Robert W. Ferguson
Attorney General
Jeffrey T. Sprung, WSBA #23607
Paul Crisalli, WSBA #40681
Lauryn K. Fraas, WSBA 53238
R. July Simpson, WSBA #45869
Nathan K. Bays, WSBA #43025
Assistant Attorneys General
Washington Attorney General's Office
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	NO. 2:19-cv-00183-SAB DECLARATION OF NATHAN K. BAYS IN SUPPORT OF STATE OF WASHINGTON'S MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR FOR SUMMARY JUDGMENT NOTED FOR: November 7, 2019 With Oral Argument at 10:00 AM Location: Spokane, Washington

I, Nathan K. Bays, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am an Assistant Attorney General with the Washington State Office of the Attorney General and am counsel of record for the State of

Washington in this matter.

3. Attached hereto as Exhibit 1 is a true and correct copy of the Department of Health & Human Services letter regarding OCR Transaction Number 17-259696, AR 541967–68.

4. Attached hereto as Exhibit 2 is a true and correct copy of the Department of Health & Human Services letter regarding Transaction 11-122388, AR 541805–06.

5. Attached hereto as Exhibit 3 is a true and correct copy of the 2009 Christian Medical and Dental Association Survey, AR 548707–10.

6. Attached hereto as Exhibit 4 is a true and correct copy of the 2011 Christian Medical Association Survey, AR 537609–13.

7. Attached hereto as Exhibit 5 is a true and correct copy of the Department of Health & Human Services Office of Civil Rights Discrimination Complaint against the Washington State Department of Corrections, AR 544188–95.

8. Attached hereto as Exhibit 6 is a true and correct copy of the public comment letter submitted by Kaiser Permanente, AR 139639–49.

9. Attached hereto as Exhibit 7 is a true and correct copy of the public comment letter submitted by Blue Cross Blue Shield Association, AR 140265–77.

10. Attached hereto as Exhibit 8 is a true and correct copy of the public

comment letter submitted by the American Nurses Association, AR 56915–22.

11. Attached hereto as Exhibit 9 is a true and correct copy of the public comment letter submitted by the Center for American Progress, AR 160639–53.

12. Attached hereto as Exhibit 10 is a true and correct copy of the public comment letter submitted by the Planned Parenthood Federation of America, AR 160751–71.

13. Attached hereto as Exhibit 11 is a true and correct copy of the public comment letter submitted by the Consortium for Citizens with Disabilities, AR 160775–78.

14. Attached hereto as Exhibit 12 is a true and correct copy of the public comment letter submitted by the American Medical Association, AR 139587–93.

15. Attached hereto as Exhibit 13 is a true and correct copy of the public comment letter submitted by Lambda Legal, AR 161476–95.

16. Attached hereto as Exhibit 14 is a true and correct copy of the public comment letter submitted by the American College of Emergency Physicians, AR 147981–85.

17. Attached hereto as Exhibit 15 is a true and correct copy of the public comment letter submitted by the American Civil Liberties Union, AR 147746–66.

18. Attached hereto as Exhibit 16 is a true and correct copy of the public comment letter submitted by the National Women's Law Center, AR 149141–

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

1 56.

2 19. Attached hereto as Exhibit 17 is a true and correct copy of the public
3 comment letter submitted by the National Health Law Program, AR 139858–85.

4 20. Attached hereto as Exhibit 18 is a true and correct copy of the public
5 comment letter submitted by the Washington State Department of Health, AR
6 67173–75.

7 21. Attached hereto as Exhibit 19 is a true and correct copy of the public
8 comment letter submitted by the National Family Planning & Reproductive
9 Health Association, AR 138102–12.

10 22. Attached hereto as Exhibit 20 is a true and correct copy of the public
11 comment letter submitted by the National Center for Lesbian Rights AR 134728–
12 50.

13 23. Attached hereto as Exhibit 21 is a true and correct copy of the public
14 comment letter submitted by Physicians for Reproductive Health, AR 148138–
15 52.

16 I declare under penalty of perjury under the laws of the State of
17 Washington and the United States that the foregoing is true and correct.

18 DATED this 20th day of September, 2019, at Seattle, Washington

19

20 */s/ Nathan K. Bays*
NATHAN K. BAYS, WSBA #43025
21 Assistant Attorney General

22

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's CM/ECF System which will serve a copy of this document upon all counsel of record.

DATED this 20th day of September, 2019, at Seattle, Washington.

/s/ Jeffrey T. Sprung
JEFFREY T. SPRUNG, WSBA #23607
Assistant Attorney General

Exhibit 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

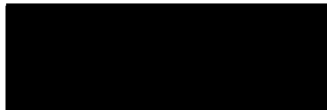
Office of the Secretary

Chicago Office
233 North Michigan Avenue, Suite 240
Chicago, IL 60601

Kansas City Office
601 East 12th Street, Room 353
Kansas City, MO 64106

Office for Civil Rights
Midwest Region
Website: http://www.hhs.gov/ocr
Voice - (800) 368-1019
TDD - (800) 537-7697

April 18, 2017



OCR Transaction Number: 17-259696

Dear

Thank you for your letter received on January 19, 2017 by the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR). In your complaint, you state that CVS Caremark discriminated against you when it continuously sent you literature describing contraceptives after you advised CVS Caremark that your sincerely held religious beliefs and practices don't allow for the funding of, or association with, contraceptives.

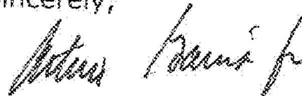
Among other things, OCR enforces Federal civil rights laws that prohibit discrimination in the delivery of health and human services because of race, color, national origin, age, disability, and, under certain circumstances, sex and religion. OCR has also been designated to receive complaints brought pursuant to the Federal health care provider conscience protection statutes, which prohibit recipients of certain HHS FFA from discriminating against health care providers and health care personnel because of their refusal or willingness to participate in certain health care services they find religiously or morally objectionable.

We have carefully reviewed your complaint and we are closing this case without further investigation because you have not raised facts sufficient to support a claim of discrimination on the basis of your religious beliefs or moral convictions under the laws OCR enforces.

OCR's determination as stated in this letter applies only to the allegations in this complaint that were reviewed by OCR. Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

We regret we are unable to assist you further. Thank you.

Sincerely,



Steven M. Mitchell
Acting Regional Manager

Exhibit 2

DEPARTMENT OF HEALTH & HUMAN SERVICES **OFFICE OF THE SECRETARY**

Voice - (404) 562-7886, (800) 368-1019
TDD - (404) 562-7884, (800) 537-7697
(FAX) - (404) 562-7881
http://www.hhs.gov/ocr/

Office for Civil Rights, Region IV
61 Forsyth Street, Suite 3B70
Atlanta, Georgia 30303

January 26, 2011

Matthew Bowman, Esq
Alliance Defense Fund
801 G Street N.W., Suite 509
Washington, D.C. 20001

Julia Caldwell Morris, Deputy General Counsel
Sheree Wright, Sr. Associate General Counsel
Vanderbilt University
Office of General Counsel
2100 West End Ave., Suite 750
Nashville, TN 37203

Re: Transaction - 11-122388
Ann Marie Dust v Vanderbilt University

Dear Mr. Bowman, Ms. Morris, and Ms. Wright:

The Office for Civil Rights (OCR) has completed its investigation of the complaint filed against Vanderbilt University. The OCR has jurisdiction over programs and entities that receive Federal financial assistance from HHS in cases involving discrimination based on race, color, national origin, age, disability and, under certain circumstances, sex and religion. OCR also has been designated to receive complaints of discrimination and coercion that violate the Church Amendments, 42 U.S.C. §300a-7, and its implementing regulation, 45 C.F.R. Part 88. As a recipient of Federal financial assistance Vanderbilt University is obligated to comply with 42 U.S.C. § 300a-7 and its implementing regulation.

Issue Presented

The Alliance Defense Fund (Complainant) filed a complaint on behalf of [redacted] (Affected Party) against Vanderbilt University (Covered Entity) on January 11, 2011. The complaint alleged a violation of the Alleged Party's federal rights of conscience under 42 U.S.C. § 300a-7 and was filed with this office pursuant to 45 C.F.R. Part 88. Specifically, the complaint alleges that as a condition to admission to Vanderbilt University's Nurse Residency Program, applicants must in writing, promise that they will assist in termination of pregnancy procedures during their employment in the residency program, or their application for the program will be denied.

Discussion

On January 19, 2011, OCR notified the Covered Entity of the complaint filed against it by telephone. The Covered Entity provided OCR with assurances that it does not require nurses or

others to perform or participate in the performance of termination of pregnancy procedures if it is inconsistent with their religious or moral beliefs. The Covered Entity explained that if an employee raises an objection to participating in the performance of a termination of pregnancy, the employee may request an accommodation.

In order to resolve this matter, the Covered Entity has provided OCR with documentation that it has voluntarily taken the following corrective actions:

1. The Covered Entity emailed a clarification to all active nurse residency candidates [candidates who already submitted an online application and who met the basic qualifications for the position] concerning its policies regarding participation in termination of pregnancy and accommodations for religious beliefs or moral convictions.
2. The Covered Entity has eliminated the previous acknowledgment form from its Nurse Residency Program Application Packet and replaced it with a notice form that clarifies its policies regarding participation in termination of pregnancy and accommodations for religious beliefs or moral convictions.
3. Revised information packets and the clarification were sent to new candidates, including the Affected Party, on January 13, 2011.

On January 25th, OCR contacted the Complainant. The Complainant, who had expressed satisfaction with the measures taken by the Covered Entity in the [redacted] edition of *The Tennessean,* informed OCR that the Complainant had withdrawn the complaint based on those steps. The Complainant faxed to OCR a copy of the withdrawal letter dated January 12th, which OCR had not previously received.

Based on the foregoing voluntary corrective action, OCR is closing this matter. The closure of this case is not intended and should not be construed to cover any other issues regarding compliance with 45 C.F.R. Part 88 that may exist but were not specifically addressed during our investigation.

OCR shall place no restriction on the publication of the contents of this letter and may release this document and related materials consistent with the Freedom of Information Act, 5 U.S.C Section 522, and its implementing regulation 45 C.F.R. Part 5.

Thank you for your cooperation. If you have any questions, please do not hesitate to contact [redacted].

Sincerely,

Roosevelt Freeman
Regional Manager

Exhibit 3

TO: Interested Parties

FROM: Kellyanne Conway, President & CEO
the polling company™, inc./WomanTrend

DATE: April 8, 2009

RE: Key Findings on Conscience Rights Polling

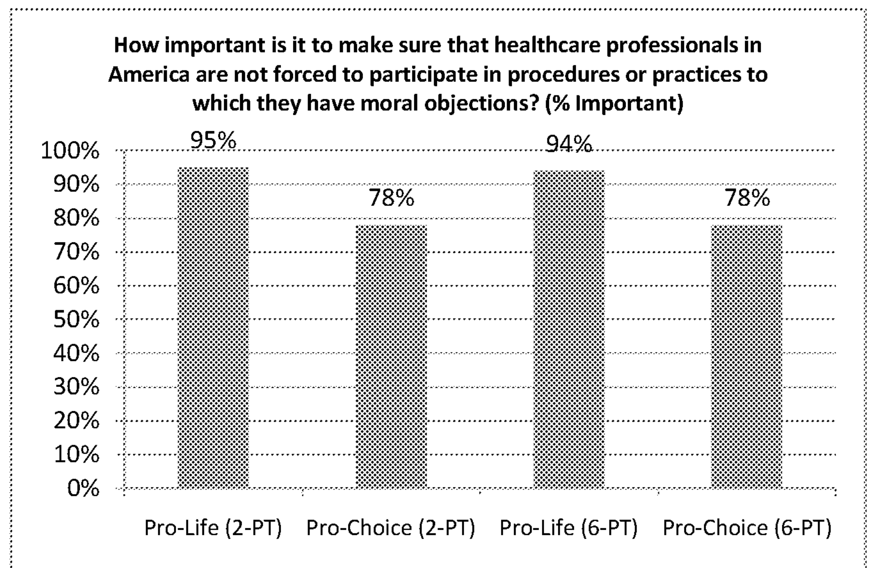
On behalf of the Christian Medical & Dental Association (CMDA), the polling company™, inc./ WomanTrend *conducted a nationwide survey of 800 American adults and an online survey of members of faith-based medical organizations. Full statements of methodology can be found at the conclusion of this document.*

Americans of All Demographic Characteristics and Political Stripes Seek a Shared a Set of Values with their Healthcare Providers.

Fully 88% of American adults surveyed said it is either "very" or "somewhat" important to them that they enjoy a similar set of morals as their doctors, nurses, and other healthcare providers. Intensity was strong, as 63% described this as "very" important while at the other end of the spectrum, just 6% said it is "not at all important," a ratio of more than 10-to-1.

Healthcare Providers' Conscience Protections Viewed as an Inalienable Right

A sizable 87% of American adults surveyed believed it is important to ***"make sure that healthcare professionals in America are not forced to participate in procedures and practices to which they have moral objections."*** Support for this protection garnered considerable intensity as well, with 65% of respondents considering it very essential. Majorities of men, women, and adults of all ages, races, regions, and political affiliations considered it critical to defend the rights of healthcare providers to refuse to perform certain procedures on moral grounds. Also joining with these majorities were 95% of respondents who self-identified as "pro-life," 78% who considered themselves "pro-choice," 94% who voted for Senator McCain in November 2008 and 80% who cast a ballot for (now) President Obama.



Americans Oppose The *Principle* of Forcing Healthcare Providers to Act Against Their Consciences...

A majority (57%) of American adults opposed regulations ***"that require medical professionals to perform or provide procedures to which they have moral or ethical objections."*** In contrast, 38% favored such rules. The potency of opposition was twice that of the supporters: 40% strongly objected to the laws while just 19% strongly backed them. Politically, a majority of conservative Republicans (69%), moderate Republicans (69%), and conservative Democrats (59%), as well as the plurality of liberal/moderate Democrats (49%), joining together to reject policies to that require doctors and nurses to act against their personal moral code or value set.

…Support <u>Laws</u> That Protect Them From Doing So…
Without any names or political parties being mentioned, respondents were provided with a short description of the new conscience protection law and its recent inception: ***<u>"Just two months ago, a federal law known as 'conscience protection' went into effect after reports of doctors being discriminated against for declining to perform abortions. It protects doctors and other medical professionals who work at institutions that receive federal money from performing medical procedures to which they object on moral or religious grounds."</u>***

After hearing this short description, support for this new law outpaced opposition by a margin of more than 2-to-1 (63% vs. 28%). Intensity favored the law, with 42% strongly backing it and 19% strongly rejecting it. Endorsements for the rule spanned demographic and political spectra, with majorities in all cohorts offering their support. **<u>In fact, even 56% of adults who said they voted for President Obama last fall and 60% of respondents who self-identified as "pro-choice" said they favor this two-month old conscience protection rule.</u>**

… And Oppose Any Efforts to Remove Such Laws.
Next, respondents were asked to react to the proposed rescission of the conscience protection law: *"Earlier this month, officials from the U.S. Department of Health and Human Services introduced a rule change that would effectively eliminate the two-month-old conscience protection. This could mean that doctors and other medical professionals could be coerced to participate in medical procedures to which they object on moral or religious grounds."*

Opposition to revocation of the conscience protection law outpaced support by a margin of more than 2-to-1 (62% vs. 30%). As was the case in the previous question, intensity favored retention of the law (44% strongly opposing rescission versus 17% strongly supporting it). Again, there was consistent demographic alignment, as a majority of men, women, and adults of all ages, races, incomes, regions, and geographic types stood together to reject removal of the law. And, there was cohesiveness across political lines, as 52% of self-identified Democrats, 67% of self-identified Independents, and 73% of self-identified Republicans, as well as 50% of liberals, 65% of moderates, and 69% of conservatives also opposed nullification. A narrow majority (53%) of people who considered themselves to be "pro-choice" opposed rescission. Notably, a small number (7%) were ambivalent or undecided, saying they did not know or lacked the information to render an opinion one way or the other.

Rescission of Conscience Protection Viewed by a Majority as Government Insinuating Itself into the Patient-Physician Relationship.
When asked whether rescission of the rule and a resulting forced participation of doctors in abortions is a sign of more, less, or the right amount of government involvement in medicine, the majority (58%) said it exemplified excessive participation. Just 18% thought it reflected the ideal role and 11% believed it was still too minimal.

The Political Currency Calculus: Voters Will Punish Politicians Who Fail to Defend Healthcare Providers' Rights to Refuse to Violate Their Conscience in the Name of Medicine.
Finally, when asked how they would view their Member of Congress if he or she voted ***against*** conscience protection rights, 54% indicated they would be less likely to back their United States Representative. In fact, 36% said they would be *much less likely*, a figure three times greater than the 11% who said they would be *much more likely*. Furthermore, 43% of respondents who said they voted for President Obama indicated that they would be less inclined to back a Member of Congress if he or she opposed conscience protection rights.

Rescission of Conscience Protections May be a Priority for Obama Administration, but not for his Constituents.

When presented with a list of 13 areas for the sitting Congress and current President to address and allowed to select multiple answers, only 10% of American adults preferred that Washington devote its time and energy to abortion policy. In fact, the issue of abortion was ranked 9th out of 13 among the issues offered to survey respondents. Moreover, adults desirous of action on abortion policy were six times more likely to be "pro-life" than "pro-choice" (19% vs. 3%). In contrast, no less than 68% of any demographic or political cohort studied said that President Obama and Congressional leaders should focus on the economy and jobs.

Real Effects Likely to Be Felt in Medical Community If Doctors Forced to Act Against Their Moral and Ethical Codes

In the survey of 2,865 members of faith-based organizations, doctors and other medical professionals voiced their concerns that serious consequences could occur if doctors are forced to participate in or perform practices to which they have moral or ethical objections. Nearly three-quarters (74%) believed that elimination of the conscience protection could result in "fewer doctors practicing medicine," 66% predicted "decreased access to healthcare providers, services, and/or facilities for patients in low-income areas," 64% surmised "decreased access to healthcare providers, services, and/or facilities for patients in rural areas," and 58% hypothesized "fewer hospitals providing services."

When asked how rescission of the conscience rule would affect them personally, fully 82% said it was either "very" or "somewhat" likely that they personally would limit the scope of their practice of medicine. This was true of 81% of medical professionals who practice mainly in rural areas and 86% who work full-time in serving poor and medically-underserved populations.

Conscience Protection Rule Fundamental and Necessary in the Medical Profession, According to Members of the Christian Medical & Dental Association, the Catholic Medical Association, and the Christian Pharmacists Fellowship International

Fully 97% of members who participated in the survey supported the two-month-old conscience protection clause and 96% objected to rescission of the rule.

The Department of Health and Human Services has asked whether the objectives of the conscience protection law can be achieved "through non-regulatory means, such as outreach and education." Nearly nine-in-ten (87%) members surveyed – those who are on the ground, in hospitals and clinics across the country – felt "outreach and education" alone were insufficient to accomplish the goal.

Ninety-two percent declared the codification of conscience protection to be necessary (83% "very" and 9% "somewhat") based on their knowledge of "discrimination in healthcare on the basis of conscience, religious, and moral values." Many respondents held this opinion due in part to their own personal experience. When asked to assess their educational experiences:

- 39% have "experience pressure from or discrimination by faculty or administrators based on [their] moral, ethical, or religious beliefs"
- 33% have "considered not pursuing a career in a particular medical specialty because of attitudes prevalent in that specialty that is not considered tolerant of [their] moral, ethical or religious beliefs."
- 23% have "experienced discrimination during the medical school or residency application and interview process because of [their] moral, ethical or religious beliefs."

And, when asked to assess their professional experiences:

- 32% have "been pressured to refer a patient for a procedure to which [they] had moral, ethical, or religious objections
- 26% have "been pressured to write a prescription for a medication to which [they] had moral, ethical, or religious objections
- 17% have "been pressured to participate in training for a procedure to which [they] had moral, ethical, or religious objections."
- 12% have "been pressured to perform a procedure to which you had moral, ethical, or religious objections."

STATEMENT OF METHODOLOGY

Nationwide Survey of Adults:
On behalf of the **Christian Medical & Dental Association,** the polling company™, inc./ WomanTrend conducted a nationwide survey of 800 American Adults (18+). The survey contained one screener question, 10 substantive questions, and 13 demographic inquiries. All substantive questions were closed-ended in nature.

The survey was fielded March 23-25, 2009 at a Computer-Assisted Telephone Interviewing (CATI) facility using live callers. The sample was drawn utilizing Random Digit Dial, a computer dialing technique that ensures that every household in the nation with a landline telephone has an equal chance of being called. Each respondent was screened to ensure he or she was 18 years of age.

Sampling controls were used to ensure that a proportional and representative number of people were interviewed from such demographic groups as age, race and ethnicity, and region according to the most recent figures available from the U.S. Census Bureau and voter registration and turnout figures. After data collection, weighting was used to ensure that the sample reflected the current population. This is a common and industry-accepted practice. Age, race, and gender were allowed four points of flexibility in pre-set quotas while three points of flexibility was permitted on region.

The overall margin of error for the survey is ± 3.5% at a 95% confidence interval, meaning that in 19 out of 20 cases, the data obtained would not differ by any more than 3.5 percentage points in either direction if the survey were repeated multiple times employing this methodology and sampling method. Margins of error for subgroups are higher.

Online Survey of Members of Faith-Based Medical Organizations:
On behalf of the **Christian Medical & Dental Association,** the polling company™, inc./ WomanTrend conducted an online survey of members of faith-based organizations. The Catholic Medical Association and Christian Pharmacists Fellowship International also invited their members to participate.

The survey was fielded March 31, 2009 to April 3, 2009 and was completed by 2,865 members of the Christian Medical and Dental Association (CMDA), 400 members of the Catholic Medical Association (CMA), 69 members of the Fellowship of Christian Physicians Assistants, 206 members of the Christian Pharmacists Fellowship International, and 8 members of Nurses Christian Fellowship. Respondents were allowed to select membership in multiple organizations.

Each respondent was provided with a unique hyperlink to take the survey, allowing no member to take the survey more than once and prohibiting respondents from passing the link to another individual after completing the survey.

This survey is intended to demonstrate the views and opinions of members surveyed. It is not intended to be representative of the entire medical profession nor of the entire membership rosters of these organizations. Respondents who participated in the survey were self-selecting.

Exhibit 4

May 2011: National poll shows majority support healthcare conscience rights, conscience law

Highlights of *the polling company, inc*. Phone Survey of the American Public

On May 3, 2011, the Christian Medical Association and the Freedom2Care coalition released the results of a nationwide, scientific poll conducted April 29-May 1, 2011 by the polling company^{TM}, inc./ WomanTrend. Survey of 1000 American Adults, Field Dates: April 29-May 1, 2011, Margin of Error=±3.1.

1. **77%** of American adults surveyed said it is either "very" or "somewhat" important to them that **"**that healthcare professionals in the U.S. are **not forced to participate** in procedures or practices to which they have **moral objections**." **16%** said it is not important.

ALL		*PRO-CHOICE* (n=465)	*PRO-LIFE* (n=461)
77%	Total **important** (net)	68%	85%
52%	Very important	42%	64%
25%	Somewhat important	26%	21%
16%	Total **not important** (net)	24%	8%
8%	Not too important	11%	5%
8%	Not at all important	13%	3%
8%	Do not know/depends	8%	6%
1%	Refused	*	

2. **50%** of American adults surveyed "strongly" or "somewhat" support "a **law** under which federal agencies and other government bodies that receive federal funds could **not discriminate** against hospitals and health care professionals who **decline to participate in abortions**." **35%** opposed.

ALL		*PRO-CHOICE* (n=465)	*PRO-LIFE* (n=461)
50%	Total **support** (net)	45%	58%
29%	Strongly support	20%	40%
21%	Somewhat support	25%	18%
35%	Total **oppose** (net)	43%	32%
14%	Somewhat oppose	20%	10%
21%	Strongly oppose	23%	22%
7%	It depends/need more info.	7%	5%
7%	Do not know	6%	5%
1%	Refused	1%	1%

April, 2009: Two National Polls[1] Reveal Broad Support for Conscience Rights in Health Care

Highlights of *the polling company, inc.* Phone Survey of the American Public

39% Democrat • 33% Republican • 22% Independent

1. **88%** of American adults surveyed said it is either "very" or "somewhat" **important to them that they share a similar set of morals as their doctors**, nurses, and other healthcare providers.
2. **87%** of American adults surveyed believed it is important to "make sure that healthcare professionals in America are **not forced to participate** in procedures and practices to which they have moral objections."
3. Support for the conscience protection regulation (rule finalized Dec. 2008):
   - **63% support conscience protection regulation**
   - 28% oppose conscience protection regulation
4. Support for Obama administration proposal to eliminate the new conscience protection regulation:
   - 30% support Obama administration proposal
   - **62% oppose Obama administration proposal**
5. Likelihood of voting for current Member of Congress who supported eliminating the conscience rule:
   - 25% more likely to vote for Member who supported eliminating rule
   - **54% less likely to vote for Member who supported eliminating rule**
6. "In 2004 the Hyde-Weldon Amendment was passed. It ruled that taxpayer funds must not be used by governments and government-funded programs to discriminate against hospitals, health insurance plans, and healthcare professionals who decline to participate in abortions. Do you support or oppose this law?"
   - **58% support Hyde-Weldon Amendment**
   - 31% oppose Hyde-Weldon Amendment

Highlights of Online Survey of Faith-Based Professionals

2,865 faith-based healthcare professionals

1. **Over nine of ten** (91%) faith-based physicians agreed, "I would **rather stop practicing medicine** altogether than be forced to violate my conscience."
2. **32%** of faith-based healthcare professionals report having "been **pressured to refer a patient** for a procedure to which [they] had moral, ethical, or religious objections."
3. **39%** of faith-based healthcare professionals have "experienced pressure from or **discrimination by faculty** or administrators based on [their] moral, ethical, or religious beliefs"
4. **20%** of faith-based medical students say they are "**not pursuing a career in Obstetrics or Gynecology"** because of perceived discrimination and coercion in that field.

---

[1] Results of both 2009 surveys released April 8. On behalf of the Christian Medical Association, the polling companyTM, inc./ WomanTrend conducted a nationwide survey of 800 American adults. Field Dates: March 23 -25, 2009. The overall margin of error for the survey is ± 3.5% at a 95% confidence interval. The polling companyTM, inc./ WomanTrend also conducted an online survey of members of faith-based organizations, fielded March 31, 2009 to April 3, 2009. It was completed by 2,298 members of the Christian Medical Association, 400 members of the Catholic Medical Association, 69 members of the Fellowship of Christian Physicians Assistants, 206 members of the Christian Pharmacists Fellowship International, and 8 members of Nurses Christian Fellowship. http://www.freedom2care.org/learn/page/surveys

Freedom2Care www.Freedom2Care.org and The Christian Medical Association www.cmda.org

April 2009 Phone Survey of the American Public

Americans of all characteristics and politics seek shared values with healthcare professionals.

Fully 88% of American adults surveyed said it is either "very" or "somewhat" important to them that they enjoy a similar set of morals as their doctors, nurses, and other healthcare providers. Intensity was strong, as 63% described this as "very" important while at the other end of the spectrum, just 6% said it is "not at all important," a ratio of more than 10-to-1.

Voters will punish politicians who fail to defend healthcare providers' conscience rights.

Finally, when asked how they would view their Member of Congress if he or she voted against conscience protection rights, 54% indicated they would be less likely to back their United States Representative. In fact, 36% said they would be much less likely, a figure three times greater than the 11 % who said they would be much more likely. Furthermore, 43% of respondents who said they voted for President Obama indicated that they would be less inclined to back a Member of Congress if he or she opposed conscience protection rights.

Healthcare providers' conscience protections are viewed as an inalienable right.

A sizable 87% of American adults surveyed believed it is important to "make sure that healthcare professionals in America are not forced to participate in procedures and practices to which they have moral objections." 65% of respondents considered it very essential. Also joining with these majorities were 95% of respondents who self-identified as "pro-life," 78% who considered themselves "pro-choice," 94% who voted for Senator McCain in November 2008 and 80% who cast a ballot for (now) President Obama.

Americans oppose forcing healthcare providers to act against their consciences...

A majority (57%) of American adults opposed regulations "that require medical professionals to perform or provide procedures to which they have moral or ethical objections." In contrast, 38% favored such rules. A full 40% strongly objected to the rules while just 19% strongly backed them. A majority of conservative Republicans (69%), moderate Republicans (69%), and conservative Democrats (59%), as well as the plurality of liberal/moderate Democrats (49%), joining together to reject policies to that require doctors and nurses to act against their personal moral code or value set.

...Support laws that protect them from doing so...

Without any names or political parties being mentioned, support for the new conscience protection rule outpaced opposition by a margin of more than 2-to-1 (63% vs. 28%). Intensity favored the rule, with 42% strongly backing it and 19% strongly rejecting it. Endorsements for the rule spanned demographic and political spectra, with majorities in all cohorts offering their support. In fact, even 56% of adults who said they voted for President Obama last fall and 60% of respondents who self-identified as "pro-choice" said they favor this two-month old conscience protection rule.

... And oppose any efforts to remove such rules.

Opposition to revocation of the conscience protection rule outpaced support by a margin of more than 2- to-1 (62% vs. 30%). Intensity favored retention of the rule (44% strongly opposing rescission versus 17% strongly supporting it). There was consistent demographic alignment and cohesiveness across political lines, as 52% of self-identified Democrats, 67% of self-identified Independents, and 73% of self- identified Republicans, as well as 50% of liberals, 65% of moderates, and 69% of conservatives also opposed nullification. A narrow majority (53%) of people who considered themselves to be "pro-choice" opposed rescission. Notably, a small number

(7%) were ambivalent or undecided, saying they did not know or lacked the information to render an opinion one way or the other.

Online Survey of Faith-Based Medical Professionals

1. Medical access will suffer if doctors are forced to act against their moral and ethical codes.

In the survey of 2,865 members of faith-based organizations, doctors and other medical professionals voiced their concerns that serious consequences could occur if doctors are forced to participate in or perform practices to which they have moral or ethical objections. Nearly three-quarters (74%) believed that elimination of the conscience protection could result in "fewer doctors practicing medicine," 66% predicted "decreased access to healthcare providers, services, and/or facilities for patients in low-income areas," 64% surmised "decreased access to healthcare providers, services, and/or facilities for patients in rural areas," and 58% hypothesized "fewer hospitals providing services."

Asked how rescission of the rule would affect them personally, 82% said it was either "very" or "somewhat" likely that they personally would limit the scope of their practice of medicine. This was true of 81% of medical professionals who practice in rural areas and 86% who work full-time serving poor and medically-underserved populations.

The conscience protection rule is fundamental and necessary in the medical profession.

Fully 97% of members who participated in the survey supported the two-month-old conscience protection clause and 96% objected to rescission of the rule. 91% of physicians agreed, "I would rather stop practicing medicine altogether than be forced to violate my conscience." The Department of Health and Human Services has asked whether the objectives of the conscience protection rule can be achieved "through non-regulatory means, such as outreach and education." Nearly nine-in-ten (87%) members surveyed – those who are on the ground, in hospitals and clinics across the country – felt "outreach and education" alone were insufficient to accomplish the goal. Ninety-two percent declared the codification of conscience protection to be necessary (83% "very" and 9% "somewhat") based on their knowledge of "discrimination in healthcare on the basis of conscience, religious, and moral values."

Discrimination is widespread in education and professional practice.

Asked to assess their educational experiences:

- 39% have "experienced pressure from or discrimination by faculty or administrators based on [their] moral, ethical, or religious beliefs"
- 33% have "considered not pursuing a career in a particular medical specialty because of attitudes prevalent in that specialty that is not considered tolerant of [their] moral, ethical or religious beliefs."
- 23% have "experienced discrimination during the medical school or residency application and interview process because of [their] moral, ethical or religious beliefs."

Asked to assess their professional experiences:

- 32% have "been pressured to refer a patient for a procedure to which [they] had moral, ethical, or religious objections."
- 26% have "been pressured to write a prescription for a medication to which [they] had moral, ethical, or religious objections."
- 17% have "been pressured to participate in training for a procedure to which [they] had moral, ethical, or religious objections."
- 12% have "been pressured to perform a procedure to which [they] had moral, ethical, or religious objections."

Freedom2Care www.Freedom2Care.org and The Christian Medical Association www.cmda.org

Discrimination is forcing faith-based medical students to shun careers in Obstetrics and Gynecology.

- 20% of students surveyed agreed with the statement, "I am **not pursuing a career in Obstetrics or Gynecology** mainly because I do not want to be forced to compromise my moral, ethical, or religious beliefs by being required to perform or participate in certain procedures or provide certain medications."
- **96%** of medical students support (90% "Strongly Support") the conscience protection regulation.
- 32% of medical students say they "have experienced pressure from or **discrimination by faculty** or administrators based on your moral, ethical, or religious beliefs."

Exhibit 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

CIVIL RIGHTS DISCRIMINATION COMPLAINT

Form Approved: OMB No. 0990-0269.
See OMB Statement on Reverse.

YOUR FIRST NAME	YOUR LAST NAME
[redacted]	[redacted]
HOME / CELL PHONE (Please include area code)	WORK PHONE (Please include area code)
[redacted]	

STREET ADDRESS	CITY
[redacted]	[redacted]

STATE	ZIP	E-MAIL ADDRESS (If available)
[redacted]	[redacted]	[redacted]

Are you filing this complaint for someone else? ☐ Yes ☒ No

If Yes, whose civil rights do you believe were violated?

FIRST NAME	LAST NAME

I believe that I have been (or someone else has been) discriminated against on the basis of:

☐ Race / Color / National Origin ☐ Age ☒ Religion / Conscience ☐ Sex

☐ Disability ☐ Other (specify): ____________

Who or what agency or organization do you believe discriminated against you (or someone else)?

PERSON/AGENCY/ORGANIZATION

Washington State Department of Corrections

STREET ADDRESS	CITY
7345 Linderson Way SW	Tumwater

STATE	ZIP	PHONE (Please include area code)
Washington	98501	(360) 725-8213

When do you believe that the discrimination occurred?

LIST DATE(S)

10/02/2017

Describe briefly what happened. How and why do you believe that you have been discriminated against? Please be as specific as possible. (Attach additional pages as needed)

No reasonable accommodation provided for my religious objection to prescribing hormones to men wanting to transition into women. When other providers offered to prescribe hormones to these patients under my care they were told by DOC leadership that they could not see my patients and no accommodation has been provided. Attached is a more detailed account as well as emails from my Facility Medical director, Chief medical officer, and the health care authority.

Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

SIGNATURE	DATE *(mm/dd/yyyy)*
[redacted]	03/06/2018

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of Sections 1553 and 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, and other civil rights statutes. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible discrimination, for internal systems operations, or for routine uses, which include disclosure of information outside the Department of Health and Human Services (HHS) for purposes associated with civil rights compliance and as permitted by law. It is illegal for a recipient of Federal financial assistance from HHS to intimidate, threaten, coerce, or discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under Federal civil rights laws. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's web site at: **www.hhs.gov/ocr/civilrights/complaints/index.html**. To submit a complaint using alternative methods, see reverse page (page 2 of the complaint form).

The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.

Do you need special accommodations for us to communicate with you about this complaint? (Check all that apply)

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter (specify language): ______

☐ Foreign language interpreter (specify language): ______ ☐ Other: ______

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME
HOME PHONE (Please include area code)	WORK PHONE (Please include area code)

STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS (If available)

Have you filed your complaint anywhere else? If so, please provide the following. (Attach additional pages as needed)

PERSON/AGENCY/ORGANIZATION/ COURT NAME(S)

EEOC, DOC internal discrimination complaint

DATE(S) FILED	CASE NUMBER(S) (If known)
02/06/2018, 11/16/2017	null, null

To help us better serve the public, please provide the following information for the person you believe was discriminated against (you or the person on whose behalf you are filing).

ETHNICITY (select one)

☐ Hispanic or Latino

☒ Not Hispanic or Latino

RACE (select one or more)

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American ☒ White ☐ Other (specify): ______

PRIMARY LANGUAGE SPOKEN (if other then English) ______

How did you learn about the Office for Civil Rights?

☒ HHS Website/Internet Search ☐ Family/Friend/Associate ☐ Religious/Community Org ☐ Lawyer/Legal Org ☐ Phone Directory ☐ Employer

☐ Fed/State/Local Gov ☐ Healthcare Provider/Health Plan ☐ Conference/OCR Brochure ☐ Other (specify): ______

To submit a complaint, please type or print, sign, and return completed complaint form package (including consent form) to the OCR Headquarters address below.

U.S. Department of Health and Human Services
Office for Civil Rights
Centralized Case Management Operations
200 Independence Ave., S.W.
Suite 515F, HHH Building
Washington, D.C. 20201
Customer Response Center: (800) 368-1019
Fax: (202) 619-3818
TDD: (800) 537-7697
Email: ocrmail@hhs.gov

Burden Statement
Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail complaint form to this address.**

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, which are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

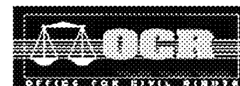
Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

Please read and review the documents entitled, *Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights* and *Protecting Personal Information in Complaint Investigations* for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.



- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose information, including personally identifying information, which it has gathered as part of its investigation of my complaint.

- In addition, I understand that as a complainant I am covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS' investigation, conciliation, or enforcement process.

