning after pil); Ella Ulipristal Acetate (the week after pil); copper intrauterine devices; hormonal intrauterine devices; as we l as any other drug device procedure or mechanism which has the purpose or effect of preventing an already fertilized egg from developing further by inhibiting or terminating its attachment to the uterus"		Other	Fully insured	

Notifications

	M	N	O	P	Q	R	S	T	U	V	W
5	Service Provider Information								Action Taken		
6	Contact information for issuer (enter N/A if none)	Name of TPA (enter N/A if none)	Contact information for TPA (enter N/A if none)	Original information or updated information?	For updated information, date the information is effective	For updated information, summary of changes	For fu ly insured plans, date letter sent to issuer by HHS	For self-insured plan, date notification forwarded to DOL	For for-profit organizations, date letter sent to organization (see instruction #1 above)	Notes	
26	Redacted	Redacted	Redacted	Updated	1/ /2015	Redacted					
27				Updated	1/1/2015						
28				Updated	1/1/2015						
29				Original	N/A						
30				Original	N/A						
31				Original	N/A						
32				Original	N/A						
33											
34				Original	N/A						
35				Original	N/A						
36											
37											
38				Original	N/A						

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5				Eligible Organization Information					Plan Information			
6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in Litigation? (Yes or No) (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
39	Redacted	11/20/2014	E-mail	J.E. Dunn Construction Group Inc.	Redacted	Other		· Plan B (levonorgestrel) and its generic equivalents · ella (ulipristal acetate) · ParaGard (copper IUD) · Mirena and Skyla (levonorgestrel-releasing IUDs)	Redacted	Other	Self-insured	Redacted
40										Other	Self-insured	
41		12/5/2014	E-mail	Greenv lle College		Non-profit		Plan B Ella and a l IUDs		Other	self-insured	
42										Other	self-insured	
43										Other	self-insured	
44		12/9/2014	E-mail	Covenant Presbyterian Church		Non-profit						
45		12/17/2014	E-mail	Trinity Schools Inc. D/B/A Trinity School at River Ridge		Non-profit	No			Other?	Fully Insured?	
46		12/17/2014	E-mail	People of Praise Minnesota Inc.		Non-profit	No			Other?	Fully Insured?	
47		12/2 /2014	E-mail	Oral Roberts University		Non-profit		EC Plan B One-step (the morning after pil); Ella Ulipristal Acetate (the week after pil); copper intrauterine devices; hormonal intrauterine devices; as we l as any other drug device procedure or mechanism which has the purpose or effect of preventing an already fertilized egg from developing further by inhibiting or terminating its attachment to the uterus"		Other	self-insured	
48		1/9/2015	Ma l	ParishSOFT LLC		Other		"All contraceptive medicatioins and procedures (ster lization abortions Rx contraceptive devices etc.)"		Other	Fully Insured	
49										Other	Fully Insured	
50		1/12/2015	Ma l	DAS Companies Inc.		Other		All		Other	self-insured	
51		1/30/2015	E-mail	Illinois Baptist Children's Home and Fam ly Services		Non-profit	No					
53		2/1 /2015	Ma l	Olivet Nazarene University		Non-profit	No	"the Health Plan w ll not provide pay for and/or facilitate access to abortion-inducing products and related counseling. This includes the use of Yaz EllaOne and the Copper-T IUD when prescribed with a diagnosis of pregnancy." The Health Plan will require a prior authorization for the dispensing of Yaz EllaOne and the Copper-T IUD. Coverage of these products will not be allowed until a doctor confirms the use of the medications for non-abortifacient purposes." Plan B will be non-covered."		Other	Fully Insured	
53		4/15/2015	Ma l	St. Raphael Health Plan - all participating employers (196 4)		Non-profit		All		Church Plan	self-insured	

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39	Redacted	Redacted	Redacted	Original	N/A	Redacted					
40				Original	N/A						
41				Original	N/A						
42				Original	N/A						
43				Original	N/A						
44											
45					N/A						
46					N/A						
47				Updated	1/1/2015						
48				Original	N/A						
49				Original	N/A						
50				Original	N/A						
51				Original	N/A						
53				Original	N/A						
53				Original	N/A						

Notifications

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5				Eligible Organization Information					Plan Information			
6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in Litigation? (Yes or No) (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
54	Redacted	5/4/2015	Ma l	Society of the Precious Blood	Redacted	Non-profit		All	Redacted	Other	Fully insured	Redacted
55		5/22/2015	E-mail	Michael James Sales Tax Solutions LLC		Other		"Any and a l abortifacients"		Other	Fully insured	
56		07/087/15	Litigation (Zub k v. Burwell)	The ROMAN CATHOLIC DIOCESE OF PITTSBURGH (* exempt)		Non-profit	Yes	All		Church Plan	self-insured	
57		07/087/15	Litigation (Zub k v. Burwell)	THE ROMAN CATHOLIC DIOCESE OF ERIE (*exempt)		Non-profit	Yes	All		Church Plan	self-insured	
58		07/087/15	Litigation (Zubik v. Burwell)	CATHOLIC CHARITIES OF THE DIOCESE OF PITTSBURGH INC.		Non-profit	Yes	All		Church Plan	self-insured	
59		07/087/15	Litigation (Zubik v. Burwell)	THE CATHOLIC CEMETERIES ASSOCIATION OF THE DIOCESE OF PITTSBURGH		Non-profit	Yes	All		Church Plan	self-insured	
60		07/087/15	Litigation (Zubik v. Burwell)	ST. MARTIN CENTER INC.		Non-profit	Yes	All		Church Plan	self-insured	
61		07/087/15	Litigation (Zubik v. Burwell)	PRINCE OF PEACE CENTER INC.		Non-profit	Yes	All		Church Plan	self-insured	
62		07/087/15	Litigation (Zub k v. Burwell)	ERIE CATHOLIC PREPARATORY SCHOOL		Non-profit	Yes	All		Church Plan	self-insured	
63		8/3/2015	Mail	Oral Roberts University		Non-profit		EC Plan B One-step (the morning after pil); Ella Ulipristal Acetate (the week after pil); copper intrauterine devices; hormonal intrauterine devices; as we l as any other drug device procedure or mechanism which has the purpose or effect of preventing an already fertilized egg from developing further by inhibiting or terminating its attachment to the uterus"		Student	Fully insured	

Notifications

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5	Service Provider Information					Action Taken					
6	Contact information for issuer (enter N/A if none)	Name of TPA (enter N/A if none)	Contact information for TPA (enter N/A if none)	Original information or updated information?	For updated information, date the information is effective	For updated information, summary of changes	For fu ly insured plans, date letter sent to issuer by HHS	For self-insured plan, date notification forwarded to DOL	For-profit organizations, date letter sent to organization (see instruction #1 above)	Notes	
54	Redacted	Redacted	Redacted	Original	N/A	Redacted					
55				Original	N/A						
56				Original	N/A						
57				Original	N/A						
58				Original	N/A						
59				Original	N/A						
60				Original	N/A						
61				Original	N/A						
62				Original	N/A						
63				Original	N/A						

