

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

CAMI JO TICE-HAROUFF,

Plaintiff

v.

CAROLE JOHNSON, *et al.*,

Defendants.

Case No. 6:22-cv-00201-JDK

NOTICE

In their response to the Plaintiff's Motion for a Temporary Restraining Order and Preliminary Injunction, the Defendants attached a declaration asserting that, *inter alia*, "[Fertility Awareness Based Methods of] instruction is included in the 2021 Guidelines, as part of contraceptive counseling and education. Pursuant to Section 2713 of the PHS Act, all preventive services included in the 2021 Guidelines are required to be covered by Subject Health Insurers, without cost-sharing." Dkt. 20 at Ex. A, ¶ 6.

The Defendants are filing this Notice to inform the Court and the Plaintiff that on July 18, 2022, the Health Resources & Services Administration (HRSA) added a footnote to the HRSA-supported Women's Preventive Services Guidelines (the Guidelines) for Contraception, available at HRSA's website (<https://www.hrsa.gov/womens-guidelines/index.html>), that clarifies that "[e]ducation and counseling includes all methods of contraception, including but not limited to, hormonal, devices, surgical, barrier, and *fertility-based awareness methods*, including lactation amenorrhea" (emphasis added). A copy of this page is included as Exhibit A to this Notice.

In addition, on or about July 28, 2022, the Center for Consumer Information and Insurance Oversight (CCIIO), one of the federal agencies tasked with implementing aspects of the Affordable

Care Act, including the requirements that insurers provide no cost coverage of services covered by the Guidelines, updated the “Frequently Asked Questions” (FAQs) section of its website (<https://www.cms.gov/files/document/faqs-part-54.pdf>). The FAQs include the following question and answer:

Q4: The currently applicable 2019 HRSA-Supported Guidelines recommend instruction in fertility awareness-based methods including the lactation amenorrhea method for women desiring an alternative method. Under the 2021 HRSA-Supported Guidelines, are plans and issuers required to continue to provide coverage for instruction in fertility awareness based methods without cost sharing?

Yes. The 2021 HRSA-Supported Guidelines include “screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period).” Counseling and education under the 2021 HRSA-Supported Guidelines includes instruction in fertility awareness-based methods, including lactation amenorrhea.

A copy of the relevant section of these FAQs is included as Exhibit B to this Notice.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of August 2022, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

/s/ James Gillingham

JAMES GILLINGHAM



Health Resources & Services Administration


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Women's Preventive Services Guidelines

Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being

The Affordable Care Act (ACA) – the health insurance reform legislation passed by Congress and signed into law by President Obama on March 23, 2010 – helps make prevention services affordable and accessible for all Americans by requiring most health insurance plans to provide coverage without cost sharing for certain recommended preventive 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.

Under the ACA, most private health insurers must provide coverage of women's preventive health care – such as mammograms, screenings for cervical cancer, prenatal care, and other services –with no cost sharing. Under section 2713 of the Public Health Service Act, as modified by the ACA, non-grandfathered group health plans and 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.

The law recognizes and HHS understands the unique health needs of women across their lifespan. The purpose of WPSI is to improve women's health across the lifespan by identifying preventive services and screenings to be used in clinical practice and, when supported by HRSA, incorporated in the Guidelines.

HRSA-Supported Women's Preventive Services Guidelines: Background

The HRSA-supported Women's Preventive Services Guidelines (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 the establishment of the Guidelines, there have been advancements in science and gaps identified in clinical practice. To address these, in 2016, the Health Resources and Services Administration (HRSA) awarded a five-year cooperative agreement, the Women's Preventive Services Initiative (WPSI), to the American College of Obstetricians and Gynecologists (ACOG) to convene a coalition of clinician, academic, and consumer-focused health professional organizations to conduct a scientifically rigorous review to develop recommendations for updated Guidelines in accordance with the model created by the NAM Clinical Practice Guidelines We Can Trust. The American College of Obstetricians and Gynecologists (ACOG) formed an expert panel, also called the WPSI, for this purpose.