After reading the above information, please check ONLY ONE of the following boxes:

[X] **CONSENT:** I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me in my case file to persons at the entity or agency under investigation or to other relevant persons, agencies, or entities during any part of HHS' investigation, conciliation, or enforcement process.

[ ] **CONSENT DENIED:** I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of my complaint and may result in closure of the investigation.

Signature: [redacted] Date: 03/06/2018

**Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.*

Name (Please print): [redacted]

Address: [redacted]

Telephone Number: [redacted]

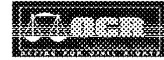
NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act
The Privacy Act of 1974 (5 U.S.C. § 552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion, and conscience under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d *et seq.*), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794), the Age Discrimination Act of 1975 (42 U.S.C. § 6101 *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et seq.), Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§ 295m and 296g), Section 1553 of the Affordable Care Act (42 U.S.C. § 18113), the Church Amendments (42 U.S.C. § 300a-7), the Coats-Snowe Amendment (42 U.S.C. § 238n) and the Weldon Amendment (*e.g.*, Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, Tit. V, § 507);
(ii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§ 291 *et seq*. and 300s *et seq*.) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill- Burton facilities);
(iii) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(iv) Title II of the Americans with Disabilities Act (42 U.S.C. § 12131 et seq.) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.
(v) The Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule) at 45 C.F.R. Part 160 and Subparts A and E of Part 164, which enforce the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. § 1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of Federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of Federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.



OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. § 552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. § 5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act
A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. § 552) (FOIA) and HHS regulations at 45 C.F.R. Part 5.

Fraud and False Statements
Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry".

PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Because of the Privacy Act, OCR will use your name or other personal information with a signed consent and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

Access to OCR's files and records is controlled by the Freedom of Information Act (FOIA). Under FOIA, OCR may be required to release information about this case upon public request. In the event that OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals, or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If OCR receives protected health information about you in connection with a HIPAA Privacy Rule investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under the Freedom of Information Act and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages; please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed $100.00.

If you have any questions about this complaint and consent package, Please contact OCR at http://www.hhs.gov/ocr/office/about/contactus/index.html

OR

Contact the Customer Response Center at (800) 368-1019

(see contact information on page 2 of the Complaint Form)

Exhibit 6

Kaiser Foundation Health Plan
Program Offices

Submitted electronically to: *www.regulations.gov*

March 27, 2018

Attention: Conscience NPRM, RIN 0945-ZA03
Office for Civil Rights
Department of Health and Human Services
Room 509F
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Docket No. HHS–OCR–2018–0002*

Dear Sir or Madam:

Kaiser Permanente offers the following comments in response to the proposed rule, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority* (the Proposed Rule) issued in the Federal Register (83 FR 3880) on January 26, 2018, which intends to promulgate regulations to ensure that the Department of Health and Human Services (the Department) funds do not support discriminatory practices or policies.

Kaiser Permanente is the largest private integrated health care delivery system in the United States, delivering health care to nearly 12 million members in eight states and the District of Columbia. Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii (Health Plan); the not-for-profit Kaiser Foundation Hospitals (Hospitals), which operates 39 hospitals and 680 other clinical facilities; and the Permanente Medical Groups (Medical Groups), independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

This Proposed Rule will broadly impact Kaiser Permanente – as a provider of health care, through its Medical Groups, Hospitals and pharmacy system; as a health plan; and as a large employer of approximately 290,000 persons, including 22,100 physicians and 58,000 nurses.

Kaiser Permanente recognizes the importance of protecting the religious or moral beliefs of our workforce. We adhere to strict policies and practices that protect our workforce from religious and moral compromise and related discrimination. However, Kaiser Permanente also recognizes the importance of ensuring our members equitable access to high quality, affordable care. The Proposed Rule fails to acknowledge that conscience objections may conflict with patient rights

One Kaiser Plaza, 27L
Oakland, CA 94612

and professional obligations and fails to suggest or even allow for acceptable practices that balance the rights of the workforce with the needs of patients. A Final Rule should interpret the statutory language to balance the conscience protections of the health care workforce with the needs and rights of patients.

The Proposed Rule is at odds with numerous Department policies that place the patient at the center of health care delivery and focus on measurable quality of care, patient satisfaction, and access. Examples of this can be seen in the Department's strategic goals and movement towards value-based payment that rewards providers for improved patient outcomes and satisfaction. Similarly, the Rule is at odds with numerous state efforts to protect patients and improve their care experience. Additional guidance is needed to understand the intersection of the Proposed Rule with existing federal and state policies.

Kaiser Permanente's greatest concerns with the Proposed Rule are:

- The Department's proposed definitions for "assist in the performance" and "referral or refer" permit providers to withhold not just needed services, but information or referral to another provider or source of information, eliminating options for ensuring patients' access to needed care.
- The Proposed Rule's broad interpretation of the federal statutes appears to create conflicts with other federal and state laws and the Rule provides limited guidance on how to resolve such conflicts.
- The Proposed Rule's broad interpretation of the authorizing statutes creates confusion in several key areas that impact the business operations of physicians, hospitals, pharmacists, laboratories, health plans and others in the health care sector, including the rules governing relationships with employees, contracts with other entities, and systems of compliance. This will lead to significant administrative and financial burdens for health care businesses that will further strain health care resources.

Our detailed recommendations for clarifying or modifying the Proposed Rule follow.

Section 88.2. Definitions

Issue:
The Proposed Rule creates sweeping definitions for statutory terms that broaden the reach of those statutes and diminish health care entities' ability to ensure that the needs and rights of patients are met without compromising the moral or religious beliefs of the workforce. Additionally, several vague definitions create operational difficulties for health care entities required to comply with the regulations.

Recommendations:
Assist in the Performance. The Department would define "assist in the performance" to include participation "in any program or activity with an articulable connection to a procedure, health service, health program, or research activity." This includes but is not limited to "counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity." The definition encompasses an inappropriately broad scope of activities in

using the open-ended "articulable connection." The Proposed Rule provides examples of an "articulable connection" – counseling, referral, training, and other arrangements – but these examples only broaden the scope of the definition and create additional ambiguity.

Defining "assist in the performance" to include counseling and referral could conflict with physicians,' hospitals' and health plans' obligations and regulatory requirements to provide patients access to health care services and could potentially endanger patient health and safety in certain circumstances. For example, this definition would allow a provider with religious or moral objections to blood transfusions to refuse to offer that treatment to a patient with a life-threatening condition and fail to refer the patient to a provider who does not have an objection. As another example, the Proposed Rule would allow a provider with religious or moral objections to refuse to vaccinate a newborn or provide parents with information about recommended childhood vaccinations. Both situations could lead to immediate and irreparable harm to patients.

The Department should replace the open-ended "articulable connection" with language that directly connects the assistance to the objectionable procedure or service and limit it to the clinical setting. This definition should include a complete, not illustrative, description of the activities subject to the rule (i.e., providing, training, or ordering a procedure) and should not include counseling or referral.

Referral or Refer for. The Proposed Rule defines "referral or refer for" to include "the provision of any information… by any method…pertaining to a health care service, activity, or procedure..."[1] This definition would create an overly broad scope by allowing a single individual interacting with a patient to block access to information about medically necessary care. This definition would conflict with health care providers' legal and professional ethical obligations to refer patients who need medically necessary services.

This definition also eliminates an effective process for health care entities, particularly entities like Kaiser Permanente that use an integrated model of care, to protect the religious rights of our workforce. Referral allows providers to refrain from performing or assisting in the performance of an activity, while allowing organizations like ours to meet our legal obligations to provide access to services and treatment guaranteed under contract and frequently mandated under state law. The proposed language creates a dichotomy in which a health plan may be obligated to provide or arrange for a covered service but be unable to do so if a provider has a religious or moral objection to performing or referring for that service. The Department should permit and encourage providers to refer or otherwise arrange for patient care if they cannot provide it themselves due to religious or moral objections. In a Final Rule that includes "referral," we suggest narrowing the definition of "referral" to active facilitation of access.

Discriminate or Discrimination. The Proposed Rule's definition of "Discriminate or Discrimination" is also overly broad and creates operational challenges for employers. The definition appears to preclude an employer from denying employment to an applicant who objects on moral or religious grounds to performing the primary job responsibilities, even where no reasonable accommodation exists and the applicant's inability to perform the responsibilities

[1] 83 FR 3924

would disrupt business operations. Similarly, if a current employee expresses an objection to performing primary job responsibilities on religious grounds, removing the employee from the position and reassigning them to a comparable position could run afoul of the Rule.

Federal Financial Assistance. The Proposed Rule defines "Federal Financial Assistance" to include "[a]ny Federal agreement, arrangement, or other contract that has as one of its purposes the provision of assistance."[2] The inclusion of any "arrangement" and the "provision of assistance" make this particularly challenging for business entities that provide health care and coverage to interpret. The Final Rule's definition of "Federal Financial Assistance" should not include the ill-defined category "arrangement" and should clarify whether this definition includes any claim for payment, payments in exchange for health care services, or applications to participate in a federal program through which payment would be made.

Health Care Entity. The Proposed Rule states that the definition of "health care entity" includes health care professionals and health care personnel, among other categories. The Department should specifically define "health care professional" or "health care personnel" in the definition of "health care entity." Health care businesses should know specifically which employees are included under this definition.

Sub-Recipient. The definition for "Sub-Recipient" is overly broad and has the potential to bring into scope individuals and entities that indirectly receive any amount of federal financial assistance. Administrative and operational costs to health care businesses to identify subrecipients and to track their compliance with the Proposed Rule would be significant. The Final Rule should specifically limit sub-recipients to those for whom there is a direct pass-through of federal financial assistance and who are identified as sub-recipients of such dollars in contracts with the direct recipient. This definition should not subsume every contracting party of a recipient of federal financial assistance.

Workforce. The Proposed Rule includes "volunteers" and "contractors" in the definition of "workforce." The Department should modify this definition to include only volunteers or contractors performing or assisting the performance of health care activities. If the Rule maintains a broader definition of "volunteers" and "contractors," it should clarify the statutory basis to support the decision to use such a broad definition.

Religious or Moral Objections. The Final Rule should define "Religious or Moral Objections" and thereby clarify the group of individuals who can object to performing or assisting in the performance of services. The Final Rule should adopt similar definitions of these terms as provided in the employment and First Amendment context when religious accommodations and protections are sought.

[2] 83 FR 3924

Requirements for Conscience Objections

Issue:
The Proposed Rule does not provide guidance about the processes that should be in place to enable a health care provider to raise a conscience objection, making it more challenging for health care businesses to ensure quality and patient satisfaction.

Recommendations:
The Proposed Rule fails to create an obligation for the objecting provider or employee to notify, in advance or otherwise, the employer of what services they object to providing. Without a duty to inform employers, an individual could be hired into and remain in a job he or she cannot fully perform. There are no guardrails that enable employers to take advance steps to ensure patients get the care they need. Likewise, there are no guardrails to ensure that employers are informed at the time when patients do not receive medically necessary services or information about those services. Particularly in an emergency, notice is critically important to patient safety.

Without appropriate notification requirements, the Rule will introduce inconsistencies in the quality of care patients receive, as it would depend on their providers' religious and moral beliefs. This limits health care entities' ability to ensure high-value coordinated care, patient safety and patient satisfaction and is inconsistent with numerous other Department policies.

The Final Rule should establish processes that an individual should follow when raising a conscience objection. Health care workers with a religious or moral objection to performing a service should have a duty to notify their employer or putative employer so that reasonable accommodations can be considered to respect the workers' beliefs, as well as the needs and rights of the patient. Under current law, employees are required to provide notice and request accommodation of disabilities and religious beliefs. The Final Rule should specify how a provider should exercise a conscience objection if an individual is in an emergency and in need of health care services.

Section 88.4 Assurance and Certification

Issue:
The Proposed Rule conditions the continued receipt of Federal financial assistance or Federal funds on an assurance and certification. Payment conditioned on assurance and certification goes beyond the intent of the underlying statutes. The broad enforcement remedies allow the Office for Civil Rights to choose an appropriate and effective means of enforcement, which is sufficient to increase awareness of and compliance with the requirements of the regulation. As drafted, the proposed Rule could result in health care entities being subject to both civil litigation and regulatory action.

Recommendations:
Section 88.4 of the Proposed Rule describes, as a condition of receipt of Federal financial assistance or Federal funds, the requirement that applicants or recipients provide written assurance and certification of compliance with federal conscience laws. The Department has stated that certifications "provide a demonstrable way of ensuring that applicants for such funding

know of, and attest that they will comply with, applicable Federal health care conscience and associated anti-discrimination laws" and that assurances and certifications "would provide an important vehicle for increasing awareness of [those] laws and thereby increas[e] compliance."[3]

Tying certification to payment is not necessary to accomplish the Department's stated goals, which can be met through the submission process for the proposed attestations and certifications themselves. Payment conditioned on certification is additionally unnecessary given the broad remedies proposed in Section 88.7 (Enforcement). Section 88.7 delegates to the Office for Civil Rights the authority to enforce the federal conscience laws, including handling complaints, conducting investigations, referring to the Department of Justice, and "tak[ing] other appropriate remedial action as the Director of OCR deems necessary and as allowed by law…."[4] The Proposed Rule also grants the Office for Civil Rights the authority to temporarily withhold cash payments, deny and/or terminate use of federal monies, refer matters to the Attorney General, and "tak[e] any other remedies that may be legally available."[5] The proposed remedies allow the Office for Civil Rights to choose an appropriate means of enforcement, bounded by law and the intent of the underlying statutes.

In contrast, requiring that certification be tied to payment does not effectuate the intent of the underlying statutes, and potentially provides an avenue for third party litigation outside of the Office for Civil Rights' purview. Under the Proposed Rule, a health care entity could be found to have violated the assurance and certification requirement, potentially subjecting it to two separate processes: one pursued by the Office for Civil Rights and civil litigation filed and pursued by a *qui tam* plaintiff. A health care entity would be required to defend against the litigation regardless of whether the Office for Civil Rights found an assurance and certification violation or otherwise pursued a remedy against the entity.

The Final Rule should not include an assurance or certification requirement tied to payment.

Section 88.5 Notice

Issue:
The notice requirements of the Proposed Rule will be administratively and financially burdensome to health care entities. The notice text in Appendix A may be misleading.

Recommendations:
The Proposed Rule requires the Department and all recipients to post the notice text in Appendix A within 90 days of the publication of the Final Rule on websites and in conspicuous physical locations.

Kaiser Permanente's experience with ACA Section 1557 Nondiscrimination and Language Assistance Notices (1557 Notices) leads us to believe that the notice requirements will create significant administrative and financial burdens on health care entities and that the Proposed Rule underestimates that burden. Various regulators required the publication of multiple versions

[3] 83 FR 3896
[4] Section 88.7(a)
[5] Section 88.7(j)

of the 1557 Notices with variations in content. The Department's recommended 1557 content for commercial plans differed from that required by the Centers for Medicare and Medicaid Services' for Medicare and/or Medicaid plans, and that required by state regulators based on state code requirements for nondiscrimination disclosures. For an integrated health system operating in eight states and the District of Columbia, this resulted in approximately 20 different versions of the 1557 Notices and an unexpected and ongoing operational impact to manage numerous versions of notices used with different types of documents based on line of business, region of operation, and medium. The varying requirements of both federal and state agencies created confusion and uncertainty. Without clarifying the notice requirements, we anticipate health care businesses and government agencies spending considerable time and resources responding to employees' inquiries.

We do not believe the notice requirements in the Proposed Rule will be any less burdensome. As written, the rule requires use of the exact text in Appendix A and claims that this approach maximizes efficiency and economies of scale, but the Department also authored ACA Section 1557 notices and the benefits were not realized due to the variations in regulatory guidance.

The Final Rule should reduce the burden on health care businesses by seeking ways to streamline notice requirements. The Department should coordinate with other federal and state agencies to align on the content of the Notice in the Final Rule's Appendix A. Additionally, the notice language in Appendix A may be overbroad in stating that "you" may decline to "refer for" or "pay for" "certain health care-related treatments, research, or services." Not all individuals have the right, in all circumstances, to refuse to refer for or pay for treatments. The text of the Notice in the Final Rule's Appendix A should be adjusted to more accurately reflect the scope and coverage of individual rights.

Section 88.6 Compliance

Issue:
If the Proposed Rule is adopted, health care entities will require additional guidance for implementing or modifying organizational compliance policies.

Recommendations:
The Proposed Rule states that recipients and sub-recipients must maintain records evidencing compliance. The Department should delineate what records must be retained and how an entity affirmatively demonstrates compliance or this provision should be deleted.

The Proposed Rule requires recipients and sub-recipients to inform Departmental funding components if they are subject to an Office for Civil Rights compliance review, investigation, or complaint related to a religious or moral objection. The Proposed Rule does not describe the process through which covered entities would inform Departmental Components. Health care businesses would benefit from more detail on these requirements and some limitations. Since large organizations may receive federal financial assistance from many different sources and for many different purposes, it is far too sweeping to require that recipients notify funding sources of any investigation into compliance.

Reporting should only be required when an investigation relates to alleged non-compliance during activities conducted with the federal funding provided by the funding component. The Final Rule should require federal agencies to communicate and not to place the burden on investigated entities to inform all agencies from which they obtain funding.

The Proposed Rule requires recipients and sub-recipients to disclose, with any application for new or renewed Federal financial assistance or Departmental funding, the existence of compliance reviews, investigation, and complaints filed with the Office for Civil Rights for five years from such complaints' filing. Given that recipients are subject to enforcement actions due to violations of sub-recipients, clarification is needed on whether recipients must disclose the compliance reviews, investigations, and complaints filed on sub-recipients. The Final Rule should exempt unsubstantiated complaints from the five-year retrospective reporting obligation on applications, since they are not relevant to a consideration of an entity's eligibility for funding.

Under the Proposed Rule, funding restrictions may be imposed on recipients if their sub-recipients are non-compliant. It is excessive for recipients to lose funds because one of their sub-recipients engaged in prohibited actions. At a minimum, this should be discretionary based upon the degree of fault or non-compliance by the recipient. Additionally, the only funding that should be at risk is the funding that the primary recipient received for the project or business relationship undertaken with the sub-recipient.

The Proposed Rule creates risks for recipients related to the behavior of sub-recipients, but does not account for the limited influence a recipient may have over sub-recipients regarding compliance. To the extent the Proposed Rule encourages recipients to control the compliance activities of its sub-recipients, the Propose Rule may potentially expose recipients to joint employer liability under other federal or state labor and employment laws. The guidelines should instead address how recipients may establish processes, including contractual representations and warranties, that can be used to support sub-recipient compliance and provide information to recipients to ensure sub-recipient compliance, including disclosure of any Office for Civil Rights compliance reviews, investigations, and complaints.

The Final Rule should contain guidelines for compliance and a more thorough discussion of how the complaint system and enforcement of these nondiscrimination regulations will operate. The Rule should model guidelines after the policies and procedures in current federal and state employment discrimination laws and regulations. The guidelines should specify who in the Department should be informed of compliance reviews, investigations, or complaints, at what frequency and what information the Department wishes to receive.

Section 88.7 Enforcement

Issue:
The section of the Proposed Rule authorizing the Office for Civil Rights to enforce the Rule, inappropriately expands the class of persons who can bring complaints against health care entities.

Recommendations:

Pursuant to the Proposed Rule, anyone may file a complaint with the Office for Civil Rights, not only the person or entity whose rights have been potentially violated. The Department specifies "[t]he complaint filer is not required to be the person, entity, or health care entity whose rights under the Federal health care conscience and associated anti-discrimination laws or this part have been potentially violated."[6] Similarly, the Preamble states, "[u]nder the proposed rule, OCR would also be explicitly authorized to investigate 'whistleblower' complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by conscience and associated anti-discrimination laws."[7]

As noted above, the Office for Civil Rights has various remedies, including withholding, denying, suspending payments, awards, and Federal financial assistance, and referral to the Department of Justice. The remedies can be triggered "when there appears to be a failure" or even a "threatened" failure to comply with the underlying laws or the proposed regulation.

The Final Rule should limit those who can file a complaint to those who have suffered harm, as defined by the Rule and the statutes from which the Rule gains its authority. The Final Rule should eliminate the references to the apparent and "threatened" failures to comply with the law and reserve the remedies for those who have failed to comply.

Section 88.8 Relationship to Other Laws

Issue:
The Proposed Rule's broad interpretation of the federal statutes from which it derives its authority may create conflicts with other federal and state laws:

- Title VII of the Civil Rights Act of 1964 and other applicable federal and state laws authorize employers to engage in the interactive process with an employee to explore whether the employee's religious practices can be reasonably accommodated without incurring an undue hardship. Under Title VII, there may be instances in which a health care entity is unable to accommodate the employee's refusal to perform, or assist in performing, a health care activity because the accommodation is not reasonable or would pose an undue hardship.

- 42 U.S.C. 5106i(b) requires states to permit child protective services to pursue legal remedies to provide treatment to children whose parents have objected to treatment on religious grounds in certain circumstances. The Proposed Rule interprets 29 U.S.C. 290bb-36(f) as prohibiting requiring a parent or legal guardian to provide a child any medical service or treatment against their religious beliefs or moral objections. Under the Rule, States are neither required to find nor prohibited from finding child abuse or neglect in cases in which parents or legal guardians rely solely or partially on spiritual means rather than medical treatment.

[6] 88.7(b)
[7] 83 F.R. 3898

- Federal and state laws mandate coverage for certain care and treatment. For example, providers who accept Medicare Part A and/or Medicaid must provide transgender individuals equal access to facilities and services and must treat transgender individuals consistent with their gender identity.[8] A provider may assert a religious or moral objection and deny services to transgender individuals in violation of those patients' rights.

- Public health law authorizes federal agencies to establish communicable disease control policies that may impose requirements on providers related to services, counseling or reporting.[9]

- State laws require pharmacists to fill any legal prescription, even those to which he or she has a moral or religious objection.[10]

- State laws may require that patients receive notice about providers or hospitals that do not cover certain services.[11]

- Existing state laws address the following issues: Advanced directives; abortion, sterilization, and contraception; physician assisted suicide; newborn hearing screening; vaccinations and immunizations; privacy; sexual orientation; and transgender care.

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[8] 45 C.F.R. § 92.206 (stating that healthcare services and health coverage may not be denied because a person's gender identity differs from his/her sex assigned at birth. Providers may not limit a transgender person's access to services ordinarily available to people of only one sex based on the transgender person's sex assigned at birth or gender identity).

[9] 42 U.S.C. § 264. The Public Health Services Act authorizes the Secretary of Health and Human Services to make and enforce regulations necessary "to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."

[10] Recent state laws and proposed legislation have addressed pharmacists' rights and responsibilities in dispensing contraception/emergency contraception. Some states would allow pharmacists to refuse, on moral grounds, to fill a prescription for contraceptives; other states would require pharmacists to fill any legal prescription for birth control. *See* http://www.ncsl.org/programs/health/conscienceclauses.htm

[11] *See* California Health & Safety Code 1363.02 (a) The Legislature finds and declares that the right of every patient to receive basic health information necessary to give full and informed consent is a fundamental tenet of good health policy and has long been the established law of this state. Some hospitals and other providers do not provide a full range of reproductive health services and may prohibit or otherwise not provide sterilization, infertility treatments, abortion, or contraceptive services, including emergency contraception. It is the intent of the Legislature that every patient be given full and complete information about the health care services available to allow patients to make well informed health care decisions.

(b) On or before July 1, 2001, a health care service plan that covers hospital, medical, and surgical benefits shall do both of the following:

(1) Include the following statement, in at least 12-point boldface type, at the beginning of each provider directory:

"Some hospitals and other providers do not provide one or more of the following services that may be covered under your plan contract and that you or your family member might need: family planning; contraceptive services, including emergency contraception; sterilization, including tubal ligation at the time of labor and delivery; infertility treatments; or abortion. You should obtain more information before you enroll. Call your prospective doctor, medical group, independent practice association, or clinic, or call the health plan at (insert the health plan's membership services number or other appropriate number that individuals can call for assistance) to ensure that you can obtain the health care services that you need."

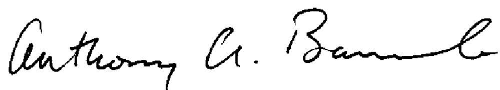
<u>Recommendations</u>:
The Final Rule should contain guidelines and a more thorough discussion of how the provider conscience regulations will intersect with federal and state laws and discuss how situations will be evaluated when there is a federal or state law that is contrary to the provider conscience regulations. Section 88.8, governing the Proposed Rule's relationship to other laws, clarifies that the Rule is not intended to preempt any Federal, State or local law equally protective of religious freedom and moral convictions. It is not clear how it will be determined whether state laws are, in fact, "equally protective." Clarification is needed whether the Department will defer to state and local regulatory interpretation of whether their laws are equally protective of religious freedom and moral convictions.

The preemption standard seems to create the undesirable consequence of preempting state laws that are protective of patients when those protections conflict with the religious freedom and moral convictions of the health care workforce. The Department should discuss how provider conscience objections can be exercised without taking away the ability of states to regulate areas that are traditionally the subject of state jurisdiction.

The Final Rule should clarify how a health care entity should respond to an employee's refusal to participate or assist in participating in a health service in circumstances addressed by an applicable collective bargaining agreement. Where a health care entity has reached a bargained agreement with a union that addresses how to respond to a represented employee's objection to participating in a medical procedure, the Proposed Rule does not clarify whether that bargained agreement can continue to be enforced.

We appreciate the opportunity to comment on these important issues. Please contact Leah Newkirk at (510) 271-5938 or leah.g.newkirk@kp.org with any questions.

Sincerely,



Anthony Barrueta
Senior Vice President
Government Relations
Kaiser Permanente

Stephen M. Parodi, MD
Associate Executive Director
The Permanente Medical Group
Executive Vice President, External Affairs
The Permanente Federation LLC

Exhibit 7

BlueCross BlueShield Association

An Association of Independent
Blue Cross and Blue Shield Plans

March 27, 2018

The Honorable Roger Severino
Director
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945–ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: Protecting Statutory Conscience Rights in Health Care Proposed Rule, RIN 0945–ZA03

Dear Director Severino:

The Blue Cross Blue Shield Association ("BCBSA") appreciates the opportunity to provide comments on the proposed rule, Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. 3880 (January 26, 2018; "Proposed Rule").

BCBSA is a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield Plans ("Plans") that collectively provide healthcare coverage for one in three Americans. For more than 80 years, Blue Cross and Blue Shield companies have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare, and Medicaid.

Blue Cross and Blue Shield Plans support federal nondiscrimination laws and have operated in compliance with those laws. However, we are concerned that the Proposed Rule will create significant unwarranted economic and regulatory burdens on Plans and other health insurance issuers and group health plans that are far removed from the actual performance of health care services. The Preamble's examples of situations in which discrimination could occur do not involve health insurance issuers, but focus on health care providers. Therefore, we suggest clarifications in the Proposed Rule to alleviate unnecessary burdens for Blue Cross Blue Shield Plans.

Recommendations

Our recommendations are as follows:

- **Scope:** The final rule should limit any obligations and duties under the Weldon Amendment to the governmental entities included in the Weldon Amendment and not

extend these obligations and duties to health insurance issuers and health plans which do not have any duties or obligations under the statute.

- **"Assist in the Performance:"** The final rule should eliminate the complex, expansive proposed definition of "assist in the performance." If this definition is retained, the final rule should use the term "reasonable," which was used in the 2008 Final Rule instead of the word "articulable" in the definition of "assist in the performance."

- **"Referral:"** The definition of "referral" should be narrowed to only include referral by health care providers or their employees, and the final rule should include a specific exemption for health insurance issuer employees performing administrative functions such as answering questions from covered individuals or processing claims.

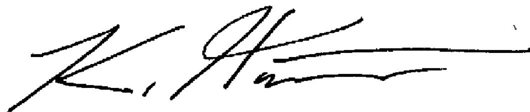
- **Written Assurance and Certification:** The requirement for written assurances should be eliminated and the final rule should only require a single annual certification.

- **Notice:** The final rule should eliminate the notice requirement for health insurance issuers and group health plans. If health insurance issuers are required to provide notice, the final rule should only require notice to an issuer's workforce, not the public.

- **Effective Date:** The final rule should not be effective prior to January 1, 2019, with the requirement for notices being effective January 1, 2020.

We appreciate your consideration of our comments and we look forward to working with you on implementation of conscience protections provided by federal statutes. If you have any questions or want additional information, please contact Richard White at Richard.White@bcbsa.com or 202.626.8613.

Sincerely,



Kris Haltmeyer
Vice President
Legislative and Regulatory Policy
Blue Cross Blue Shield Association

* * *

BCBSA DETAILED COMMENTS ON PROTECTING STATUTORY CONSCIENCE RIGHTS IN HEALTH CARE PROPOSED RULE

I. Application of Weldon Amendment to Health Insurance Issuers and Health Plans (Proposed §§ 88.2, 88.3)

Issue:

The Proposed Rule would extend the nondiscrimination requirements applicable to governmental entities under the Weldon Amendment to private entities.

Recommendation:

Revise the rule to limit any obligations and duties under the Weldon Amendment to the governmental entities included in the Weldon Amendment and do not extend it to health insurance issuers and health plans which do not have any duties or obligations under the statute.

Rationale:

The Weldon Amendment, by its terms, prohibits a "Federal agency or program, [or]…a State or local government" from discriminating against a health care entity that does not provide, pay for, provide coverage of, or refer for abortions. Weldon Amendment, Consolidated Appropriations Act, 2009, Pub. L. No. 111-117, 123 Stat 3034, section 508. The Amendment defines the term "health care entity" to "include[] an individual physician or other 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." Section 508(d)(2). Thus, under Weldon, a federal agency or program, or a state or local government, cannot receive funding from an act to which Weldon is attached, if the agency, program or government discriminates against health care entities that refuse to provide, pay for or refer for abortions.

The Proposed Rule interprets the statutory definition of "health care entity" to include health insurance issuers and health plans, including the sponsors of health plans. 83 Fed. Reg. 3880, 3890. The Weldon Amendment clearly protects, among others, HMOs and health insurance issuers from discrimination by agencies, programs, or governments that receive funding from an Act to which the Weldon Amendment is attached.

However, the Weldon Amendment does not impose any duties or obligations on HMOs, health insurance issuers, or group health plans. They are protected by the Weldon Amendment, but they are not regulated by the Weldon Amendment. OCR should revise the rule to make clear that the only entities that are subject to duties, requirements, or obligations as the result of the Weldon Amendment are governmental agencies and programs that are funded by an act that includes the Weldon Amendment.

II. Application of the "Assist in the Performance" Provision (Proposed § 88.2)

Issue:

The "assist in the performance" provision is limited to the Church Amendments, but the Proposed Rule creates a complex definition expanding this provision beyond the text of the Church Amendments.

Recommendation:

Eliminate the complex, expansive definition of "assist in the performance" or limit the definition to health care providers and researchers.

Rationale:

The term "assist in the performance" is used in the text of the Church Amendments. The Church Amendments are one section in the "Population Research and Voluntary Family Planning Programs" subchapter of the Public Health Service Act. The surrounding subchapters describe various grants and contracts available for family planning services organizations.

In this context – population research and voluntary family planning – the Church Amendments specifically and explicitly protect health care providers and researchers from discrimination based on their refusal to provide sterilization or abortion services because of religious beliefs and moral convictions. For example, the Church Amendments refer to performing or assisting in performing abortions, 42 U.S.C. § 300a-7(b)(1), requiring entities to make facilities or personnel available to perform sterilization or abortions, *id.* at (b)(2), discrimination against physicians and other health care personnel who refuse to perform sterilization or abortion, *id.* at (c). Subsections (b) and (c) apply to the direct provision of medical services or medical research.

It follows, then, that the reference to "individual" in paragraph (d) – which says that no individual shall be "required to perform" or "assist in the performance" if the performance or assistance would be contrary to the individual's religious beliefs or moral convictions – refers to the same individuals that Congress referred to in (b) and (c) – physicians, health care personnel, and others (including non-medical personnel) who directly provide health care services related to voluntary family planning programs or perform population research. "Individual", in this context, cannot extend to include every individual that works for an entity that receives federal funds from HHS. "The definition of words in isolation…is not necessarily controlling in statutory construction. A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute." *Dolan v. U.S. Postal Serv.,* 546 U.S. 481, 486 (2006). Here, the purposes and context of the statute is to regulate population research and voluntary family planning programs, not commercial health insurance or group health plans..

In contrast, the Proposed Rule provides, in relevant part, that:

> Any entity that carries out any part of any health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services is required to comply with paragraph (a)(2)(vi) of this section and §§ 88.4, 88.5, and 88.6 of this part.

Proposed § 88.3(a)(v). And the Proposed Rule defines "health service program" to "include[] any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and is funded, in whole or part, by the Department. It may also include components of State or local programs." Proposed § 88.2.

While the Church Amendments do not define "health service program," the context clearly suggests that the Church Amendments are concerned with protecting population researchers and family planning providers – *e.g.,* physicians – who refuse to perform "certain health care procedures" from discrimination by entities that receive funds from HHS administered programs, Proposed Rule, Preamble, 83 Fed. Reg. 3880, 3882, as well as medical researchers. *Jarecki v. G. D. Searle & Co.,* 367 U.S. 303, 307, 81 S. Ct. 1579, 1582, 6 L. Ed. 2d 859 (1961) ("'Discovery' is a word usable in many contexts and with various shades of meaning. Here, however, it does not stand alone, but gathers meaning from the words around it. These words strongly suggest that a precise and narrow application was intended in [section] 456.") The Proposed Rule goes much further however, applying the Church Amendments far beyond health care providers and researchers and as written could be read to apply to employees of commercial health insurance issuers and health plans that have no connection with the context of the amendment.

Because the Church Amendments protect voluntary family planning health care providers and population researchers, there is no need to for the rule to define "assist in the performance" to have an "articulable connection;" the Church Amendments are clear that the provider and researcher do not have to "perform" or "assist" in the provision of a sterilization or abortion. They do not have to have an "articulable connection" – they may simply refuse to perform or assist in the performance of the sterilization, abortion, or medical research. "Assist in the performance" only needs a complex and expansive definition because OCR has mistakenly extended it beyond the statutory text. If OCR includes a definition it should be limited to health care providers and researchers.

Further, including health insurance issuers within the "assist in the performance" provision violates Executive Orders requiring reduction of regulatory burdens. Exec. Order No. 13765, relating to minimizing the economic burdens of the ACA, requires the heads of all executive departments and agencies with responsibilities under the ACA to "…minimize the unwarranted economic and regulatory burdens of the [ACA]…." 82 Fed. Reg. 8351 (January 24, 2017). This approach was echoed in a subsequent Executive Order stating that "…it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations." Exec. Order No. 13771, 82 Fed. Reg. 9339 (February 3, 2017).

III. Definition of "Assist in the Performance" Under the Church Amendments (Proposed § 88.2)

Issue:

The Proposed Rule uses the term "articulable connection," which is so broad that it appears to have no bounds. This is much more expansive than the 2008 Final Rule's use of the term "reasonable connection" and expands the reach of the rule far beyond the rights protected by statute. The change in this one word has significant implications for health insurance issuers, which do not actually have staff that perform or assist in the performance of procedures or services covered by the statute.

Recommendation:

The final rule should use the term "reasonable" which was used in the 2008 Final Rule instead of the word "articulable" in the definition of "assist in the performance," and thus should read:

> "Assist in the Performance" means "to participate in any activity with a **reasonable** connection to a procedure, health service or health service program, or research activity, but does not include providing information, assisting with claims or premiums, or addressing any questions under the terms of an applicable group health plan or health insurance policy."

Rationale:

The Preamble to the Proposed Rule states:

> The Department proposes that "assist in the performance" means "to participate in any activity with an articulable connection to a procedure, health service or health service program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes counseling, referral, training, and other arrangements for the procedure, health service, or research activity." *This definition mirrors the definition used for this term in the 2008 Rule.*

83 Fed. Reg. 3880, 3892 (January 26, 2018) (emphasis added).

Unfortunately, the Proposed Rule does not "mirror" the 2008 Final Rule, which used the term "reasonable connection." 45 C.F.R. § 88.2, effective January 1, 2009 ("Assist in the Performance means to participate in any activity with a reasonable connection to a procedure, health service or health service program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes counseling, referral, training, and other arrangements for the procedure, health service, or research activity.") As HHS explained at that time,

> As a policy matter, the Department believes that limiting the definition of the statutory term "assist in the performance" only to those activities that constitute direct involvement with a procedure, health service, or research activity, falls

> short of implementing the protections Congress intended under federal law. *However, we recognized the potential for abuse if the term* ***was unlimited****. Accordingly, we proposed – and here finalize – a definition of "assist in the performance" that is limited to "any activity with a reasonable connection to a procedure, health service or health service program, or research activity."*

73 Fed. Reg. 78072, 78075 (December 19, 2008) (emphasis added).

The Department further explained:

> …the Department *sought to guard against potential abuses of these protections* by limiting the definition of "assist in the performance" to only those individuals who have a reasonable connection to the *procedure, health service or health service program, or research activity* to which they object.