Notifications

	A	B	C	D	E	F	G	H	I	J	K	L
5				Eligible Organization Information					Plan Information			
6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in Litigation? (Yes or No) (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
64	Redacted	8/2 /2015	E-mail	Cummins-Al ison Corp and Cummins Il inois Inc	Redacted	Other	No	Plan B Ella Mirena Copper IUDs	Redacted	Other	self-insured	Redacted
65		9/25/2015	E-mail	Weingartz Supply Co. Inc. & W & P Management LLC		Other	Yes	All contraceptive services		Other	Fully insured	
66		10/14/2015	Ma l	Carolyn's Place Inc.		Non-profit		All contraceptive services			Fully insured	
67		10/14/2015	Ma l	Dakota Tube Inc		Other						
68		10/28/2015	Ma l	Tyndale House Publishers Inc.		Other		post-conceptive medications and devices namely emergency contraceptives such as the "morning-after pill " the "week-after pi l " and intrauterine devices		Other	Self-insured	
69		10/29/2015	E-mail	Electrolock Inc. Dunstone Co. Inc. and Stone River Mgmt. Co. LLC.		Other		All		Other	self-insured	
70		11/19/2015	Ma l	Management Analysis and Ut lization Inc.		Other		Ella Plan B Plan B One Step Next Choice Next Choice One Dose My Way and Take Action		Other	Fully insured	
71											Fully Insured	
72											self-insured	
73		12/17/2015	SWIFT	Conestoga Wood Specialties Corp. Conestoga Transportation Inc. Phone: 717-445-6701		Other	Yes	Any hormonal drugs or IUDs		Other	self-insured	
74		12/2 /2015	E-mail	St. Joseph's Abby (AKA. Cistercian Abby of Spencer)		Non-profit	No	**ALL** contraceptive services required to be covered under PHS Act section 2713 as added by the Affordable Care Act and incorporated into ERISA section 715 and Code section 9815		Church Plan	Fully insured	
75		12/2 /2015	Ma l	Dakota Tube Inc.		Other						
76		1/28/2016	Ma l	Community Foundation of Northwest Indiana Inc. St. Mary Medical Center St. Catherine Hospital		Non-profit		All - "objection to providing coverage of all contraceptive services required to be covered under PHS Act section 2713 as added by the Affordable Care Act and incorporated into ERISA section 715 and Code section 9815."		Other	Self-insured	
77		2/2 /2016	E-mail	Miller Contracting Services Inc.		Other		All		Other		
78		3/3/2016	E-mail	Earth Sun Moon Trading company Inc		Other		All		Other	Fully insured	

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64	Redacted	Redacted	Redacted	Original	N/A	Redacted					
65				Original	N/A						
66				Original	N/A						
67											
68				Original	N/A						
69				Original	N/A						
70				Original	N/A						
71				Original	N/A						
72				Original	N/A						
73				Original	N/A						
74				Original	N/A						
75											
76				Original	N/A						
77				Original	N/A						
78				Original	N/A						

	A	B	C	D	E	F	G	H	I	J	K	L
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6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in Litigation? (Yes or No) (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
79	Redacted	3/7/2016	E-mail	Luurtsema Sales	Redacted	Other		All	Redacted	Other	Fully insured	Redacted
80		3/24/2016	E-mail	Continuum Health Partnerships Inc.		Other		Abortion causing drugs devices and sterilizations; patient education and counseling for all women with reproductive capacity.		Other	self-insured	
81				Continuum Health Management LLC								
82				Mountain States Health Properties LLC.								
83		3/28/2016	E-Mail	Fresh Unlimited Inc.		Other		All		Other	Fully Insured	
84		4/1/2016	E-mail	Sarkes Tarzian Inc.		Other		All		Other	Fully Insured	
85		7/19/2016	E-Mail	Mersino Management Company		Other	Yes	All		Other	self-insured	
86				Mersino Southwest. LLC								
87				Mersino Enterprise Inc.								
88				Global Pump Company								
89				Mersino Properties Company. LLC								
90				Mersino Dewatering Inc.								
91		7/26/2016	Litigation: 2nd Circuit Court 1:12-cv-02542-BMC Catholic Health Care System	Catholic Health Care System (aka ArchCare)			Yes	abortion-inducing drugs sterilizations contraceptives			self-insured	
92				Cardinal Spellman High School			Yes				self-insured	
93				Monsignor Farrell High School							self-insured	
94				Catholic Health Services of Long Island			Yes				self-insured	
95		7/26/2016	Litigation: Geneva 3nd Circuit Court 2:12-cv-00207	Geneva College (employee)			Yes	abortion-inducing drugs		Other	Fully Insured	
96				Geneva Co lege (Student)			Yes			Student	Fully Insured	
97		7/26/2016	Litigation: Persico 3nd Circuit Court 1-13-cv-00303	The Roman Catholic Diocese of Erie* (exempt)		Non-profit	Yes	abortion-inducing drugs contraceptives or sterilization		Church Plan	self-insured	
98				Erie Catholic Preparatory School		Non-profit						
99				PRINCE OF PEACE CENTER INC.		Non-profit						
100				ST. MARTIN CENTER INC.		Non-profit						
101		7/26/2016	Litigat on Zubik 3nd Circuit Court 2-12-cv-00676	Catholic Charities of Pittsburgh		Non-profit	Yes	abortion-inducing drugs contraceptives or sterilization		Church Plan	self-insured	
102				Diocese of Pittsburgh* (Exempt)								
103		7/26/2016	Litigation: Catholic Diocese of Beaumont 5th Circuit Court	Catholic Charities of Southeast Texas			Yes	abortifacients contraception and ster lization		Other	self-insured	
104				Catholic Diocese of Beaumont* (Exempt)								

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79	Redacted	Redacted	Redacted	Original	N/A	Redacted					
80				Original	N/A						
81											
82											
83				Original	N/A						
84				Original	N/A						
85											
86											
87											
88				Original	N/A						
89											
90											
91				Original	N/A						
92				Original	N/A						
93				Original	N/A						
94				Original	N/A						
95				Original	N/A						
96				Original	N/A						
97				Updated	N/A						
98											
99											
100											
101				Updated	N/A						
102											
103				Original	N/A						
104											

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105	Redacted	7/26/2016	Litigation: ETBU 5th Circuit Court 4:12-CV-3009	East Texas Baptist University (employee)	Redacted		Yes	"abortion-inducing drugs ... and related services" NOT including contraceptives (compl. ¶ 28)	Redacted	Other	self-insured	Redacted
106				Houston Baptist			Yes				self-insured	
107				Westminster			Yes					
108		7/26/2016	Litigation: University of Dallas 5th Circuit Court 4:12-cv-314	Roman Catholic Diocese of Fort Worth* (Exempt)		Non-profit	Yes	"abortion-inducing drugs " sterilization and contraception		Church Plan	self-insured	
109				University of Dallas (employee)			Yes	"abortion-inducing drugs" and steri ization			self-insured	
110				University of Da las (student)			Yes	"abortion-inducing drugs " sterilization and contraception (prescribed to treat a medical condition only not to prevent pregnancy)		Student	Fully-insured	
111				Catholic Charities of Fort Worth			Yes	abortion-inducing drugs sterilization and contraception			Fully Insured	
112		7/26/2016	Litigation: Catholic Diocese of Nashville 6th Circuit Court 3:13-cv-01303	Aquinas College Nashv lle			Yes	"abortion-inducing products " steri ization and contraception			Fully Insured	
113				Camp Marymount Inc.								
114				Catholic Charities of Tennessee								
115				The Catholic Diocese of Nashvi le* (Exempt)								
116				Dominican Sisters of St. Cecilia* (Exempt)								
117				Mary Queen of Angels								
118				St. Mary's V lla Inc.								
119		7/26/2016	Litigat on MCC 6th Circuit Court 1:13-cv-01247-GJQ	Catholic Family Services (aka Catholic Charities of Kalamazoo)			Yes	contraception and steri ization			self-insured	
120				Michigan Catho ic Conference* (Exempt)								
121		7/26/2016	Litigation: Catho ic Charities of Ft. Wayne 7th Circuit Court 1:12-cv-00159-JD-RBC	Catholic Charities of Ft. Wayne			Yes	"abortion-inducing products " steri ization and contraception			Self-insured	
122				Diocese of Ft. Wayne* (Exempt)			Yes	"abortion-inducing products " steri ization and contraception			Self-insured	
123				Franciscan Alliance			Yes	"abortion-inducing products " steri ization and contraception			Both	
124				Our Sunday Visitor			Yes	"abortion-inducing products " steri ization and contraception			Self-insured	
125				Specialty Physicians of I linois			Yes	"abortion-inducing products " steri ization and contraception			Fully-insured	
126				St. Anne Home			Yes	"abortion-inducing products " steri ization and contraception			Self-insured	
127				University of St. Francis			Yes	"abortion-inducing products " steri ization and contraception			Self-insured	