In March 2021, ACOG was awarded a subsequent cooperative agreement to review and recommend updates to the Guidelines. Under ACOG, WPSI reviews existing Women's Preventive Services Guidelines biennially, or upon the availability of new evidence, as well as new preventive services topics. New topics for future consideration can be submitted on a rolling basis at the [Women's Preventive Services Initiative website](#).

HRSA-Supported Women's Preventive Services Guidelines

Learn More

- [HRSA/MCHB Preventive Guidelines and Screening for Women, Children, and Youth](#)
- [Historical Files](#)
- [2019 Guidelines](#)
- [2016 Guidelines](#)
- Institute of Medicine: [Clinical Preventive Services for Women \(2011\)](#)
- [Bright Futures](#)
- [Advisory Committee on Heritable Disorders in Newborns and Children](#)

For Further Information

Contact
wellwomancare@hrsa.gov.

HRSA supports the Guidelines listed below that address health needs specific to women. In December 2021, HRSA approved a new guideline on obesity prevention for midlife women and updates to five existing preventive services guidelines: Well-Women Preventive Visits, Breastfeeding Services and Supplies, Counseling for Sexually Transmitted Infections (STIs), Screening for Human Immunodeficiency Virus (HIV) Infection, and Contraception.*

New and Updated Guidelines

| Type of Preventive Service ↕ | Current Guidelines ↕ | Updated Guidelines Beginning With Plan Years Starting in 2023 ↕ |
|---|---|--|
| <p>Obesity Prevention in Midlife Women</p> | | <p>(NEW) WPSI recommends counseling midlife women aged 40 to 60 years with normal or overweight body mass index (BMI) (18.5-29.9 kg/m²) to maintain weight or limit weight gain to prevent obesity. Counseling may include individualized discussion of healthy eating and physical activity.</p> |
| <p>Breastfeeding Services and Supplies</p> | <p>WPSI recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.</p> | <p>WPSI recommends comprehensive lactation support services (including consultation; counseling; education by clinicians and peer support services; and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding.</p> <p>Breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be a priority to optimize breastfeeding and should not be predicated on prior failure of a manual pump. Breastfeeding equipment may also include equipment and supplies as clinically indicated to support dyads with breastfeeding difficulties and those who need additional services.</p> |
| <p>Contraception ** ***</p> | <p>WPSI recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth</p> | <p>WPSI recommends that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent</p> |

| Type of Preventive Service ↕ | Current Guidelines ↕ | Updated Guidelines Beginning With Plan Years Starting in 2023 ↕ |
|------------------------------|--|---|
| | <p>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.</p> <p>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.</p> | <p>unintended pregnancies and improve birth outcomes. Contraceptive care includes screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period).**** Contraceptive care also includes follow-up care (e.g., management, evaluation and changes, including the removal, continuation, and discontinuation of contraceptives).</p> <p>WPSI recommends that the full range of U.S. Food and Drug Administration (FDA)-approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care.</p> <p>The full range of contraceptives includes those currently listed in the FDA's Birth Control Guide*****: (1) sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), (7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate), and any additional contraceptives approved, granted, or cleared by the FDA.</p> |

| Type of Preventive Service ↕ | Current Guidelines ↕ | Updated Guidelines Beginning With Plan Years Starting in 2023 ↕ |
|---|--|--|
| <p>Counseling for Sexually Transmitted Infections (STIs)</p> | <p>WPSI 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 STIs.</p> <p>WPSI 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 judgment.</p> | <p>WPSI recommends directed behavioral counseling by a health care clinician or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for STIs.</p> <p>WPSI recommends that clinicians review a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors include, but are not limited to, 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 judgment.</p> |

| Type of Preventive Service ↕ | Current Guidelines ↕ | Updated Guidelines Beginning With Plan Years Starting in 2023 ↕ |
|--|--|---|
| <p>Screening for Human Immunodeficiency Virus Infection (HIV)</p> | <p>WPSI recommends prevention education and risk assessment for 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.</p> <p>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.</p> | <p>WPSI recommends all adolescent and adult women, ages 15 and older, receive a screening test for HIV at least once during their lifetime. Earlier or additional screening should be based on risk, and rescreening annually or more often may be appropriate beginning at age 13 for adolescent and adult women with an increased risk of HIV infection.</p> <p>WPSI recommends risk assessment and prevention education for HIV infection beginning at age 13 and continuing as determined by risk.</p> <p>A screening test for HIV is recommended for all pregnant women upon initiation of prenatal care with rescreening 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.</p> |