73 Fed. Reg. 78072, 78090 (December 19, 2008) (emphasis added).

While we understand that OCR may want to include a definition of "assist in the performance" in the final rule because that definition was completely removed from the rule in 2011 (76 Fed. Reg. 9968, February 23, 2011), introducing the new term "articulable" as opposed to reverting to the term "reasonable" used in the 2008 Final Rule introduces a definition that is in effect **unlimited** and that the 2008 Final Rule recognized as having the potential for abuse. If the term "articulable" were used, issuers would have to implement changes to their operations contemplating the most extreme connection that an employee could articulate, no matter how unreasonable it may be.

For example, "participate in any activity with an articulable connection to" could potentially be read to allow a health insurance issuer's claims processor to refuse to process a claim for a procedure to which they have a conscience objection even though the procedure has already been performed. How is this "assisting in the performance" although an individual could articulate that they felt it was and that they had a conscience objection to participating? Taking this example further, would a member inquiry to a customer service representative as to or whether a claim for sterilization has been received, paid, or how to appeal a decision made by the issuer regarding sterilization be subject to a valid objection by the customer service representative? As noted above, we do not believe that employees of a health insurance issuer who are performing administrative functions were within the scope of what Congress intended when it passed the various conscience protection laws; however, the use of the term "articulable connection," because it has minimal (if any) limitations, would require issuers to prepare for the most unreasonable claims of discrimination by their employees.

We believe that using the term "reasonable connection" and limiting the scope of "assist in the performance" to actual medical procedures and the arrangements for such procedures (including referrals and counseling) is more in line with the scope of the statutory protections, as well as the intent of the 2008 Final Rule. In the Preamble to the 2018 Proposed Rule, the Department noted that

> In interpreting the term "assist in the performance," the Department seeks to provide broad protection for individuals, consistent with the plain meaning of the

> statutes. The Department believes that a more narrow definition of the statutory term "assist in the performance," such as a definition restricted to those activities that constitute direct involvement with a procedure, health service, or research activity, would fall short of implementing the protections Congress provided. But the Department acknowledges that the rights in the statutes are not unlimited, and it proposes to limit the definition of "assist in the performance" to activities with an articulable connection to the procedure, health service, health service program, or research activity in question.

83 Fed. Reg. 3880, 3892.

Recognizing the limits of the statutory protections at issue is not new. For example, in the 2008 Final Rule, the Department recognized that "[t]hese statutory provisions protect the rights of health care entities/entities, both individuals and institutions, *to refuse to perform* health care services and research activities to which they may object for religious, moral, ethical, or other reasons." 45 C.F.R. § 88.1 (emphasis added). The primary focus of the protection is the physical health care service (*i.e.,* medical procedure or research) and not an explanation of the coverage terms of a health insurance policy.

In addition, the comments on the 2008 rule reveal the abuses intended to be addressed by limiting "assist in the performance" to only those individuals who have a "reasonable connection" to the procedure, health service or health service program, or research activity to which they object. For example, one commenter stated that:

> There may be a fine line between a moral conviction that can be accommodated in refusal of care and the harboring of a prejudice. The [2008 proposed rule] invites abuses and prejudicial implementation. It shifts the defining quality of conscience refusal onto a subjective self determined "ethic" and away from or untethered to listed procedures such as those a neutral third party like Congress explicitly enacted Title X of the Public Health Service Act to address.

(Footnotes omitted). The Proposed Rule disregards this type of abuse by using the term "articulable." While the Preamble states the statutory rights named in the Proposed Rule "are not unlimited," 83 Fed. Reg. 3880, 3892, OCR's attempt to impose some limit through its "articulable connection" language in Proposed § 88.2 is unavailing and does not seem to impose any limit at all.

If OCR does not use "reasonable connection" instead of "articulable connection," OCR should provide examples of situations where there is no "articulable connection" between the religious beliefs of a health insurance issuer employee and health care services. For example, if an issuer employee refuses to participate in processing a claim for sterilization due to the employee's religious beliefs, is that an "articulable connection" that would allow that single employee to in effect deny an otherwise covered claim?

As noted above, "articulable connection" is far broader than "reasonable connection." It is possible to articulate an unreasonable connection; it seems less likely that a reasonable connection is inarticulable. Therefore, OCR should define "assist in the performance" as a "reasonable connection" to a procedure, health service or health service program, or research

activity, but does not include providing information, assisting with claims or premiums, or addressing any questions under the terms of an applicable group health plan or health insurance policy.

IV. "Referral" Included in "Assist in the Performance" (Proposed § 88.2)

Issue:

"Referral" as used in the "assist in the performance" definition is very broad and may affect the ability of health insurance issuers to deliver customer service to their members. In some cases, this could impact the ability of these members to obtain information as to coverage of their insurance benefits or coverage for the actual services, thus potentially impacting members' health as well as potentially putting insurers at risk of violating state and federal laws.

Recommendation:

The definition of "referral" should be narrowed to only include referral by health care providers or their employees and the final rule should include a specific exemption for health insurance issuer employees performing administrative functions such as answering questions from covered individuals or processing claims.

Rationale:

The definition of "referral" in the Proposed Rule is very broad and includes

> …the provision of any information…pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral.

83 Fed. Reg. 3880, 3924.

The term "referral" or "refer for" is referenced in the Weldon Amendment, and as noted above (Part I), the Weldon Amendment protects health insurance issuers and group health plans (as well as providers) from discrimination by a governmental entity, and imposes no obligation on the protected entities. To the extent health insurance issuers and group health plans are protected under the Weldon Amendment, the rule should apply only to health insurance issuers and group health plans as protected entities, but not to their employees. As such, the definitions in the rule should be written in such a way as to limit their use to the appropriate statute and intent of the underlying statute, and not sweep other classes of individuals into the broad requirements and protections under the rule.

The Weldon Amendment prohibits governmental agencies that receive federal funds, like HHS and states that receive Medicaid funding from HHS, from discriminating against a health care entity that does not provide, pay for, provide coverage of, or refer for abortions. Weldon Amendment, Consolidated Appropriations Act, 2009, Pub. L. No. 111-117, 123 Stat 3034, section 508. A governmental agency that discriminates against a health care entity for its failure to provide, pay for, or refer for abortions will lose the federal funds provided under an Act that includes the Weldon Amendment (the funds will not be "available" to the discriminating agency). Application of "referral" or "refer for" beyond these statutory requirements is inappropriate.

The reason for restricting "referral" or "refer for" to their statutory meaning is that a broader definition may affect the care of health insurance issuer members. The proposed definition of "referral" or "refer for" may allow health insurance issuer employees to simply refuse to provide information, for example, in response to questions about claims, benefits, or other administrative matters, including also not *referring* (*i.e.,* transferring) the member to another employee who can answer those questions. This will leave members uncertain about how to pursue their health care and could affect their care.

This places health insurance issuers in a difficult position. They have an obligation to honor their contracts for coverage and respond to member inquiries. Failure to comply may result in regulatory sanctions by state or federal regulators (or both) as well as private litigation for damages. On the other hand, an issuer requiring an employee to provide information to members due to an "articulable connection" between an employee's religious beliefs and the health care services sought by the member may also expose the issuer to regulatory sanctions and litigation for damages.

The final rule should avoid these multiple and inconsistent obligations by narrowing the definition of "referral" to only include referral by health care providers or their employees and include a specific exemption for health insurance issuer employees performing administrative functions such as answering questions from covered individuals related to benefits or claims.

V. Written Assurance and Certification (Proposed § 88.4)

Issue:

The requirements for written assurances and certification are unnecessarily duplicative.

Recommendation:

The requirement for written assurances should be eliminated and only require a single annual certification.

Rationale:

The Proposed Rule would require written assurances for every reapplication for funds, but does not explain what these multiple assurances add to the compliance regime. In fact, they add nothing and should be eliminated.

The only stated reasons for the written assurances are that they would inform the "health care industry" of the applicable laws and make the requirements for the statutes listed in the Proposed Rules more like other civil rights laws. 83 Fed. Reg. 3880, 3896. These are inadequate reasons for duplicative paperwork.

First, there is no need for a separate written assurance to provide information about the statutes if affected entities certify compliance. By providing the certification, affected entities know about the statutes in question. Making administration of these statutes more like the administration of other statutes (83 Fed. Reg. 3880, 3896) is no reason to impose unnecessary regulatory requirements.

Second, as noted above (Part II), imposing additional regulatory requirements such as a duplicative, unnecessary written assurance violates Executive Orders requiring reduction of regulatory burdens. Exec. Order No. 13765, relating to minimizing the economic burdens of the ACA, requires the heads of all executive departments and agencies with responsibilities under the ACA to "…minimize the unwarranted economic and regulatory burdens of the [ACA]…." 82 Fed. Reg. 8351 (January 24, 2017). This approach was echoed in a subsequent Executive Order stating that "…it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations." Exec. Order No. 13771, 82 Fed. Reg. 9339 (February 3, 2017).

To avoid the imposition of unneeded regulatory burdens, the final rule should drop the written assurance requirement and require only a single annual certification.

VI. Notice (Proposed § 88.5)

Issue # 1:

The proposed notice requirement has no basis in statute for health insurance issuers and group health plans. Additionally, OCR specifically asked if there are categories of recipients of federal funds that should be exempted from posting notices. 83 Fed. Reg. 3880, 3897.

Recommendation:

Eliminate the notice requirement for health insurance issuers and group health plans.

Rationale:

As noted above in Parts I and II, the Church and Weldon Amendments *protect* health insurance issuers and group health plans from discrimination in granting funds by government agencies. These amendments do not *regulate* health insurance issuers. Therefore, the notice requirement is unnecessary and should not apply to health insurance issuers in the final rule.

Issue # 2:

The Proposed Rule presents the notice requirement in a confusing way. The Preamble states that the Proposed Rule

> …requires the Department and recipients to notify the *public, patients*, and employees, which may include students or applicants for employment or training, of their protections under the Federal health care conscience and associated antidiscrimination statutes and this regulation.

83 Fed. Reg. 3880, 3897 (emphasis added). However, the actual Proposed Rule text (§ 88.5(a)) requires that the notice be provided on "recipient website(s)" and at a "…physical location in every…recipient establishment where notices to the public and notices to their workforce are customarily posted to permit ready observation."

Recommendation:

The final rule should only require the notice to be provided where the workforce as defined in the Proposed Rule can view it and should not be provided to the general public. Further, notices in solely electronic form should be permitted.

Rationale:

The conscience protection laws primarily impose requirements related to protecting health care providers and other health care staff from having to perform or assist in performing services to which they have a conscience objection. Thus, it is the workforce of health care providers who need to receive the notice, not members of the general public who are not the primary beneficiaries of the statutes relating to the Proposed Rule. As such, notices should only be required to be provided in a manner that is accessible to the workforce as defined in the Proposed Rule and not the public or patients.

Further, notices in solely electronic form should be permitted. Posting paper notices at physical facilities is a holdover from the era before the widespread electronic communications used today. This outmoded form of communication should not be perpetuated in the final rule.

VII. Effective Date

Issue:

The Proposed Rule does not provide a clear effective date nor does it give adequate time for compliance, particularly for the notice requirement.

The Proposed Rule does not specify an effective date for the overall Proposed Rule. The Preamble notes that the Proposed Rule is economically significant, 83 Fed. Reg. 3880, 3902, so it would be a "major rule" and would become effective 60 days after publication in the *Federal Register* if another effective date is not specified. 5 U.S.C. §§ 801(a)(3)(A), 804(2).

The Proposed Rule has confusing provisions on the effective date of compliance with the notice requirement. The Preamble states that notices must be posted 90 days after the date of publication of the final rule in the *Federal Register*. 83 Fed. Reg. 3880, 3897. However, the

actual text of the Proposed Rule (§ 88.5(a)) requires posting of notices by April 26, 2018, or, as to new recipients, within 90 days of becoming a recipient.

For certification and written assurances, the Preamble says that HHS components would be given discretion to phase-in the written assurance and certification requirements by no later than the beginning of the next fiscal year following the effective date of the final rule. 83 Fed. Reg. 3880, 3896. The actual text of the Proposed Rule does not provide for an effective date for providing written assurances and certifications.

Recommendation:

The final rule should not be effective prior to January 1, 2019, with the requirement for notices being effective January 1, 2020.

Rationale:

While the conscience protection laws are in place and health plans have taken actions to comply, the Proposed Rule has new provisions that would take time to implement, particularly the requirements related to certification, written assurances, and notices.

Having a uniform time for the certification and written assurances requirement would reduce the confusion that would result if each HHS component is allowed to establish its own effective date. A January 1, 2019, effective date would allow adequate time for the HHS components to integrate the new requirements into their application and contracting processes.

Allowing additional time before the notice requirement is effective recognizes that impacted organizations must analyze the materials on their web pages (such as employee manuals, orientation materials, and job posting/application web pages) to determine the necessary modifications. Then they must allocate the programming resources to make the required changes. These resources are very likely working on other projects, so time must be allowed to implement these new requirements so that organizations are able to comply.

Other areas of communication that require review and revision include:

- Certification/written assurances for the qualified health plan (“QHP”) application process;
- Certification/written assurances for the Medicare bid process; and
- Annual maintenance/updates to any of the above items.

Note that providing adequate time for compliance is not a question of delaying the time in which persons may claim conscience protections. These protections are in effect now and may be claimed at any time by affected persons. Our request is that adequate time be given to implement the requirement to provide formal notice, etc., in recognition of the regulatory and administrative burden of providing notices, written assurances, and certifications. This is consistent the Executive Orders cited above (Parts II, V) requiring the reduction of regulatory burdens, especially relating to the ACA.

Exhibit 8

March 23, 2018

Office for Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Constitution Avenue, NW
Washington, DC 20210

Attention: Conscience Notice of Proposed Rule Making (NPRM), RIN 0945-ZA03

Submitted electronically to www.regulations.gov

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority
[HHS-OCR-2018-0002; RIN 0945-ZA03]

Dear Sir/Madam:

The American Nurses Association (ANA) and the American Academy of Nursing (AAN) submit the following comments in response to the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) Proposed Rule: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*. This proposed rule requests comment on a number of provisions contained therein, and ANA and AAN through this comment letter seek to highlight the potential negative and unintended impacts which might follow from the final implementation of such, and offers policy recommendations. ANA is the premier organization representing the interests of the nation's 3.6 million registered nurses (RNs), through its state and constituent member associations, organizational affiliates, and individual members. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. AAN serves the public and the nursing profession by advancing health policy and practice through the generation, synthesis, and dissemination of nursing knowledge. The Academy's more than 2,400 fellows are nursing's most accomplished leaders in education, management, practice, and research.

ANA and AAN strongly support the right and prerogative of nurses - and all healthcare workers – to heed their moral and ethical values when making care decisions. However, the primacy of the patient in nursing practice is paramount, and the moral and ethical considerations of the nurse should never, under any circumstance, result in the inability of the patient to receive quality, medically necessary, and compassionate care.

ANA and AAN are concerned that this proposed rule, in strengthening the authority of OCR to enforce statutory conscience rights under the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, and other federal statutes, could lead to inordinate discrimination against certain patient populations – namely individuals seeking reproductive

health care services and lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) individuals. Proliferation of such discrimination – which in the case of LGBTQ individuals is unlawful under Section 1557 of the Affordable Care Act (ACA) – could result in reduced access to crucial and medically necessary health care services and the further exacerbation of health disparities between these groups and the overall population.

Discrimination in health care settings remains a grave and widespread problem for many vulnerable populations and contributes to a wide range of health disparities. Existing religion-based exemptions already create hardships for many individuals. The mission of HHS is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, patient care, public health, and social services. This proposed rule fails to ensure that all people have equal access to comprehensive and nondiscriminatory services, and dangerously expands the ability of institutions and entities, including hospitals, pharmacies, doctors, nurses, even receptionists, to use their religious or moral beliefs to discriminate and deny patients health care. All patients deserve universal access to high quality care and we as health care providers must guard against any erosion of civil rights protections in health care that would lead to denied or delayed care.

ANA and AAN believe that HHS should rescind this proposed rule and instead, through OCR, should create a standard for health systems and individual practices to ensure prompt, easy access to critical health care services if an individual provider has a moral or ethical objection to certain health care services; such a standard should build on evidence-based and effective mechanisms to accommodate conscientious objections to services including abortion, sterilization, or assisted suicide as cited in the proposed rule. ANA and AAN also believe that in no instance should a nurse – or any health care provider – refuse to treat a patient based on that patient's individual attributes; such treatment violates one of the central tenets of the professional *Code of Ethics for Nurses*. No patient should ever be deprived of necessary health care services or of compassionate health care; it is incumbent upon HHS to work to create accommodations to that end.

Code of Ethics for Nurses and Moral and Ethical Obligations

The critical importance of the relationship between the patient and the nurse is inherent in the fact that Provision 1 and Provision 2 of the *Code of Ethics for Nurses*[1] deal explicitly with these topics.

Affirming Health through Relationships of Dignity and Respect: *Provision 1 of the Code of Ethics:* states that "The nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person."[2] This includes respect for the human dignity of the patient and the demand that nurses must never behave prejudicially – which is to say, with

[1]American Nurses Association. *Code of Ethics for Nurses with Interpretive Statements*. 2015: Second Edition.
[2]Ibid: Pg. 1.

unjust discrimination. Nurses can and should base patient care on individual attributes, but only in the sense that those individual attributes inform the patient's care plan; nurses must always respect the dignity of such individual attributes.

Health care professionals work within a matrix of legal, institutional, and professional constraints and obligations, and their primary commitment to patients remains the foundational responsibility of health care.[3] *Provision 2* states that "The nurse's primary commitment is to the patient, whether an individual, family, group, community, or population."[4] Provision 2 explicitly establishes the primacy of the patient's interests in health care settings; this principle also situates the nurse-patient relationship within a larger "ethic of care" which encompasses the entire relational nexus in which the nurse and patient are situated, including the patient, the patient's family or close relationships, the nurse, the healthcare team, the institution or agency, and even societal expectations of care."[5]

While the primacy of the patient is not the only consideration when a nurse makes a care decision, it is the consideration which carries by far the most relative weight. Nurses then must base care decisions primarily on patients' needs. If a nurse feels that a moral or ethical consideration prevents him or her from delivering health care services, then the nurse, the full medical team, and/or the practice, institution, health system, or agency, should make an exhaustive and good-faith effort to ensure that the patient easily and promptly receives those health care services. In addition to the provisions contained within this proposed rule, OCR must implement guidelines by which the aforementioned stakeholders must ensure access to essential and quality health care services for all patients.

Considerations for Access to Reproductive Health Care Services

In addition to providing competent, professional and high quality care, there is also an emphasis on providing evidence-informed patient education and support as part of the nursing standard of care. The nursing profession holds sacred the patient's right of autonomy to make informed decisions to direct his or her care, as well as the crucial role that nurses play in supporting the patient. Patient education and advocacy are essential elements of the nursing process. Thus, it is the patients' decisions, regardless of faith or moral convictions, that should guide healthcare providers' care of patients, as articulated in the Code of Ethics for Nurses with Interpretive Statements.

For nurses who have concerns about the provision of specific healthcare services, existing laws and ethical guidelines are more than adequate to protect the rights of health care providers to follow their moral and religious convictions. There already exist effective models to accommodate providers' moral and religious beliefs in training and practice, while striking a

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[3]Stahl, Ronit Y. and Emanuel, Ezekiel J. *Physicians, Not Conscripts — Conscientious Objection in Health Care*. The New England Journal of Medicine: 2017 April; 376: 1380-1385.
[4]American Nurses Association. Code *of Ethics for Nurses*: Pgs. 25-26.
[5]Ibid: Pg. 28.

crucial balance with delivering evidence-based, patient-centered care.[6] This proposed rule skews that balance, lowers the bar for care necessary for patients in vulnerable populations, and exposes women who seek reproductive health care to discrimination and harmful delays.[7] Such discrimination is well-documented – one study notes that 24% of women were denied treatment by a health care provider for pregnancy termination.[8] The proposed rule defines "discrimination" for the first time in a way that subverts the language of landmark civil rights statutes to shield those who discriminate, rather than protecting against discrimination.[9]

The proposed rule provides a broad definition of "assist in the performance" of an activity to which an individual can refuse to participate. The definition allows for blanket discrimination by permitting a broad interpretation of not only what type of services that can be refused but also the individuals who can refuse. For example, under this proposed rule, a receptionist can refuse to schedule a patient's pregnancy termination or appointment for contraception consultation. This expansion violates the plain meaning of the existing law and goes against the stated mission of HHS.

Data suggest that health care providers believe that even when they are morally opposed to offering care, they are willing to make referrals and coordinate care according to care coordination standards to ensure adequate, timely and safe care, as well as full information about standard of care and available services, is provided for all patients.[10] Yet, the proposed rule creates a definition of "referral" that allows refusal to provide any information that could help the patient receive the proper care necessary; withholding information or complete care recommendations (e.g., professionals withholding diagnostic or treatment information) is unethical.

International professional associations such as the World Medical Association, as well as national medical and nursing societies and groups such as the American Congress of Obstetricians and Gynecologists and the Royal College of Nursing, Australia, have similarly agreed that the provider's right to conscientiously refuse to provide certain services must be secondary to his or her first duty, which is to the patient.[11] This right to refuse must be bound

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[6]National Women's Law Center. *Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care.* February 16, 2018. Web: https://nwlc.org/resources/trump-administration-proposes-sweeping-rule-to-permit-personal-beliefs-to-dictate-health-care/
[7]Ibid.
[8]Biggs, M. Antonia and John M. Neuhaus and Diana G. Foster. *Mental Health Diagnoses 3 Years After Receiving or Being Denied an Abortion in the United States.* The American Journal of Public Health: 2015 December; 105(12): 2557-2563.
[9]National Women's Law Center. *Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care.*
[10]Harris, LH et al. *Obstetrician-gynecologists' objections to and willingness to help patients obtain an abortion.* Obstetrics and Gynecology: 2011 October; 118(4): 905-912.
[11]Chavkin, W. et al. *Conscientious objection and refusal to provide reproductive healthcare: a White Paper examining prevalence, health consequences, and policy responses.* The International Journal of Gynaecology and Obstetrics: 2013 December; 123 Supplement 3: S41-56.

by obligations to ensure that the patient's autonomous rights to information and services are not infringed upon.[12]

Considerations for the Protection of LGBTQ Access to Health Care Services

LGBTQ populations experience a significant rate of discrimination in health care settings, and also experience negative health outcomes compared with the overall population. The reasons for this are complex and varied, but many stem from a pattern of societal stigma and discrimination[13] exacerbated by the historical designation of homosexuality as a mental disorder[14], the onset of the HIV/AIDS epidemic[15], religious prejudice with respect to homosexuality[16], and government policy such as *Don't Ask, Don't Tell*.[17] Indeed, the current administration filed a brief in federal court with the U.S. Court of Appeals for the 2nd Circuit in the case of *Zarda v. Altitude Express* arguing that sex discrimination provisions under Title VII of the 1964 Civil Rights Act do not protect employees from discrimination based on sexual orientation.[18]

HHS in May 2016 issued a rule to implement Section 1557 of the ACA, which clarifies that discrimination based on sex stereotyping and gender identity is impermissible sex discrimination under the law.[19] The current administration has failed to defend this regulation in federal court in the case of *Franciscan Alliance v. Burwell* (a different federal court recently ruled that Section 1557 *ipso facto* provides for the rule's aforementioned protections);[20] this seems to point to a preferential pattern of treatment in favor of religious conscience objections over the civil rights of LGBTQ populations despite consistent federal court opinions to the contrary.

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[12]Ibid.
[13]U.S. Centers for Disease Control and Prevention. *Gay and Bisexual Men's Health: Stigma and Discrimination.* February 29, 2016. Web: https://www.cdc.gov/msmhealth/stigma-and-discrimination.htm
[14]Burton, Neel. *When Homosexuality Stopped Being a Mental Disorder.* Psychology Today (Blog). September 18, 2015. Web: https://www.psychologytoday.com/blog/hide-and-seek/201509/when-homosexuality-stopped-being-mental-disorder
[15]Barnes, David M. and Meyer, Ilan H. *Religious Affiliation, Internalized Homophobia, and Mental Health in Lesbians, Gay Men, and Bisexuals.* American Journal of Orthopsychiatry: 2012 October; 82(4): 505-515.
[16]DeCarlo, Pamela and Ekstrand, Maria. *How does stigma affect HIV prevention and treatment*? University of California, San Francisco: October 2016. Web: https://prevention.ucsf.edu/library/stigma
[17]U.S. Department of Defense. *Don't Ask, Don't Tell Is Repealed.* September 2011. Web: http://archive.defense.gov/home/features/2010/0610_dadt/
[18]Feuer, Alan and Weiser, Benjamin. *Civil Rights Act Protects Gay Workers, Appeals Court Rules.* The New York Times: February 26, 2018. Web: https://www.nytimes.com/2018/02/26/nyregion/gender-discrimination-civil-rights-lawsuit-zarda.html
[19]Gruberg, Sharita and Bewkes, Frank J. *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial.* Center for American Progress: March 7, 2018: Pg. 1. Web: https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/
[20]Ibid: Pg. 2.

OCR is responsible for accepting and investigating such complaints under Section 1557; the Center for American Progress in 2018 conducted an independent analysis of such complaints from May 2010 to January 2017 and found the following breakdown of complaint issues:[21]

- Denied care because of gender identity – non-transition related (24.3%)
- Misgendering or other derogatory language (18.9%)
- Denied insurance coverage for transition care (13.2%)
- Provider denied transition care (10.8%)
- Inadequate care because of gender identity (10.8%)
- Other discrimination based on sexual orientation (8.1%)
- Denied insurance coverage because of gender identity – non-transition-related (5.4%)
- Denied care because of sexual orientation or HIV status (5.4%)
- Inadequate care because of sexual orientation (2.7%)

It is worth noting that the number of Section 1557 complaints during this 7-year period (34) is comparable to the number of health care conscience complaints (44) during the 10-year period cited in the proposed rule. This comparison not only highlights the balance that must be struck between these two types of complaints, but also raises the question as to how such discrimination translates to actual health outcomes.

Negative health outcomes that disproportionately impact LGTBQ individuals include: increased instances of mood and anxiety disorders and depression, and an elevated risk for suicidal ideation and attempts; higher rates of smoking, alcohol use, and substance use; higher instances of stigma, discrimination, and violence; less frequent use of preventive health services; and increased levels of homelessness among LGBTQ youth.[22] Men who have sex with men (MSM) and transgender women also experience significantly higher rates of HIV/AIDS infections, complications, and deaths; this burden falls particularly heavily on young, African-American MSM and transgender women. As evidenced in the Section 1557 complaints above, this disease burden is itself known to contribute to discrimination against LGBTQ individuals. Transgender individuals also face particularly severe discrimination in health care settings: 33% of transgender patients say that a health care provider turned them away because of being transgender.[23]

As noted in the "*Code of Ethics for Nurses and Moral and Ethical Obligations*" section of this comment letter, nurses are obligated to respect the human dignity of all patients and to ensure that all patients receive quality, medically necessary, and compassionate care that is timely and safe. The health disparities highlighted in this section demonstrate the negative outcomes

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[21]Ibid: Pg. 5.
[22]U.S. Institute of Medicine Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding.* Washington, DC: National Academies Press; 2011.
[23]James, Sandy E. et al. *The Report of the U.S. Transgender Survey.* 2016: 96-97. Web: www.ustranssurvey.org/report

associated with failure to provide such care. The civil rights of LGBTQ individuals – including the accessibility of quality health care services for LGBTQ individuals – should be protected in a manner consistent with the statutory conscience rights of health care workers under this proposed rule; the protection of such conscience rights should never impede the ability of LGBTQ individuals to access health care services.

Policy Recommendations and Conclusion

ANA and AAN do not wish to diminish the role of moral and ethical considerations in patient care. In fact, the *Code of Ethics for Nurses* acknowledges both implicitly and explicitly that such considerations play critical roles when it comes to a patient's care plan. ANA and AAN do, however, reiterate the primacy of the patient in nursing care; ensuring that all patients are able to access quality, medically necessary, and compassionate care is paramount to nursing practice. ANA and AAN also acknowledge the dual roles that OCR plays with respect to simultaneously enforcing the ACA's Section 1557 provisions and the statutory conscience rights provisions referenced in the proposed rule, including those under the Church Amendments, the Coats-Snowe Amendment, and the Weldon Amendment.

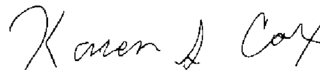
To this end, ANA and AAN believe that in order to accommodate both priorities, OCR should implement guidelines for individual providers, practices, agencies, health systems, and institutions to accommodate both employees and patients. Namely, these guidelines must ensure that if any of the aforementioned stakeholders has a moral or ethical objection to providing certain health care services, they must have in place an organized plan by which the patient – without creating or exacerbating inequities - is able to easily access the quality, affordable, compassionate, and comprehensive health care that they need. Such guidelines reflect the primacy of the patient while at the same time recognizing that various federal statutes protect the conscience rights of health care workers. HHS and OCR must also work with stakeholders to implement existing, evidence-based models that facilitate a standard of care that integrates timely care coordination when health care providers or their employers exhibit a moral or ethical objection to providing certain health care services; such models must also protect the ability of the patient to access evidence-informed care and must not expose women and other marginalized populations to discrimination.

ANA and AAN also reiterate in no uncertain terms that nurses (or any other health care provider) cannot cite conscience rights protections as a reason for refusing to treat certain patient populations, including women seeking reproductive health care and LGBTQ populations. Such refusals go far beyond the provisions of any of the federal statutes cited in the proposed rule, a fact again borne out consistently in federal court opinions. As noted above, the nurse's primary concern is the patient's care. To provide inequitable care for an individual, or to refuse to provide that care entirely, would demonstrate unjust discrimination toward that patient. Such care (or lack thereof) directly contradicts one of the central tenets of nursing practice, violates federal law – including Section 1557 of the ACA – and leads to negative health outcomes and population health disparities.

ANA and AAN believe that this proposed rule should be rescinded and that HHS should develop a standard for accommodation for conscientious objection to certain services which in no way limits the ability of the patient to receive timely, affordable, quality, and compassionate care. This proposed rule is restrictive with respect to ensuring such care. Given the current administration's track record when it comes to defending religious objections at the expense of individual rights, it seems to follow that this proposed rule would represent a significant lurch toward such defense in the health care field. This is unacceptable; in health care practice, patients come first, and HHS must make every attempt to strike an equitable balance between conscientious objections and patients' inalienable rights.

ANA and AAN welcome an opportunity to further discuss the issue of statutory conscience rights protections for health care workers. If you have questions, please contact Liz Stokes, Director, Center for Ethics and Human Rights (liz.stokes@ana.org) or Mary Beth Bresch White, Director, Health Policy (marybreschwhite@ana.org).

Sincerely,



Pamela F. Cipriano, PhD, RN, NEA-BC, FAAN
President
American Nurses Association

Karen S. Cox, PhD, RN, FACHE, FAAN
President
American Academy of Nursing

cc: Debbie Hatmaker, PhD, RN, FAAN, Interim Chief Executive Officer, American Nurses Assoc.
Cheryl G. Sullivan, MSES, Chief Executive Officer, American Academy of Nursing

Exhibit 9

1333 H Street, NW, 10th Floor
Washington, DC 20005
Tel: 202 682.1611 • Fax: 202 682.1867

www.americanprogress.org

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
200 Independence Avenue, S.W. Room 509F
Washington, D.C. 20201

March 27, 2018

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

Dear Secretary Azar,

The Center for American Progress ("Center") is committed to ensuring that all individuals have access to quality, affordable health care and believes that a health care provider's personal beliefs should never determine the care a patient receives. That is why we strongly oppose the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.[1]

The Proposed Rule seeks to unlawfully expand refusals to provide care by attempting to allow individuals and health care entities that receive federal funding to refuse to provide *any* part of a health service or program. In addition, the Proposed Rule unlawfully attempts to create new refusals seemingly out of thin air. Such expansions exceed the Department's authority; violate the Constitution; undermine the ability of states to protect their citizens; undermine critical HHS programs like Title X; interfere with the patient-provider relationship; distort essential protections for religious freedom to justify discrimination; and threaten the health and well-being of people across the country and around the world.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department seeks to inappropriately reprioritize OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons, the Center calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

The Proposed Rule Unlawfully Exceeds the Department's Authority by Impermissibly Expanding Religious Refusals to Provide Care

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (*to be codified at* 45 C.F.R. pt. 88) [*hereinafter* Rule].

The Proposed Rule attempts to expand the reach not only of existing harmful refusal of care laws but also to create new refusals of care where none were intended.

a. The Proposed Rule Seeks to Allow the Refusal of any Health Service Based on Personal Belief

The Proposed Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and transition-related care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[2] Read in conjunction with the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

b. The Proposed Rule Unlawfully Expands Already Harmful Abortion/Sterilization Refusal of Care Laws

Already existing refusal of care laws are used across the country to deny patients the care they need.[3] The Proposed Rule attempts to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.[4] But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on.[5] For example, a receptionist may refuse to schedule an abortion for a patient, citing moral objections, or an ambulance driver may refuse to drive a woman experiencing severe pregnancy complications to a hospital, citing a religious objection to participating in procedures that may end the pregnancy.[6]

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[2] *See id.* at 12.
[3] *See, e.g.*, *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[4] The Church Amendments, 42 U.S.C. § 300a-7 (2018).
[5] *See* Rule *supra* note 1, at 185.
[6] *See Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care*, NAT'L WOMEN'S L. CTR. (2018), https://nwlc.org/resources/trump-administration-proposes-sweeping-rule-to-permit-personal-beliefs-to-dictate-health-care/.

Such an attempted expansion goes beyond what the statute enacted by Congress allows.[7] Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things, individuals working under global health programs funded by the Department, thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

In addition, even though longstanding legal interpretation applies section (d) of the Church Amendments singularly to participation in abortion and sterilization procedures, the Proposed Rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason, potentially including not just sterilization and abortion procedures, but treatments that have an incidental effect on fertility, including Pre-Exposure Prophylaxis services, infertility care, treatments related to gender dysphoria, and HIV treatment. Some providers may try to claim even broader refusal abilities, as our recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are.[8] Any rule, if it is to advance, must make the limitation of this statute clear.

If religious or moral exemptions related to sterilization are misinterpreted to include treatments that simply have an incidental effect on fertility—as the vague and sweeping language of this rule encourages—it can lead to refusals that go beyond what federal law allows and allow individuals and institutions to refuse a dangerously broad range of medically-needed treatments. For example, the Proposed Rule would allow a medical provider to refuse to treat an HIV positive transgender patient or to provide emergency care simply because the patient is transgender.[9]

Another example of the Proposed Rule's overly broad expansion of section (d) is the preamble's statement that the exemption applies to the Unaccompanied Alien Children ("UAC") program because the program contracts out health care for unaccompanied minors in the Department's custody. The rule's preamble indicates an intent for this to be far-reaching and permit any grantee or contractor caring for an unaccompanied minor to deny access to any form of care the grantee or contractor objects to.[10] For example, if an unaccompanied minor in the Department's custody is sexually assaulted, they are entitled to access emergency contraception and, although the Department does not fund abortion services for unaccompanied minors outside of very limited circumstances, unaccompanied minors in the UAC program still have a legal right to these health services. The Department's classification of the UAC program as a health service

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[7] The Church Amendments, 42 U.S.C. § 300(c)(2)(B)(2018).

[8] *See* Sharita Gruberg & Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, CTR. FOR AM. PROGRESS (2018), https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.

[9] *See TLC condemns illegal HHS rule granting 'license to discriminate',* TRANSGENDER LAW CTR. (2018), https://transgenderlawcenter.org/archives/14188

[10] *See* Sharita Gruberg, et al., *How Overly Broad Religious Exemptions Are Putting Children at Risk of Sexual Abuse*, CTR. FOR AM. PROGRESS (2016), https://www.americanprogress.org/issues/immigration/news/2016/05/12/137356/how-overly-broad-religious-exemptions-are-putting-children-at-risk-of-sexual-abuse/.

program in the rule's preamble reveals the Department's intent to permit grantees and contractors to block access to these health services for unaccompanied minors in the Department's custody.

The Proposed Rule also defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.[11] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.[12]

Furthermore, the Proposed Rule's new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the Proposed Rule seeks to enforce. Specifically, under the Coats and Weldon Amendments, "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[13] In addition to the statutory definitions of health care entities under the Coats and Weldon Amendments, the Proposed Rule would expand those definitions to include: health care personnel; applicants or participants for training or study in the health professions; laboratories; entities engaging in biomedical or behavioral research; plan sponsors, issuers, or third-party administrators; and components of State and local governments.[14] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity," Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert.[15]

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide and to fundamentally block access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination."[16] In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as

[11] *Id.* at 180.
[12] *Id.* at 183.
[13] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[14] *See* Rule *supra* note 1, at 182.
[15] The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[16] *See* Rule *supra* note 1, at 180.

discrimination."[17] In a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further, such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

The Proposed Rule Carries Severe Consequences for Patients and will Exacerbate Already Existing Inequities

a. Refusals of Care Make it Difficult for Many Individuals to Access the Care They Need

Across the country, refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[18] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[19] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[20] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[21] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[22] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, as her condition grew more severe, the hospital did not give her full information about her condition and treatment options.[23]

b. Refusals of Care are Especially Dangerous for Those Already Facing Barriers to Care

Refusals of care based on personal beliefs have a disproportionate impact on those who already face barriers to care. This is especially true for immigrant patients who often lack access to

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[17] *Id.*
[18] *See, e.g.*, *supra* note 3.
[19] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[20] *See* Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[21] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[22] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.
[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

transportation and may have to travel great distances to get the care they need.[24] In rural areas, there may be no other sources of health and life preserving medical care.[25] This problem is exacerbated by anti-choice state laws, which force women in rural areas to drive longer distances multiple times or lose hours of pay because of a lack of options for abortion care where they live. Many rural clinics that do offer reproductive healthcare services do not provide abortion services: In Washington State, a 1998 study found that of 31 clinics in rural areas of the state, only one offered abortion services.[26]

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[27] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs), which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[28] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals and, as a result, women were delayed care or transferred to other facilities at great risk to their health.[29] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[30]

In developing countries where many health systems are weak, health care options and supplies are often unavailable.[31] In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care,

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[24] Athena Tapales, et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[25] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[26] *See* Kathleen Reeves, *A Pioneering Effort to Increase Rural Women's Access to Safe Abortion in Iowa*, REWIRE (Apr. 23, 2010), https://rewire.news/article/2010/08/23/ppiowas-pioneering-efforts-ensure-rural-access/.