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105	Redacted	Redacted	Redacted	Original	N/A	Redacted					
106				Original	N/A						
107											
108				Original	N/A						
109				Original	N/A						
110				Original	N/A						
111				Original	N/A						
112											
113											
114											
115				Original	N/A						
116											
117											
118											
119				Original	N/A						
120											
121				Original	N/A						
122				Original	N/A						
123				Original	N/A						
124				Original	N/A						
125				Original	N/A						
126				Original	N/A						
127				Original	N/A						

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5				Eligible Organization Information					Plan Information			
6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in Litigation? (Yes or No) (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
128	Redacted	7/26/2016	Litigation: Grace Schools 7th Circuit Court 3:12-cv-00459-JD-CAN	Biola University (employee)	Redacted		Yes	"abortion-inducing drugs ike ella and Plan B" but not other contraceptives	Redacted		Fully Insured	Redacted
129				Biola University (student)			Yes	"abortion-inducing drugs ike ella and Plan B" but not other contraceptives		Student	Fully Insured	
130				Grace Schools (employee)			Yes	"abortifacient drugs" but not all contraceptives			Self-insured	
131				Grace Schools (student)			Yes	"abortifacient drugs" but not all contraceptives		Student	Fully Insured	
132		7/26/2016	Litigation: CNS 8th Circuit Court 2:12-cv-00092	CNS International Ministries (holding company for other listed plaintiffs: Sharpe Holdings Inc. Ozark Nat'l Life Ins. Co. and N.L.S. Financial Services Inc)			Yes	Plan B ella Copper IUDs			Self-insured	
133				Heartland Christian Co lege			Yes	Plan B ella Copper IUDs			Self-insured	
134		7/26/2016	Litigation: Dordt 8th Circuit Court 5:13-cv-04100	Cornerstone University			Yes	"post-coital 'emergency contraceptives'" such as "ella Plan B and IUDs"			Fully-insured	
135				Dordt Co lege (employee)							Self-insured	
136				Dordt College (student)						Student	Fully-insured	
137		7/26/2016	Litigation: Little Sisters 0th Circuit Court No. 13-1540 (10th Cir) Appeal of No. 1:13-CV-02611 (D. Co.)	Little Sisters of the Poor Baltimore Inc. (Little Sisters of Baltimore")		Non-profit	Yes	"sterilization contraceptives and drugs that cause abortions." "contraceptives abort facient drugs sterilizations and related education and counseling "			self-insured	
138				Little Sisters of the Poor Home for the Aged Denver Colorado ("Little Sisters of Denver")		Non-profit						
139		7/26/2016	Litigation: Reaching Souls	Reaching Souls			Yes	ella Plan B Plan B one-step Next Choice Copper IUDs IUDs w/Progestin		Church Plan	self-insured	
140				Truett-McConnell College								
141		7/26/2016	Litigation: Southern Nazarene 0th Circuit Court No. 14-6026 (10th Cir) appeal of No. 5:13 CV-01015-F (W.D. Okla.)	Mid-America Christian			Yes	"contraceptives abortifacients [such as Plan B and e la] and related counseling to their employees and students."			self-insured	
142				Oklahoma Baptist (employee)							Fully-insured	
143				Oklahoma Baptist (student)						Student	Fully-insured	
144				Oklahoma Wesleyan				Plan B ella and IUDs			Fully-insured	
145				Southern Nazarene University (employee)				"contraceptives abortifacients [such as Plan B and e la] and related counseling to their employees and students."			Partially self-insured. Insured for claims over $100 000	

Notifications

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128	Redacted	Redacted	Redacted	Original	N/A	Redacted					
129				Original	N/A						
130											
131				Original	N/A						
132				Original	N/A						
133				Original	N/A						
134				Original	N/A						
135				Original	N/A						
136				Original	N/A						
137				Original	N/A						
138											
139				Original	N/A						
140											
141											
142											
143											
144				Original	N/A						
145											

Notifications

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5				Eligible Organization Information					Plan Information			
6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in Litigation? (Yes or No) (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
146	Redacted			Southern Nazarene University (student)	Redacted				Redacted	Student	Fully-insured	Redacted
147		7/26/2016	Litigation: Priests for Life DC 1:13-cv-01261	Priests for Life			Yes	"contraception sterilization [and] abortifacients"			Fully-insured	
148		7/26/2016	Litigation: RCAW DC 1:13-cv-01441	Archdiocese of Washington (isted in complaint as "Roman Catholic Archbishop of Washington D.C." andas "Archdiocese of Washington")* (exempt)			Yes	abortion-inducing products contraception or sterilization			self-insured	
149				Catholic Charities of the Archdiocese of Washington Inc.								
150				Catholic Information Center Inc								
151				The Catholic University of America							Fully-insured	
152				The Catholic University of America (student)						Student	Fully-insured	
153				The Consortium of Catholic Academies of the Archdiocese o Washington D.C.							self-insured	
154				Archbishop Carroll High School								
155				Don Bosco Cristo Rey High School of the Achdiocese of Washington D.C.								
156				Mary of Nazareth Roman Catholic Elementary School Inc.								
157				Roman Catholic Archbishop of Washington								
158				Victory Housing Inc.								
159				Thomas Aquinas College								
160		7/26/2016	Litigation: Beckwith Electric 11th Circut (M.D. Fl.) 8:16-cv-01944	Beckwith Electric Co. Inc.		Other	Yes	"emergency contraception " "abort facients " "any drugs devices and services capable of ending innocent human life" (spec fica ly lists Plan B ella and the IUD as examples of "abortifacients")		Other	self-insured	
161		7/26/2016	Litigation: Johnson Welded DC(DCC) 1:16-cv-00557	Johnson Welded Products Inc.		Other	Yes	"all of the contraceptive services required by the contraceptive services mandate"		Other	Not Indicated	
162		8/5/2016	Ma l	Society of the Precious Blood		Non-profit	No	All		Other	Fully insured	
163		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Catholic Charities of the Archdiocese of Philadelphia d/b/a Catho ic Social Services		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
164		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	St. John's Orphan Asylum		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	

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146	Redacted	Redacted	Redacted			Redacted					
147				Original	N/A						
148				Original	N/A						
149											
150											
151				Original	N/A						
152				Original	N/A						
153											
154											
155											
156				Original	N/A						
157											
158											
159											
160				Original	N/A						
161				Original	N/A						
162				Updated	7/1/2016						
163				Original	N/A						
164				Original	N/A						