| Type of Preventive Service ↕ | Current Guidelines ↕ | Updated Guidelines Beginning With Plan Years Starting in 2023 ↕ |
|--|--|---|
| <p>Well-Woman Preventive Visits</p> | <p>WPSI 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.</p> | <p>WPSI recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure the provision of all 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. These services may be completed at a single or as part of a series of visits that take place over time to obtain all necessary services depending on a woman's age, health status, reproductive health needs, pregnancy status, and risk factors. Well-women visits also include prepregnancy, prenatal, postpartum and interpregnancy visits.</p> |

Existing Guidelines

| Type of Preventive Service ↕ | Current Guidelines ↕ |
|--|---|
| <p>Breast Cancer Screening for Average-Risk Women</p> | <p>WPSI 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.</p> <p>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.</p> |
| <p>Screening for Anxiety</p> | <p>WPSI recommends screening for anxiety in adolescent and adult women, including those who are pregnant or postpartum. Optimal screening intervals are unknown and clinical judgement should be used to determine screening frequency. Given the high prevalence of anxiety disorders, lack of recognition in clinical practice, and multiple problems associated with untreated anxiety, clinicians should consider screening women who have not been recently screened.</p> |

| Type of Preventive Service ◆ | Current Guidelines ◆ |
|---|---|
| Screening for Cervical Cancer | WPSI 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. |
| Screening and Counseling for Interpersonal and Domestic Violence | WPSI 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. |
| Screening for Diabetes Mellitus after Pregnancy | WPSI recommends women with a history of gestational diabetes mellitus (GDM) who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes mellitus should be screened for diabetes mellitus. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum (see Table 1). Women with a negative initial postpartum screening test result should be rescreened at least every 3 years for a minimum of 10 years after pregnancy. For women with a positive postpartum screening test result, testing to confirm the diagnosis of diabetes is indicated regardless of the initial test (e.g., oral glucose tolerance test, fasting plasma glucose, or hemoglobin A1c). Repeat testing is indicated in women who were screened with hemoglobin A1c in the first 6 months postpartum regardless of the result. |
| Screening for Gestational Diabetes Mellitus | WPSI 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. WPSI 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 Urinary Incontinence | WPSI recommends screening women for urinary incontinence annually. Screening should ideally assess whether women experience urinary incontinence and whether it impacts their activities and quality of life. The Women's Preventive Services Initiative recommends referring women for further evaluation and treatment if indicated. |

Implementation Considerations

While not included as part of the HRSA-supported guidelines, the Women's Preventive Services Initiative, through ACOG, also developed implementation considerations, available at the [Women's Preventive Services Initiative website](#), 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 30, 2022. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the guidelines as previously updated in 2019.

** (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).

*** General Notice

On July 29, 2019, the District Court for the Northern District of Texas issued an injunction preventing the enforcement of “the Contraceptive Mandate, codified at 42 U.S.C. § 300gg-13(a)(4), 45 C.F.R. § 147.130(a)(1)(iv), 29 C.F.R. § 2590.715-2713(a)(1)(iv), and 26 C.F.R. § 54.9815-2713(a)(1)(iv), against any group health plan, and any health insurance coverage provided in connection with a group health plan, that is sponsored by an Employer Class member[,]” to the extent that such coverage conflicts with the Employer Class member’s sincerely held religious objections to such coverage, in connection with *DeOtte v. Azar*, No. 4:18-CV-00825-O, 2019 WL 3786545 (N.D. Tex. July 29, 2019). The injunction also prevents the enforcement of “the Contraceptive Mandate” to the extent it requires an “Individual Class member[] to provide coverage or payments for contraceptive services” to which the individual objects based on sincerely held religious beliefs, if a health insurance issuer and, if applicable, a sponsor of a group health plan, is willing to offer the Individual Class member a separate policy or plan that omits such contraceptive coverage. On December 17, 2021, the Fifth Circuit vacated the injunction in *DeOtte v. Nevada*, No. 19-10754 (5th Cir. Dec. 17, 2021). However, as of the date of this publication, the Fifth Circuit has yet to issue a mandate in connection with its order, and the injunction remains in place.