[27] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[28] *See id.* at 10-13.

[29] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

[30] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

[31] *See* Nurith Aizenman, *Health Care Costs Push a Staggering Number of People into Extreme Poverty*, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggering-number-of-people-into-extreme-poverty; *Tracking Universal Health Coverage: 2017 Global Monitoring Report*, WORLD HEALTH ORG. & THE WORLD BANK (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.

including a broad and harmful refusal provision contained within the statute governing such programs.[32]

For lesbian, gay, bisexual, transgender and queer (LGBTQ) patients, obtaining access to quality, culturally competent care already poses significant challenges. We recently found that 8 percent of lesbian, gay, bisexual and queer (LGBQ) survey respondents and 29 percent of transgender respondents reported a doctor or other health care provider refusing to see them because of their actual or perceived sexual orientation or gender identity.[33] This type of discrimination has a tangible impact on LGBTQ people's health: 8 percent of LGBQ respondents and 22 percent of transgender respondents reported avoiding or postponing needed medical care in the past year due to disrespect or discrimination from health care staff, delaying medically necessary care and treatment.[34] Discrimination also negatively impacts LGBTQ patients' relationship with their doctors: LGBTQ people who reported experiencing some form of anti-LGBTQ discrimination in the past year were nearly three times as likely to avoid doctor's offices out of fear of discrimination. The proposed regulation threatens to make health care even more inaccessible for LGBTQ patients by removing recourse and encouraging further discrimination from providers or hospitals.

When LGBTQ patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—to find a viable alternative. In a recent study we conducted, one in five LGBTQ people, including 31 percent of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41 percent reporting that it would be very difficult or impossible to find an alternative provider.[35] For these patients, being turned away by a medical provider is not just an inconvenience; it often means being denied care entirely and having no viable alternative options.

c. In Proposing this Rule, the Agency has Abandoned its Legal Obligations to Adequately Account for Harm to Patients

By expanding refusals of care, the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on

[32] *See The Mexico City Policy: An Explainer*, KAISER FAMILY FOUND. (June 1, 2017), https://www.kff.org/global-health-policy/fact-sheet/mexico-city-policy-explainer/.
[33] See Shabab Ahmed et al., *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AM. PROGRESS (2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.
[34] *See id.*
[35] *See id.*

society."[36] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[37]

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[38] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[39]

The Proposed Rule Will Undermine Critical Federal Health Programs, including Title X

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.[40] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[41] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[42] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[43] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of

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[36] Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.
[37] *See* Rule *supra* note 1, at 94-177.
[38] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
[39] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.
[40] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's Family Planning Program*, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.
[41] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[42] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[43] *See, e.g.*, Rule *supra* note 1, at 180-185.

federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[44] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements and violate Section 1557 of the Affordable Care Act (ACA), but could also undermine Title X's fundamental objectives. Every year, millions of low-income, under-insured, and uninsured individuals rely on Title X clinics to access services they otherwise might not be able to afford.[45] Of the four million clients who Title X clinics serve, almost two-thirds have family incomes at or below the federal poverty level, for whom Title X clinics provide no-cost services, and over half are women of color.[46]

The Proposed Rule Will Carry Severe Consequences for Providers and Undermine the Patient-Provider Relationship

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, religious, or moral convictions of these providers.[47] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide. Indeed, the Proposed Rule ignores that many providers' religious and moral convictions compel them to prioritize their patients' health and that such broad exemptions for institutions may create a burden on the beliefs of providers in addition to the beliefs of patients.

The Proposed Rule threatens informed consent, a necessary principle intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.[48] Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[49] Various associations of medical and advocacy groups, such as the American College of Physicians, have released statements outlining concerns that laws and regulations concerning medicine are not "supported by evidence-based guidelines and/or [are] not individualized to the needs of the specific patient."[50] By allowing providers, including hospital and health care

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[44] *See* NFPRHA *supra* note 34.
[45] *See id.*
[46] *Title X Family Planning Annual Report: 2016 National Summary*, DEP'T OF HEALTH AND HUMAN SERVS. (2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
[47] *See* Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[48] *See* TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).
[49] *See id.*
[50] *See* Donna Barry, et al., *Changing the Conversation on Abortion Restrictions*, CTR. FOR AMERICAN PROGRESS (2015), https://www.americanprogress.org/issues/women/reports/2015/09/30/121940/changing-the-conversation-on-abortion-restrictions/.

institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.[51]

These conversations are already fraught with undue requirements, especially in regard to abortion care. Physicians in several states across the country are required to mandate waiting periods and counseling, discuss fetal development and pain, and advise on the risks of abortion, most of which have been debunked by medical research.[52] The Proposed Rule further intrudes on the patient-provider relationship when it comes to abortion care by allowing personal religious beliefs to interfere with the provision of comprehensive information to the patient.

The Proposed Rule also undermines adherence to evidence-based clinical practice guidelines and established standards of care by allowing providers to ignore existing guidelines and standards, particularly those for reproductive and sexual health. Clinical practice guidelines and standards of care establish the accepted course of care for specific conditions. For example, the standard of care for treating individuals with a range of common medical conditions such as heart disease, diabetes, epilepsy, lupus, obesity, and some cancers includes counseling, referral, and provision of contraceptives and, in some cases, abortion services.[53] Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines without clinical justification and deny recommended evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[54] No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[55] Instead, the Proposed Rule appropriates

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[51] *See* Rule *supra* note 1, at 150-151.
[52] See *Counseling and Waiting Periods for Abortion*, GUTTMACHER INST. (2018), https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion.
[53] *See* Susan Berke Fogel, *Health Care Refusals: Undermining Quality Care for Women*, NAT'L HEALTH LAW PGRM. (2012), http://www.healthlaw.org/issues/reproductive-health/health-care-refusals/health-care-refusals-undermining-care-for-women#.Wrku35Pwbfa.
[54] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[55] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health

language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce.[56] Recipients of HHS federal financial assistance are required to complete and file an "Assurance of Compliance with Non-Discrimination Laws and Regulations", in which they agree to comply with non-discrimination provisions in a number of laws, including Section 1557 of the ACA.[57] The requirements will significantly burden health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[58] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[59] Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the fact that hospitals

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and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[56] *See* Rule *supra* note 1, at 203-214.

[57] *See Assurance of Compliance*, DEP'T OF HEALTH AND HUMAN SERVS. OFFICE FOR CIVIL RIGHTS, https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf (retrieved Mar. 27, 2018).

[58] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

[59] *See, e.g.*, *Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

serving predominantly people of color tend to be teaching or not-for-profit hospitals and have higher rates of risk-adjusted mortality.[60] And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth.[61] Further, the disparity in maternal mortality is growing rather than decreasing,[62] which in part may be due to the reality that women of color have long been the subject of discrimination in health care. For example, women's pain is routinely undertreated and often dismissed.[63] And due to gender biases and disparities in research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[64] Similarly, lesbian, gay, bisexual and transgender patients disproportionately experience higher rates of chronic conditions as well as earlier onset of disabilities in comparison to cisgender and heterosexual individuals but simultaneously face significant barriers to accessing health care, including cultural stigma, cost-related issues, and gaps in coverage.[65]

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[66]

The Proposed Rule Conflicts with Other Existing Federal Law

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals to care it would create.

For example, the Proposed Rule makes no mention of Title VII,[67] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[68] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when

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[60] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.
[61] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.
[62] *See id.*
[63] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).
[64] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. of the Am. Heart Ass'n 1 (2015).
[65] *See* Jennifer Kates, et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the US.* KAISER FAMILY FOUND. (2017), https://www.kff.org/disparities-policy/issue-brief/health-and-access-to-care-and-coverage-for-lesbian-gay-bisexual-and-transgender-individuals-in-the-u-s/.
[66] *See supra* note 46.
[67] 42 U.S.C. § 2000e-2 (1964).
[68] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

requested, unless the accommodation would impose an "undue hardship" on an employer.[69] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[70]

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling even though the employer would not be required to do so under Title VII.[71] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency department to provide to anyone who comes to the emergency department an appropriate medical screening to determine whether an emergency medical condition exists, necessary stabilizing treatment, and appropriate transfer of the individual to another hospital if either the person requests the transfer or the hospital does not have the capability or capacity to provide the necessary stabilizing treatment.[72] Under EMTALA, every Medicare hospital is required to comply – even those that are religiously affiliated.[73] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

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[69] *See id.*
[70] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.
[71] *See* Rule *supra* note 1, at 180-181.
[72] 42 U.S.C. § 1395dd(a)-(c).
[73] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

The Proposed Rule Will Make It Harder for States to Protect their Residents

The Proposed Rule will have a chilling effect on the enforcement and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. By granting broad exemptions for providers, hospitals, insurance companies, and support staff to refuse care to patients based on religious or moral beliefs, the Proposed Rule creates conflicts with hundreds of state and local health care nondiscrimination laws. It is therefore disingenuous for the Department to claim that the Proposed Rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132. In addition, the preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[74] Moreover, the Proposed Rule invites states to further expand refusals of care laws by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[75]

The Department's Rushed Rulemaking Process Failed to Follow Required Procedures

The Department rushed to publish this rule without first publishing any notice regarding it in its Unified Regulatory Agenda, as is normally required but in this case was not enforced. The failure to follow proper procedure reflects an inadequate consideration of the Proposed Rule's impact on patients' health.

The timing of the Proposed Rule also illustrates a lack of sufficient consideration. The Proposed Rule was published just two months after the close of a public comment period for a Request for Information closely related to this rule. The 12,000-plus public comments were not all posted until mid-December, a month before this Proposed Rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the Proposed Rule—namely, the refusal of care by federally funded health care institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the Request for Information (RFI) and whether the Proposed Rule was developed in an arbitrary and capricious manner. Many faith-based organizations submitted comments for the RFI articulating a strong objection to the idea that faith-based organizations face any barriers to engaging with HHS and calling for a commitment by HHS to ensure equal access to healthcare for all. These organizations have been left to wonder if, despite claiming an interest in protecting religious and moral objections, the process has accounted for their feedback at all.[76]

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[74] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[75] *See id.*
[76] See *Rabbi Jonah Dov Pesner 'to' Center for Faith-Based and Neighborhood Partnerships*, Nov. 21, 2017, RELIGIOUS ACTION CTR. FOR REFORM JUDAISM, https://rac.org/sites/default/files/HHS%20RFI%20Comment%20November%2021%202017.pdf; *The Coalition Against Religious Discrimination 'to' Center for Faith-Based and Neighborhood Partnerships*, Nov. 24, 2017, COALITION AGAINST RELIGIOUS DISCRIMINATION, https://transequality.org/sites/default/files/docs/2017-11-24%20-%20CARD%20Response%20to%20HHS%20RFI%20FINAL.PDF.

Conclusion

The Proposed Rule will allow health care providers, hospitals, insurance companies and support staff to cite personal religious and moral objections in order to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is arbitrary, capricious and discriminatory, violates multiple federal statutes and the Constitution, is burdensome to states, contradicts the positions of a wide array of religious groups who support balancing religious liberty with other critical freedoms, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, the Center calls on the Department to withdraw the Proposed Rule in its entirety.

Sincerely,

Shilpa Phadke
Vice President, Women's Initiative
Center for American Progress

Exhibit 10

Planned Parenthood
Federation of America

Planned Parenthood Action Fund

March 27, 2018

VIA ELECTRONIC TRANSMISSION

Secretary Alex Azar
Director Roger Severino
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 509F
Hubert H. Humphrey Building
Washington, DC 20201

Re: RIN 0945-ZA03 Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar and Director Severino:

Planned Parenthood Federation of America (Planned Parenthood) and Planned Parenthood Action Fund (the Action Fund) submit these comments in response to the Protecting Statutory Conscience Rights in Health Care; Delegation of Authority, released by the Department of Health and Human Services (the Department) Office for Civil Rights (OCR) and Office of the Secretary on January 19, 2018 and published in the federal register on January 26, 2018. As a trusted women's health care provider and advocate, Planned Parenthood takes every opportunity to weigh in on policy proposals that impact the communities we serve across the country.

Planned Parenthood is the nation's leading women's health care provider and advocate and a trusted, nonprofit source of primary and preventive care for women, men, and young people in communities across the United States. Each year, Planned Parenthood's more than 600 health centers provide affordable birth control, lifesaving cancer screenings, testing and treatment for sexually transmitted diseases (STDs), and other essential care to 2.4 million patients. We also provide abortion services and ensure that women have accurate information about all of their reproductive health care options. One in five women in the U.S. has visited a Planned Parenthood health center. The majority of Planned Parenthood patients have incomes at or below 150 percent of the Federal Poverty Level (FPL).

As a health care provider, Planned Parenthood knows how important it is that people have access to quality health care and information they can trust. Already, too many people in this country are denied, often without realizing it, access to medically-appropriate information and care because of a health care provider's or employer's personal beliefs. Instead of protecting

patients' access to quality care, this rule -- if finalized -- would make it easier for health care workers to refuse care, disproportionately impacting women, LGBTQ people, people with low incomes, people from rural areas, and other people already experiencing barriers to care. Importantly, the proposed rule goes beyond the reach of the statutes the Department claims to be implementing, undermining the intent of the statutes and exceeding the authority given by Congress. Further, as outlined below, the proposed rule potentially conflicts with existing civil rights statutes and state laws, and it fails to adequately account for costs.

Indeed, this proposed rule is unprecedented in its reach and harm, seeking to allow almost any worker in a health care setting to refuse services and information to a patient because of personal beliefs, which notably would include "religious, moral, ethical, or other reasons."[1] This means that under this proposed rule, a pharmacist could refuse to fill a prescription for birth control or antidepressants, a woman could be denied life-saving treatment for cancer, or a transgender patient could be denied hormone therapy. And while the proposed rule purports to be protecting the conscience rights and "personal freedom" of health care workers "with a variety of moral, religious, and philosophical backgrounds," it selectively ignores the many workers who are prevented from following their conscience by *restrictions* on care imposed by their employers.

The Department has an obligation to follow parameters established by Congress and aim for equality in health care access across the country, including for women, LGBTQ people, and people living with HIV. To this end, the Department must withdraw this proposed rule.

I. The proposed rule would endanger patients and obstruct their access to health care.

The proposed rule reflects bad public health policy. Women -- particularly women of color and women living in rural areas -- LGBTQ people, and people living with HIV already experience barriers to care, and this proposed rule would further limit health care access and result in poor health care outcomes. The proposed rule will also interfere with the ability of patients and providers to make informed medical decisions. Notably, the proposed rule does not provide any exceptions for necessary care in the case of an emergency.

A. The proposed rule would exacerbate existing barriers to health care.

The rule would erect more barriers to reproductive health care, transition-related services, and other services, and place women, LGBTQ people, and people living with HIV at greater risk of not getting the services they need. Access to comprehensive reproductive health care, including abortion, is already limited. According to a recent report, nearly half of the women of reproductive age have to travel between 10 to 79 miles, and some women have to travel 180 miles or more, to access an abortion.[2] Importantly, the proposed rule improperly expands upon

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[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3923 (Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88).

[2] J. Mearak, et. al., Disparities and change over time in distance women would need to travel to have an abortion in the USA; spatial analysis, The Lancet (Nov. 2017), http://www.thelancet.com/pdfs/journals/lanpub/PIIS2468-2667(17)30158-5.pdf.

existing refusal laws and policies that already harm an untold number of people, who are often denied information and care.

It is already the case that women with pregnancy complications who seek care at religiously-affiliated hospitals have been denied information or abortion care, even when that information is critical to their health. An often-cited case is that of Tamesha Means, who was rushed to Mercy Health Partners in Muskegon, Michigan after her water broke at 18 weeks of pregnancy. She was sent home twice in excruciating pain despite the fact that there was no chance that her pregnancy would survive and that continuing the pregnancy posed significant risks to her health. Due to the hospital's religious affiliation, Ms. Means was not informed that terminating her pregnancy was the safest course for her condition, and therefore her health was put at risk.[3] Another woman, Mikki Kendall, went to an emergency room after experiencing a placental abruption. Even though her pregnancy would not survive and Ms. Kendall could have died due to the amount of blood loss, the doctor on call refused to perform an abortion and refused to contact another physician to perform the procedure. Fortunately, Ms. Kendall was able to receive the care she needed after several risky and agonizing hours.[4] Unfortunately, many people are not even aware that they may be denied medically-appropriate care and information, even in emergency situations. For instance, nearly 40 percent of the people who regularly visit Catholic hospitals do not know of the religious affiliation, and even patients that are aware of the affiliation frequently do not know the hospital refuses to provide certain services.[5]

Certain communities are particularly affected by denials of care. Health care refusals disproportionately impact Black women, and the expansions outlined in this proposed rule would likewise disproportionately impact Black women. For example, according to a recent report, hospitals in neighborhoods that are predominately Black are more likely to be governed by ethical and religious directives for Catholic health care services.[6] Additionally, people living in rural areas are significantly impacted if their provider refuses to provide necessary or preventive care. Women living in in rural areas already experience provider shortages and have to travel long distances for health care, resulting in significant gaps in care and low health outcomes.[7] By making it easier for providers to refuse care, the proposed rule would further restrict these options or cut off access to care altogether, which would compromise patient health still further.

The proposed rule also threatens access to transition-related services and HIV prevention and care -- including pre-exposure prophylaxis -- disproportionately impacting LGBTQ people and

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[3] ACLU, Tamesha Means v. United States of Catholic Bishops (June 30, 2015), https://www.aclu.org/cases/tamesha-means-v-united-states-conference-catholic-bishops.

[4] Mikki Kendall, Abortion Saved my Life, Salon (May 26, 2011), https://www.salon.com/2011/05/26/abortion_saved_my_life/. .

[5] *Id.*

[6] K. Shepherd, et. al., Bearing Faith: The Limits of Catholic Health Care for Women of Color, Columbia Law School (January 2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf?mc_cid=51db21f500&mc_eid=780170d2f0.

[7] The American College of Obstetricians and Gynecologists, Health Disparities in Rural Women (2014, reaffirmed 2016), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co586.pdf?dmc=1&ts=20160402T0931414521.

people living with HIV. Discrimination in health care settings already prevents LGBTQ people from accessing the care they need. For instance, nearly one-third of transgender people surveyed said a doctor or health care provider refused to treat them due to their gender identity.[8] Related, people living with HIV frequently experience stigma in the health care system.[9] The proposed rule would increase this stigma and make it more likely that these communities are denied necessary health care.

B. The proposed rule will hinder the delivery of care.

While the Department claims that the proposed rule will "facilitat[e] open communication between providers and their patients," in fact, it would do the opposite. Specifically, the proposed rule encourages medical professionals to conceal information if they believe that information might enable a patient to seek care (even elsewhere) of which they disapprove. It also inhibits communication by increasing the risk that *patients* will conceal medically relevant information, such as sexual orientation, out of fear that their provider would refuse them care.

The proposed rule itself notes that mainstream medical groups have recognized the negative effects refusing care can have on patients and that these organizations have called for patient protections when refusals may compromise health. For example, the American Congress of Obstetricians and Gynecologists (ACOG) ethics opinion states that "in an emergency in which referral is not possible or might negatively affect patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections."[10] The American Medical Association's (AMA) constitution and bylaws similarly note that physicians are required to be "moral agents" and "being a conscientious medical professional may well mean at times acting in ways contrary to one's personal ideals in order to adhere to a general professional obligation to serve patients' interests first." The constitution and bylaws further state that "having discretion to follow conscience with respect to specific interventions or services does not relieve the physician of the obligation to not abandon a patient."[11] The proposed rule would exacerbate these concerns by making it harder for medical organizations and providers to preserve existing access to reproductive health care.[12]

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[8] S. Mirza & C. Rooney, Discrimination Prevents LGBTQ people from Accessing Health Care, Ctr. for Amercian Progress (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.

[9] CDC, HIV Among Gay and Bisexual Men, https://www.cdc.gov/hiv/group/msm/index.htm; CDC, HIV Among African-Americans, https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-hiv-aa-508.pdf.

[10] 83 Fed. Reg. at 3888; ACOG, The Limits of Conscientious Refusal in Reproductive Medicine (Nov. 2007, reaffirmed 2016), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine.

[11] American Medical Association, Physician Exercise of Conscience: Report of the Council on Ethical and Judicial Affairs, https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/i14-ceja-physician-exercise-conscience.pdf.

[12] By ignoring these harms, the Department has failed in its obligation to acknowledge and consider the impact of a proposed rule on family well-being. *See* 83 Fed. Reg. at 3919.

C. The proposed rule does not include exceptions for medical emergencies and potentially conflicts with existing federal law.

The proposed rule could endanger women's lives because it fails to make sure that the protections of the Emergency Medical Treatment and Active Labor Act (EMTALA) apply and take precedence when a patient is facing a medical emergency. EMTALA requires virtually every hospital to provide an examination or treatment to individuals that come into the emergency room, including care for persons in active labor, and the hospital must provide an appropriate transfer if the hospital cannot stabilize the patient.[13] The proposed rule does not address EMTALA and the potential legal conflict between that Act and the proposed rule. In particular, it is unclear if the Department or a state or local government would be considered to have engaged in prohibited "discrimination" if it penalized a hospital for failing to comply with EMTALA when a pregnant woman needs an abortion in an emergency situation.[14] There is no dispute that some pregnant women develop serious medical complications for which the standard treatment is pregnancy termination.[15] The proposed rule's silence on medical emergencies could create confusion among health care institutions or even allow them to refuse to comply with existing federal requirements to treat patients with medical emergencies and thereby endanger women's lives.[16]

II. The proposed rule exceeds the authority granted under the underlying statutes.

While purporting to interpret long-standing statutes, the Department is expanding the requirements of the statutes beyond what Congress intended. The Department claims that it is seeking to clarify the scope and application of existing laws, but this rule would in fact drastically alter, not clarify, existing requirements. The Department both creates expansive definitions that did not exist before and reinterprets the provisions of the underlying laws in harmful ways.

A. The proposed rule expands the definition of various terms beyond their well-settled meanings and beyond congressional intent.

The proposed rule expands the definitions of well-settled terms used in the relevant refusal laws far beyond their commonly understood meanings, defining terms so broadly as to encompass a

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[13] 42 U.S.C. § 1395dd.

[14] The government can clearly take such action under Title VII. *See* Shelton v. Univ. of Med. & Dentistry of N.J. 223 F.3d 220, 228 (3d Cir. 2000).

[15] See *e.g.*, *Planned Parenthood v. Casey*, 505 U.S. 833, 880 (1992) ("[It is undisputed that under some circumstances each of these conditions [preeclampsia, inevitable abortion, and premature rupture of membrane] could lead to an illness with substantial and irreversible consequences.").

[16] Federal abortion policy generally has recognized the need to protect women's lives. *See e.g.*, 18 U.S.C. § 1531(a) (prohibiting abortion procedure except where "necessary to save the life of a mother"); 10 U.S.C. § 1093 (banning almost all abortion services at U.S. military medical facilities, and prohibiting Department of Defense funds, which includes health insurance payments under Civilian Health and Medical Program for the Uniformed Services, from being used to perform abortions, "except where the life of the mother would be endangered if the fetus were carried to term"); Consolidated Appropriations Act, 2017, Pub. L. No. 115-131, Title V §§ 507 131 Stat. 135 (2017) (prohibiting that funds appropriated under the Act be used to pay for an abortion except where, among other narrow exceptions, "where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed").

ridiculously wide array of activities that go well beyond congressional intent. As an initial matter, although the Department purports to be bringing the refusal laws in line with other civil rights laws, the rule proposes to define "discrimination" contrary to how it is has been long understood in those laws. Under the Department's proposed rule, "discrimination" is more broadly defined to include a large number of activities, including denying a grant, employment, benefit or other privilege, as well an unspecified catch-all phrase "any activity reasonably regarded as discrimination." It also includes any laws or policies that would have the effect of defeating or substantially impairing accomplishment of a "health program or activity." The term, "health program or activity" is then defined to include, among other things, "health studies, or any other services related to health or wellness whether directly, through payments, grants contracts, or other instruments, through insurance, or otherwise."[17] The inclusion of any impairment of a "health program or activity," as defined, only adds to an unreasonably expansive definition of "discrimination" that could be applied to anything with a tangential connection to health or wellness. As set forth below, the rule's all-encompassing definition of "discrimination" fails to account for established anti-discrimination law that reflect a balancing of interests -- protecting against religious discrimination but recognizing it is not discriminatory to require an employee to perform functions that are essential to the position for which she applied and was hired.

The proposed rule also improperly stretches the definition of "refer" to include providing "any information … by any method … that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity or procedure."[18] This means that any health care entity, including both individuals and institutions, could refuse to provide any information that could help an individual to get the care they need, including even to provide patients with a standard pamphlet. The objecting entity would be able to refuse to provide that information even if they believe that a particular health care service is only the "possible outcome of the referral."[19] This definition would allow health care providers to deny patients full, accurate, and comprehensive information on health care options that allow people to make their own health care decisions.

The proposed rule also defines "assist in the performance of" far more broadly than its common meaning, to include participating in any program or activity with "an articulable connection" to a procedure, health service, health program, or research activity. The proposed rule specifically notes that this includes *but is not limited to* counseling, referral, training, and other arrangements.[20] Even though the Department claims to acknowledge "the rights in the statutes are not unlimited," this definition could in effect create an unlimited right to refuse services. For example, it is unclear if an employee whose task it is to mop the floors at a hospital that provides abortion would be considered to "assist in the performance" of the abortion under this proposed rule. A definition this limitless provides no functional guidance to health care providers as to what they can ask of their employees, and the refusals permitted by health care providers and non-medical staff.

The proposed rule also broadens the health care workers that can claim "discrimination," potentially allowing a range of health care workers not directly involved in delivering care to

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[17] 83 Fed. Reg. at 3924.
[18] Referral is defined far more narrowly elsewhere in federal law. *See, e.g.*, 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351.
[19] 83 Fed. Reg. at 3924.
[20] 83 Fed. Reg. at 3923.

refuse to perform their duties at a health care facility. Specifically, the proposed rule seeks to expand the definition of "health care entity," "individual," and "workforce" to include a broad range of workers and organizations, including volunteers, trainees, and contractors.[21] The proposed rule notes that the workers included in the definitions are illustrative and not exhaustive, potentially creating the opportunity for non-medical personnel, such as receptionists or facilities staff, to refuse to perform job tasks. In particular, the notion that an individual who agrees to volunteer to perform a service for an entity has the right to then refuse to perform that service, but presumably without losing his or her status as "volunteer," is absurd. This nonsensical interpretation of the statutes exceed the Department's regulatory authority. In short, if this provision is finalized, a wide range of workers may be able to deny access to care - even if the worker's job is only tangentially related to that care.

The proposed rule also seeks to expand the health care providers and institutions that are subject to the rule's burdensome requirements. The proposed rule's broad definition of "entity" to include individuals as well as corporations, would greatly expand the individuals and institutions subject to the underlying laws' requirements.[22]

In general, the proposed rule's unreasonably expansive definitions could inhibit health care providers and institutions from offering a broad range of health care services to patients, and would ultimately limit patients' access to care. This is particularly so because in addition to expanding the terms used in the refusal laws beyond any possible meaning Congress intended, the Department has also expanded the substance of the refusal laws beyond their statutory text, as is discussed below. Thus, rather than clarify statutes that are as much as forty-years old, the proposed rule has stretched the meaning of key terms. This will lead to illogical, unworkable, and unlawful results.

B. The Department broadly interprets the Church Amendments in violation of the statute.

The Department is exceeding its statutory authority by interpreting the Church Amendments far beyond what Congress intended. Each provision of the Church Amendments was enacted at a different point in time to address specific concerns. The first two provisions of the Church Amendments were enacted in 1973 during the public debate following the *Roe v. Wade* decision, and they clarify that receipt of certain federal funds does not require a health care entity to perform abortions or sterilizations or make its facilities available for abortions or sterlizations.[23] These provisions of the Church Amendments, codified at 42 U.S.C. § 300a-7(b) and (c)(1), permit individuals to refuse to perform or assist in the performance of a sterilization or abortion in certain federally funded programs if it is contrary to their religious or moral beliefs. Sections (d) and (e) of the Amendments were passed as a part of the National Research Act, which aimed at funding biomedical and behavioral research, and ensuring that research projects involving human subjects were performed in an ethical manner. [24] The Department's purported

[21] 83 Fed. Reg. at 3923–3924.
[22] 83 Fed. Reg. at 3924.
[23] The implicated funds are the Public Health Service Act [42 U.S.C. § 201 *et seq*.], the Community Mental Health Centers Act [42 U.S.C. § 2689 *et seq*.], and the Developmental Disabilities Services and Facilities Construction Act [42 U.S.C. § 6000 *et seq*.].
[24] See 119 Cong. Rec. 2917 (1973).

interpretation of these provisions goes far beyond both the statutory text and Congressional intent in at least two ways.

First, section (b) of the Church Amendments states that courts, public officials, and public authorities are not authorized to require the performance of abortions or sterilizations, *based on the receipt of* any grant, contract, loan, or loan guarantee under the Public Health Service Act (PHSA), the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act. The proposed rule goes beyond the text of the statute and interprets it to prohibit public authorities from *requiring any individual or institution* to perform these services if they receive a grant, contract, loan or loan guarantee under the PHSA. Therefore, while the Church Amendments only make it clear that public authorities are not allowed to require the performance or assistance in the performance of abortion or sterilization based on the receipt of certain federal funding, the proposed rule imposes a blanket prohibition on any requirements related to individuals or institutions performing or assisting in the performance of abortion and sterilization if the institution or individual receives the specified funding. Combined with the expanded definition of “assist in the performance” that impacts sections (b)(1) and (b)(2)(B), the proposed rule allows for denials of services related to abortion and sterilization by both individual providers and those ancillary to the provision of health care. It could also prevent states and the federal government from requiring a hospital to provide an abortion, even if a patient’s health or life is threatened.

Second, the proposed rule interprets section (d) of the Church Amendments in a way that goes well beyond the statute and that has the potential to allow any individual employed at a vast number of health care institutions to refuse to provide care that is central to the institution. Importantly, this provision was intended to apply only to individuals who work for entities that receive grants or contracts for biomedical or behavioral research. The proposed rule incorrectly claims that paragraph (d) of the Church Amendments is not based on receiving specified funding through a specific appropriation, instrument, or authorizing statute, but applies to “[a]ny entity that carries out any part of a health service program or research activity funded in whole or in part under a program administered by” the Department.[25]

The expansive definitions of “entity,” “health service program” and “assist in the performance” only serve to exacerbate this unlawful expansion. As noted, “entity” is defined broadly in the proposed rule to include a “‘person’, as defined in 1 U.S.C. 1 or a State, political subdivision of any State, instrumentality of any State or political subdivision thereof, or any public agency, public institution, public organization, or other public entity in any State or political subdivision of any state.” “Health service program” is discussed by the Department in the proposed rule as not only including programs where the Department provides care or health services directly, but programs administered by the Secretary that provide health services through grants, cooperative agreements or otherwise; programs where the Department reimburses another entity to provide care; and “health insurance programs where Federal funds are used to provide access to health coverage (e.g. CHIP, Medicaid, Medicare Advantage).” It also may include components of State or local governments.[26]

Thus, under the proposed rule, virtually any individual could refuse to provide any type of health care or any job task that has a minimal connection to the provision of health care. This provision

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[25] 83 Fed. Reg. at 3925.
[26] 83 Fed. Reg. at 3894.

would not only allow individuals to refuse to provide any type of care that they object to, but could also prevent states from protecting patients by requiring the provision of health care or fulfillment of other job duties by individuals in a medical facility. This could include, for instance, enforcing a state law that requires individual pharmacists to fill all the prescriptions they receive.

Nothing in the legislative history of section (d) of the Church Amendments suggests that this provision was meant to restrict the actions of this broad range of health care related individuals and organizations, nor that it was meant to apply to these individuals and institutions in the context of such a broad range of health-related programs.[27] The Department has clearly exceeded its statutory authority by attempting to create a catch-all provision that would allow almost any health care provider in the country to refuse to provide services based on a 40-year old law that was targeted to the receipt of specific, and limited, federal funds.

C. The Department's interpretation of the Weldon Amendment is not consistent with the plain language of the statute.

The Department has proposed a similarly broad -- and impermissible -- expansion of the Weldon Amendment. That amendment was added to the appropriations bill for the Departments of Labor, Health and Human Services, and Education in 2004 and each subsequent appropriations bill. It prohibits funds appropriated by those three agencies to be provided to a federal agency or program, or to a state or local government, if such agency, program, or government requires any institutional or individual health care entity to provide, pay for, provide coverage of, or refer for abortions.[28] While the text of the statute is limited to state and local governments and federal agencies or programs, the rule would apply the Weldon Amendment to "any entity that receives funds through a program administered by the Secretary or under an appropriations act [HHS]."[29] This interpretation of the Weldon Amendment would impermissibly turn private entities into "federal agencies or programs" by virtue of their receipt of HHS funding.

In addition to conflicting with the plain meaning of the statute, the Department's broad interpretation is also contrary to the legislative history of the Weldon Amendment. During final floor debates on the appropriations bill that included the first Weldon Amendment, one of its supporters explained: "The addition of conscience protection to the Hyde amendment remedies current gaps in Federal law and promotes the right of conscientious objection by forbidding federally funded government bodies to coerce the consciences of health care providers."[30] In other words, the Weldon Amendment's reference to "federal agency or program" was intended as a restriction on government bodies only, not on private entities that receive federal funds.

Indeed, the Department of Justice (DOJ) has taken the formal position that the receipt of federal funds does not mean that an organization is a federal agency or program. In litigation, the DOJ stated: the term "federal agency or program" does not automatically include private, individual family planning clinics that receive federal funds; the Weldon Amendment does not clearly

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[27] Indeed, section (d) of the Church Amendments does not by its terms impose any restrictions on health care providers. Rather, it is framed as an exemption to individuals from certain federal requirements that are contrary to their religious or moral beliefs. 42 U.S.C. § 300a-7(d).

[28] Weldon Amendment, Consolidated Appropriations Act 2017, Pub. L. 115-31, Div. H, Tit. V, Sec. 507(d).

[29] 83 Fed. Reg. at 3925.

[30] 150 Cong. Rec. H10095 (daily ed. Nov. 20, 2004) (statement of Rep. Smith) (emphasis added).

provide that an individual Title X clinic would constitute a “federal agency or program” covered by the statute, and “no agency responsible for the implementation or enforcement of the statute has adopted a reading to that effect.”[31] If Congress intended for the Weldon Amendment to apply to virtually every private hospital, pharmacy, and outpatient care center in the country, and hundreds of thousands of private doctors and other health care practitioners, it surely would have said so more directly, either at the time the Weldon Amendment was enacted or in the 14 years that the amendment has been interpreted otherwise.

The unreasonably broad definitions of “discrimination” and “health care entity” also act to greatly expand the reach of the Weldon Amendment. By defining discrimination to include any adverse actions without any balancing of the interests of employers or patients, this provision could be used to attempt to strike down neutral state laws that protect access to health care. The term, “health care entity” is already defined in the Weldon Amendment, so a proposal to add certain entities via regulation clearly exceeds the authority of the Department. For example, the inclusion of “a plan sponsor, issuer, or third party administrator” expands the reach of the provision by allowing employers that provide health insurance (even if they have no connections to health care) to become “health care entities” for purposes of this protection from “discrimination.”

Finally, the legislative history cited above makes it clear that the Weldon Amendment was intended to be limited to objections based on conscience, but under the proposed rule, the Department would allow refusal for *any* reason, including, for example, a financial one. All of these expansions are contrary to law and, more importantly, work to deny women access to information about and access to lawful medical services.