Notifications

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165	Redacted	9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	St. Edmond's Home for Crippled Children	Redacted	Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
166		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Don Guanella Village of the Archdiocese of Philadelphia		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
167		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Divine Providence Village		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
168		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Philadelphia Protectory for Boys d/b/a St. Gabriel's System		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
169		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Catholic Community Services Inc.		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
170		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Nutritional Development Services Inc.		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
171		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Catho ic Health Care Services - Supportive Independent Living d/b/a Villa St. Martha and Community Based Services		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
172		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	St. John Vianney Center		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
173		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Catholic Clinical Consultants		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
174		9/1/2016	Litigation: Catho ic Charities Archdiocese of Ph ladelphia 3rd Circuit 2:14-cv-03096-AB	Roman Catholic Archdiocese of Philadelphia		Non-profit	Yes	"a l of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
175		9/15/2015	Litigation: Diocese of Cheyenne 10th Circuit court 14-8040	Diocese of Cheyenne		Non-profit	Yes	"to providing procuring or fac litating access to abortion-inducing products abortion steri ization or contraceptives" except when "prescribed with the intent of treating a medical condition not with the intent to prevent pregnancy or to induce abortion."		Church Plan	Self-insured	
176		9/15/2015	Litigation: Diocese of Cheyenne 10th Circuit court 14-8040	Catho ic Charities of Wyoming		Non-profit	Yes	"to providing procuring or fac litating access to abortion-inducing products abortion steri ization or contraceptives" except when "prescribed with the intent of treating a medical condition not with the intent to prevent pregnancy or to induce abortion."		Church Plan	Self-insured	
177		9/15/2015	Litigation: Diocese of Cheyenne 10th Circuit court 14-8040	Saint Joseph's Children's Home		Non-profit	Yes	"to providing procuring or fac litating access to abortion-inducing products abortion steri ization or contraceptives" except when "prescribed with the intent of treating a medical condition not with the intent to prevent pregnancy or to induce abortion."		Church Plan	Self-insured	

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165	Redacted	Redacted	Redacted	Original	N/A	Redacted					
166				Original	N/A						
167				Original	N/A						
168				Original	N/A						
169				Original	N/A						
170				Original	N/A						
171				Original	N/A						
172				Original	N/A						
173				Original	N/A						
174				Original	N/A						
175				Original	N/A						
176				Original	N/A						
177				Original	N/A						

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178	Redacted	9/15/2015	Litigation: Diocese of Cheyenne 10th Circuit court 14-8040	St. Anthony Tri-Parish Catholic School	Redacted	Non-profit	Yes	"to providing procuring or fac litating access to abortion-inducing products abortion steri ization or contraceptives" except when "prescribed with the intent of treating a medical condition not with the intent to prevent pregnancy or to induce abortion."	Redacted	Church Plan	Self-insured	Redacted
179		9/15/2015	Litigation: Diocese of Cheyenne 10th Circuit court 14-8040	Wyoming Catholic College		Non-profit	Yes	" abortion-inducing products or ster lization" except " contraceptives only when prescribed with the intent of treating a medical condition not with the intent to prevent pregnancy."		Church Plan	self-insured	
180		9/15/2015	Litigation: Colorado Christian University 10th Circuit Court 14-1329	Colorado Christian University (employee)		Non-profit	Yes	"coverage for a l services drugs and devices that could terminate human life from the moment of conception including medical abortions emergency contraceptives l ke Plan B and E la and IUDs" and "other contraceptives."		Other	self-insured	
181		9/15/2015	Litigation: Colorado Christian University 10th Circuit Court 14-1330	Colorado Christian University (student)		Non-profit	Yes	"coverage for abortions and all contraceptives including emergency contraceptives and IUDs."		Student	Fully Insured	
182		9/15/2015	Litigation: Dobson 10th Circuit Court 14-1233	Family Talk		Non-profit	Yes	"abortion-inducing or implantation-preventing drugs abortifacient items and related education and counseling spec fically IUDs and 'emergency contraception' such as Plan B and Ella" and "any counse ing or referrals to promote or refer for ... such abortion-inducing drugs and IUDs "		Other	Partia ly Self-Insured with a stop-loss provider and a third-party administrator	
183		9/15/2015	Litigation: Ass'n of Christian Schools Int'l v. Burwell 10th Circuit Court No. 14-1492	Association of Christian Schools International (employee)		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion (including abortion-causing drugs and devices like Plan B ella and IUDs)"		Other	self-insured	
184		9/15/2015	Litigation: Ass'n of Christian Schools Int'l v. Burwell 10th Circuit Court No. 14-1492	Samaritan Ministries International (employee)		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion (including abortion-causing drugs and devices like Plan B ella and IUDs)"		Other	self-insured	
185		9/15/2015	Litigation: Ass'n of Christian Schools Int'l v. Burwell 10th Circuit Court No. 14-1492	Taylor University (employee)		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion (including abortion-causing drugs and devices like Plan B ella and IUDs)"		Other	self-insured	
186		9/15/2015	Litigation: Ass'n of Christian Schools Int'l v. Burwell 10th Circuit Court No. 14-1492	Indiana Wesleyan University		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion (including abortion-causing drugs and devices like Plan B ella and IUDs)"		Other	self-insured	
187		9/15/2015	Litigation: Ass'n of Christian Schools Int'l v. Burwell 10th Circuit Court No. 14-1492	Asbury Theological Seminary		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion (including abortion-causing drugs and devices like Plan B ella and IUDs)"		Other	self-insured	
188		9/15/2015	Litigation: Ass'n of Christian Schools Int'l v. Burwell 10th Circuit Court No. 14-1492	Alliance Defending Freedom		Non-profit	Yes	"emergency contraceptive medications hormonal contraceptive medications and devices and implanted contraceptive devices or related counseling or referrals to promote the use of such items"		Other	self-insured	
189		9/20/2016	Litigation: Catholic Benefits Ass'n LCA v. Burwell 10th Circuit Court Nos. 14-6163 14-6171	Good Will Pub ishers Inc.		Other	Yes	"contraception abortion-inducing drugs or devices sterilization and related counseling"		Other	Fully-insured	
190		9/20/2016	Litigation: Catholic Benefits Ass'n LCA v. Burwell 10th Circuit Court Nos. 14-6163 14-6171	Catholic Charities of the Archdiocese of Oklahoma City		Non-profit	Yes	"contraception abortion-inducing drugs or devices sterilization and related counseling"		likely church plan but never alleged	self-insured	
191		9/20/2016	Litigation: Catholic Benefits Ass'n LCA v. Burwell 10th Circuit Court Nos. 14-6163 14-6171	All Saints Catholic School		Non-profit	Yes	"contraception abortion-inducing drugs or devices sterilization and related counseling"		likely church plan but never alleged	self-insured	

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178	Redacted	Redacted	Redacted	Original	N/A	Redacted					
179				Original	N/A						
180				Original	N/A						
181				Original	N/A						
182				Original	N/A						
183				Original	N/A						
184				Original	N/A						
185				Original	N/A						
186				Original	N/A						
187				Original	N/A						
188				Original	N/A						
189				Original	N/A						
190				Original	N/A						
191				Original	N/A						