**** Education and counseling includes all methods of contraception, including but not limited to, hormonal, devices, surgical, barrier, and fertility-based awareness methods, including lactation amenorrhea.

***** FDA’s Birth Control Guide

This refers to [FDA’s Birth Control Guide](#) (PDF - 450 KB) as posted on December 22, 2021 with the exception of sterilization surgery for men, which is beyond the scope of the WPSI.

Date Last Reviewed: July 2022

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CCIIO OG MWRD 2514

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 54

July 28, 2022

Set out below are Frequently Asked Questions (FAQs) regarding implementation of the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#Affordable_Care_Act), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

COVERAGE OF PREVENTIVE SERVICES

Public Health Service (PHS) Act section 2713 and its implementing regulations relating to coverage of preventive services¹ require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover, without the imposition of any cost-sharing requirements, the following items or services:²

- Evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009;³
- 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) with respect to the individual involved;

¹ See 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; and 45 CFR 147.130.

² In addition, under section 3203 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act and its implementing regulations, plans and issuers must cover, without cost-sharing requirements, any qualifying coronavirus preventive service pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). The term “qualifying coronavirus preventive service” means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved (1) an evidence-based item or service that has in effect a rating of “A” or “B” in the current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP (regardless of whether the immunization is recommended for routine use). On November 6, 2020, the Departments published interim final rules with a request for comment regarding this requirement, *Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* (85 FR 71142).

³ The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of Division H of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2023.

Guidelines, including contraceptive products more recently approved, cleared, or granted by FDA.²⁰ This coverage must also include the clinical services, including patient education and counseling, needed for provision of the contraceptive product or service.

Q3: May plans and issuers use reasonable medical management techniques for contraceptive products or services *not included* in the categories described in the HRSA-Supported Guidelines?

For contraceptive services or FDA-approved, cleared, or granted contraceptive products that are not included in a category described in the HRSA-Supported Guidelines, plans and issuers may use reasonable medical management techniques, as permitted under 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4), to determine which specific products to cover without cost sharing only if multiple, substantially similar services or products that are not included in a category described in the Guidelines are available and are medically appropriate for the individual.²¹ If a plan or issuer uses reasonable medical management techniques with respect to multiple, substantially similar services or products, the plan or issuer must cover at least one such service or product without cost sharing.

If the individual's attending provider recommends a particular service or FDA-approved, cleared, or granted product not included in a category described in the HRSA-Supported Guidelines based on a determination of medical necessity with respect to that individual (including if there is only one service or product that is medically appropriate for the individual, as determined by their attending provider), the plan or issuer must cover that service or product without cost sharing. The plan or issuer must defer to the determination of the attending provider, and make available an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome so the individual or their provider (or other individual acting as the individual's authorized representative) can obtain coverage for the medically necessary service or product without cost sharing as required under PHS Act section 2713 and its implementing regulations and guidance.

Q4: The currently applicable 2019 HRSA-Supported Guidelines recommend instruction in fertility awareness-based methods including the lactation amenorrhea method for women desiring an alternative method. Under the 2021 HRSA-Supported Guidelines, are plans and issuers required to continue to provide coverage for instruction in fertility awareness-based methods without cost sharing?

Yes. The 2021 HRSA-Supported Guidelines include "screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period)."²² Counseling and education under the 2021 HRSA-Supported Guidelines includes instruction in fertility awareness-based methods, including lactation amenorrhea.

²⁰ See FAQs Part 51, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf>.

²¹ For more information on reasonable management techniques, see Q8.

²² See Women's Preventive Service Guidelines, available at <https://www.hrsa.gov/womens-guidelines>.