D. The Department similarly expands the applicability of the Coats Amendment.

The proposed rule’s broad definitions of “health care entity,” “refer,” and “discrimination” would also expand the applicability of the Coats Amendment beyond its statutory language and intent. The Coats Amendment was adopted in 1996 in response to a new standard adopted by the Accrediting Council for Graduate Medical Education, requiring all obstetrics and gynecology residency programs to provide induced abortion training.[32] Senator Coats offered the amendment to “prevent any government, Federal or State, from discriminating against hospitals or residents that do not perform, train, or make arrangements for abortions.”[33]

The amendment prohibits the federal government, or any state or local government that receives federal financial assistance, from discriminating against medical residency programs or individuals enrolled in those programs based on a refusal to undergo, require, or provide abortion training.[34] Under the Coats Amendment, the term “health care entity” is limited to “an individual physician, a postgraduate physician training program, and a participant in a program

[31] Brief of Respondent, *NFPRHA v. Gonzales*, 391 F.Supp.2d 200 (D.D.C. 2004) (No. 04-2148).
[32] *See* 142 Cong. Rec. 5159 (March 19, 1996) (Senator Frist stating that “this amendment arose out of a controversy over accrediting standards for obstetrical and gynecological programs”).
[33] 142 Cong. Rec. 4926 (March 14, 1996). *See also* 142 Cong. Rec. 5158 (March 19, 1996) (Senator Coats stating he offered the language in the bill because “it is [not] right that the Federal Government could discriminate against hospitals or ob/gyn residents simply because they choose, on a voluntary basis, not to perform abortions or receive abortion training, for whatever reason.”).
[34] *See* 42 U.S.C. § 238n.

of training in the health professions."[35] However, the proposed rule's definition of health care entity would prohibit "discrimination" not just against those specified in the Coats Amendment, but also against other health care professionals, health care personnel, an applicant for training or study in the health professions, a hospital, a laboratory, an entity engaging in biomedical or behavioral research, a health insurance plan, a provider-sponsored organization, a health maintenance organization, a plan sponsor, issuer, third-party administrator, or any other kind of health care organization, facility or plan. Similar to the proposed rule's changes to the Weldon Amendment, the Department has taken a narrow statute that was enacted to address a specific concern and used the proposed rule to promote broader discrimination in health care.

III. The proposed rule would undermine health care access in programs that Congress intended to expand care for women with low incomes and their families.

The proposed rule would impact health care programs, both domestically and internationally, that are intended to expand access and quality of care for women, people with low incomes, people living with HIV, and others. The expanded scope of the rule would reach both the Title X Family Planning Program (Title X) and the President's Emergency Plan for AIDS Relief (PEPFAR).

A. The Department's proposal would reduce access to vital services through Title X and other programs by allowing objectors to ignore their general requirements contrary to the intent of these programs.

The Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned. We find this particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for people with low-incomes. When it comes to Title X, the proposed rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objective of expanding access to reproductive health care to underserved communities.

Several of the Department's proposed provisions and definitions appear to exempt recipients of federal funds from following the rules that govern federal programs if they have an objection to doing so. As discussed above, the proposed rule's expansion of the Weldon Amendment turns private entities into "federal agencies or programs" and then bars them (as well as the Department) from "discriminating" against a "health care entity" based on its refusal to provide "referrals" for abortion.[36] "Discrimination" includes, among other things, denying federal awards or sub-awards to objectors.[37] Similarly, the proposed rule provides that the Department cannot require recipients of grants provided under the Public Health Service Act to "assist in the performance of an abortion."[38] Such "assistance" includes an unreasonably broad range of conduct, including "counseling, referral, training, and other arrangements." Also, the proposed rule provides that entities receiving Public Health Service Act grants cannot be required to

[35] 42 USC § 238n(c)(2).
[36] 83 Fed. Reg. at 3925.
[37] 83 Fed. Reg. at 3923–3924.
[38] 83 Fed. Reg. at 3925.

provide personnel for "the performance or assistance in the performance of any . . . abortion;" the overbroad definition of "assistance" again applies here.[39]

Federal agencies routinely provide financial assistance to eligible entities in the form of grants, contracts, or other agreements in exchange for the performance of a prescribed set of services or activities. The Department's approach would seem to give objectors a virtually unlimited right to ignore these generally applicable requirements and may even force the Department to fund entities that refuse to advance the fundamental goals of the programs in which they seek to participate. Nowhere in the proposed rule does the Department acknowledge that its exemptions in these areas would allow conduct that conflicts with pre-existing legal requirements. Nor does it consider how overriding these rules could undermine important health care objectives that are central to the effective administration of federally supported health programs.

The proposed rule's defects come into clear focus in the context of Title X, the nation's program for birth control and reproductive health. Title X of the Public Health Service Act empowers the Department to make grants to public and not-for-profit entities for the purpose of providing confidential family planning and related preventive services.[40] Title X gives priority to services for people with low incomes and, depending on their income and insurance status, patients may be eligible for free or discounted Title X services.[41] In 2016, Title X-funded providers served over 4 million people.[42] This total includes a disproportionate share of individuals from groups that face longstanding racial and ethnic inequities; for example, 32 percent of Title X patients identified as Hispanic or Latino, and 21 percent identified as Black in 2016.[43] Title X-funded projects offer a range of reproductive health care and information, including counseling and services related to a broad range of contraceptive methods, HIV/STI services, cancer screenings, and other care.

The Department's proposal appears to sanction conduct that would interfere with Title X's legal requirements. For example, although Title X funds are barred from going toward abortion, the program's regulations expressly require providers to offer non-directive options counseling to patients, including abortion counseling and referrals upon request.[44] Even before its codification in regulation, longstanding Departmental interpretations held that non-directive options counseling was a basic and necessary Title X service.[45] The centrality of non-directive options counseling in Title X is reinforced every year through legislative mandates in annual appropriations measures.[46] These prescriptions reflect well-settled principles of medical ethics: patients are entitled to prompt, accurate, and complete information to enable them to make informed decisions about their health. And, especially when an entity does not offer a desired

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[39] 83 Fed. Reg. at 3925.
[40] 42 U.S.C. §§ 300 - 300a-8.
[41] 42 U.S.C. § 300a–4(c).
[42] Christina Fowler, et al., RTI International, *Family Planning Annual Report: 2016 national summary* (2017), available at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
[43] *Id.*
[44] 42 U.S.C. § 300a-6 (prohibiting funding for abortion); 42 C.F.R. § 59.5(a)(5) (requiring non-directive options counseling and referral).
[45] *See* Comptroller General of the United States, "Restrictions on Abortion and Lobbying Activities In Family Planning Programs Need Clarification" (Sept. 1982), available at http://www.gao.gov/assets/140/138760.pdf.
[46] *See, e.g.*, Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, 131 Stat 135 (2017).

service such as abortion, health professionals have a responsibility to provide the information and referrals needed to ensure that such services are provided to patients in a timely and competent manner. Yet, under the proposal, entities that object to "assist[ing] in the performance of abortion" could claim a right to refuse to offer non-directive options counseling and referrals to Title X patients.

On top of interfering with counseling and referrals under Title X, the proposed rule could also override other program requirements. For instance, Title X requires projects to provide medical services, including "a broad range of acceptable and effective medically approved family planning methods."[47] This unquestionably includes long-acting reversible contraceptive methods such as intrauterine devices (IUDs). The central place of IUDs, which are exceptionally effective, in the family planning repertoire is cemented by the Centers for Disease Control and Prevention's (CDC) Quality Family Planning recommendations. These recommendations provide, for example, that "[c]ontraceptive services should include consideration of a full range of FDA-approved contraceptive methods," and a "broad range of methods, including long-acting reversible contraception (i.e., intrauterine devices [IUDs] and implants), should be discussed with all women and adolescents."[48] Despite these national clinical standards of care, some individuals are opposed to contraception or certain forms of contraception, and under the proposed impermissible expansion of Church (d) discussed above, any individual working for an entity participating in Title X could claim a right to refuse to provide information or services related to contraception for Title X patients.

If allowed by the Department, such exemptions not only would overtake pre-existing legal rules, but could also thwart the critical health care objectives that federal programs are meant to advance. For example, Congress's purpose in passing Title X was, in part, "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services," and "to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services."[49] Permitting health care entities to withhold vital counseling, referrals, and services is hardly conducive to the "comprehensive" approach that was contemplated by Congress. In practical terms, such policies could cut off access to basic, preventive health care and information for the low-income and uninsured people who turn to Title X-funded providers.

Since the inception of these important public health programs, entities that do not want to provide the required services are free to decline to participate. All recipients of federal funds, however, should be bound by the same, general requirements and serve the same priorities in order to serve program beneficiaries and faithfully adhere to Congress's aims.

B. The proposed rule would severely undermine the purpose and effectiveness of U.S. funded health programs around the world.

The Department's global health programs include those focused on combating HIV/AIDS and malaria, improving maternal and child health, and enhancing global health security. In addition

[47] 42 C.F.R. § 59.5(a)(1).
[48] Centers for Disease Control and Prevention, *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, 7, 8, (2014), available at https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.
[49] Act of Dec. 24, 1970, Pub. L. No. 91-572, § 2, 84 Stat. 1504 (1970).

to funds directly appropriated to the Department for global health, considerable funding is transferred to the Department by the State Department and USAID to administer global AIDS programs under PEPFAR.

We strongly oppose the statutory prohibition on the use of foreign aid funding for abortion as a method of family planning, known as the Helms Amendment, both as it is written and the broader manner in which it is applied, and the broad and harmful refusal provision contained within the statute governing PEPFAR, which are both cited in the proposed regulation.[50] The Helms Amendment effectively coerces women into continuing unwanted pregnancies because the health care they are able to access is provided with U.S. funding. The outcome of this harmful policy is increased unwanted pregnancies and maternal morbidity and mortality.

PEPFAR's statutory refusal provision, which applies only to organizations, already puts beneficiaries at risk and undermines the overall program. For example, this restriction allows PEPFAR-participating organizations to refuse to provide condoms (or any other service to which they object) or even information about condoms to people served by the program -- despite the fact that the purpose of the program is to combat HIV/AIDS and condom provision is proven to be an essential component of effective HIV prevention programs. Organizations may even refuse to coordinate their activities or have any other relationship with programs that provide the services or information to which they object, creating a serious barrier to ensuring that the full range of HIV prevention, care, and treatment activities are available in any one community or to any individual client.

The proposed rule would go even further than the statutory refusal provision and under the guise of paragraph (d) of the Church Amendments allow any individual working under global health funds from the Department (whether the funds are from direct appropriations or transferred from another agency and then administered by the Department) to refuse to perform or assist in any part of a health service program. As explained above, this expansion of Church (d) is contrary to Congress' intent in enacting this provision. The result is to magnify the harm of PEPFAR's refusal provision by appearing to allow individuals to refuse to treat any patient if doing so would violate his or religious beliefs or moral convictions, without concern for the needs of the patient and regardless of what type of health service the patient needs -- whether it be contraception, a blood transfusion, a vaccination, condoms to prevent HIV transmission, sexually transmitted infection screenings and treatment, or even information about health care options. The proposed rule would impact a limitless array of health services.

Moreover, individuals could potentially use this broad interpretation of section (d) of the Church Amendments to pick and choose which patients to assist, making LGBTQ individuals, adolescent girls and young women, and other marginalized populations particularly vulnerable to discrimination in the provision of services. This is particularly egregious in the context of HIV/AIDS programs where these communities face elevated risk in many parts of the world. In developing countries where health systems are especially weak, there is a shortage of available health care options and supplies, and individuals often travel long distances to obtain the services that they need; it is particularly critical that individual health care providers do not deny patients the information and services that they need. Such action undermines the purpose of the programs and the rights of those they intend to serve.

[50] 83 Fed. Reg. at 3926–3927.

Furthermore, the proposed rule does not refer or defer to any but a small set of federal provisions governing U.S. foreign policy and foreign assistance, or to the agencies entrusted to set this policy. This could create confusion or even conflict with existing laws and policies, which may differ, for example, across PEPFAR implementing agencies and departments.

Finally, we are deeply concerned that the proposed rule defines recipient and subrecipient as including foreign and international organizations, including agencies of the United Nations. There are likely unique and severe compliance and certification burdens on international recipients and subrecipients, including, but not limited to with regard to translation and conflict with local law and policy. The proposed rule may directly conflict with the laws and policies of other countries where global health programs operate, putting those implementing the global health programs in an untenable position. For example, some countries may require health care providers to provide necessary care in emergency situations or information or referral for all legal health services - requirements that would be in direct conflict with this proposed regulation. The application of these requirements to UN agencies, such as the World Health Organization (WHO) with whom the Department works on issues like measles and polio, may be wholly unworkable given their missions and structures and could completely jeopardize the ability of these agencies to partner with the Department.

V. The proposed rule would cause chaos and confusion as it is inconsistent with federal and state laws designed to prohibit discrimination and increase people's access to care.

The Department claims that it is creating a regulatory scheme that is "comparable to the regulatory schemes implementing other civil rights laws." First, the proposal does not warrant the broad enforcement authority delegated to the newly created division within OCR. The proposed rule and underlying statutes are not civil rights laws, and the proposed rule seeks to grant OCR the authority to take enforcement actions. Further, the proposed rule is not consistent with civil rights laws as it fails to provide covered entities due process protections afforded under Title VI of the Civil Rights Act (Title VI). Finally, the proposed rule would create confusion as to the interaction with existing federal and state laws. In particular, the proposed rule does not explain how it interacts with Title VII of the Civil Rights Act (Title VII) and it undermines states' ability to require care.

A. The proposed rule provides expanded enforcement authority to OCR, while at the same time lacking necessary due process protections, such as those provided by Title VI.

While the proposed rule purports to model itself after "the general principles . . . enshrined in Title VI of the Civil Rights Act (Title VI)," it includes draconian enforcement provisions that are wildly out of sync with those in Title VI. Title VI requires a four step process before a federal agency may deny or terminate a recipient's federal funds: 1) the recipient must be notified that it has been found not in compliance with the statutes and that it can voluntarily comply; 2) the recipient must be afforded an opportunity for a hearing on the record and the agency must make an express finding of failure to comply; 3) the Secretary or head of the agency must approve the decision to suspend or terminate funds; and 4) the Secretary of the agency must file a report with the House and Senate legislative committees with jurisdiction over the applicable programs that explains the grounds for the agency's decision, and the agency may not terminate funds

until 30 days after the report is filed.[51] The proposed rule affords no such procedural due process for those accused, investigated, or those found in violation of the underlying requirements. In particular, if the proposed rule were to become law as is, then a recipient could have its financial assistance withheld in whole or in part, have its case referred to DOJ, or face a range of other unspecified actions – all without the opportunity to explain or defend its actions.

Additionally, Title VI clearly requires that an agency must engage in a concerted effort to obtain voluntary compliance *before* it may begin enforcement proceedings against an entity found to be in violation.[52] Specifically, federal law states that "effective enforcement of Title VI requires that agencies take prompt action to achieve voluntary compliance in all instances in which noncompliance is found."[53] The proposed rule loosely states that "OCR will inform relevant parties and the matter will be resolved informally wherever possible," and notes that while attempting to obtain this informal compliance, OCR can simultaneous engage in a range of enforcement actions.[54] This is not consistent with Title VI as it does not require the Department to attempt to achieve voluntary compliance from an entity *before* enforcement actions are taken.

Further, no guidance is given about the actions that would trigger each enforcement mechanism. For instance, would failure to meet the rule's requirement to post a notice result in millions of dollars of funds being withheld? Can failure to certify intention to comply with the rule result in a referral to DOJ? This proposed rule seems to allow OCR unlimited discretion to choose its enforcement mechanism -- including withdrawal of all federal funding and/or a referral to DOJ within any assurance that the Department's actions are proportionate to the violation. The Supreme Court has found government overreach when Congress authorized the Department to utilize federal financial assistance to control recipients' actions. Specifically, in *National Federation of Independent Business v. Sebelius*, the Supreme Court held that Congress exceeded its authority when it authorized the Department to withhold federal financial assistance from a state's Medicaid program if the state failed to expand the program's eligibility.[55] The Court explained if the Department withheld all federal funding from a state for failing to comply with conditions attached to the funding, then States would not have a "genuine choice whether to accept the offer" for funding.[56] Such financial inducement was found to be akin to a "gun to the head."[57] Therefore, the Department does not have unbridled authority to withhold federal financial assistance, and the Department's actions must be proportionate to the violation.

The enforcement actions contemplated under the proposed rule resulting from a formal or informal complaint are all the more problematic given that the entity may ultimately not be found in violation of the proposed rule's requirements. Covered entities subject to a "compliance review or investigation" must inform any Department funding component of such review, investigation, or complaint, and for five years, the entity must disclose on applications for new or renewed federal financial assistance or Department funding that it has been the subject of a

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[51] 42 U.S.C. § 2000d-1.
[52] 42 U.S.C. § 2000d-1.
[53] 28 C.F.R. § 42.411(a).
[54] 83 Fed. Reg. at 3930.
[55] National Federation of Independent Business v. Sebelius, 567 U.S. 519, 588 (2012).
[56] *Id.* at 584.
[57] *Id.* at 582.

review, investigation, or complaint.[58] This disclosure must be done even if the compliance reviews or investigations are found frivolous or do not lead to a finding of violation. The Department can conduct compliance reviews "whether or not a formal complaint has been filed." The Department is also "explicitly authorized to investigate 'whistleblower' complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by" the refusal laws.

The Department's sweeping enforcement authority, coupled with the lack of specific guidance to covered entities about what the proposed rule would require, places an unwarranted burden upon covered entities. The proposed rule is not consistent with Title VI - in particular, the rule does not offer due process and affords the Department complete discretion to impose penalties disproportionate to actions or alleged actions.

B. The proposed rule upsets the balance for religious objection long enshrined in law by Title VII.

For more than 50 years, Title VII has provided protections against religious discrimination.[59] In defining "discrimination" in a way that can be understood as both different from and far broader than it has long been understood, the Department has both exceeded its authority and caused confusion. In particular, the proposed rule does not clearly state that "discrimination" has the same limits as it does in the context of religious discrimination under Title VII and in particular that the "reasonable accommodation/undue hardship" framework for assessing if there has been "discrimination" also applies under the proposed rule. On its face, it is unclear if the proposed rule adopts Title VII's reasonable accommodation/undue hardship standard, or rather, creates a *per se* rule that allows employees' beliefs to take precedence over the needs and interests of health care providers and their patients under any circumstance.

Under Title VII and the case law interpreting it: [A]n employer, once on notice, [must] reasonably accommodate an employee whose sincerely held religious belief, practice or observance conflicts with a work requirement, *unless providing the accommodation would create an undue hardship, . . . [meaning] that the proposed accommodation in a particular case poses a "more than de minimis" cost or burden.*[60] Court cases that have addressed the issue of religious refusal have found that there are limits to what employers must do to accommodate refusals, and specifically that it is legal and appropriate for employers to prioritize maintaining patient access to care.[61] Additionally, years of case law interpreting religious accommodation

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[58] 83 Fed. Reg. at 3929–3930.

[59] 42 U.S.C. § 2000e(j).

[60] U.S. Equal Employment Opportunities Comm'n, Section 12: Religious Discrimination, Compliance Manual 46 (2008), *available at* http://eeoc.gov/policy/docs/religion.html [hereinafter EEOC Compliance Manual] (emphasis added).

[61] *See*, *e.g.*, *Walden v. Centers for Disease Control & Prevention*, 669 F.3d 1277 (11th Cir. 2012) (The plaintiff was employed as a counselor through CDC's employment assistance program, but refused to counsel people in same-sex relationships. After she was laid off, the court held that CDC "reasonably accommodated Ms. Walden when it encouraged her to obtain new employment with the company and offered her assistance in obtaining a new position"); *Bruff v. N. Miss. Health Servs.*, 244 F.3d 495, 501 (5th Cir. 2001) (the accommodation requested by plaintiff—a counselor who refused to counsel individuals on certain topics that conflicted with her religious beliefs—constituted an undue hardship

provisions of Title VII has made clear that an accommodation should not place an unfair load on co-workers.[62] Finally, case law has made it clear that "Title VII does not require an employer to reasonably accommodate an employee's religious beliefs if such accommodation would violate a federal statute."[63] The proposed rule fails to give any consideration to this binding precedent or suggest why "discrimination" should be given any different meaning in the context of the refusal laws.

By requiring a balancing of interests between the employee, the employer, and the employer's clients, Title VII ensures that accommodating the religious beliefs of an employee in the health care field does not harm patients by denying them health care and/or health care information. Title VII also avoids placing employers in the untenable position of having employees on staff who will not fulfill core job functions. The Department has ignored that balancing, undermining its stated goal to "ensure knowledge, compliance, and enforcement of the Federal health care conscience and associated antidiscrimination laws."[64] In so doing, the Department should bear in mind that a decision not to incorporate the Title VII reasonable accommodation/undue hardship balancing would lead to absurd and disastrous results. For example, a health care provider could be forced to hire employees who refuse to be involved in medical services that form the core of the medical care it offers. The Department should also bear in mind Executive Order 13563's injunction, which as the Department notes requires it to "avoid creating redundant, inconsistent, or overlapping requirements applicable to already highly-regulated industries and sectors."

The ability of health care employers to continue providing medically appropriate services and information would be significantly compromised if they are forced to operate under a rule which could be understood to compel them to hire, retain, and/or not transfer employees who refuse to provide medically necessary health services and information to patients -- or face a possible penalty of loss of all federal funding.

C. The proposed rule limits states' authority to increase health care access for their citizens.

This rule would undermine states' ability to protect and expand health care access. States have an important role to play when addressing the harm from denials of health care. State laws that require institutions to provide information, referrals, prescriptions, or care in the event of a life or health risk are vital safeguards for individuals who might be impacted by religious refusals. The expansion of the Weldon and Church Amendments through new definitions and a

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because it would have required her co-workers to assume her counseling duties whenever she refused to do so, resulting in a disproportionate workload on co-workers); *see also Haliye v. Celestica Corp.*, 717 F. Supp. 2d 873, 880 (D. Minn. 2010) ("when an employee has a religious objection to performing one or more of her job duties, the employer may have to offer very little in the way of an accommodation—perhaps nothing more than a limited opportunity to apply for another position within the organization") (citing Bruff).

[62] *See, e.g., Tagore v. United States*, 735 F.3d 324, 330 (5th Cir. 2013) ("more than de minimis adjustments could require coworkers unfairly to perform extra work to accommodate the plaintiff"); *Harrell v. Donahue*, 638 F.3d 975, 980 (8th Cir. 2011) ("an accommodation creates an undue hardship if it causes more than a de minimis impact on co-workers").

[63] *Yeager v. First Energy Generation Corp.*, 777 F.3d 362, 363 (6th Cir. 2015).

[64] 83 Fed. Reg. at 3887.

reinterpretation of existing law could render useless any existing or future state laws that protect patients and consumers.

The Department makes it clear that there are certain types of state laws that they seek to eliminate by reinterpreting the federal refusal laws. For example, the Department clearly wants to undermine state laws that require coverage of abortion. To do so, the Department not only reverses their position on the application of the Weldon amendment, but actually changes the existing (and statutory) definition of "health care entity" so as to include plan sponsors and third party administrators. This will mean more individuals are covered under the statute. The Department has previously rejected this interpretation noting "by its plain terms, the Weldon Amendment's protections extend only to health care entities and not individuals who are patients of, or institutions, or individuals that are insured by such entities."[65]

The Department also highlights state laws that require crisis pregnancy centers to provide information or referrals, as well as state laws and previous lawsuits that seek to require the provision of health care by an institution when a patient's health or life is at risk. The Department clearly wishes to contort the federal refusal laws to address state laws that it finds objectionable. If Congress had wanted to prohibit federal, state, and local governments from ever requiring health care entities to provide, pay for, cover, or refer for abortions, it could easily have done so. The Department now reinterprets these laws to attempt to limit the reach of state laws that protect patients from harmful denials of health care, including laws that simply require referrals to another provider.

The proposed rule invites those who oppose access to reproductive health to make OCR complaints by allowing any individual to file a complaint, whether or not they are the subject of any potential violation. This may have a chilling effect on states' willingness to enforce their own laws. The uncertainty regarding whether enforcement of state laws is "discrimination," especially as to health care entities that refuse to provide medical services or insurance coverage for reasons other than moral or religious reasons, would inhibit states' ability to increase access and provide for the well-being of their citizens. The negative effects of such confusion and uncertainty in our public health care system would certainly fall disproportionately on the millions of people in this country who already experiences barriers to health care access and worse health outcomes, including but not limited to women, LGBTQ people, and people living with HIV.

VI. The proposed rule fails to properly account for the enormous costs it would impose on providers, patients, and the public.

The Department purports to have conducted an economic analysis for the proposed rule, as required by Executive Order 12866 as well as the Regulatory Flexibility Act, but that analysis is deficient in at least two respects.[66] First, and critically, the Department's analysis ignores entirely the cost to patients of reduced access to health care, fewer health care options, less

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[65] Letter from Jocelyn Samuels, Director, Office for Civil Rights to Catherine Short, Life Legal Defense Foundation et. al. re: OCR Transaction Numbers: 14-193604, 15-193782, & 15-195665 (June 21, 2016), http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf.

[66] That Act requires an analysis of a rule's effects on small businesses, including non-profits. The proposed rule's analysis at 83 Fed. Reg. 3918 is inadequate because as explained below it radically underestimates costs. And while the proposed rule notes that some entities are exempted from some requirements based on cost concerns, it fails to explain why those exemptions (which at any rate would not mitigate the costs described below) were so limited.

comprehensive medical information, impeded ability for patients to make their own health care choices, and interference with provider-patient relationships.[67] Also contrary to Executive Order 12866, it fails to account for how these costs are distributed, e.g. whether they will fall disproportionately on women, rural residents, individuals with low incomes, people of color, LGBTQ people, and people living with HIV. It fails to account for the public health costs associated with reduced patient access to medical information, contraception, abortion, and other reproductive health care, or delays in accessing care due to refusals. Thus, it clearly fails multiple requirements under Executive Order 12866, including the requirement that the Department analyze "any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs."

Second, the Department's estimate of costs that the rule imposes on health care providers is far too low. Given the new burdensome notice and attestation policies, it is unrealistic to think that health care providers -- who as of 2015, employed more than 12 million employees -- would be able to adjust all of their policies, train all of their hiring managers, and ensure and document compliance with the proposed rules, for less than $1000 the first year and less than $900 in subsequent years.[68] Moreover, the Department's cost analysis ignores entirely the enormous cost imposed on health care providers if they were required to employ people unwilling to fulfill job functions necessary to deliver care.

Therefore, the Department's estimate that the proposed rule would cost over $812 million dollars within the first five years is inadequate.[69] But even if it would *only* cost the amount estimated by the Department (which it would not), that sum could be far better used to *provide* health care to individuals and correct inequities in the health care system. While the Department claims the rule is required to "vindicate" the religious or moral conscience of health care providers, significant portions of the proposed rule have nothing to do with the Department's purported motivation. Rather, certain sections give license to HMOs, health insurance plans, or any other kind of health care organization to refuse to pay for, or provide coverage of necessary abortion services for any reason—even financial.[70] These provisions do not protect anyone's conscience, they simply undercut providers' ability to deliver care and consumers' ability to obtain and pay for medical services. The limited resources of the Department and health care providers should be better spent.

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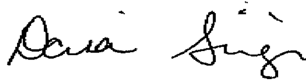
We strongly urge the Department to withdraw this rule. In 2011, the Department withdrew a

[67] The Department claims that the rule provides non-quantifiable benefits, such as more diverse and inclusive workforce, improved provider patient relationships; and equity, fairness, and non-discrimination. This proposed rule would in fact lead to the exact opposite of these intended benefits. While the Department claims to be protecting the psychological, emotional, and financial well-being of health care workers who refuse to provide care, the proposed rule does not mention the psychological, emotional, or financial harms to patients of well-being associated with being denied access to care.
[68] Kaiser Family Foundation, State Facts: Total Health Care Employment (May 2015), https://www.kff.org/other/state-indicator/total-health-care-employment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.
[69] The economic analysis estimates the cost at $312 million dollars in year one alone and over $125 million annually in years two through five. And those estimates are based on "uncertain" assumptions that the costs would decrease after five years. 83 Fed. Reg. at 3902.
[70] 83 Fed. Reg. at 3925.

similar rule that was enacted in 2008 noting that the 2008 rule attempting to clarify existing laws had "instead led to greater confusion." This rule has the potential to cause even more confusion and, more egregiously, to reduce access to critical health care even more severely than the 2008 rule. It would jeopardize many people's health and lives. Planned Parenthood strongly urges the Department to follow the law and withdraw this dangerous rule.

Respectfully,



Dana Singiser
Vice President of Public Policy and Government Relations
Planned Parenthood Action Fund
Planned Parenthood Federation of America
1110 Vermont Avenue NW, Suite 300
Washington, DC 20005

Exhibit 11

March 27, 2018

Secretary Alex Azar
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on HHS proposed rule on Protecting Statutory Conscience Rights in Health Care, HHS–OCR–2018–0002, RIN 0945-ZA03

Dear Secretary Azar:

The co-chairs of the Consortium for Citizens with Disabilities (CCD) Rights Task Force submit these comments in response to HHS's proposed rule interpreting religious refusal laws. CCD is the largest coalition of national organizations working together to advocate for federal public policy that ensures the self-determination, independence, empowerment, integration, and inclusion of children and adults with disabilities in all aspects of society.

As advocates for the rights of individuals with disabilities to full and equal participation in all aspects of our society, we have serious concerns about the vagueness and breadth of the proposed rule's provisions and the potential impact that it may have on the application of disability and civil rights laws, such as the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act. For example, the proposed provisions at 45 C.F.R. §§ 88.3(a)(2)(v) and 88.3(a)(2)(vi) seem to allow health care providers and staff extremely broad latitude in refusing to perform or assist in the provision of any lawful health service on the ground that doing so would be contrary to his or her religious beliefs. The proposed rule fails to discuss how these broad interpretations of religious refusal laws would interact with civil rights laws. To the extent that its provisions may be interpreted to limit the rights of people with disabilities under the ADA, Section 504, or other civil rights laws to receive health care services, however, we strongly object to them.

Congress provided a "broad mandate" in the ADA and Section 504 "to remedy widespread

discrimination against disabled individuals."[1] The ADA was designed "to provide clear, strong, *consistent, enforceable* standards addressing discrimination against individuals with disabilities."[2] Religious beliefs, regardless of the sincerity with which they are held, cannot be used as a shield for discrimination in contravention of disability rights mandates.

Discrimination in the provision of health care based on religious grounds presents particular concerns for people with disabilities because many people with disabilities rely heavily on religiously affiliated service providers for daily supports. In fact, many people with disabilities have little choice but to receive needed services from such service providers. And those service providers—particularly residential providers—are frequently responsible for assisting with many aspects of a person's life.

People with disabilities have sometimes been excluded from needed services or faced barriers to receiving those services due to service provider objections. For example, group homes have sometimes refused to allow people with disabilities to live with their spouses or romantic partners - even in the case of a heterosexual married couple.[3] Recent federal regulations concerning Medicaid home and community-based services now more clearly require residential service providers for people with disabilities to allow choice of roommate and overnight visitors.[4] Allowing religiously-affiliated service providers to deny residential services to people with disabilities based on a religious objection such as this could dramatically undermine their clients' right to pursue relationships and exercise fundamental rights of association.

The broad language of the proposed rule might also be interpreted to mean that the service providers on whom people with disabilities rely to coordinate necessary services or to provide transportation, personal care services, or other key services could refuse to provide these services, even if the person is entitled to receive them through Medicaid, Medicare, or another program. For example, these provisions might permit a case manager to refuse to set up a medical appointment for a person with a disability to see a gynecologist if contraceptives might be discussed, might permit a personal care services provider to refuse to assist a person with a disability in performing parenting tasks because the person was married to someone of the same gender, might permit a mental health service provider to refuse to provide needed treatment to an individual based on the fact that the individual was transgender, and might permit a sign language interpreter to refuse to help a person communicate with a doctor about sexual health. As these examples demonstrate, a denial of service based on a provider's personal moral

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[1] *PGA Tour, Inc. v. Martin*, 532 U.S. 661, 674 (2001).
[2] 42 U.S.C. § 12101(b)(2) (emphasis added). Section 504 contains virtually identical requirements.
[3] *See Forziano v. Independent Grp. Home Livin Prog.*, No. 13-cv-00370 (E.D.N.Y. Mar. 26, 2014) (dismissing lawsuit against group homes, including a religiously affiliated group home, that refused to allow married couple with intellectual disabilities live together).
[4] 42 C.F.R. §§ 441.710(a)(vi)(B)(2), 441.710(a)(vi)(D).

objection can potentially impact every facet of life for a person with disabilities – including autonomy, parental rights, and access to the community.

In addition, individuals with particular disabilities have historically faced discrimination on the basis of religious beliefs.[5] Cases abound where religious scruples have been invoked to deny services to HIV-infected people; as recently as 2009, pharmacists unsuccessfully challenged a Washington law prohibiting pharmacies from refusing to deliver lawfully prescribed or approved medicines.[6] This is also an extremely relevant issue for the disability community since 4.6 percent of Deaf people are infected with HIV/AIDS, four times the rate for the African-American population,[7] the most at-risk racial group in the U.S.[8]

People with disabilities not only experience health disparities themselves, but those disparities are compounded by the health disparities that they face as members of other demographic groups such as women, people of color, and LGBTQ people. While disability affects people of all races, ethnicities, genders, languages, sexual orientations, and gender identities, disability does not occur uniformly among racial and ethnic groups. Disability prevalence is highest among African Americans, who report disability at 20.5 percent compared to 19.7 percent for non-Hispanic whites, 13.1 percent for Hispanics/Latinos and 12.4 percent of Asian Americans.[9] Disability prevalence among American Indians and Alaskan Natives is 16.3 percent.[10] An Institute of Medicine report has already observed that there are "clear racial differences in medical service utilization rates of people with disabilities that were not explained by socioeconomic variables," and "persistent effects of race/ethnicity [in medical service utilization] could be the result of culture, class, and/or discrimination."[11] These compounded disparities place people with disabilities at greater risk of denials of needed health care.

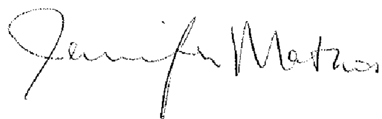
[5] National Women's Law Center, *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.
[6] *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1116 n.7 (9th Cir. 2009)
[7] Disability Policy Consortium, Seth Curtis and Dennis Heaphy, *Disabilities and Disparities: Executive Summary* 3 (March 2009).
[8] *Id*.
[9] U.S. Census Bureau, Matthew Brault, *Americans With Disabilities: 2005, Current Population Reports* 117 (2008). Many of the differences between the disability rates by race and Hispanic origin can be attributed to differences in the age distributions of their populations. For example, Hispanics are predominantly younger than non-Hispanic whites.
[10] U.S. Census Bureau, *2009 American Community Survey, S1810, Disability Characteristics 1 year estimates* (2009) http://factfinder.census.gov/servlet/STTable?_bm=y&¬qr_name=ACS _2009_1YR_G00_S1810&-geo_id=01000US&¬ds_name=ACS_2009_1YR_G00_&-_lang=en&- format=&-CONTEXT=st.
[11] Institute of Medicine, *The Future of Disability in America* 92 (2007).

Finally, we note that Title III of the ADA already exempts from coverage "religious entities or entities controlled by religious organizations, including places of worship."[12] The sweeping language of the proposed rule has the potential to create conflicts with Title III and to preempt enforcement of similar state and local laws protecting people with disabilities.

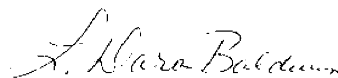
For the foregoing reasons, we urge you to revise the proposed rule to ensure that the religious refusal provisions are not interpreted to preempt civil rights protections.

Sincerely,

CCD Rights Co-Chairs
On behalf of CCD Rights Task Force

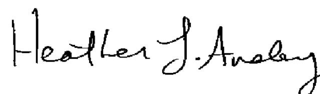


Jennifer Mathis
Bazelon Center for Mental Health Law



Dara Baldwin
National Disability Rights Network

Mark Richert
American Foundation for the Blind



Heather Ansley
Paralyzed Veterans of America

Samantha Crane
Autistic Self Advocacy Network

[12] 42 U.S.C. § 12187.

Exhibit 12

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

March 27, 2018

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (RIN 0945-ZA03), 83 Fed. Reg. 3880 (January 26, 2018)

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments to the Department of Health and Human Services (HHS) in response to the Notice of Proposed Rulemaking (Proposed Rule or Proposal) on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," issued by the Office of Civil Rights (OCR). In its Proposed Rule, OCR proposes to revise existing regulations and create new regulations to interpret and enforce more than 20 federal statutory provisions related to conscience and religious freedom. Under OCR's broad interpretation of these provisions, individuals, health care organizations, and other entities would be allowed to refuse to provide or participate in medical treatment, services, information, and referrals to which they have religious or moral objections. This would include services related to abortion, contraception (including sterilization), vaccination, end-of-life care, mental health, and global health support, and could include health care services provided to patients who are lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ).

For the reasons discussed below, the AMA believes the Proposed Rule would undermine patients' access to medical care and information, impose barriers to physicians' and health care institutions' ability to provide treatment, impede advances in biomedical research, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients. We are very concerned that the Proposed Rule would legitimize discrimination against vulnerable patients and in fact create a right to refuse to provide certain treatments or services. Given our concerns, we urge HHS to withdraw this Proposal.

The AMA supports conscience protections for physicians and other health professional personnel. We believe that no physician or other professional personnel should be required to perform an act that violates good medical judgment, and no physician, hospital, or hospital personnel should be required to perform any act that violates personally held moral principles. As moral agents in their own right, physicians are informed by and committed to diverse cultural, religious, and philosophical traditions and beliefs. According to the *AMA Code of Medical Ethics*, "physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities."

Conscience protections for medical students and residents are also warranted. The AMA supports educating medical students, residents, and young physicians about the need for physicians who provide termination of pregnancy services, the medical and public health importance of access to safe termination of pregnancy, and the medical, ethical, legal, and psychological principles associated with termination of pregnancy, while maintaining that the observation of, attendance at, or any direct or indirect participation in abortion should not be required.