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19	Redacted	9/20/2016	Litigation: Catholic Benefits Ass'n LCA v. Burwell 10th Circuit Court Nos. 14-6163 14-6171	The Cathedral Foundation d/b/a Catholic Review Media	Redacted	Non-profit	Yes	"contraception abortion-inducing drugs or devices sterilization and related counseling"	Redacted	likely church plan but never alleged	self-insured	Redacted
19		9/20/2016	Litigation: Catholic Benefits Ass'n LCA v. Burwell 10th Circuit Court Nos. 14-6163 14-6171	Vi la St. Francis Catholic Care Center Inc.		Non-profit	Yes	"contraception abortion-inducing drugs or devices sterilization and related counseling"		Other	Fully-insured	
19		10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta et al. v. Secretary U.S. Dep't of Health & Human Servs et al Nos. 14-12890 14-13239	THE ROMAN CATHOLIC ARCHDIOCESE OF ATLANTA an association of churches and schools		Non-profit	Yes	"abortion-inducing products contraception steri ization and related counse ing" "unless they are necessary for medica ly diagnosed conditions unrelated to contraception."		Church Plan	self-insured	
19		10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta et al. v. Secretary U.S. Dep't of Health & Human Servs et al Nos. 14-12890 14-13240	THE MOST REVEREND WILTON D GREGORY and his successors Archbishop of the Roman Catholic Archdiocese of Atlanta		Non-profit	Yes	"abortion-inducing products contraception steri ization and related counse ing" "unless they are necessary for medica ly diagnosed conditions unrelated to contraception."		Church Plan	self-insured	
19		10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta et al. v. Secretary U.S. Dep't of Health & Human Servs et al Nos. 14-12890 14-13241	CATHOLIC CHARITIES OF THE ARCHDIOCESE OF ATLANTA INC. a Georgia non-profit corporation		Non-profit	Yes	"abortion-inducing products contraception steri ization and related counse ing" "unless they are necessary for medica ly diagnosed conditions unrelated to contraception."		Church Plan	Self-Insured	
19		10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta et al. v. Secretary U.S. Dep't of Health & Human Servs et al Nos. 14-12890 14-13242	Catho ic Education of North Georgia Inc. (CENGI)		Other	Yes	"abortion-inducing products contraception steri ization and related counse ing" "unless they are necessary for medica ly diagnosed conditions unrelated to contraception."		Church Plan	Self-Insured	
19		10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta et al. v. Secretary U.S. Dep't of Health & Human Servs et al Nos. 14-12890 14-13243	THE ROMAN CATHOLIC DIOCESE OF SAVANNAH an ecclesiastical territory		Non-profit	Yes	"abortion-inducing products contraception steri ization and related counse ing" "unless they are necessary for medica ly diagnosed conditions unrelated to contraception."		Church Plan	Self-Insured	
19		10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta et al. v. Secretary U.S. Dep't of Health & Human Servs et al Nos. 14-12890 14-13244	THE MOST REVEREND JOHN HARTMAYER and his successors Bishop of The Roman Catholic Diocese of Savannah et al.		Non-profit	Yes	"abortion-inducing products contraception steri ization and related counse ing" "unless they are necessary for medica ly diagnosed conditions unrelated to contraception."		Church Plan	Self-Insured	
20		10/6/2016	Eternal Word Television Network v. Burwell No. 14-12696	Eternal Word Television Network Inc.		Non-profit	Yes	"artificial contraception ster lization or abortion or related education and counseling."		other	Self-Insured	
20		11/ /2016	Email/mail	Bick Group Inc.		Other	Yes	"all contraceptive services"		Other	Fully-insured	
20		11/9/2016	Email	The Energy Lab INC		Other	No	All		Other	Fully-insured	
20		11/2 /2016	Email	Marian University		Non-profit	No	All		Church Plan	self-insured	

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192	Redacted	Redacted	Redacted	Original	N/A	Redacted					
193				Original	N/A						
194				Original	N/A						
195				Original	N/A						
196				Original	N/A						
197				Original	N/A						
198				Original	N/A						
199				Original	N/A						
200				Original	N/A						
201				Original	N/A						
202				Original	N/A						
203				Original	N/A						

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204	Redacted	11/29/2016	Litigation: Louisiana College v. Burwell et al. No. 14-31167	Louisiana College	Redacted	Non-profit	Yes	Objects to providing: RU-486; Plan B; ella; "counseling regarding the use of abortifacients like ella and Plan B;" and any "drugs devices services or procedures contrary to its faith." Sec. Am. Compl. Dist. Ct. Dkt 77 at ¶¶ 27-33 "While excluding abortifacients like ella and Plan B LC's employee health plan does cover contraceptives that prevent ovulation." Sec. Am. Compl. Dist. Ct. Dkt 77 at ¶ 37	Redacted	Church Plan	self-insured	Redacted
205		4/2 /2017	Mail	Continuum Health Partnerships Inc.		Other	No	Abortion causing drugs devices and sterilizations; patient education and counseling for all women with reproductive capacity.		Other	self-insured	
206				Continuum Health Management LLC								
207				Mountain States Health Properties LLC.								
208												
209												

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204	Redacted	Redacted	Redacted	Original	N/A	Redacted					
205				Updated	4/1/2017						
206											
207											
208											
209											

Notifications


Redacted

EXHIBIT X

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

DIVISION OF SOCIAL JUSTICE
HEALTH CARE BUREAU

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December 5, 2017

Via Federal eRulemaking Portal
Acting Secretary Eric Hargan
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW., Room 445–G
Washington, DC 20201

Re: Comments on Interim Final Rules: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act, and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act
45 C.F.R §§ 147.130-147.133

Dear Acting Secretary Hargan:

The undersigned State Attorneys General submit these comments in response to the Departments of Health and Human Services, Labor, and Treasury's (the "Departments") issuance of the proposed interim final rules ("IFRs"): the Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (filed Oct. 6, 2017), and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (filed Oct. 6, 2017). By creating broad new exemptions from the Affordable Care Act's contraceptive mandate, thereby allowing employers to deprive women of contraceptive health coverage, the IFRs will harm women and children, and the public health in general, and result in significant financial and administrative burdens to the States. As discussed more fully below, the IFRs violate the Administrative Procedure Act, the equal protection guarantee of the Fifth Amendment, and the Establishment Clause of the First Amendment, and as such, the undersigned Attorneys General urge that the IFRs be rescinded.[1]

[1] State Attorneys General have also filed lawsuits challenging the IFRs. *See* States' Notice Mot. & Mot. Prelim. Inj., with Mem. P. & A., § I.A.–E., at 11–27, California v. Eric D. Hargan, No. 4:17-cv-05783-HSG (N.D. Cal. filed Nov. 9, 2017) ("*CA Br.*") (attached as Exhibit 1); Mem. Law Support Pls.' Mot. Prelim. Inj., § I.A., C.–D., at 18–

I. Background

Before implementation of the Affordable Care Act ("ACA"), one in seven women with private health insurance, and nearly one-third of women covered by Medicaid, either postponed or went without needed health care because they could not afford it.[2] With respect to birth control in particular, women were forced to spend between 30 percent and 44 percent of their total out-of-pocket health costs.[3] These out-of-pocket costs prevented many women, not solely those with lower incomes, from accessing preventive services, including contraception.[4]

During this period before the ACA's passage, an estimated 49 percent of all pregnancies in the United States were unintended, and 42 percent of those unintended pregnancies ended in abortion.[5] Unintended pregnancies are associated with increases in maternal and child morbidity, including increased odds of preterm birth, low birth weight, and the potentially life-long negative health effects of premature birth.[6] Significantly, the risk of unintended pregnancy is greatest for the most vulnerable women: young, low-income, minority women, without high school or college education.[7]

Within this public health landscape, Congress passed the "Women's Health Amendment" ("WHA") to expand women's access to preventive health services through health plan coverage and no cost-sharing responsibilities.[8] The Department of Health and Human Services ("HHS") commissioned the Institute of Medicine ("IOM") to issue recommendations identifying the

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22, 32–38, Pennsylvania v. Donald J. Trump, No. 2:17-cv-04540-WB (E.D. Pa. filed Oct. 11, 2017) ("*PA Br.*") (attached as Exhibit 2); Complt. Declaratory & Injunctive Relief, Massachusetts v. U.S. Dept. of Health & Human Servs., No. 17-cv-11930-NMG (D. Mass. filed Oct. 6, 2017); Complt. Declaratory & Injunctive Relief, Washington v. Trump, No. 2:17-cv-01510-RBL (W.D. Wa. filed Oct. 9, 2017). State Attorneys General have also submitted amicus briefs in support of plaintiffs in two lawsuits. *See, e.g.*, Br. for Mass. & Cal. et al. as Amici Curiae in Support of Pls.' Mot. Prelim. Inj., § II, at 18–30, Pennsylvania v. Donald J. Trump, No. 2:17-cv-04540-WB (E.D. Pa. filed Oct. 11, 2017) ("*Amici Br.*") (attached as Exhibit 3).