Nonetheless, while we support the legitimate conscience rights of individual health care professionals, the exercise of these rights must be balanced against the fundamental obligations of the medical profession and physicians' paramount responsibility and commitment to serving the needs of their patients. As advocates for our patients, we strongly support patients' access to comprehensive reproductive health care and freedom of communication between physicians and their patients, and oppose government interference in the practice of medicine or the use of health care funding mechanisms to deny established and accepted medical care to any segment of the population.

According to the AMA *Code of Medical Ethics*, physicians' freedom to act according to conscience is not unlimited. Physicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient. Physicians have stronger obligations to patients with whom they have a patient-physician relationship, especially one of long standing; when there is imminent risk of foreseeable harm to the patient or delay in access to treatment would significantly adversely affect the patient's physical or emotional well-being; and when the patient is not reasonably able to access needed treatment from another qualified physician. The Code provides guidance to physicians in assessing how and when to act according to the dictates of their conscience. Of key relevance to the Proposed Rule, the *Code* directs physicians to:

- Take care that their actions do not discriminate against or unduly burden individual patients or populations of patients and do not adversely affect patient or public trust.
- Be mindful of the burden their actions may place on fellow professionals.
- Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.
- In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer. When a deeply held, well-considered personal belief leads a physician also to decline to refer, the physician should offer impartial guidance to patients about how to inform themselves regarding access to desired services.
- Continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethics guidance.

The ethical responsibilities of physicians are also reflected in the AMA's long-standing policy protecting access to care, especially for vulnerable and underserved populations, and our anti-discrimination policy, which opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age. We are concerned that the Proposed Rule, by attempting to allow individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program based on religious beliefs or moral convictions, will allow discrimination against patients, exacerbate health inequities, and undermine patients' access to care.

We would like to note that no statutory provision requires the promulgation of rules to implement various conscience laws that have been in existence for years. We believe physicians are aware of their legal obligations under these requirements and do not think that the promulgation of this rule is necessary to enforce the conscience provisions under existing law. OCR has failed to provide adequate reasons or a satisfactory explanation for the Proposed Rule as required under the Administrative Procedure Act (APA). As OCR itself acknowledges, between 2008 and November 2016, OCR received 10 complaints alleging violations of federal conscience laws; OCR received an additional 34 similar complaints between November 2016 and January 2018. In comparison, during a similar time period, from fall 2016 to fall 2017, OCR received over 30,000 complaints alleging violations of either HIPAA or civil rights. These numbers demonstrate that the Proposed Rule to enhance enforcement authority over conscience laws is not necessary.

OCR's stated purpose in revising existing regulations is to ensure that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate, in violation of federal laws. We believe that several provisions and definitions in the Proposed Rule go beyond this stated purpose and are ambiguous, overly broad, and could lead to differing interpretations, causing unnecessary confusion among health care institutions and professionals, thereby potentially impeding patients' access to needed health care services and information. The Proposed Rule attempts to expand existing refusal of care/right of conscience laws—which already are used to deny patients the care they need—in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object. But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on. Such an attempted expansion goes beyond what the statute enacted by Congress allows.

We are concerned that the scope of the services and programs that would be covered under the Proposed Rule is broader than allowed by existing law. While OCR claims that it is trying to clarify key terms in existing statutes, it appears that they are actually redefining many terms to expand the meaning and reach of these laws. For example, "health program or activity" is defined in the proposed regulatory text to include "the provision or administration of any health-related services, health service programs and research activities, health-related insurance coverage, health studies, or any other service related to health or wellness whether directly, through payments, grants, contracts, or other instruments, through insurance, or otherwise." Likewise, "health service program" is defined in the proposed regulatory text to include "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded, in whole or in part, by [HHS]." These definitions make clear that OCR intends to interpret these terms to include an activity related <u>in any way</u> to providing medicine, health care, or any other service related to health or wellness, including programs where HHS provides care directly, grant programs such as Title X, programs such as Medicare where HHS provides reimbursement, and health insurance programs where federal funds are used to provide access to health coverage, such as Medicaid and CHIP. The definitions inappropriately expand the scope of the conscience provisions to include virtually any medical treatment or service, biomedical and behavioral research, and health insurance.

Furthermore, the Proposed Rule's new and expanded definitions often exceed, or are not in accordance with, existing definitions contained within the existing laws OCR seeks to enforce. For example, "health care entity" is defined under the Coats and Weldon Amendments to include a limited and specific range of individuals and entities involved in the delivery of health care. However, the Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term by including a wide range of individuals, e.g., not just health care professionals, but any personnel, and institutions, including not only health care facilities and insurance plans, but also plan sponsors and state and local governments. This impermissibly expands statutory definitions and will create confusion.

We are also concerned that the proposed rule expands the range of health care institutions and individuals who may refuse to provide services, and broadens the scope of what qualifies as a refusal under the applicable law beyond the actual provision of health care services to information and counseling about health services, as well as referrals. For example, "assist in the performance" is defined as "participating in any program or activity with an articulable connection to a given procedure or service." The definition also states that it includes "counseling, referral, training, and other arrangements for the procedure, health service, or research activity." While "articulable connection" is not further explained, OCR states in the preamble that it seeks to provide broad protection for individuals and that a narrower definition, such as a definition restricted to those activities that constitute direct involvement with a procedure, health service, or research activity, would not provide sufficient protection as intended by Congress.

However, this definition goes well beyond what was intended by Congress. Specifically, the Church Amendments prohibit federal funding recipients from discriminating against those who refuse to perform, or "assist in the performance" of, sterilizations or abortions on the basis of religious or moral objections, as well as those who choose to provide abortion or sterilization. The statute does not contain a definition for the phrase "assist in the performance." Senator Church, during debate on the legislation, stated that, "the amendment is meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation." Read in conjunction with the rest of the proposed rule, it is clear this definition is intended to broaden the amendment's scope far beyond what was envisioned when the amendment was enacted. It allows any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

In a similar fashion, the proposed definition of "workforce" extends the right to refuse not only to an entity's employees but also to volunteers and trainees. When both of these definitions are viewed together, this language seems to go well beyond those who perform or participate in a particular service to permit, for example, receptionists or schedulers to refuse to schedule or refer patients for medically necessary services or to provide patients with factual information, financing information, and options for medical treatment. It could also mean that individuals who clean or maintain equipment or rooms used in procedures to which they object would have a new right of refusal and would have to be accommodated. We believe this could significantly impact the smooth flow of health care operations for physicians, hospitals, and other health care institutions and could be unworkable in many circumstances.

The AMA is concerned that the Proposed Rule fails to address the interaction with existing federal and state laws that apply to similar issues, and thus is likely to create uncertainty and confusion about the rights and obligations of physicians, other health care providers, and health care institutions. Most notably, the Proposal is silent on the interplay with Title VII of the Civil Rights Act of 1964 and guidance by the Equal Employment Opportunity Commission, which along with state laws govern religious discrimination in the workplace. Title VII provides an important balance between employers' need to accommodate their employees' religious beliefs and practices—including their refusal to participate in specific health care activities to which they have religious objections—with the needs of the people the employer must serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs or practices, unless doing so places an "undue hardship" on the employer's business. It is unclear under the Proposed Rule if, for example, hospitals would be able to argue that an accommodation to an employee is an undue hardship in providing care. The Proposed Rule also could put hospitals, physician practices, and other health care entities in the impossible position of being forced to hire individuals who intend to refuse to perform essential elements of a job. Under Title VII, such an accommodation most likely would not be required.

Additional concerns exist for physicians with respect to their workforce under this Proposal. The Proposed Rule is unclear about what a physician employer's rights are in the event that an employee alleges discrimination based on moral or religious views when in fact there may be just cause for adverse employment decisions. For example, if a physician declines to hire an individual based on a lack of necessary skill, compensation and/or benefit requests out of the physician's budget, or simply because the individual is not a good fit in the office, but the individual also happens to be opposed to providing care to LGBTQ patients, does the physician open him/herself up to risk of a complaint to OCR? If so, physicians will be forced to substantially increase their documentation related to hiring and other decision-making related to human resources, adding administrative burden to already overworked practices. These considerations must not be overlooked by regulators, as OCR's enforcement mechanisms include the power to terminate federal funding for the practice or health care program implicated.

Adding to a practice's administrative burden is the Proposal's requirement that physicians submit both an assurance and certification of compliance requirements to OCR. Despite its reasoning in the preamble that HHS is "concerned that there is a lack of knowledge" about federal health care conscience and associated anti-discrimination laws, it remains unclear why OCR would require physicians to make two separate attestations of compliance to the same requirements, particularly given the administration's emphasis on reducing administrative burden in virtually every other space in health care. At the very least, OCR should (1) streamline the certification and assurance requirements with those already required on the HHS portal; and (2) expand the current exemptions from such requirements to include physicians participating not only in Medicare Part B, but also in Medicare Part C and Medicaid, as was the case in the 2008 regulation implementing various conscience laws. We reiterate, however, that we believe the overall compliance attestation requirements are unnecessary. If HHS' concern is about lack of awareness of the conscience laws, the AMA stands ready to assist with the agency's educational efforts in place of increased administrative requirements.

The Proposed Rule also seems to set up a conflict between conscience rights and federal, state, and local anti-discrimination laws, as well as policies adopted by employers and other entities and ethical codes of conduct for physicians and other health professionals. These laws, policies, and ethical codes are designed to protect individuals and patients against discrimination on the basis of race, gender, gender

identity, sexual orientation, disability, immigration status, religion, and national origin. It is unclear under the Proposed Rule how these important anti-discrimination laws, policies, and ethical codes will apply in the context of the expanded conscience rights proposed by OCR. The Proposed Rule also fails to account for those providers that have strongly held moral beliefs that motivate them to treat and provide health care to patients, especially abortion, end-of-life care, and transition-related care. For example, the Church Amendment affirmatively protects health care professionals who support or participate in abortion or sterilization services yet there is no acknowledgement of it in the Proposal.

Moreover, the Proposed Rule appears to conflict with, and in fact contradict, OCR's own mission, which states that "The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; *to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination*; and to protect the privacy and security of health information in accordance with applicable law" (emphasis added). In the past, HHS and OCR have played an important role in protecting patient access to care, reducing and eliminating health disparities, and fighting discrimination. There is still much more work to be done in these areas given disparities in racial and gender health outcomes and high rates of discrimination in health care experienced by LGBTQ patients. The Proposed Rule is a step in the wrong direction and will harm patients.

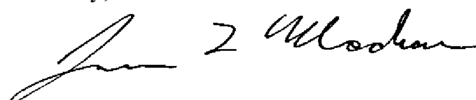
Likewise, the Proposed Rule does not address how conscience rights of individuals and institutions apply when emergency health situations arise. For example, the federal Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals that have a Medicare provider agreement and an emergency room or department to provide an appropriate medical screening to any patient requesting treatment to determine whether an emergency medical condition exists, and to either stabilize the condition or transfer the patient if medically indicated to another facility. Every hospital, including those that are religiously affiliated, is required to comply with EMTALA. By failing to address EMTALA, the Proposed Rule might be interpreted to mean that federal refusal laws are not limited by state or federal legal requirements related to emergency care. This could result in danger to patients' health, particularly in emergencies involving miscarriage management or abortion, or for transgender patients recovering from transition surgery who might have complications, such as infections.

We are also concerned that the Proposed Rule could interfere with numerous existing state laws that protect women's access to comprehensive reproductive health care and other services. For example, the Proposed Rule specifically targets state laws that require many health insurance plans to cover abortion care (e.g., California, New York, and Oregon). OCR overturns previous guidance that was issued by the Obama administration providing that employers sponsoring health insurance plans for their employees were not health care entities with conscience rights; OCR argues that the previous guidance misinterpreted federal law, and, as discussed previously, proposes to add plan sponsors to the definition of health care entities. Likewise, the Proposed Rule could conflict with, and undermine, state laws related to contraceptive coverage. In addition, the Proposed Rule requires entities to certify in writing that they will comply with applicable Federal health care conscience and associated anti-discrimination laws. Under the broad language of the rule, hospitals, insurers, and pharmacies could claim they are being discriminated against if states attempt to enforce laws that require insurance plans that cover other prescription drugs to cover birth control, ensure rape victims get timely access to and information about emergency contraception, ensure that pharmacies provide timely access to birth control, and ensure that

hospital mergers and sales do not deprive patients of needed reproductive health services and other health care services.

In conclusion, the AMA believes that, as currently drafted, the Proposed Rule could seriously undermine patients' access to necessary health services and information, negatively impact federally-funded biomedical research activities, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients. Given our concerns, we urge HHS to withdraw this proposed rule. If HHS does decide to move forward with a final rule, it should, at the very least, reconcile the rule with existing laws and modify the provisions we have identified to ensure that physicians and other health providers understand their legal rights and obligations.

Sincerely,



James L. Madara, MD

Exhibit 13

March 27, 2018

VIA ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Rule, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom It May Concern:

Lambda Legal Defense and Education Fund, Inc. ("Lambda Legal") appreciates the opportunity provided by the Department of Health and Human Services ("HHS" or the "Department") to offer comments in response to the Proposed Rule, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03 ("Proposed Rule" or "Rule"), published in the Federal Register on January 26, 2018.[1] As described herein, the Proposed Rule both exceeds its statutory authority and contravenes this Department's mission, the legal rights of patients, the ethical obligations of health professionals, and the legal rights and responsibilities of institutional health care providers. It should be withdrawn.

Lambda Legal is the oldest and largest national legal organization dedicated to achieving full recognition of the civil rights of lesbian, gay, bisexual, and transgender ("LGBT") people and everyone living with HIV through impact litigation, policy advocacy, and public education. For decades, Lambda Legal has been a leader in the fight to ensure access to quality health care for our vulnerable communities. In recent years, Lambda Legal has submitted a series of comments to HHS regarding the importance of reducing discrimination against LGBT people in health care services, the fact that current law already protects health worker conscience rights appropriately, and the ways that conscience-based exemptions to health standards endanger LGBT people and others.[2] Recently, Lambda Legal also has opposed an HHS proposal to expand

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[1] 83 Fed. Reg. 3880 *et seq*. (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88).

[2] *Lambda Legal Comments on Proposed Rule 1557 Re: Nondiscrimination in Health Programs and Activities, 1557 NPRM (RIN 0945-AA02)* (submitted Nov. 9, 2015) ("Lambda Legal 1557 Comments"), https://www.lambdalegal.org/in-court/legal-docs/hhs_dc_20151117_letter-re-1557; *Lambda Legal Comments on Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities (RIN 0945-AA02 & 0945-ZA01)* (submitted Sept. 30, 2013) ("Lambda Legal Nondiscrimination Comments"), https://www.lambdalegal.org/in-court/legal-docs/ltr_hhs_20130930_discrimination-in-health-services. *See also* Brief of Amici Curiae Lambda Legal et al., *Zubik v. Burwell*, 136 S. Ct. 1557

the ability of religiously-affiliated health care institutions and individuals to impose their religious beliefs on workers and on patients, cautioning in detail about the likely harmful consequences of any such expansions for LGBT people and people living with HIV.[3]

As to the Proposed Rule now under consideration, Lambda Legal emphatically recommends its withdrawal because:

(1) It improperly expands statutory religious exemptions in multiple ways, including by:

(a) permitting workers to refuse job duties that cannot reasonably be understood as "assisting" with an objected-to procedure, [4] and instead have merely an "articulable" connection to the procedure[5];

(b) expanding who may assert religious objections from employees performing or assisting in specified procedures to any member of the workforce[6];

(c) using an improperly expanded definition of "referral"[7] that includes providing any information or directions that could assist a patient in pursuing care; and

(d) defining "discrimination" to focus on protecting the interests of health care providers in continuing to receive favorable financial, licensing or other treatment, rather than on patients' interest in receiving medically appropriate care[8]; and

(e) defining health care entity to include health insurance plans, plan sponsors, and third-party administrators.[9]

(2016) (Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, 15-191), http://www.lambdalegal.org/in-court/legal-docs/zubik_us_20160217_amicus.

[3] *See, e.g., Lambda Legal Comments on Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (RIN 0938-AT46)* (submitted Dec. 5, 2017), https://www.lambdalegal.org/in-court/legal-docs/dc_20171205_aca-moral-exemptions-and-accommodations; *Lambda Legal Comments on Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (RIN 0938-AT20)* (submitted Dec. 5, 2017), https://www.lambdalegal.org/in-court/legal-docs/dc_20171205_aca-religious-exemptions-and-accommodations.

[4] 42 U.S.C.A. § 300a-7(b) and (d).

[5] Section 88.2, 83 Fed. Reg. at 3923.

[6] Section 88.2, 83 Fed. Reg. at 3924.

[7] *Id.*

[8] *Id.*

[9] *Id.*

(2) It encourages workers and institutions to refuse care and does not acknowledge the rights of patients, such as the right against sex discrimination provided by Section 1557 of the Affordable Care Act.[10]

(3) It encourages workers and institutions to refuse care and does not acknowledge the legal rights and duties of health care providers, such as those under Title VII of the Civil Rights Act of 1964,[11] or health professionals' ethical obligations to patients.

(4) Using broad, vague language, it addresses a purported "problem" of health workers being pressed to violate their conscience, suggesting that workers should have broad religious rights to decline care and refuse other work of any sort in any context, going far beyond the narrow contexts specified in the authorizing statutes.

(5) Its proposed enforcement mechanisms are draconian, threatening the loss of federal funding and even the potential of funding "claw backs," with limited if any due process protections, all of which would skew health systems improperly in favor of religious refusals and against patient care.

(6) The heavy-handed enforcement mechanisms inevitably would invite discrimination and aggravate existing health disparities and barriers to health care faced by LGBT people and others, contrary to the mission of HHS and, in particular, its Office for Civil Rights.

(7) It is the result of a rushed, truncated process inconsistent with procedural requirements including the Administrative Procedure Act.[12]

In sum, the role of the HHS Office for Civil Rights ("OCR") described in the Proposed Rule is not to promote access to health care and to safeguard patients against discrimination, but instead to impose vague, overbroad *restraints* on health care provision, as a practical matter elevating "conscience" objections of workers over the needs of patients. In so doing, the Proposed Rule turns the mission of HHS/OCR on its head. Freedom of religion is a core American value, which is why it is already protected by the First Amendment of the Constitution. But, that freedom does not and must not allow anyone to impose their beliefs on others or to discriminate. This basic principle is nowhere more important than in medical contexts where religion-based refusals can cost patients their health and even worse.

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[10] 42 U.S.C.A. § 18116.

[11] Civil Rights Act of 1964 § 7, 42 U.S.C.A. § 2000e *et seq.* (1964).

[12] 5 U.S.C.A. § 500 *et seq.*

I. The Proposed Rule Improperly Expands Statutory Religious Exemptions.

The Proposed Rule improperly expands statutory religious exemptions beyond their narrow, specific parameters in numerous ways. It includes definitions that would broaden the exemptions in the Church Amendments, which currently allow health workers to decline to assist in an abortion or sterilization procedure if doing so "would be contrary to [their] religious beliefs or moral convictions."[13] The Proposed Rule reinterprets what it means to "assist in the performance" of a procedure from participating in "any activity with a *reasonable* connection" to a procedure [14] to "any … activity with an *articulable* connection" to an objected-to procedure.[15] In other words, any connection that can be described, no matter how tenuous, potentially could suffice. Confirming the potentially indefinite expansion of *what* can be deemed "assistance" is a broad definition of *who* may object. From the prior common language understanding of who might be involved in a medical procedure, the new definition appears to authorize any member of the workforce to object to performing their job duties.[16]

The Proposed Rule also includes an aggressive expansion of the concept of "referral" from the common understanding of actively connecting a patient with an alternate source of a particular service to the provision of any information or directions that could possibly assist a patient who might be pursuing a form of care to which the employee objects.[17] This goes far beyond a reasonable understanding of what the underlying statute justifies.

Similarly, where the statute authorizes "health care entities" to assert religious objections, the Proposed Rule grossly expands the entities covered by that term to include health insurance plans, plan sponsors, and third-party administrators.[18] It also adds a definition of "discrimination" that focuses not on patients' interest in receiving equal, medically appropriate services, but rather on protecting health care providers' interests in continuing to receive favorable financial, licensing or other treatment while refusing on religious or moral objections to provide care despite medical standards, nondiscrimination rules, or other requirements.[19]

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[13] 42 U.S.C.A. § 300a-7.

[14] 45 C.F.R. § 88.2 (2008) (emphasis added).

[15] Proposed Rule, 83 Fed. Reg. at 3923 (emphasis added).

[16] Section 88.2, 83 Fed. Reg. at 3924.

[17] Section 88.2, 83 Fed. Reg. at 3924.

[18] Section 88.2, 83 Fed. Reg. at 3924.

[19] Section 88.2, 83 Fed. Reg. at 3924.

In numerous places, the Proposed Rule seems to indicate that HHS is adopting interpretations that would extend the Amendments' reach beyond current understanding that the exemptions only concern abortion and sterilization and follow the common medical understanding of those terms.[20] As one example, it seems likely that the "sterilization" references within the Proposed Rule could be applied to deny health care to transgender patients because the Rule itself, at footnote 36, cites *Minton v. Dignity Health* approvingly.[21] *Minton* addresses whether a Catholic hospital was legally justified when it blocked a surgeon from performing a hysterectomy for a transgender man as part of the prescribed treatment for gender dysphoria. The hospital defended on religious freedom grounds, arguing that it was bound "to follow well-known rules laid down by the United States Conference of Catholic Bishops," including rules prohibiting "direct sterilization."[22]

But, to equate hysterectomy to treat gender dysphoria with direct sterilization is medically inaccurate. Sterilization procedures undertaken for the *purpose* of sterilization are fundamentally different from procedures undertaken for other medical purposes that incidentally affect reproductive functions. Regardless of whether the United States Conference of Catholic Bishops considers gender transition-related care to be sterilization as a religious matter, were the federal government to approve a religious rationale as grounds for stretching a federal statute and permitting denial of medically necessary care would be problematic for both statutory interpretation and Establishment Clause reasons.

The Proposed Rule's apparent embrace of the Bishops' view poses an overtly discriminatory and unacceptable threat to transgender patients. This concern is not speculative. The Proposed Rule's footnote referencing *Minton* supports the following statement: "Many religious health care personnel and faith-based medical entities have further alleged that health care personnel are being targeted for their religious beliefs."[23] For the Proposed Rule to equate a transgender patient expecting to receive medically necessary care from health care personnel with those personnel "being targeted for their religious beliefs" is a chilling indicator of the direction the Proposed Rule would take health care in this country. Not only would health providers be invited to turn away transgender patients, but those that abide by their obligation to

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[20] *Compare* cases describing statute's applicability to provision or refusal provide abortions or sterilization, *e.g.*, *Cenzon-DeCarlo v. Mount Sinai Hosp.*, 626 F.3d 695 (2d Cir. 2010), *and Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308 (9th Cir. 1974), *with Geneva Coll. v. Sebelius*, 929 F. Supp. 2d 402 (W.D. Pa. 2013), *on reconsideration in part* (May 8, 2013) (statute does not apply to provision of emergency contraception, which is not abortion or sterilization).

[21] No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017).

[22] Defendant Dignity Health's Reply Brief in Support of Demurrer to Verified Complaint, *Minton v. Dignity Health*, No. 17-558259, at 2 (Calif. Super. Ct. Apr. 19, 2017) (filed Aug. 8, 2017), https://www.aclusocal.org/sites/default/files/brf.sup_.080817_defendant_dignity_healths_reply_in_support_of_demurrer_to_verified_complaint.pdf.

[23] Proposed Rule, 83 Fed. Reg. at 3888 n. 36.

provide nondiscriminatory care and require their employees to act accordingly could be stripped of federal funding if equal treatment of those patients offended any workers' personal beliefs.

The overbroad definitions and suggestive language all contribute to the alarming overall theme of the Proposed Rule—that it addresses a purported problem of health workers ostensibly being pressed wrongfully to act against their rights of conscience. The Proposed Rule's suggested cure appears to be that workers should have broad religious rights to decline care of any sort in any context. This theme starts with the broad language stating the Proposed Rule's purpose and runs throughout the rule.[24] It creates at least a serious concern that, for example, language long understood to be bounded by its statutory context only to concern abortion and sterilization could be misconstrued as authorizing health care providers to refuse to participate in *any* part of *any* health service program or research activity "contrary to [their] religious beliefs or moral convictions."[25] While such an interpretation obviously could be challenged legally, many patients have neither the knowledge nor the means to resist such improper care refusals and would simply suffer the delay or complete denial of medically needed treatments.

II. The Proposed Rule Invites Workers And Institutions To Refuse Care And Does Not Acknowledge The Rights Of Patients.

By issuing the Proposed Rule, HHS invites health workers and institutions to refuse to provide medical care for religious reasons, without acknowledging that patients often have countervailing rights. Yet, all federal agencies, including HHS, must comply with the federal statutes that protect LGBT people and others from discrimination, such as Section 1557 of the Affordable Care Act, which bars discrimination based on sex in federally funded health services and programs.[26] Properly understood, Section 1557 protects transgender patients from discriminatory denials of care based on their gender identity or transgender status.[27] It also protects lesbian, gay, and bisexual patients.[28] Even if it were not contrary to the mission of OCR

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[24] *See, e.g.,* Section 88.1 (Purpose); Appendix A (required notice to employees) to 45 C.F.R., 83 Fed. Reg. at 3931 (declaring broad right to accommodation for any religious or moral belief); 83 Fed. Reg. at 3881, 3887-89, 3903 (addressing "problem" of workers being required to meet patient needs despite their personal beliefs).

[25] 42 U.S.C.A. § 300a-7(d). See cases cited *supra* note 20.

[26] 42 U.S.C.A. § 18116.

[27] *Rumble v. Fairview Health Services*, 2015 WL 1197415 (D. Minn. March 16, 2015) (Affordable Care Act, Section 1557). *See also Whitaker v. Kenosha Unified School District No. 1 Board of Education, 858 F.3d 1034 (7th Cir. 2017*) (analogous protection against sex discrimination in Title IX protects transgender students); *EEOC v. R.G. v. G.R. Harris Funeral Homes, Inc.*, __ F.3d __, 2018 WL 1177669 (6th Cir. March 7, 2018) (analogous protection against sex discrimination in Title VII protects transgender workers).

[28] *Cf. Zarda v. Altitude Express, Inc.*, 883 F.3d 100 (2d Cir. 2018) (sexual orientation discrimination is sex discrimination under Title VII); *Hively v. Ivy Tech Comm'ty College*, 853 F.3d 339 (7th Cir. 2017) (same).

to undermine patient protections against discrimination, the agency lacks the authority to reduce the protections provided to patients by separate statutes.

The ACA also includes patient protections to ensure access to essential health services, including reproductive health services. Yet, the Proposed Rule's aggressive approach to advancing conscience rights offers nothing to explain how those refusal rights are to coexist with patients' rights under the ACA. As to these conflicts, Lambda Legal joins the comments submitted by the National Health Law Program.

Moreover, the Proposed Rule also is inconsistent with several core constitutional guarantees: (1) each of us is entitled to equal protection under law; (2) the Establishment Clause forbids our government from elevating the religious wishes of some above the needs of others to be protected from harm, including the harms of discrimination; and (3) congressional spending powers have limits. On the latter point, the Proposed Rule references the spending powers of Congress as grounds for the new enforcement powers created for HHS to condition federal funding upon health care providers' acquiescence in religious refusal demands of their workers.[29] However, as well-established by *South Dakota v. Dole*[30] and its progeny, Congress's spending powers are limited. Any exertion of power must be in pursuit of the general welfare; must not infringe upon states' abilities "to exercise their choice knowingly, cognizant of the consequences of their participation"; must be related "'to the federal interest in particular national projects or programs;'" and must be otherwise constitutionally permissible.[31]

Multiple Equal Protection and Establishment Clause concerns implicate the final prong of the *South Dakota v. Dole* test for unconstitutional conditions on federal funds. But the first prong deserves immediate focus because it obviously does not serve the general welfare to use severe de-funding threats to intimidate medical facilities into deviating from medical practice standards in favor of religious interests in secular settings, to the detriment of individual and public health.

In addition, with its explicit intention to enforce federal "conscience" rights despite contrary state and local protections for patients, the Proposed Rule further implicates federalism concerns. It states: "Congress has exercised the broad authority afforded to it under the Spending Clause to attach conditions on Federal funds for respect of conscience, and such conscience conditions supersede conflicting provisions of State law[.]"[32] It then asserts that it "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.[33] Yet, by inviting health professionals and

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[29] Proposed Rule, 83 Fed. Reg. at 3889.

[30] 483 U.S. 203 (1987).

[31] *Id.* at 207-08.

[32] Proposed Rule, 83 Fed. Reg. at 3889.

[33] *Id.* at 3918-19.

other workers to turn away patients and refuse job duties in such a sweeping way, the Proposed Rule directly conflicts with state and local nondiscrimination laws and other patient protections. Its assertions to the contrary are patently inaccurate.

III. The Proposed Rule Invites Workers To Refuse Care And Does Not Acknowledge The Legal Rights And Duties, And Ethical Obligations, Of Health Care Providers.

The Proposed Rule aims improperly to empower workers to object to job duties without addressing the impacts on employers and coworkers left somehow to try to ensure that patient needs are met by others, with whatever increased costs, workload, and other burdens it may entail. The proposed approach fails to acknowledge that the federal employment nondiscrimination law, Title VII of the Civil Rights Act of 1964, limits the extent to which employers are to be burdened by employee demands for religious accommodation.[34] Undue burdens on employers could include objections by coworkers to unfair additional job duties or to coworker proselytizing. Likewise, it certainly would impose unjustifiable burdens to require employers to hire duplicate staff simply to ensure patient needs are met by employees willing to perform basic job functions. Indeed, courts have confirmed that when denial of a requested accommodation is "reasonably necessary to the normal operation of the particular business or enterprise,"[35] employers, including health care employers,[36] need only show that they "offered a reasonable accommodation *or* that a reasonable accommodation would be an undue burden."[37]

Such limitations on employee religious rights are essential to ensure that health care employers can hire those who will perform the essential functions of their jobs, and will comply with all statutory obligations including prohibitions against discrimination. If instead, employees who claim "conscience" objections to providing the health care services to LGBT people or people living with HIV are empowered by the Proposed Rule to threaten their employees with loss of federal funding if they do not allow such discrimination, employers will face logistical

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[34] 42 U.S.C.A. § 2000e *et seq. See*, *e.g.*, *See, e.g., Bruff v. North Miss. Health Servs., Inc.*, 244 F.3d 495, 497-98 (5th Cir. 2001) (Title VII duty to accommodate employees' religious concerns did not require employer to accommodate employee's requests to be excused from counseling patients about non-marital relationships, which meant "she would not perform some aspects of the position itself"); *Berry v. Dep't of Social Servs.*, 447 F.3d 642 (9th Cir. 2006) (employer entitled to prohibit employee from discussing religion with clients).

[35] 42 U.S.C.A. § 2000e-2(e).

[36] *See, e.g., Grant v. Fairview Hosp. & Healthcare Servs.*, No. Civ. 02-4232JNEJGL, 2004 WL 326694 (D. Minn. Feb. 18, 2004) (hospital wasn't required to accommodate employee's request to be able to proselytize or provide pastoral counseling to patients to try to persuade them not to have abortions); *Robinson v. Children's Hosp. Boston*, Civil Action No. 14-10263-DJC, 2016 WL 1337255 (D. Mass. Apr. 5, 2016) (granting hospital employee's request to forgo flu shot would have been an undue hardship for hospital).

[37] *See, e.g., Sánchez-Rodríguez v. AT & T Mobility P. R., Inc.*, 673 F.3d 1, 8 (1st Cir. 2012).

nightmares and the employees without such beliefs will be unfairly subjected to increased workloads.

This seems like an inevitable repercussion particularly in light of the Proposed Rule's explanation in its definition of prohibited "discrimination" that "religious individuals or institutions [must] be allowed a level playing field, and that their beliefs not be held to disqualify them from participation in a program or benefit."[38] This definition lacks any qualifying language confirming that employers may condition employment on willingness to perform essential parts of a job. The likely effects would include increased burnout among those staff who have additional work delegated to them when religious exemptions are claimed. The Proposed Rule also would drain institutional resources as employers must respond (with management time and legal fees) to complaints filed by overburdened workers and by those who file implausible "conscience" objections upon receiving negative work evaluations. The waste of essential health care resources in service of improper denials of medical care cannot be justified.

Moreover, the Proposed Rule similarly ignores that health professionals are bound by ethical standards to do no harm and to put patient needs first. Concerning the application of this point to ensuring patients' reproductive health needs are not improperly subordinated to others' religious concerns, Lambda Legal endorses the comments submitted by the National Health Law Program. Concerning patients' needs to be treated equally regardless of gender identity, sexual orientation, and other irrelevant personal characteristics, the Joint Commission's accreditation standards and the ethical rules of the American Medical Association and other leading medical associations all impose a duty of nondiscrimination. For example, AMA Ethical Rule E-9.12 prohibits discrimination against patients and Ethical Rule E-10.05 provides that health professionals' rights of conscience must not be exercised in a discriminatory manner.[39] But that is precisely what results when, for example, a medically necessarily hysterectomy is denied to a patient because it is needed as treatment for gender dysphoria, and is provided to other patients as treatment for fibroids, endometriosis, or cancer.[40]

The Tennessee Counseling Association has expressed the bottom line cogently. Like many medical associations across the country, the TCA has codified the "do no harm" mandate and issued a formal statement opposing legislation proposing to allow denials of medical care through religious exemptions in that state: "When we choose health care as a profession, we

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[38] Proposed Rule, 83 Fed. Reg. at 3892.

[39] AMA ethical rule E-9.12, "Patient-Physician Relationship: Respect for Law and Human Rights," E-10.05, "Potential Patients."

[40] See discussion of Proposed Rule reference to *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017), at page 5, footnote 22. *See also Conforti v. St. Joseph's Healthcare Sys.* (D. N.J. filed Jan. 5, 2017), case documents at https://www.lambdalegal.org/in-court/cases/nj-conforti-v-st-josephs; Amy Littlefield, *Catholic Hospital Denies Transgender Man a Hysterectomy on Religious Grounds*, Rewire.News, Aug. 31, 2016, https://rewire.news/article/2016/08/31/catholic-hospital-denies-transgender-man-hysterectomy-on-religious-grounds/.

choose to treat all people who need help, not just the ones who have goals and values that mirror our own."[41]

IV. The Proposed Rule's Enforcement Mechanisms Are Draconian And Would Skew Health Systems In Favor Of Religious Refusals And Against Patient Care.

The Proposed Rule's enforcement mechanisms include aggressive investigation, require medical facilities to subject themselves to an extensive scheme of regulatory surveillance by HHS, and allocate authority to OCR "to handle complaints, perform compliance reviews, investigate, and seek appropriate action."[42] The Proposed Rule even "make[s] explicit the Department's authority to investigate and handle violations and conduct compliance reviews *whether or not a formal complaint has been filed*."[43] In addition to conditioning federal funding on prospective pledges to comply with broad, vague requirements, penalties can include not just the loss of future federal funding but even the potential of funding "claw backs,"[44] all with limited if any due process protections.

For many major medical providers, the threat of loss of federal funding is a threat to the facilities' very existence. It is nearly unfathomable that the government intends to force medical facilities either to forego their ethical obligations not to harm their patients or to close their doors. But, that easily could be the effect of the Proposed Rule in many instances. More often, the likely result would be simply to skew health systems dangerously in favor of religious refusals and against patient care. Doing so would both invite discrimination and aggravate existing health disparities and barriers to health care faced by LGBT people and others, contrary to the mission of HHS and, in particular, its Office for Civil Rights.

V. The Proposed Rule Inevitably Would Invite Discrimination And Worsen Health Disparities Affecting LGBT People And Others.

Discrimination and related health disparities already are widespread problems for LGBT people and people living with HIV.[45] In 2010, Lambda Legal conducted the first-ever national

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[41] *See* Emma Green, *When Doctors Refuse to Treat LGBT Patients*, The Atlantic, April 19, 2016, https://www.theatlantic.com/health/archive/2016/04/medical-religious-exemptions-doctors-therapists-mississippi-tennessee/478797/, citing Tenn. Counseling Assoc., *TCA Opposes HB 1840* (2016), http://www.tncounselors.org/wp-content/uploads/2016/03/TCA-Opposes-HB-1840-3.9.16.pdf.

[42] Proposed Rule, 83 Fed. Reg. at 3898.

[43] *Id*. (emphasis added).

[44] *Id*.