[2] Usha Ranji & Alina Salganicoff, *Women's Health Care Chartbook: Key Findings from the Kaiser Women's Health* Survey, HENRY J. KAISER FAMILY FOUND.1, 4 (2011), http://www.kaiserfamilyfoundation.files.wordpress.com/2013/01/8164.pdf.

[3] Laurie Sobel et al., *The Future of Contraceptive Coverage*, HENRY J. KAISER FAMILY FOUND. 1, 4 (2017), http://www.files.kff.org/attachment/Issue-Brief-The-Future-of-Contraceptive-Coverage.

[4] Su-Ying Liang et al., *Women's Out-of-Pocket Expenditures and Dispensing Patterns for Oral Contraceptive Pills between 1996 and 2006*, 83 CONTRACEPTION 491, 531 (2010); *see also* COMM. ON PREVENTIVE SERVS. FOR WOMEN & BD. ON POPULATION HEALTH & PUB. HEALTH PRACTICE, INST. OF MED. OF THE NAT'L ACADS., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19 (Nat'l Acad. Press, 2011), *available at* https://www.nap.edu/read/13181/chapter/1 ("IOM Report"). Another study of approximately 11,000 employees with employer-sponsored coverage found that cost-sharing reduced use of pap smears, preventive counseling, and mammography. Geetesh Solanki et al., *The Direct and Indirect Effects of Cost-Sharing on the Use of Preventive Services*, 34 HEALTH SERVS. RESEARCH 1331, 1342-43 (2000), *available at* http://www.pubmedcentralcanada.ca/pmcc/articles/PMC1089084/pdf/hsresearch00023-0075.pdf; *see also* David Machledt & Jane Perkins, *Medicaid Premiums & Cost-Sharing*, NAT'L HEALTH LAW PROGRAM 2-3 (2014), http://www.healthlaw.org/component/jsfsubmit/showAttachment?tmpl=raw&id=00Pd000000ANrCpEAL.

[5] IOM Report at 102.

[6] *Id.* at 103.

[7] *Id.*

[8] *See* S. Amdt. 2791, 111th Congress (2009-2010); Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010); Public Health Service Act (as amended by ACA) § 2713, 42 U.S.C. §300gg-13(a)(4).

specific preventive women's health services that should be covered under the ACA. In 2011, the IOM recommended, and the Health Resources and Services Administration ("HRSA") adopted, a list that includes all FDA-approved contraceptives, sterilization procedures, and reproductive education and counseling.[9] In 2016, the Women's Preventive Services Initiative,[10] led by the American Congress of Obstetricians and Gynecologists ("ACOG"), updated the preventive services guidelines and continued to include coverage of all FDA-approved contraceptive methods, reiterating their importance to women.

The IOM, ACOG, and other experts based their decisions to include coverage of contraception on the considerable evidence that the use of contraception has contributed to lower unintended pregnancy and abortion rates in the United States.[11] With the decrease in unintended pregnancies, there has been a corresponding decrease in the risk of maternal mortality, adverse child outcomes, behavior problems in children, and negative psychological outcomes associated with unintended pregnancies for both mothers and children.[12] Contraceptive use contributes to longer spacing between pregnancies, which decreases the risk of adverse health outcomes for pregnancies that are too closely spaced, and is especially critical for the health of women with certain medical conditions.[13]

Significantly, access to contraceptive coverage has given women the option to delay childbearing and pursue additional education, spend additional time in their careers, and increase earning power over the long-term. One-third of the wage gains women have made since the 1960s have been attributed to access to oral contraceptives.[14] Access to birth control has helped narrow the wage gap between women and men. The decrease in the wage gap among 25 to 49-year-olds between men's and women's annual incomes would have been 10 percent smaller in the 1980s and 30 percent smaller in the 1990s in the absence of widespread legal birth control access for women.[15]

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[9] *Women's Preventive Services Guidelines: Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being*, HEALTH RESOURCES & SERVS. ADMIN., http://www.hrsa.gov/womens-guidelines/index.html (last reviewed Oct. 2017).

[10] The Women's Preventive Services Initiative also included the American Academy of Family Physicians, the American College of Physicians, and the National Association of Nurse Practitioners in Women's Health.

[11] IOM Report at 104–05.

[12] *See* IOM Report 103–04.

[13] IOM Report at 103–04. There are additional benefits of contraceptive use for treating medical conditions, including menstrual disorders and pelvic pain, and long-term use of oral contraceptives has been shown to reduce women's risk of endometrial cancer, pelvic inflammatory disease, and some benign breast diseases. *Id.* at 107.

[14] *Birth Control Has Expanded Opportunity for Women–in Economic Advancement, Educational Attainment, and Health Outcomes*, PLANNED PARENTHOOD 1,1 (June 2015), http://www.plannedparenthood.org/files/1614/3275/8659/BC_factsheet_may2015_updated_1.pdf.

[15] *See* Martha J. Bailey et al., *The Opt-In Revolution? Contraception and the Gender Gap in Wages* 27 (Nat'l Bureau of Econ. Research, Working Paper No. 17322, 2012), http://www-personal.umich.edu/~baileymj/Opt_In_Revolution.pdf.

Since the ACA's requirement that health plans cover contraception benefits and services, women with employer-sponsored coverage have had increased access to contraception,[16] and have saved $1.4 billion in out-of-pocket costs on birth control pills in 2013 alone.[17] The share of women of reproductive age who had out-of-pocket spending on oral contraceptive pills fell sharply after the ACA's implementation; spending on oral contraceptive pills plummeted from 20.9 percent in 2012 to 3.6 percent in 2014, corresponding to the timing of the contraception provision.[18] Also during this time, the proportion of privately insured women who paid no out-of-pocket costs for oral contraception increased from 15 percent to 67 percent, with similar changes for injectable contraceptives, the vaginal ring and the intrauterine device.[19] To date, over 62.4 million women have benefited from ACA-mandated contraceptive coverage.[20]

Several of the undersigned States, in recognition that no-cost contraception is critical to women's health and autonomy, have enacted statutory schemes to require no-cost coverage for state-regulated plans.[21] However, the federal Employee Retirement Income Security Act of 1974 ("ERISA") preempts States from imposing coverage requirements on self-funded plans offered by employers.[22] Such plans cover about 58 percent of workers with employer-sponsored insurance.[23] The IFRs threaten this access by allowing virtually any employer with a self-insured plan to opt-out of the contraceptive-coverage requirement based on the employer's own religious or moral beliefs without offering any explanation or requiring any certification process

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[16] Adam Sonfield et al., *Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update*, 91 CONTRACEPTION 44, 45-47 (2014), *available at* http://www.contraceptionjournal.org/article/S0010-7824(14)00687-8/pdf.

[17] *Reproductive Rights & Health: The Affordable Care Act's Birth Control Benefit Is Working for Women*, NAT'L WOMEN'S LAW CTR. (Dec. 2016), http://www.nwlc.org/wp-content/uploads/2016/06/The-ACAs-Birth-Control-Benefit-1.pdf.

[18] Laurie Sobel et al., *Private Insurance Coverage of Contraception*, HENRY J. KAISER FAMILY FOUND. (2016), http://www.files.kff.org/attachment/issue-brief-private-insurance-coverage-of-contraception.

[19] Adam Sonfield et al., *Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update*, 91 CONTRACEPTIVE 44, 45 (2015), *available at* http://www.contraceptionjournal.org/article/S0010-7824(14)00687-8/pdf.

[20] *Reproductive Rights & Health: New Data Estimates 62.4 Million Women Have Coverage of Birth Control Without Out-of-Pocket* Costs, NAT'L WOMEN'S LAW CTR. 1, 2 (2017), http://www.nwlc.org/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf.

[21] An overview of State laws and regulations is provided by Guttmacher Institute. *Insurance Coverage of Contraceptives*, GUTTMACHER INST., http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives (last updated Dec. 1, 2017). *See also* Cal. Ins. Code § 10123.196; Conn. Gen. Stat. § 38A-503e; Haw. Rev. Stat. § 432:1-604.5; 215 Ill. Comp. Stat. 5/356Z.4; Iowa Code § 514C.19; Me. Rev. Stat. tit. 24, § 2332-J, amended by Public Law, Chapter 190 (June 13, 2017); Md. Code, Ins. §§ 15-826, 15-826.1; Mass. Gen. Laws. ch. 175, § 47W, amended by Chapter 120 of the Acts of 2017; N.M. Stat. Ann. §§ 59A-22-42; 59A-46-44; N.Y. Ins. Law §§ 3216, 3221, and 4303; N.C. Gen. Stat. § 58-3-178; Or. Rev. Stat. § 743A.066; R.I. Gen. Laws §§ 27-19-48, 27-18-57, 27-20-43; Vt. Stat. tit. 8, § 4099c; Wash. Admin. Code § 284-43-5150. State laws routinely include exemptions from mandatory coverage for prescription contraceptives for religious employers. *See, e.g.*, Conn. Gen. Stat. § 38A-503e; Mass. Gen. Laws. ch. 175, § 47W, amended by Chapter 120 of the Acts of 2017; N.Y. Insur. L. § 4303(cc).

[22] 29 U.S.C. § 1144(b).

[23] *Medical Expenditure Panel Survey: Percent of Private-Sector Enrollees That Are Enrolled in Self-Insured Plans at Establishments That Offer Health Insurance by Firm Size and State: United States, 2016*, U.S. DEPT. OF HEALTH & HUMAN SERVS., http://www.meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2016/tiib2b1.pdf (last visited Dec. 4, 2017) ("ARHQ Database").

by regulators charged with enforcing the ACA's requirements. Moreover, some of the undersigned States do not have state laws requiring no-cost contraception coverage for state-regulated plans, and as such, the threatened harm of the IFRs extends to *all* employee insurance plans.

II. The IFRs violate the Administrative Procedure Act

(A) *The IFRs are contrary to law.*

The IFRs violate numerous requirements of the ACA. First, the IFRs stand in direct conflict with the WHA, which mandates that employers provide health plans that cover women's preventive care with no cost-sharing.[24] While the Religious Freedom Restoration Act (RFRA) requires protection of religious beliefs, the ACA already provides religious exemptions that satisfy RFRA's requirements.[25] The IFRs' vast exemptions go well beyond what is required to avoid a substantial religious burden by permitting a broad range of employers, including publicly-traded companies, to evade compliance with the contraceptive mandate, rather than the narrower class of churches, religious non-profits, and closely held for-profit corporations that the Supreme Court has held are protected by RFRA.[26] The IFRs also excuse these employers from undertaking any steps, however minimal, to ensure that their employees retain access to contraceptive coverage through other means, eviscerating any accommodation requirements.[27] As such, the IFRs allow for noncompliance with a mandatory statute so long as there is *any* religious burden, rather than a *substantial* one. Moreover, RFRA's protection of religious belief does not authorize the IFRs' exemptions for wholly expansive moral beliefs. (*See* further discussion in *CA Br.* § I.A.1.–2., at 11–14; *PA Br.* § I.A.2.i.–ii., at 23–27; *Amici Br.* § II.B.2., at 21–24.)

Second, the IFRs violate the ACA's nondiscrimination provision that prohibits an individual from being "excluded from participation in," "denied the benefits of," or "subjected to discrimination under, any health program or activity" receiving federal funds, to the extent that the grounds for such discrimination are otherwise unlawful under federal law.[28] The IFRs violate this nondiscrimination provision because they selectively authorize denial of coverage for women's preventive care benefits only. Indeed, the Equal Employment Opportunity Commission has previously held that an employer who offers coverage for preventive

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[24] *See FAQs about Affordable Care Act Implementation Part 36*, EMPLOYEE BENEFITS SEC. ADMIN., U.S. DEPT, OF LABOR, 1, 1 (2017), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf (explaining the effects of the Women's Health Amendment on insurance coverage of women's preventive care).
[25] *Id.* at 4-5.
[26] *See Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2768–69 (2014).
[27] The IFRs also eliminate the requirement for employers to notify the federal government if they choose to avail themselves of the exemption, thereby allowing for contraceptive coverage to be quietly eliminated without oversight or transparency.
[28] 42 U.S.C. § 18116.

prescription drugs and services but does not offer coverage for contraception violates Title VII.[29] (*See* further discussion in *CA Br.* § I.A.3., at 14; *PA Br.* § II.B., at 43–46; *Amici Br.* § II.B.2., at 21–24.)

Third, the ACA prohibits the Secretary of Health and Human Services from "promulgat[ing] any regulation that creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care," or "impedes timely access to health care services."[30] The IFRs clearly violate this provision by preventing women from accessing important and often medically necessary contraceptive services. (*See* further discussion in *CA Br.* § I.A.3., at 14; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § I.A.1.–2., at 4–6.)

(B) *The IFRs are arbitrary and capricious.*

The IFRs radically depart from prior policy without adequate or reasonable justification, as required by law. First, the IFRs do not provide sufficient justification for discarding the prior regulations' finding of a compelling government interest in ensuring that women have contraceptive coverage even if their employers object to providing it. Five justices of the Supreme Court have expressly recognized such a compelling interest.[31] The IFRs cite scant evidence to support the assertion that access to contraception has little effect on unintended pregnancies, and indeed, the vast majority of studies have shown precisely the opposite.[32] Moreover, the IFRs ignore the other public health interests served by the contraceptive mandate—including the need for some women to avoid pregnancy, which can be hazardous or life-threatening to them due to a medical condition. (*See* further discussion in *CA Br.* § I.C., at 19–21; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § II.C., at 24–26.)

Second, the IFRs provide inadequate explanation for expanding the universe of employers who are exempt from compliance with the contraceptive mandate from churches, houses of worship, religious non-profits, and closely held for-profit corporations, to *any and all* non-governmental employers and *any and all* private universities. Relatedly, the IFRs fail to justify the creation of the broader religious employer exemption, rather than the narrower eligible organization accommodation, to these employers. The offered explanations for this approach is disagreement with the former Administration; but a disagreement with the previous approach is far from the reasoned and evidence-based explanation required for the evisceration of the relied-upon accommodation requirements, which balanced religious exercise and full and equal health coverage for women. (*See* further discussion in *CA Br.* § I.C., at 19–21; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § II.C., at 24–26.)