[45] *See, e.g.*, Inst. of Med., *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011) ("IOM Report") (undertaken at the request of the National Institutes of Health, and providing an overview of the public health research concerning health disparities for LGBT people and the adverse health consequences of anti-LGBT attitudes),

survey to examine the refusals of care and other barriers to health care confronting LGBT people and people living with HIV, *When Health Care Isn't Caring: Survey on Discrimination Against LGBT People and People Living with HIV*.[46] Of the nearly 5,000 respondents, more than half reported that they had experienced at least one of the following types of discrimination in care:

- Health care providers refusing to touch them or using excessive precautions;
- Health care providers using harsh or abusive language;
- Health care providers being physically rough or abusive;
- Health care providers blaming them for their health status.[47]

Almost 56 percent of lesbian, gay, or bisexual (LGB) respondents had at least one of these experiences; 70 percent of transgender and gender-nonconforming respondents had one or more of these experiences; and almost 63 percent of respondents living with HIV experienced one or more of these types of discrimination in health care.[48] Almost 8 percent of LGB respondents reported having been denied needed care because of their sexual orientation,[49] and 19 percent of respondents living with HIV reported being denied care because of their HIV status.[50] The picture was even more disturbing for transgender and gender-nonconforming respondents, who reported the highest rates of being refused care (nearly 27 percent), being subjected to harsh language (nearly 21 percent), and even being abused physically (nearly 8 percent).[51]

Respondents of color and low-income respondents reported much higher rates of hostile treatment and denials of care. Nearly half of low-income respondents living with HIV reported that medical personnel refused to touch them, while the overall rate among those with HIV was

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https://www.ncbi.nlm.nih.gov/books/NBK64806; Sandy E. James et al., Nat'l Ctr. For Transgender Equality, *The Report of the 2015 U.S. Transgender Survey* 93-129 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf; Lambda Legal, Health Care; Shabab Ahmed Mirza & Caitlin Rooney, Ctr. For Am. Progress, *Discrimination Prevents LGBTQ People from Accessing Health Care* (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[46] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010) ("Lambda Legal, Health Care"), http://www.lambdalegal.org/publications/when-health-care-isnt-caring.

[47] *Id*. at 5, 9-10.

[48] *Id*.

[49] *Id*. at 5, 10.

[50] *Id*.

[51] *Id*. at 10-11.

nearly 36 percent.[52] And while transgender respondents as a whole reported a care-refusal rate of almost 27 percent, low-income transgender respondents reported a rate of nearly 33 percent.[53] People of color living with HIV and LGB people of color were at least twice as likely as whites to report experiencing physically rough or abusive treatment by medical professionals.[54]

Also detailed in the report are particular types of discrimination in health care based on gender identity, sex discrimination against LGB people, and discrimination against people living with HIV. Such discrimination can take many forms, from verbal abuse and humiliation to refusals of care;[55] to refusal to recognize same-sex family relationships in health care settings to the point of keeping LGBT people from going to the bedsides of their dying partners;[56] to lack of understanding and respect for LGBT people.[57] The resulting harms are manifold, from transgender patients denied care postponing, delaying, or being afraid to seek medical treatment, sometimes with severe health consequences, or resorting out of desperation to harmful self-treatment;[58] to the mental and physical harms of stigma;[59] to other immediate physical harms from being denied medical care.

As described, the discriminatory treatment of LGBT people too often occurs in the name of religion. When it does, that religious reinforcement of anti-LGBT bias often increases the mental health impacts of discrimination.[60]

Since the 2010 Lambda Legal survey, other studies have similarly documented the disparities faced by LGBT people seeking health care. For example, *The Report of the 2015 U.S. Transgender Survey*, a survey of nearly 28,000 transgender adults nationwide, found that 33 percent "of respondents who had seen a health care provider in the past year reported having at least one negative experience related to being transgender, such as verbal harassment, refusal of treatment, or having to teach the health care provider about transgender people to receive

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[52] *Id.* at 11.

[53] *Id.*

[54] *Id.* at 12.

[55] *Id.* at 5-6.

[56] *Id.* at 15-16.

[57] *Id.* at 12-13.

[58] *Id.* at 6, 8, 12-13.

[59] *Id.* at 2.

[60] Ilan H. Meyer et al., *The Role of Help-Seeking in Preventing Suicide Attempts among Lesbians, Gay Men, and Bisexuals*, Suicide & Life Threatening Behavior, 8 (2014), http://www.columbia.edu/~im15/papers/meyer-2014-suicide-and-life.pdf ("[A]lthough religion and spirituality can be helpful to LGB people, negative attitudes toward homosexuality in religious settings can lead to adverse health effects") (internal citations omitted).

appropriate care" and that "23% of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person[.]"[61]

The Center for American Progress in 2017 conducted another nationally representative survey with similar results about LGBT health disparities, including findings that:

> Among lesbian, gay, bisexual, and queer (LGBQ) respondents who had visited a doctor or health care provider in the year before the survey:
>
> > 8 percent said that a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation.
> >
> > 6 percent said that a doctor or other health care provider refused to give them health care related to their actual or perceived sexual orientation.
> >
> > 7 percent said that a doctor or other health care provider refused to recognize their family, including a child or a same-sex spouse or partner.
> >
> > 9 percent said that a doctor or other health care provider used harsh or abusive language when treating them.
> >
> > 7 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).[62]
>
> Among transgender people who had visited a doctor or health care providers' office in the past year:
>
> > 29 percent said a doctor or other health care provider refused to see them because of their actual or perceived gender identity.
> >
> > 12 percent said a doctor or other health care provider refused to give them health care related to gender transition.
> >
> > 23 percent said a doctor or other health care provider intentionally misgendered them or used the wrong name.

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[61] James et al., *supra* n. 45, at 93.

[62] Mirza & Rooney, *supra* n. 45.

> 21 percent said a doctor or other health care provider used harsh or abusive language when treating them.
>
> 29 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).[63]

Independently of our own and others' research studies, Lambda Legal has become distressingly aware of the nature and scope of the discrimination problem from our legal work and requests for assistance received by our Legal Help Desks. We have repeatedly submitted information about the pattern of religion-based refusals of medical care to LGBT people in response to HHS requests. For example, in our 2013 response to the Request For Information for Section 1557 of the ACA, we documented numerous cases in which health professionals had denied medical care or otherwise discriminated against LGBT people and/or people living with HIV, based on the professionals' personal religious views, including:

- Guadalupe "Lupita" Benitez was referred for infertility care to North Coast Women's Care Medical Group, a for-profit clinic that had an exclusive contract with Benitez's insurance plan. After eleven months of preparatory treatments, including medication and unwarranted surgery, Lupita's doctors finally admitted they would not perform donor insemination for her because she is a lesbian. The doctors claimed a right not to comply with California's public accommodations law due to their fundamentalist Christian views against treating lesbian patients as they treat others. In a unanimous decision, the California Supreme Court held that religious liberty protections do not authorize doctors to violate the civil rights of lesbian patients. *North Coast Women's Care Med. Grp., Inc. v. San Diego Cnty. Superior Court (Benitez)*, 189 P.3d 959 (Cal. 2008)

- Counseling student's objections to providing relationship counseling to same-sex couples. *Keeton v. Anderson-Wiley*, 664 F.3d 865 (11th Cir. 2011) (finding student unlikely to prevail on free speech and religious liberty claims challenging her expulsion from counseling program due to her religiously based refusal to counsel same-sex couples, contrary to professional standards requiring nonjudgmental, nondiscriminatory treatment of all patients).

- Physician's objection to working with an LGB person. *Hyman v. City of Louisville*, 132 F. Supp. 2d 528, 539-540 (W.D. Ky. 2001) (physician's religious beliefs did not exempt him from law prohibiting employment discrimination based on sexual orientation or gender identity), *vacated on other grounds by* 53 Fed. Appx. 740 (6th Cir. 2002).

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[63] *Id.*

• Proselytizing to patients concerning religious condemnation of homosexuality. *Knight v. Connecticut Dep't of Pub. Health*, 275 F.3d 156 (2d Cir. 2001) (rejecting free exercise wrongful termination claim of visiting nurse fired for antigay proselytizing to home-bound AIDS patient).

• Refusal to process lab specimens from persons with HIV. *Stepp v. Review Bd. of Indiana Emp. Sec. Div.*, 521 N.E.2d 350, 352 (Ind. 1988) (rejecting religious discrimination claim of lab technician fired for refusing to do tests on specimens labeled with HIV warning because he believed "AIDS is God's plague on man and performing the tests would go against God's will").[64]

In addition, testimonies received in Lambda Legal's health survey describe similar encounters with health professionals who felt free to express their religiously grounded bias toward LGBT patients:

• Kara in Philadelphia, PA: "Since coming out, I have avoided seeing my primary physician because when she asked me my sexual history, I responded that I slept with women and that I was a lesbian. Her response was, 'Do you know that's against the Bible, against God?'"[65]

• Joe in Minneapolis, MN: "I was 36 years old at the time of this story, an out gay man, and was depressed after the breakup of an eight-year relationship. The doctor I went to see told me that it was not medicine I needed but to leave my 'dirty lifestyle.' He recalled having put other patients in touch with ministers who could help gay men repent and heal from sin, and he even suggested that I simply needed to 'date the right woman' to get over my depression. The doctor even went so far as to suggest that his daughter might be a good fit for me."[66]

Lambda Legal documented additional recent examples of health care denials or discriminatory treatment in its amicus brief to the Supreme Court in *Masterpiece Cakeshop v. Colorado Civil Rights Commission*,[67] including the following two Lambda Legal cases:

- Lambda Legal client Naya Taylor, a transgender woman in Mattoon, Illinois, who sought hormone replacement therapy (HRT), a treatment for gender dysphoria, from the health clinic where she had received care for more than a decade. When her primary care physician refused her this standard treatment, clinic staff told her that, because of

[64] Lambda Legal Nondiscrimination Comments (citations partially omitted).

[65] *Id.*

[66] *Id.*

[67] *See* Brief of Amici Curiae Lambda Legal et al., *Masterpiece Cakeshop Ltd. v. Colorado Civil Rights Comm'n*, No. 16-111, at 11-14, 17-18, 26, 30 (filed Oct. 30, 2017), https://www.lambdalegal.org/in-court/cases/masterpiece-cakes-v-co-civil-rights-commission.

the religious beliefs of the clinic's doctors, they do not have to treat "people like you."[68]

- Lambda Legal client Jionni Conforti, who was refused a medically necessary hysterectomy despite his treating physician's desire to perform the surgery. The hospital where the surgeon had admitting privileges was religiously affiliated and withholds permission for all gender transition-related care.[69]

These examples are just a tip of the iceberg, a few of many incidents across the country in which religion has been used to justify denial of health care or other discrimination against LGBT people and people living with HIV. Although courts consistently have rejected such reliance on religion to excuse discrimination, examples of religion-based discrimination in health care continue to occur with regularity.[70] This mistreatment contributes to persistent health disparities, including elevated rates of stress-related conditions.[71]

Given this landscape, Lambda Legal is deeply concerned that this Proposed Rule, designed to protect and even encourage religious refusals of health care, inevitably will facilitate further discrimination by health professionals in contexts involving sexual orientation, gender identity, or HIV status. As a result, the health of patients across the country, as well as others, would be at risk, and "conscience" claims could too easily become a way for providers to turn away LGBT patients. The past examples of religiously-based discrimination indicate there is significant likelihood that too-many individual and institutional care providers will demand exemptions from rules and standards designed to ensure that patients receive proper treatment regarding the following needs:

- Treatment of patients who need counseling, hormone replacement therapy, gender confirmation surgeries, or other treatments for gender dysphoria.
- For patients with a same-sex spouse or who are in a same-sex relationship, bereavement counseling after the loss of a same-sex partner or other mental health care that requires

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[68] In April 2014, Lambda Legal filed a claim of sex discrimination on Ms. Taylor's behalf under Section 1557 of the ACA; however, Ms. Taylor subsequently passed away and her case was voluntarily dismissed. *See* Complaint, *Taylor v. Lystila*, 2:14-cv-02072-CSB-DGB (C.D. Ill., Apr. 15, 2014), *available at* https://www.lambdalegal.org/in-court/legal-docs/taylor_il_20140416_complaint.

[69] *See Conforti v. St. Joseph's Healthcare Sys.* (D. N.J. filed Jan. 5, 2017) case documents at https://www.lambdalegal.org/in-court/cases/nj-conforti-v-st-josephs. *See also* Amy Littlefield, *Catholic Hospital Denies Transgender Man a Hysterectomy on Religious Grounds*, Rewire.News, Aug. 31, 2016, https://rewire.news/article/2016/08/31/catholic-hospital-denies-transgender-man-hysterectomy-on-religious-grounds/.

[70] *See* Lambda Legal 1557 Comments; Brief of Amici Curiae Lambda Legal et al., *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

[71] *See* Mark Hatzenbuehler, *Structural Stigma: Research Evidence and Implications for Psychological Science*, 71 AM. PSYCHOLOGIST, 742, 742–51 (2016), http://dx.doi.org/10.1037/amp0000068; IOM Report, *supra* n. 45.

respectful acknowledgment of a person's sexual orientation or gender identity.

- Care for patients living with HIV, including the option of pre-exposure prophylaxis (PrEP), a highly effective medication that dramatically reduces the risk of HIV infection among those who are otherwise at high risk, including people who are in a sexual relationship with a partner who is living with HIV.
- Treatment of patients who are unmarried or in a same-sex relationship and require infertility treatment or other medical services related to pregnancy, childbirth or pediatric needs.

In addition, the Proposed Rule threatens to undermine the community's trust in health care providers. Although there may be health care facilities that remain safer places for patients who face increased risk of discrimination in health care facilities, those facilities that are more welcoming of LGBT patients and patients seeking HIV care and willing to provide them with full health care access will become overburdened and increasingly unable to meet the needs of all who come through their doors.

If the number of health care facilities that LGBT people can feel comfortable going to, knowing they won't be turned away is reduced as the inevitable result of this Proposed Rule, access to health care will become harder, and nearly impossible for some, who, for example, are low income[72] or who live in remote areas and cannot travel long distances for medical care. Patients seeking more specialized care such as infertility treatments or HIV treatment or prevention are already often hours away from the closest facility. The Proposed Rule threatens to build even greater barriers between those who are most vulnerable and the health care they need.

For the Proposed Rule to transform the role of HHS from an agency focused on ensuring nondiscriminatory provision of health care to one that facilitates refusals of care is a disturbing about-face contrary to the Department's mission and authorizing statutes. Its failure to explain how the enhanced powers of health care providers to refuse patient care in the name of "conscience" should be reconciled with the protections for patients under the ACA and other statutes, and for employers under Title VII, make clear that this proposal is legally untenable as well as unjustifiably dangerous as a matter of federal health policy.

VI. The Proposed Rule Is The Result Of A Rushed, Truncated Process Contrary To The Department's Mission And Inconsistent With Procedural Requirements.

Considering the well-recognized health disparities and difficulty obtaining nondiscriminatory care that already confront the LGBT community, the Proposed Rule's apparent goal of inviting more discrimination and care denials to LGBT people and is peculiar

[72] Contrary to some misperceptions, LGBT people and people living with HIV are disproportionately economically disadvantaged. *See*, *e.g.*, M.V. Lee Badgett et al., *New Patterns of Poverty in the Lesbian, Gay, and Bisexual Community*, WILLIAMS INST. (June 2013), https://williamsinstitute.law.ucla.edu/research/census-lgbt-demographics-studies/lgbt-poverty-update-june-2013.

and alarming. Indeed, the lack of concern for the Proposed Rule's inevitable impacts is especially shocking because this Department itself has conducted studies revealing disparities in LGBT health outcomes. As reported in the 2014 National Health Statistics Reports:

> [R]ecent studies have examined the health and health care of lesbian, gay, and bisexual (LGB) populations and have found clear disparities among sexual minority groups (i.e., gay or lesbian and bisexual) and between sexual minorities and straight populations. These disparities appear to be broad-ranging, with differences identified for various health conditions (e.g., asthma, diabetes, cardiovascular disease, or disability) … health behaviors such as smoking and heavy drinking … and health care access and service utilization …. Across most of these outcomes, sexual minorities tend to fare worse than their nonminority counterparts.[73]

Thus, in addition to the legal and ethical conflicts it would generate, the Proposed Rule also would undermine HHS's national and local efforts to reduce LGBT health disparities. For example, this Department's "Healthy People 2020 initiative" and the Institute of Medicine have called for steps to be taken to address LGBT health disparities"[74]; medical associations including the American Medical Association, the Association of American Medical Colleges, the American College of Physicians, the American Psychiatric Association, and others are committed to improving medical care for LGBT people through education and cultural competency training; and legislation is increasingly being considered and passed to improve LGBT health access and reduce health disparities.[75] The Proposed Rule endangers the important progress made on this front.

With this Department's past focus on addressing LGBT health disparities, it would be a bizarre and disturbing reversal of course for HHS now to become an active participant in the very denials of health care and discriminatory treatment that cause these disparities. Years of careful study and deliberation went into framing the protections against discrimination implemented pursuant to Section 1557 of the ACA, including the explicit protections against gender identity discrimination and other forms of sex discrimination and the accompanying

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[73] Brian W. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey, 2013*, Nat'l Health Statistics Report No. 77, 1, (July 15, 2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.

[74] Dep't of Health & Human Servs., *Healthy People 2020: LGBT Health Topic Area* (2015), http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health; IOM Report.

[75] *See* Timothy Wang et al., The Fenway Inst., *The Current Wave of Anti-LGBT Legislation: Historic Context and Implications for LGBT Health* at 6, 8-9 (June 2016), http://fenwayhealth.org/wp-content/uploads/The-Fenway-Institute-Religious-Exemption-Brief-June-2016.pdf.

value statement that "HHS supports prohibiting sexual orientation discrimination as a matter of policy[.]"[76]

In addition, the Proposed Rule has been issued without adequate time spent considering the thousands of comments submitted on related proposals. It lacks acknowledgment of countervailing interests of patients and many health provider institutions, let alone any explanation of how those interests are to be reconciled with the proposed aggressive enforcement of inconsistent religious interests. All in all, the Department's process has been arbitrary, capricious, and dangerous. [77] Consequently, along with its numerous other legal infirmities, it also violates the Administrative Procedure Act.[78]

VII. Conclusion

The Proposed Rule would have a chilling effect on the full and unbiased provision of health care, including to members of the LGBT community and everyone living with HIV, in a manner that conflicts with ethical, legal, and constitutional standards. While freedom of religion is a fundamental right protected by our Constitution and federal laws, it does not give anyone the right to use religious or moral beliefs as grounds for violating the rights of others. Instead, the Constitution commands that any religious or moral accommodation must be "measured so that it does not override other significant interests" or "impose unjustified burdens on other[s]."[79] Indeed, when the Supreme Court addressed the related question in *Burwell v. Hobby Lobby Stores, Inc.*, it explained that a religious accommodation should be provided in that case because the impact on third parties would be "precisely zero."[80]

Here, the Proposed Rule conflicts with statutory rights of health care providers to operate with reasonable efficiency and cost, and within their ethical obligations to care for patients according to professional standards. Most importantly, it also conflicts with legal and ethical protections for patients, potentially putting their health and even lives at risk. It is ill conceived and has no place in federal health policy.

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[76] Press Release, U.S. Dep't of Health & Human Servs., HHS Finalizes Rule to Improve Health Equity Under the Affordable Care Act (May 13, 2016), https://wayback.archive-it.org/3926/20170127191750/https://www.hhs.gov/about/news/2016/05/13/hhs-finalizes-rule-to-improve-health-equity-under-affordable-care-act.html.

[77] 5 U.S.C.A. § 706(2)(a).

[78] 5 U.S.C.A. § 500 *et seq*.

[79] *Cutter v. Wilkinson*, 544 U.S. 709, 722, 726 (2005).

[80] 134 S. Ct. 2751, 2760 (2014). Indeed, every member of the Court, whether in the majority or in dissent, reaffirmed that the burdens on third parties must be considered. *See id* at 2781 n. 37; *id.* at 2786–87 (Kennedy, J., concurring); *id.* at 2790, 2790 n. 8 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting).

For the foregoing reasons, we emphatically recommend that the Department set aside this Proposed Rule.

Most respectfully,

LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.

Jennifer C. Pizer, Senior Counsel and
Director of Law and Policy
jpizer@lambdalegal.org

Nancy C. Marcus, Senior Law and Policy Attorney
nmarcus@lambdalegal.org
4221 Wilshire Blvd., Suite 280
Los Angeles, CA 90010

Sasha Buchert, Staff Attorney
sbuchert@lambdalegal.org
1875 I Street, NW, 5th Floor
Washington, DC 20006

Exhibit 14

March 27, 2018

Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW.
Washington, DC 20201

Re: RIN 0945-ZA03

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

WASHINGTON, DC OFFICE
2121 K Street NW, Suite 325
Washington, DC 20037-1886

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www.acep.org

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On behalf of more than 37,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the draft rule relating to protecting conscience rights in health care, as it affects our practice of emergency medicine and the patients we serve.

While we believe that enforcement of existing federal conscience protections for health care providers is important, we strongly object to this proposed rule and do not believe it should be finalized. As written, it does not reflect nor allow for our moral and legal duty as emergency physicians to treat everyone who comes through our doors. Both by law[1] and by oath, emergency physicians care for all patients seeking emergency medical treatment. Denial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical[2].

ACEP has specific comments on multiple sections of the proposed rule, which are found below.

Application of Proposals in Emergency Situations

As emergency physicians, we are surprised and concerned that the proposed rule does not in any way address how conscience rights of individuals and institutions interact

[1] 42 U.S. Code § 1395dd - Examination and treatment for emergency medical conditions and women in labor
[2] ACEP Code of Ethics for Emergency Physicians; Approved Jan 2017; https://www.acep.org/clinical---practice-management/code-of-ethics-for-emergency-physicians

with the mandated provision of emergency services. The Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and stabilize patients who come to the emergency department. Such patients have every right to expect the best possible care and to receive the most appropriate treatment and information about their condition.

Patients with life-threatening injuries or illnesses may not have time to wait to be referred to another physician or other healthcare professional to treat them if the present provider has a moral or religious objection. Likewise, emergency departments operate on tight budgets and do not have the staffing capacity to be able to have additional personnel on hand 24 hours a day, 7 days a week to respond to different types of emergency situations that might arise involving patients with different backgrounds, sexual orientations, gender identities, or religious or cultural beliefs. The proposed rule seems to demand that, in order to meet EMTALA requirements, an emergency department anticipate every possible basis for a religious or moral objection, survey its employees to ascertain on which basis they might object, and staff accordingly. This is an impossible task that jeopardizes the ability to provide care, both for standard emergency room readiness and for emergency preparedness. Emergency departments serve as the safety-net in many communities, providing a place where those who are most vulnerable and those in need of the most immediate attention can receive care. By not addressing the rights and needs of patients undergoing an emergency, the legal obligations of emergency physicians, and the budget and staffing constraints that emergency departments face, this rule has the potential of undermining the critical role that emergency departments play across the country.

Definition of Referrals

Under the proposed rule, health care providers could refuse not only to perform any given health care service, but also to provide patients access to information about or referrals for such services. The Department of Health and Human Services (HHS) defines a referral broadly in the rule as "the provision of any information… by any method… pertaining to a service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or direction that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."

Such a broad definition of referral as referenced under the proposed rule's prohibition could create unintended consequences, such as preventing patients from getting appropriate care now or even in the future. For example, this definition would allow a primary care physician with a moral or religious objection to abortion to deny referring a pregnant woman (who may not have any immediate intentions or desire for an abortion) to a particular obstetrician-gynecologist out of fear that the woman could eventually receive an abortion from that obstetrician-gynecologist, whether at some point in the future of this pregnancy or even for a future pregnancy.

Another situation where this definition could lead to an undesirable outcome for a patient is when a provider has an objection to a patient's end-of-life wishes expressed in an advance directive. Emergency physicians often treat patients with advanced illness, and ACEP strongly believes that providers should respect the wishes of dying patients including those expressed in advance directives. Most States today allow for a conscience objection and the right to refuse to comply with a patient's advance directive, but they all impose

an obligation to inform such patients and, more importantly, to make some level of effort to transfer the patient to another provider or facility that will comply with the patient's wishes. However, under this proposed rule, providers with a religious or moral objection to their patients' end-of-life or advanced care wishes would have no obligation to either treat these patients in accordance with their wishes or refer them to another provider who would. Unfortunately, it is unclear how such State laws would interact with or be impacted by the federal enforcement aspects of this proposed rule, were it to be finalized. What is clear however, is that if this proposed rule is finalized, the patient's wishes could be ignored and the patient ultimately loses.

In all, the proposed rule's far-reaching definition of referral will likely cause confusion about when a referral may or may not be appropriate, thereby increasing the chances that patients do not receive accurate or timely information that may be critical to their overall health and wellbeing. The proposed rule therefore threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied, or potentially whether they were even denied medically appropriate and necessary services to begin with. Additionally, given that many insurance plans such as HMOs require referrals before coverage of specialty services, the proposed rule could place patients at financial risk based on the refusal of their primary care physician to provide a referral.

The definition of referral is representative of one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them. The rule does not mention the rights of patients even once or seek comment on how patients can still be treated if providers have a moral and religious objection to their treatment. It seems to imply that these providers have no responsibility to their patients to make sure they receive the best possible care when they are unable to provide it themselves, and there is no process or guidance in place for these providers to still try to serve their patients. The lack of attention to protecting and serving patients is one of the major reasons we believe that the rule should be withdrawn.

Requirement to Submit Written Assurances and Certifications of Compliance

HHS would require certain recipients of federal funding (including hospitals that provide care to patients under Medicare Part A) to submit annual written assurances and certifications of compliance with the federal health care conscience and associated anti-discrimination laws as a condition of the terms of acceptance of the federal financial assistance or other federal funding from HHS. There are several exceptions from the proposed requirements for written assurance and certification of compliance, including physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program. However, "excepted" providers could become subject to the written certification requirement if they receive HHS funds under a separate agency or program, such as a clinical trial.

ACEP finds the lack of clarity around this requirement extremely concerning, as we believe that it will pose a significant burden on health care professionals including emergency physicians.

First, the rule does not account for all the possible circumstances or arrangements that would potentially force "excepted" physicians to file certifications. For example, some emergency physicians who are participating in Medicare Part B also have joined an accountable care organization (ACO) led by a hospital where they see patients. In many cases, the ACO has entered into a contract with the Centers for Medicare

& Medicaid Services (CMS) to be part of the Medicare Shared Savings Program or a Center for Medicare & Medicaid Innovation (CMMI) ACO model. Since the ACO includes both physicians and a hospital and therefore receives payments from both Parts A and B of Medicare, it is unclear whether emergency physicians who are part of the ACO would lose their exemption status. Numerous other alternative payment models besides ACO models are operated by CMS and involve participation from both hospitals and physicians. HHS should clarify whether physicians who are part of these models would still be exempted from the certification requirement.

Second, it is unclear whether clinicians who treat Medicaid patients are exempt from the requirement. In the rule, HHS includes Medicaid in the list of examples for why some exemptions may be appropriate[3], but does not actually list reimbursement from the program as one of the exceptions. Some of our members may see only patients with Medicaid, so this lack of clarity is of great concern to them.

Third, ACEP is concerned about the cost-burden that this proposal will have on the hospitals, free-standing emergency departments, and emergency physicians who are subject to the requirement. CMS estimates that the assurance and certification requirement alone could cost health care entities nearly $1,000 initially and $900 annually thereafter to sign documents, review policies and procedures, and update policies and procedures and conduct training. This substantial cost is on top of the cost of posting a notice, which is estimated to be $140 per entity. Since emergency physicians by law must provide services to patients regardless of their insurance status, their total reimbursement, if any, rarely covers the full cost of providing the services. By adding more burdensome government mandates that emergency departments must cover out of their own constrained budgets, the proposed rule could potentially jeopardize the financial viability of the emergency care safety net. While we believe the proposed rule should be withdrawn because it is so problematic, in the event the rule is finalized, ACEP requests that at minimum emergency departments, and the physicians and other health care providers that furnish care within them, be exempt from the written assurances and certifications of compliance requirement.

Notice Requirement

The proposed rule requires all health entities to post a notice on their websites and in locations in their organizations where public notices are typically posted. This notice advises people about their rights and the entity's obligation to abide by federal health care conscience and associated anti-discrimination laws. The notice also provides information about how to file a complaint with the Office of Civil Rights within HHS. The rule requires entities to use a prescribed notice, found in "Appendix A" of the rule, but seeks comment on whether to permit entities to draft their own notices.

ACEP objects to this posting requirement. Beyond our concerns with the burden of having to adhere to another government-imposed mandate as discussed above, we also are troubled by the fact that the notice in no way addresses the needs of patients or our responsibilities as providers to treat them. It does not provide any information about the fundamental rights of patients to receive the most accurate information and best available treatment options for their conditions. We therefore have grave concerns about posting the notice as currently drafted.

[3] On pages 73- 74 of the proposed rule, HHS states "Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions."

It is also unclear whose exact responsibility it is to post the notice(s). Most emergency physicians are employed by a group independent from the hospital that houses the emergency department where they see patients. Therefore, would the hospital's posted notice be sufficient, or would the group that the hospital's emergency physicians are employed by need to also take on this responsibility as a separate entity, with a separate, additional posting in the emergency department?

If so, posting this notice in the emergency department could potentially be considered a violation of EMTALA. EMTALA requires providers to screen and stabilize patients who come to the emergency department. Therefore, notices that could potentially dissuade patients from receiving care that is mandated by Federal law cannot be posted publicly in the emergency department. Since the notice proposed in this rule explicitly states that providers have the right to decline treatment for patients based on their conscience, religious beliefs, or moral convictions, some patients may become concerned that they would not be treated appropriately and decide to leave before they treated— a violation of EMTALA.

In light of the above concerns, ACEP urges the Department to withdraw the proposed rule. We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

Paul D. Kivela, MD, MBA, FACEP
ACEP President

Exhibit 15

WASHINGTON
LEGISLATIVE OFFICE

March 27, 2018

Department of Health and Human Services
Office for Civil Rights
Attn: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independent Avenue SW
Washington, DC 20201

Submitted electronically

AMERICAN CIVIL LIBERTIES UNION
WASHINGTON
LEGISLATIVE OFFICE
915 15th STREET, NW, 6TH FL
WASHINGTON, DC 20005
T/202.544.1681
F/202.546.0738
WWW.ACLU.ORG

FAIZ SHAKIR
DIRECTOR

NATIONAL OFFICE
125 BROAD STREET, 18TH FL.
NEW YORK, NY 10004-2400
T/212.549.2500

OFFICERS AND DIRECTORS
SUSAN N. HERMAN
PRESIDENT

ANTHONY D. ROMERO
EXECUTIVE DIRECTOR

ROBERT REMAR
TREASURER

Re: Proposed New 45 CFR Part 88 Regarding Refusals of Medical Care

The American Civil Liberties Union ("ACLU") submits these comments on the proposed rule published at 83 FR 3880 (January 26, 2018), RIN 0945-ZA03, with the title "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the "Proposed Rule" or "Rule").

For nearly 100 years, the ACLU has been our nation's guardian of liberty, working in courts, legislatures, and communities to defend and preserve the individual rights and liberties that the Constitution and the laws of the United States. With more than 2 million members, activists, and supporters, the ACLU is a nationwide organization that fights tirelessly in all 50 states, Puerto Rico, and Washington, D.C. for the principle that every individual's rights must be protected equally under the law, regardless of race, religion, gender, sexual orientation, gender identity or expression, disability, national origin, or record of arrest or conviction.

In Congress and in the courts, we have long supported strong protections for religious freedom. Likewise, we have participated in nearly every critical case concerning reproductive rights to reach the Supreme Court and advocated for policies that promote access to reproductive health care. The ACLU is also a leader in the fight against discrimination on behalf of those who historically have been denied their rights, including people of color, LGBT (lesbian, gay, bisexual, and transgender) people, women, and people with disabilities. Because of its profound respect for and experience defending religious liberty, reproductive rights, and principles of non-discrimination, the ACLU is particularly well positioned to comment on the Proposed Rule. We steadfastly protect the right to religious freedom. But the right to religious freedom does not include a right to harm others as this Proposed Rule contemplates. And, indeed, when the Bush Administration adopted similar rules, the ACLU challenged them in court. *See National Family Planning & Reproductive Health*

Association, Inc. v. Leavitt, *consolidated in* Case No. 3:09-cv-00054-RNC (D. Conn. 2009).[1]

The Proposed Rule grants health care providers unprecedented license to refuse to provide information and health care to patients and puts faith before patients' health. The Rule thus contravenes the core mission of the Department of Health and Human Services [the "Department"] to protect and advance the health of all. The Department's failure even to mention the impact of the rule on patients is clear evidence of its misplaced priorities. The Rule also flies in the face of the longstanding history of the Department to further our nation's health by addressing discrimination in health care, aiming instead to foster discrimination.

Tellingly, the Department justifies the Rule by citing as the "problem" cases in which patients sought remedies after being denied health care—to the detriment of their health and often for discriminatory reasons. *See* 83 FR 3888-89 & n.36. The problem, however, is not that patients want care, but that health care providers denied vital, even life-saving, medical care, discriminated, and imposed their religious doctrine to the detriment of patients' health. Tamesha Means, for example, should not have been turned away from the hospital where she sought urgent care even once, let alone three times, without even being provided with the information that her own life could be in jeopardy if she did not obtain emergency abortion care for her miscarriage.[2] Rebecca Chamorro should not have been required to undergo the additional stress, health risks, and cost of two surgical procedures, rather than a single one, when her doctor was ready, willing, and able to perform a standard postpartum tubal ligation.[3] Evan Minton's scheduled hysterectomy should not have been canceled on the eve of that procedure, despite his doctor's willingness to proceed with that routine operation, because the hospital became aware he was transgender.[4] These refusals, not the patients seeking justice, are the problem. Yet these are the types of refusals the Department seeks to make more commonplace with this Rule. 83 FR 3888-89 & n.36.

Moreover, if the Department is to adhere to its mission and to address discrimination, its focus should not be on expanding a purported right of institutions to refuse to provide care because of beliefs, but on eliminating the discrimination that continues to devastate communities in this country. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[5] Black women, for example, are three to four times more likely than white women to die during or after childbirth.[6] Women have long been the subject of discrimination in

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[1] That lawsuit was ultimately dismissed when the Obama Administration rescinded virtually all of the regulations. *See* 74 FR 10207, 75 FR 9968, 76 FR 9968, *infra* n.16.

[2] *See* Health Care Denied 9-10 (May 2016), *available at* https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied.

[3] *See id.* at 18.

[4] *See* Verified Complaint, *Minton v. Dignity Health,* Case No. 17-558259 (Calif. Super. Ct. April 19, 2017).

[5] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[6] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

health care and the resulting health disparities.[7] And due to gender biases and disparities in research, doctors offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[8] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[9] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care provider had refused to see them because of that aspect of their identity in the year before the survey.[10] The Department should be working to end, not foster, discrimination in health care.[11]

In the comments below, the ACLU details some of the specific ways in which the Proposed Rule exceeds the Department's authority and in so doing causes significant harm to patients.[12] The non-exhaustive examples of serious flaws in the Rule include:

- The Proposed Rule utterly fails to consider the harmful impact it would have on patients' access to health care.

- The Department lacks *any* legislative rule-making authority under the Church Amendments, 42 U.S.C. § 300a-7, the Coats-Snowe Amendment, 42 U.S.C. § 238n, and the Weldon Amendment, Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, Div. H, Tit. V, § 507(d) (collectively, the "Amendments"), the primary statutory authority for the Rule, and thus it cannot adopt these proposed force-of-law requirements to expand those Amendments.

- The Rule tries to expand the plain language Congress used in the Amendments and over a dozen other laws referenced by this rulemaking (collectively, the "Refusal Statutes"), proposing definitions that distort the ordinary meaning of words and otherwise impermissibly stretching these narrow provisions.

- The Rule's impact is not limited to individual health care providers; it attempts to greatly expand the Refusal Statutes to enable more institutions—e.g., hospitals,

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[7] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).
[8] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. of the Am. Heart Ass'n 1 (2015).
[9] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf.
[10] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.
[11] The Department's Office of Civil Rights ("OCR") has a long history of combating discrimination, protecting patient access to care, and eliminating health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.
[12] Although these ACLU comments primarily focus on examples of the Proposed Rule's flaws and harms with reference to the Church, Coats and Weldon Amendments, virtually all of the problems identified in this letter extend to the Rule's similar, unfounded extension of the over a dozen other provisions encompassed within the Rule.

clinics, and other corporate entities—to deny care, even in emergency situations, and even when individual providers at the institutions have no objection to providing the care.

- The Rule is entirely unnecessary as health care providers are already shielded by Title VII's religion protections, and addressed by the Refusal Statutes, and there is no evidence that existing mechanisms are insufficient to ensure compliance with those Refusal Statutes.

- The Rule purports to seek a "society free from discrimination," but repeatedly *invites expanded discrimination – through refusals of care* – against women, LGBT patients, and other members of historically-mistreated groups.

- Likewise, the Rule purports to advance "open and honest communication," yet it *empowers providers to withhold information* from patients about their medical condition and treatment options in contravention of legal and ethical requirements and principles of informed consent.

Because the Proposed Rule harms patient health, encourages discrimination, and exceeds the Department's rulemaking authority, it should be withdrawn. If the Department refuses to do so, it must, at a minimum, revise the Proposed Rule so that it comes into alignment with the statutory provisions it purports to implement, makes clear that it is not intended to conflict with other state and federal laws that protect patients, and mitigates the harm to patients' health and well-being.

I. The Proposed Rule Fails Even to Mention Its Impact on Patients, While Inviting More Refusals of Care That Would Fall Disproportionately on Low-Income People and Other Marginalized Groups.