Third, the IFRs extend the applicability of the religious and moral exemption to insurance companies, without reasonable explanation for this entirely new expansion. In fact, the IFRs

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[29] *See* Commission Decision on Coverage of Contraception, U.S. EQUAL EMPLOYMENT OPPORTUNITY COMM., 2000 WL 33407187 (Dec. 14, 2000), http://www.eeoc.gov/policy/docs/decision-contraception.html.
[30] 42 U.S.C. § 18114.
[31] *See Hobby Lobby*, 134 S. Ct. at 2785 (Kennedy, J., concurring); *id.* at 2799 (Ginsburg, J., dissenting).
[32] *See, e.g.*, IOM Report at 102–07 (collecting studies on effects of women's access to contraceptives).

acknowledge that the Departments are not aware of any insurance company with such an objection—it is undoubtedly arbitrary to promulgate a rule with no intended use.

III. The IFRs Violate the Equal Protection Guarantee of the Fifth Amendment

Although the ACA requires coverage for many different types of preventive services, the IFRs single out only women's health benefits and services. The President's Executive Order directed the Departments to consider allowing additional "conscience-based objections" to services mandated by the WHA specifically.[33] The IFRs create vast exemptions for contraceptive coverage only, clearly targeting women's preventive services, while leaving preventive service coverage for male employees untouched. The IFRs include a gender-based classification[34] and are thus subject to heightened scrutiny.

The government interest motivating both IFRs is articulated as providing protections for "sincerely held ['religious beliefs' or 'moral convictions'] in certain health care contexts."[35] Even if an unbounded moral conviction is found to be a compelling interest, this gender-based classification does not have an "exceedingly persuasive justification" and is not "substantially related to the achievement of those objectives."[36] The IFRs fail any "means" test as the staggering breadth of the exemptions—to virtually *any* employer for virtually *any* religious or moral objection—lacks any tailoring whatsoever, and flies in the face of any reasonable interpretation of the "substantial relationship" standard. (*See* further discussion in *CA Br.* § I.E., at 25–28; *PA Br.* § I.C., at 32–34; *Amici Br.* § II.D.2., at 29–30.)

IV. The IFRs Violate the Establishment Clause

The IFRs violate the Establishment Clause because their purpose and effect is clearly the advancement of religious beliefs.[37] The Rules do not even bother to feign a non-religious purpose. The IFRs also violate the Establishment Clause because they allow employers to obtain religious exemptions in a manner that substantially burdens female employees who may not share the employers' faith.[38] The burdens here imposed go well beyond any justified by religious exercise—they result in the potentially dramatic loss of contraceptive coverage for millions of women, with no alternative structure to obtain care. The Supreme Court relied

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[33] Exec. Order No. 13798, 82 Fed. Reg. 21,675 (May 4, 2017), http://www.gpo.gov/fdsys/pkg/FR-2017-05-09/pdf/2017-09574.pdf.

[34] The IFRs are also overtly discriminatory because they single out women's health care services, including benefits that are only used by women. Aside from the reference to only women's services, the IFRs are infused with overt references to purported "sensitive" areas of health, which all concern women's reproductive health and rely on overly-broad generalizations of women's health care. *See* 82 Fed. Reg. 47,838 (2017); 82 Fed. Reg. 47,813 (2017). The IFRs are also covertly discriminatory because they have a direct impact on women only. Women alone will be forced to struggle to pay for contraception themselves, forgo contraceptives, or to try to seek out services from some entity other than their employer.

[35] 82 Fed. Reg. 47,845 (2017); 82 Fed. Reg. 47,800 (2017).

[36] *Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1690 (2017).

[37] *See Lemon v. Kurtzman*, 403 U.S. 602, 612–13 (1971).

[38] *See* 42 U.S.C. § 2000bb–1(a) (the "government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability").

heavily on the notification and accommodation mechanisms previously in place as necessary protections of women's ability to access contraception.[39] Without such accommodation, notice, and justification requirements, the burdens on women have grown dramatically, resulting in a clear violation of the Establishment Clause. (*See* further discussion in *CA Br.* § I.D., at 21–24; *PA Br.* § I.D., at 34–38; *Amici Br.* § II. D.1., at 27–28.)

V. Conclusion

The IFRs at issue will result in harms that are both direct and indirect, tangible and intangible. Access to contraception is fundamental to women's rights to bodily freedom and to emotional autonomy. It is a public health issue, with effects on unintended pregnancy, maternal health, and infant morbidity. It also implicates economic mobility and wage parity, educational opportunity and social equality. These far-reaching effects are too great to ignore, and are protected by the Constitution, our laws and regulations. Accordingly, we urge the Secretary to rescind the IFRs.

Respectfully submitted,
ERIC T. SCHNEIDERMAN
Attorney General of the State of New York

By: */s/ Sara Haviva Mark*
SARA HAVIVA MARK
Special Counsel, Social Justice Division
LISA LANDAU
Chief, Health Care Bureau
SIKA YEBOAH-SAMPONG
Social Justice Fellow
New York State Office of the Attorney General
120 Broadway
New York, New York 10271-0332
(212) 416-8460

[39] In *Hobby Lobby*, for example, the Court explained that the accommodation sought by closely held for-profit corporations would not violate the Establishment Clause because it has "precisely zero" effect on the women employed by Hobby Lobby. The Court noted that "these women would still be entitled to all FDA-approved contraceptives without cost sharing." 134 S. Ct. at 2760. In his concurrence, Justice Kennedy underscored that an accommodation of religious exercise must not "unduly restrict other persons, such as employees, in protecting their own interests." *Id*. at 2786–87 (Kennedy, J., concurring). Similarly, the Court in *Wheaton College v. Burwell* expressly noted that its order allowing employers to notify the government rather than their insurer about a religious objection would not "affect[] the ability of [Wheaton's] employees and students to obtain, without cost, the full range of FDA approved contraceptives." 134 S. Ct. 2806, 2807 (2014).

XAVIER BECERRA
Attorney General of California
1300 I Street
Sacramento, CA 95814

MATTHEW P. DENN
Attorney General of Delaware
Carvel State Building, 6th Floor
820 North French Street
Wilmington, DE 19801

KARL A. RACINE
Attorney General of the District of Columbia
One Judiciary Square
441 4th Street, N.W.
Washington, DC 20001

DOUGLAS S. CHIN
Attorney General of Hawaii
425 Queen Street
Honolulu, HI 96813

LISA MADIGAN
Attorney General of Illinois
100 West Randolph Street
Chicago, IL 60601

JANET T. MILLS
Attorney General of Maine
6 State House Station
Augusta, ME 04333

BRIAN E. FROSH
Attorney General of Maryland
200 St. Paul Place
Baltimore, MD 21202

MAURA HEALEY
Attorney General of Massachusetts
One Ashburton Place
Boston, MA 02108

LORI SWANSON
Attorney General of Minnesota
102 State Capitol
75 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

ELLEN F. ROSENBLUM
Attorney General of Oregon
1162 Court Street N.E.
Salem, OR 97301

JOSH SHAPIRO
Attorney General of Pennsylvania
Strawberry Square
Harrisburg, PA 17120

PETER F. KILMARTIN
Attorney General of Rhode Island
150 South Main Street
Providence, RI 02903

THOMAS J. DONOVAN, JR.
Attorney General of Vermont
109 State Street
Montpelier, VT 05609

MARK R. HERRING
Attorney General of Virginia
202 North Ninth Street
Richmond, Virginia 23219

ROBERT W. FERGUSON
Attorney General of Washington
1125 Washington Street SE
PO Box 40100
Olympia, WA 98504