The Department's mission is "to enhance and protect the health and well-being of all Americans. [It] fulfill[s] that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services."[13] The Department administers more than 100 programs, which aim to "protect the health of all Americans and provide essential human services, especially for those who are least able to help themselves."[14]

It is thus extraordinary that this Notice of Proposed Rulemaking ("NPRM") is devoted solely to increasing the ability of health care entities and professionals to refuse to provide health care information and services to patients. Nowhere in the 50 pages that the NPRM spans in the Federal Register does it discuss the impact that refusals to provide information and denials of care have on patient health and well-being. In fact, patients are not even mentioned in the discussion of "affected persons and entities." 83 FR 3904. And in the Proposed Rule's flawed attempt at a cost-benefit analysis, the Department devotes a mere three paragraphs to the Rule's purported effects on patient-provider communication—and none at all to the direct harms suffered by those who are denied information and care. 83 FR 3916-17.

[13] *See* https://www.hhs.gov/about/index.html.
[14] *See* https://www.hhs.gov/programs/index.html.

But this failure to address the obvious consequences of giving federally-subsidized providers *carte blanche* to decide whom to treat or not treat based on religious or moral convictions—or indeed, based on any reasoning or none at all[15]—does not mean the harm does not exist. Indeed, the harms would be substantial. For example, as set forth in more detail below, the Proposed Rule:

- Appears to provide immunities for health care institutions and professionals who refuse to provide complete information to patients about their condition and treatment options;
- Would result in patients being denied, or delayed in getting, health care to the extent the Rule requires health care facilities to employ people who refuse to perform core functions of their jobs;
- Purports to create new "exemptions," that would leave patients who rely on federally-subsidized health care programs, such as Title X family planning services, unable to obtain services those programs are required by law to provide;
- Creates confusion about whether hospitals can refuse to provide, and bar its staff from providing, emergency care to pregnant women who are suffering miscarriages or otherwise need emergent abortion care; and
- Invites health care providers to discriminate against individuals based on who they are by, for example, refusing to provide otherwise available services to a patient for the sole reason that the patient is transgender.

These harms will fall most heavily on historically disadvantaged groups and those with limited economic resources. As the ACLU's own cases and requests for assistance reflect, women, LGBT individuals, and members of other groups who continue to struggle for equality are those who most often experience refusals of care. The Proposed Rule's unauthorized expansion of the Refusal Statutes will only exacerbate these disparities.

Likewise, people with low and moderate incomes will suffer most acutely under the Proposed Rule. The Refusal Statutes, and therefore the expansive Proposed Rule, are tied to federal funding. Individuals with limited income are more likely to rely on health care that is in some manner tied to federal funding and are therefore more likely to be subject to the refusals to provide care and information sanctioned by the Proposed Rule. Thus, for example, if a health care entity that, under the Proposed Rule, is now able to obtain a government contract to provide Title X family planning services despite its unwillingness to provide the required services, low-income individuals in the area are likely to have few, if any, other options for the care.

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[15] Although the NPRM highlights religious freedom and rights of conscience, a number of the Refusal Statutes – and the proposed expansions of those in the Rule – do not turn on the existence of any religious or moral justification. The Proposed Rule would empower not only those acting based on the basis of belief, but others acting, for example, out of bare animus toward a patient's desired care or any aspect of their identity.

Not only will this result in the outright denial of care to the detriment of patients' health, it will also impose serious economic consequences that the Proposed Rule fails to take into account. For example, the denial of care can result not only in greater health care costs, but also in lost wages (and in some cases loss of employment), increased transportation costs and increased child care costs. For women, immigrant patients, and rural patients, these snowballing effects can be particularly acute. Yet, remarkably, the Proposed Rule finds no effect at all on the "disposable income or poverty of families and children" from expanding denials of health care. 83 FR 3919. Contrary to the Department's conclusions, this Rule would impose new costs on and create new pressures for many families, especially those with the least economic means.

Rather than seek to expand patient protections, the Proposed Rule appears to launch a direct attack on existing federal legal protections that prevent or remedy discrimination against patients. *See, e.g., infra* Part IV. The Rule raises equal concern with regard to its intended effect on state laws that aim to enhance patient protection and address discrimination. The Preamble devotes extensive discussion to "Recently Enacted State and Local health care laws" that have triggered some litigation by "conscientious objectors," 83 FR 3888, characterizing those disputes as part of the rationale for the Rule.[16] But this rulemaking provides no clarity as to preservation of other legal protections and repeatedly evidences an intent to cut back on, for example, important equality safeguards for patients. At the very least, this will create severe confusion, creating competing and contradictory requirements, and in so doing put critical federal funding for vital care at risk. At worst, it targets vulnerable patients for increased refusals of care and the harms described above.

Because it is contrary to the very mission of the Department, attempts to license widespread denials of care and harm to patients, and fosters discrimination, the Proposed Rule should be withdrawn.

II. The Department Lacks the Authority to Promulgate the Proposed Rule.

Not only does the Rule undermine patient's health, it is unauthorized. For example, the Department does not possess *any* legislative rulemaking powers under the Church, Coats-Snowe or Weldon Amendments – the Amendments that form the bases for the bulk of the Rule – and thus it lacks the authority to promulgate this Rule with respect to those statutes.

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). With this Proposed Rule, the Department clearly seeks to adopt legislative rules that will impose force-of-law, substantive requirements and compliance procedures that must be followed by covered entities. But there is no authority delegated by Church, Coats-Snowe or Weldon to undertake such rulemaking. Indeed, in prior litigation, the Department itself emphasized that "[i]n the first place, it is not clear that the Weldon Amendment can be said to delegate regulatory authority to the Executive Branch at all." Br. of

[16] *See also* 83 FR 3889 (seeking to "clarify" that conscience protections "supersede conflicting provisions of State law"; pointing to state requirements, for example, that insurers include abortion coverage in health plans as illustrations of "the need for greater clarity concerning the scope and operation" of federal rights of refusal).

Defs. at 35, *National Family Planning and Reproductive Health Association v. Gonzales*, 391 F. Supp. 2d 200 (D.D.C. 2005), *available at* 2004 WL 3633834; *see also* 76 FR 9971, 9975 (discussing that the Amendments do not provide for promulgation of regulations).

None of the Amendments includes, or references, *any* explicit delegation of regulatory authority. *Compare, e.g.,* 42 U.S.C. § 2000d-1 (expressly directing all relevant federal agencies to issue "rules, regulations, or orders of general applicability" to achieve the objectives of Title VI). Nor is there any implicit delegation of legislative rulemaking authority for these provisions. As underscored by the decades that Church, Coats-Snowe and Weldon have applied without any legislative rulemaking supplementing their content, those enactments do not give the Department the power to issue force-of-law rules under them, as the Department is now – expansively – trying to do.[17] For this reason alone, the Department cannot properly proceed to adopt the Proposed Rule or any similar variation of it.

III. The Rule Proposes Numerous Expansive Definitions That Defy the Meaning of the Statutory Terms and Would Fuel Confusion, Misinformation, and Denials of Care.

Even if the Department had the necessary rulemaking authority (which it does not), the Proposed Rule's broad definition of certain terms and expansions of the Refusal Statutes' reach would far exceed any conceivable authority. An agency cannot use rulemaking to extend the scope of a statute. *See City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 297 (2013) (agency must stay within the bounds of the statute under which it acts). Yet that is what this Rule does, through numerous proposed "definitions," including, among others, those proposed for "assist in the performance," "referral or refer for," and "discrimination."

Indeed, it is telling that the Rule's Preamble devotes four pages in the Federal Register to trying to justify its over-reaching definitions, but does not attempt to describe the Rule's proposed substantive requirements at all. Instead, the Preamble claims that the substantive requirements are simply "taken from the relevant statutory language." 83 FD 3895. But that assertion is belied by, *inter alia*, the Department's proposed expansion and re-writing of those statutes through impermissible re-definition of numerous statutory terms and other sleights of hand. Any rule-making of this kind needs to attempt to explain not only the definitions of words, but how those definitions and the Rule's substantive requirements come together to regulate conduct, which the Department utterly fails to do.

For example, the Department proposes to define "assist in the performance" of an abortion or sterilization to include not only assistance *in the performance* of those actual procedures—the ordinary meaning of the phrase—but also participation in any other activity

[17] Although the Bush Administration promulgated similar rules in December 2008, those rules did not take full effect before their reconsideration and rescission commenced. The eventual replacement regulation, which became final in 2011 and remains in force today, consists of just two provisions describing solely that OCR is designated to receive complaints under the Amendments. The Department promulgated that rule under 5 U.S.C. § 301, the Department's "housekeeping" authority for adopting regulations limited to the conduct of its own affairs. Section 301 does not authorize the promulgation of substantive regulatory requirements like those in the Proposed Rule. *See* 76 FR 9975-76. Moreover, that we here highlight the lack of regulatory rule-making authority under Section 301 and under the Amendments should not be read to imply that any such authority exists under the other Refusal Statutes referenced in this NPRM; the Proposed Rule does not specify *any* authority for legislative rulemaking.

with "an articulable connection to a procedure[.]" 83 FR 8892, 3923. Through this expanded definition, the Department explicitly aims to include activities beyond "direct involvement with a procedure" and to provide "broad protection"—despite the statutory references limited to "assist[ance] in the performance of" an abortion or sterilization procedure itself. *Id.*; *cf. e.g.*, 42 U.S.C. § 300a-7(c)(1).

This would mean, for example, that simply admitting patients to a health care facility, filing their charts, transporting them from one part of the facility to another, or even taking their temperature could conceivably be considered "assist[ing] in the performance" of an abortion or sterilization, as any of those activities could have an "articulable connection" to the procedure. As described more fully below, *see infra* Part VI, the Proposed Rule would even sanction the withholding of basic information about abortion or sterilization on the grounds that "assist[ing] in the performance" of a procedure "includes but is not limited to counseling, referral, training, and other arrangements for the procedure." 83 FD 3892, 3923.

But the term "assist in the performance" does not have the virtually limitless meaning the Department proposes ascribing to it. The Department has no basis for declaring that Congress meant anything beyond actually "assist[ing] in the performance of" the specified procedure—given that it used that phrase, 42 U.S.C. § 300a-7(c)(1). There is no basis for the Department to interpret that term to mean any activity with any connection that can merely be articulated, regardless of how attenuated the claimed connection, how distant in time, or how non-procedure-specific the activity.

Likewise, the Proposed Rule's definition of "referral or refer for" impermissibly goes beyond the statutory language and congressional intent. The Rule declares that "referral or refer for" means "the provision of *any* information … by any method … pertaining to a health care service, activity, or procedure … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" it, where the entity (including a person) doing so "sincerely understands" the service, activity, or procedure to be a "possible outcome[.]" 83 FR 3894, 3924 (emphasis added). This expansive definition could have dire consequences for patients. For example, a hospital that prohibits its doctors from even discussing abortion as a treatment option for certain serious medical conditions could attempt to claim that the Rule protects this withholding of critical information because the hospital "sincerely understands" the provision of this information to the patient may assist the patient in obtaining an abortion.[18]

But by providing a green light for the refusal to provide information that patients need to make informed decisions about their medical care, the Proposed Rule not only violates basic medical ethics, but also far exceeds congressional intent. A referral, as used in common parlance and the underlying statutes, has a far more limited meaning than providing *any* information that *could* provide *any assistance whatsoever* to a person who may ultimately decide to obtain, assist, finance, or perform a given procedure sometime in the future. The meaning of "referral or refer for" in the health care context is to *direct* a patient elsewhere for care. *See* Merriam-Webster, https://www.merriam-webster.com/dictionary/referral ("referral" is "the process of directing or redirecting (as a medical case or a patient) to an appropriate specialist or agency for definitive

[18] As explained in Part VI(B), *infra*, the Proposed Rule's overbroad interpretation of the phrase "make arrangements for," 83 FR 3895, compounds the problems with the unjustified definition of referral.

treatment"); Medicare.gov, *Glossary: Referral*, https://www.medicare.gov/glossary/r.html (defining referral as "[a] written order from your primary care doctor for you to see a specialist or get certain medical services"); HealthCare.gov, *Glossary: Referral*, https://www.healthcare.gov/glossary/referral/ (same); Ctrs. for Medicare & Medicaid Services Website, *Glossary: Referral*, https://www.cms.gov/apps/glossary/default.asp?Letter=R&Language ("Generally, a referral is defined as an actual document obtained from a provider in order for the beneficiary to receive additional services."); *id.* (a referral is a "written OK from your primary care doctor for you to see a specialist or get certain services").

In addition, the Proposed Rule's definition appears to include a subjective element not present in any of the referenced statutes or in the ordinary meaning of "referral": Under the Rule, an entity's "sincere understanding" determines whether or not a referral has occurred. 83 FR 3924; *see also* 83 FR 3894 n.46 (claiming that a "referral constitutes moral cooperation with a conscientiously objected activity"). The Proposed Rule states that it is attempting to provide "broad protection for entities unwilling to be complicit in" certain services, 83 FR 3895, but transforming "refer for" into a much looser, subjective notion of being "complicit in" is a significant departure from the actual statutory language of the Refusal Statutes and plainly exceeds the Department's authority.

These expansive definitions are all the more troubling to the extent the Proposed Rule's definition of "discrimination" purports to provide unlimited immunity for institutions or employees who refuse to perform essential care. The Rule apparently attempts to provide unlimited immunity for institutions that receive some federal funds to deny abortion care, to block coverage for such care, or to stop patients' access to information, no matter what the patients' circumstances or the mandates of state or federal law. Likewise, the definition appears aimed at providing immunity for employees who refuse to perform central parts of their job, regardless of the impact on the ability of a health care entity to provide appropriate care to its patients. This expansion of "discrimination" would apparently treat virtually any adverse action—including government enforcement of a patient non-discrimination or access-to-care law—against a health care facility or individual as *per se* discrimination. Indeed, the definition of discrimination appears designed to provide a tool to stop enforcement of state laws providing more protection of patients, particularly those seeking abortion care. But "discrimination" does not mean any negative action, and instead requires an assessment of context and justification, with the claimant showing unequal treatment on prohibited grounds under the operative circumstances.[19] *See infra* Parts IV-V.

While this comment letter does not attempt to detail all of the unfounded definitional expansions included in the Proposed Rule, other examples abound. *See e.g.*, 83 FR 3893

[19] The Rule should not be expanded even further by an unfounded "disparate impact" concept that has no place in implementing these narrowly-targeted Refusal Statutes. While the Proposed Rule does not explain its proffered "disparate impact" concept, such a concept might empower the Department, for example, to forbid *any* enforcement of a general state government policy that is contrary to a particular institution's religious dictates, or of a neutral employment rule that is contrary to some employees' beliefs (rather than accepting that an employer's obligations are at most reasonable accommodation of particular employees, if possible without undue hardship, *see infra* Part IV).

(proposing to define "health care entity" to include those employers and others who sponsor health plans but "are *not* primarily in the business of health care") (emphasis added), 3894 (proposing to define "workforce" to include volunteers and contractors, despite those individuals' independence from any corporate or public entities employing workers), 3894 (erroneously expanding definition of "health service program"), 3923-24.[20] The Department has no authority to expand the Refusal Statutes in this way, and these irrational definitions that are contrary to both the Refusal Statutes and congressional intent should be explicitly rejected.

IV. The Proposed Rule Threatens to Upend the Appropriate Balance Struck by Long-Standing Federal Laws.

A. The Proposed Rule Ignores the Careful Balance Title VII Strikes Between Protecting Employees' Religious Beliefs and Ensuring Patients Can Obtain the Health Care They Need.

The Proposed Rule is not only unauthorized and harmful to patients, it is also unnecessary as federal law already amply protects individuals' religious freedom—freedom the ACLU has fought to protect throughout its nearly 100-year history.

For example, for more than four decades, Title VII has required employers to make reasonable accommodations for current and prospective employers' religious beliefs so long as doing so does not pose an "undue hardship" to the employer. 42 U.S.C. §§ 2000e(j), 2000e-2(a).[21] An "undue hardship" occurs under Title VII when the accommodation poses a "more than *de minimis* cost" or burden on the employer's business. *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); EEOC Guidelines, 29 C.F.R. § 1605.2(e)(1). Thus, Title VII—while protecting employees' freedom of religion—establishes an essential balance. It recognizes that an employer cannot subject an employee to less favorable treatment solely because of that employee's religion and that generally an employer must accommodate an employee's religious practices. However, it does not require accommodation when the employee objects to performing core job functions, particularly to the extent those objections harm patients, depart from standards of care, or otherwise constitute an undue hardship. *Id.*; *see also Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985). This careful balance between the needs of employees, patients, and employers is critical to ensuring that health care employers are able to provide quality health care.

Despite this long-standing balance, nowhere does the Proposed Rule mention these basic legal standards or the need to ensure patient needs are met. Instead, by presenting a seemingly unqualified definition of what constitutes "discrimination," 83 FR 3923-24, the Department

[20] Moreover, the Proposed Rule not only re-defines words and phrases from the Refusal Statutes, but also adds words. For example, Section 1303 of the Patient Protection and Affordable Care Act ("ACA"), 42 U.S.C. § 18023(b)(1)(A)(i), refers to "abortion services"; the Proposed Rule expands that to "abortion or abortion-related services," without defining what that added term – found nowhere in the statute – purports to cover. 83 FR 3926; *see also, e.g.,* 83 FR 3924 (defining "health program or activity" without any apparent use of phrase in a Refusal Statute though it is used to protect patients in Section 1557 of the ACA).
[21] For purposes of Title VII, religion includes not only theistic beliefs, but also non-theistic "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." Equal Employment Opportunity Commission ("EEOC") Guidelines, 29 C.F.R. §1605.1.

appears to attempt to provide complete immunity for religious refusals in the workplace, no matter how significantly those refusals undermine patient care, informed consent, or the essential work of health care institutions. Indeed, the Rule is explicit in seeking an unlimited ability to "be[] free not to act contrary to one's beliefs," regardless of the harm it causes others. 83 FR 3892. This definition thus raises real concerns that the Proposed Rule could be invoked by employees or job applicants who refuse to perform core elements of the job. For example, job applicants may attempt to claim that a family planning provider is required to hire them as pregnancy options counselors even though they refuse to provide any information about the option of abortion and even where the provision of such information is required by the provider's federal funding.

However, neither the Refusals Statutes, nor any other federal law, permits such an unprecedented re-definition of "discrimination." When Congress prohibited discrimination in certain Refusal Statutes, it did not *sub silentio* create an absolute right to a job even if the employee refuses to perform essential job functions, as that has never been the meaning, legal or otherwise, of "discrimination." *See, e.g., McDonnell Douglas Corp. v. Green*, 411 U.S. 793, 802 (1973) (employment discrimination claim requires proof that employee was qualified for the position, and employer may articulate a legitimate, non-discriminatory job-related reason to defeat such a claim). Such an unfounded definitional shift for "discrimination" improperly expands narrow congressional enactments and attempts to reinterpret federal laws, all long construed to be harmonious, to instead be conflicting and contradictory. It turns the Department's mission on its head. If the Department does not withdraw the entire Rule, it should explicitly limit its reach and attempt to clarify how Title VII's balance can continue to have full force and effect in the workplace.

B. Rather than Ensuring Patients Can Get Care in an Emergency, the Proposed Rule Describes the Obligation to Provide Critical Care as Part of the "Problem."

The Proposed Rule puts patients at risk by ignoring the federal Emergency Medical Treatment and Labor Act ("EMTALA") and hospitals' obligations to care for patients in an emergency. As Congress has recognized, a refusal to treat patients facing an emergency puts their health and, in some cases, their lives at serious risk. Through EMTALA, Congress has required hospitals with an emergency room to provide stabilizing treatment to any individual experiencing an emergency medical condition or to provide a medically beneficial transfer. 42 U.S.C. § 1395dd(a)-(c).

The Refusal Statutes do not override the requirements of EMTALA or similar state laws that require health care providers to provide abortion care to a patient facing an emergency. *See, e.g., California v. U.S.*, Civ. No. 05-00328, 2008 WL 744840, at *4 (N.D. Cal. March 18, 2008) (rejecting notion "[t]hat enforcing [a state law requiring emergency departments to provide emergency care] or the EMTALA to require medical treatment for emergency medical conditions would be considered 'discrimination' under the Weldon Amendment"). Indeed, after a challenge to the Weldon Amendment was filed on the ground that it could inhibit the enforcement of statutes requiring hospitals to provide emergency abortion care, Representative

Weldon emphasized that his amendment did not disturb EMTALA's requirement that critical-care facilities provide appropriate treatment to women in need of emergency abortions.[22]

It is particularly troubling, therefore, to have the Department include the long-standing legal and ethical obligation to provide emergency care to patients in the Rule's Preamble as *justification* for expanding the Refusal Statutes – in other words, as justification to *relieve* hospitals or hospital personnel of any obligation, for example, to perform an emergency abortion when a patient is in the midst of a miscarriage, or even to "refer" a patient whose health is deteriorating for an emergency abortion. 83 FR 3888, 3894. But the ethical imperative is the opposite: "In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." 83 FR 3888 (quoting American Congress of Obstetricians and Gynecologists ("ACOG") ethics opinion and describing it as part of the problem the Proposed rule is meant to address).

Tragically, such concerns are far from hypothetical. As noted above, Tamesha Means was turned away from critical care three times, exposing her to serious risk and putting her life in jeopardy, and in the midst of being discharged the third time, was finally helped only when she started to deliver. Another miscarrying patient collapsed at home and almost bled to death after being turned away three different times from the only hospital in her community which refused to provide her the emergency abortion she needed.[23] Refusals such as these disproportionately affect women of color who are more likely than other women to receive their care at Catholic hospitals, which follow directives that can keep providers from following standards of care and governing law.[24]

The Proposed Rule suggests that hospitals that fail to provide patients like these with appropriate emergency care should be given a free pass. Any such license to refuse patients emergency treatment, including emergency abortions, however, would not only violate EMTALA, but also the legal, professional, and ethical principles governing access to health care in this country. For that reason, if not withdrawn in its entirety, the Proposed Rule should, as one of many necessary limitations, clarify that it does not disturb health care providers' obligations to provide appropriate care in an emergency.

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[22] *See* 151 Cong. Rec. H176-02 (Jan. 25, 2005) (statement of Rep. Weldon) ("The Hyde-Weldon Amendment is simple. It prevents federal funding when courts and other government agencies force or require physicians, clinics, and hospitals and health insurers to participate in *elective* abortions.") (emphasis added); *id.* (Weldon Amendment "ensures that in situations where a mother's life is in danger a health care provider must act to protect a mother's life"); *id.* (discussing that the Weldon Amendment does not affect a health care facility's obligations under EMTALA). Nor were the other Refusal Statutes intended to affect the provision of emergency care. *See*, e.g., 142 Cong. Rec. S2268-01, S2269 (March 19, 1996) (statement of Senator Coats in support of his Amendment) ("a resident needs not to have [previously] performed an abortion … to have mastered the procedure to protect the health of the mother if necessary"); *id.* at S2270 (statement of Senator Coats) ("[T]he similarities between the procedure which [residents] are trained for, which is the D&C procedure, and the procedures for performing an abortion are essentially the same and, therefore, [residents] have the expertise necessary, as learned in those training procedures, should the occasion occur and an emergency occur to perform an abortion.").

[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[24] *Id.* at 12 (2018).

C. The Proposed Rule Fosters Discrimination.

The Proposed Rule also puts patients at risk by ignoring the federal Patient Protection and Affordable Care Act ("ACA"), which explicitly confers on patients the right to receive nondiscriminatory health care in any health program or activity that receives federal funding. 42 U.S.C. § 18116. Incorporating the prohibited grounds for discrimination described in other federal civil rights laws, the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. *Id.* at § 18116(a).

The Refusal Statutes must be read to coexist with the nondiscrimination requirements of the ACA and similar state nondiscrimination laws. If a nondiscrimination requirement has any meaning in the healthcare context, it must mean that patients cannot be refused care simply because of their race, color, national origin, sex, age, or disability. And as courts have recognized, the prohibition on sex discrimination under the federal civil rights statutes should be interpreted to prohibit discrimination against transgender people. *See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017) (discrimination against transgender students violates Title IX, which is the basis for the ACA's prohibition on sex discrimination); *see also EEOC v. R.G. & G.R. Funeral Homes, Inc.*, __ F.3d __, 2018 WL 1177669 at *5-12 (6th Cir. Mar. 7, 2018) (Title VII); *Glenn v. Brumby*, 663 F.3d 1312, 1316-19 (11th Cir. 2011) (Title VII); *Rosa v. Park W. Bank & Tr. Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187, 1201-03 (9th Cir. 2000) (Gender Motivated Violence Act).

Notwithstanding these protections, as well as explicit statutory protections from discrimination based on gender identity and sexual orientation in many states, the Proposed Rule invites providers to discriminate against LGBT patients, particularly transgender people. The Department includes as a *justification* for expanding the Refusals Statutes a California lawsuit—*Minton v. Dignity Health*—in which a transgender patient is suing under the state nondiscrimination law, alleging that he was denied care a religiously-affiliated hospital routinely provided to other patients, simply because he is transgender. 83 FR 3888-89 & n.36. The Proposed Rule thus suggests that discrimination against a patient simply because he is transgender is permissible—in violation not only of California's nondiscrimination law, but also of the ACA. For that reason, if not withdrawn in its entirety, the Proposed Rule should, as one of many necessary limitations, clarify that it does not disturb health care providers' obligations to provide nondiscriminatory care.

D. The Proposed Rule Creates Confusion That Threatens to Deprive Title X Clients of Services That the Underlying Statutes and Regulations Require.

Finally, the Proposed Rule threatens to undermine the Title X program, which for more than four decades has provided a safety net upon which millions of low-income, under-insured, and uninsured individuals rely each year for family planning essential to their health and the promise of equality. For example, Congress requires that all pregnancy counseling within the Title X program be neutral and "nondirective." *See, e.g.*, Pub. L. No. 115-31 at 521. The Department's own regulations also require that pregnant women receive "neutral, factual

information" and "referral[s] upon request" for prenatal care and delivery, adoption, and/or abortion. 42 C.F.R. § 59.5(a)(5). Yet the Proposed Rule's unauthorized expansion of the Weldon Amendment, *see infra* Part V(C), creates confusion about whether health care entities that refuse to provide non-directive options counseling (which includes discussion of abortion) and abortion referrals may seek to claim an exemption from these requirements and therefore a right to participate in the Title X program despite their refusal to provide the services to which Title X clients are entitled. The Department cannot promulgate a rule that conflicts with federal law in this manner and if it is not withdrawn, the Department should make explicit that it does not provide an exemption to the Title X requirements.

* * *

None of the Refusal Statutes was intended or designed to disrupt the balance between existing federal laws—such as Title VII, EMTALA, Title X and also later-in-time statutes, such as Section 1557 of the ACA—or to create categorical and limitless rights to refuse to provide basic health care, referrals, and even information. Thus, even if the Department had the authority to promulgate the Proposed Rule (which it does not), the Proposed Rule is so untethered to congressional language and intent that it must be withdrawn or substantially modified.

V. The Rule Attempts Impermissibly Transform the Referenced Statutes Into Shields for Inadequate or Discriminatory Care.

The Proposed Rule not only distorts the definitions of words in the statutes, but also alters their substantive provisions in other ways to attempt to expand the ability of entities and individuals to deny care in contravention of legal and ethical requirements and to the severe detriment of patients. Some of these additional statutory expansions, are highlighted below.

A. Examples of Impermissible Church Amendment Expansions.

Subsection (b) of the Church Amendments, for example, specifies only that the receipt of Public Health Service Act funding *in and of itself* does not permit a court or other public authority to require that an individual perform or assist in the performance of abortion or sterilization, or require that an entity provide facilities or personnel for such performance. *See, e.g.*, 42 U.S.C. 300a-7(b) ("The receipt of any grant, contract or loan guarantee under the Public Health Service Act . . . by any individual does not authorize any court or any public official or other public authority to require . . . such individual to perform or assist in the performance of any sterilization procedure or abortion if [doing so] would be contrary to his religious beliefs or moral convictions."). The Proposed Rule, however, attempts to transform that limited prohibition – that receipt of certain federal funds alone does not create an obligation to provide abortions or sterilizations – into an across-the-board shield that forbids any public entity from determining that *any* source of law requires that the entities provide these services. 83 FR 3924-25. If the Rule is not withdrawn, the Department should modify the Rule so that it does not exceed the statute.

Similarly, the Proposed Rule apparently aims to vastly expand the prohibitions contained in subsection (d) of the Church Amendments in a manner that is contrary to the legislative language, the statutory scheme, and congressional intent. Congress enacted Subsection (d) of the Church Amendment in 1974 as part of Public Law 93-348, a law that addressed biomedical and behavioral research, and appended that new Subsection (d) to the pre-existing subsections of Church from 1973, which all are codified within 42 U.S.C. § 300a-7: the "Sterilization or Abortion" section within the code subchapter that relates to "Population Research and Voluntary Family Planning Programs."

Despite this explicit and narrow context for Subsection (d), the Proposed Rule attempts to transform this Subsection into a much more general prohibition that would apply to *any* programs or services administered by the Department, and that would assertedly prevent any entity that receives federal funding through those programs or services from requiring individuals to perform or assistance in the performance of *any* actions contrary to their religious beliefs or moral convictions. *See* 83 FR 3894, 3906, 3925. This erroneous expansion of Church (d) could prevent health care institutions from ensuring that their employees provide appropriate care and information: It would purportedly prevent taking action against members of their workforce who refuse to provide any information or care that they "sincerely understand" may have an "articulable connection" to some eventual procedure to which they object, no matter what medical ethics, their job requirements, Title VII or laws directly protecting patient access to care may require.

The ACLU is particularly concerned that the Proposed Rule's erroneous expansion of Church (d) could be used to deny services because of the identity of the individual seeking help. To name a few of the many possibilities that could result from the Proposed Rule's emboldening of personal-belief-based care denials:

- A nurse could deny access to reproductive services to members of same-sex or inter-racial couples, because her religious beliefs condemn them;

- A physician could refuse to provide treatment for sexually transmitted infections to unmarried individuals, because of her opposition to non-marital sex;

- Administrative employees could refuse to process referrals or insurance claims, just as health care professionals could deny care itself, because they object to recognizing transgender individuals' identity and medical needs.

This inappropriately expanded conception of Church Subsection (d) conflicts with statutory language, the anti-discrimination protections of Section 1557 of the ACA, the requirements of EMTALA, and the balance established by Title VII, and otherwise manifestly overreaches in a number of respects. Instead, the Department should clarify that the Church Amendments are limited to what the statute provides and Congress intended.

B. Examples of Impermissible Coats-Snowe Amendment Expansions.

The Proposed Rule similarly stretches the Coats-Snowe Amendment beyond its language and Congress' clear intent. In 1996, Congress adopted the Coats-Snowe Amendment, entitled "Abortion-related-discrimination in governmental activities regarding training and licensing of physicians," in response to a decision by the Accrediting Council for Graduate Medical Education to require obstetrician-gynecologist residency programs to provide abortion training. The Proposed Rule, however, entirely omits that context.

Rather than being confined to training and licensing activities as the statute is, the Proposed Rule purports to give all manner of health care entities, including insurance companies and hospitals, a broad right to refuse to provide abortion and abortion-related care. In addition, the Rule's expansion of the terms "referral" and "make arrangements for" extends the Coats-Snowe Amendment to shield any conduct that would provide "any information … by any method … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" an abortion or that "render[s] aid to anyone else reasonably likely" to make such an abortion referral. 83 FR 3894-95, 3924 (emphasis added). This expansive interpretation not only goes far beyond congressional intent and the terms of the statute, it also could have extremely detrimental effects on patient health. For example, it would apparently shield, against any state or federal government penalties, a women's health center that required any obstetrician-gynecologist practicing there who diagnosed a pregnant patient as having a serious uterine health condition to refuse even to provide her with the name of an appropriate specialist, because that person "is reasonably likely" to provide the patient with information about abortion.

Again, if the Proposed Rule is not withdrawn, it should be pared back and clarified so as to be faithful to both the statutory text and congressional intent.

C. Examples of Impermissible Weldon Amendment Expansions.

The Department attempts the same sort of improper regulatory expansion of the Weldon Amendment, which is not a permanent statutory provision but a rider that Congress has attached to the Labor, Health and Human Services and Education Appropriations Act annually since 2004. As written, the Weldon Amendment is no more than a bar on particular appropriated funds flowing to federal agencies or programs, or state or local government, if any of those government institutions discriminate on the basis that a health care entity does not provide, pay for, provide coverage of, or refer for abortion. But the Proposed Rule attempts to vastly increase the Amendment's reach in multiple ways. First, the Proposed Rule explicitly extends the reach of the Weldon Amendment beyond the appropriations act to which it is attached, by stating that it also applies to any entity that receives any other "funds through a program administered by the Secretary," which would include, for example, Medicaid. 83 FR 3925. Second, although the terms of the Amendment itself bind only federal agencies and programs and state and local governments, the Rule expands Weldon's reach to also proscribe the behavior of any person, corporation, or public or private agency that receives any of this newly enlarged category of funds. *Id.*

The Rule then provides that no one of this greatly expanded universe of parties may subject any institutional or individual health care entity[25] to discrimination for refusal to provide, pay for, provide coverage for, or refer for abortions. Such unauthorized expansions of limited appropriations language seem designed to encourage broad and harmful denials of care. For example, under the expanded definitions contained in the Proposed Rule, an employer, even one with no religious or moral objection to abortion, may attempt to claim that it has a right to deny its employees' insurance coverage for abortion irrespective of state law. Or a private health care network that receives Medicaid reimbursement could face employees asserting not only the ability to refuse to participate in certain abortion-related care, but also to remain in their positions without repercussions. This is not implementation of the Weldon Amendment; this is a new scheme. If the Rule is not withdrawn, the Department should modify the Rule so that it does not exceed the statute.[26]

VI. The Proposed Rule Appears Intended to Provide a Shield for Health Care Providers Who Fail to Provide Complete Information to Patients in Violation of Both Medical Ethics and Federal Law.

The Proposed Rule also appears to allow providers to let their own personal preferences distort provider-patient communications and deprive patients of critical health care information about their condition and treatment options. The Proposed Rule's Preamble suggests the Rule will improve physician-patient communication because it will purportedly "assist patients in seeking counselors and other health-care providers who share their deepest held convictions." 83 FR 3916-17. But patients are already free to inquire about their providers' views and providers must already honor patients' own expressions of faith and decisions based on that faith. *Cf. id.* Allowing *providers* to decide what information to share—or not share—with patients, as the Rule would do, regardless of the requirements of informed consent and professional ethics would gravely harm trust and open communication in health care.

As the American Medical Association's Code of Medical Ethics ("AMA Code") explains, the relationship between patient and physician "gives rise to physicians' ethical responsibility to place patients' welfare about the physician's own self-interest[.]" AMA Code § 1.1.1. Even in instances where a provider opposes a particular course of action based on belief, the AMA states that the provider must "[u]phold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects." *Id.* § 1.1.7(e). Similarly, ACOG emphasizes that "the primary duty" is to the patient, and that without exception "health care providers must impart accurate and unbiased information so that patients can make informed decisions about their health care." ACOG Committee Opinion No. 385, Recommendations 1-2 (Nov. 2007) (Reaffirmed 2016). Therefore, under well-established principles of informed consent and medical ethics, health care providers must provide patients with all of the information they need to make their own decisions; providers

[25] Although the Weldon Amendment itself defines "health care entity" to include individual health care professionals or "any other kind of health care facility, organization or plan," the Proposed Rule's definitions, as discussed above, try to further extend "health care entity" to also encompass companies or associations whose primary purpose is *not* health care, but who happen to sponsor a health care plan. This appears to reach employers.
[26] Moreover, for any promulgated Rule, the Department must explain its practical operation in detail, so that any affected public or private actors can ascertain the Department's meaning.

may not allow their own religious or moral beliefs to dictate whether patients receive full information about their condition, the risks and benefits of any procedure or treatment, and any available alternatives.

By erroneously expanding the meaning of "assist in the performance of," "refer for" and "make arrangements for," as described above, however, the Proposed Rule purports to allow health care providers to refuse to provide basic information to patients in ways that were never contemplated by the underlying statutes. As described above, these broad definitions may be used to immunize the denial of basic information about a patient's condition as well as her treatment options. Protecting health care professionals when they withhold this vital information from patients violates fundamental legal and ethical principles, deprives patients of the ability to make informed decisions and leads to negligent care. If the Department moves forward with the Proposed Rule, it should modify it to make clear that it does not subvert basic principles of medical ethics and does not protect withholding information from a patient about her condition or treatment options.

VII. The Rule Would Violate the Establishment Clause Because It Authorizes Health Care Providers to Impose their Faith on their Patients, to the Detriment of Patient Health.

The Proposed Rule imposes the significant harms on patients identified above in service of institutional and individual religious objectors. It purports to mandate that their religious choices take precedence over the health care needs of patients. But the First Amendment forbids government action that favors the free exercise of religion to the point of forcing unwilling third parties to bear the burdens and costs of someone else's faith. As the Supreme Court has emphasized, "[t]he principle that government may accommodate the free exercise of religion does not supersede the fundamental limitation imposed by the Establishment Clause." *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *accord Bd. of Educ. of Kiryas Joel Village School Dist. v. Grumet*, 512 U.S. 687, 706 (1994) ("accommodation is not a principle without limits").

Because the Rule attempts to license serious patient harms in the name of shielding others' religious conduct, it is incompatible with our longstanding constitutional commitment to separation of church and state. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708-10 (1985) (rejecting, as Establishment Clause violation, law that freed religious workers from Sabbath duties, because the law imposed substantial harms on other employees); *see also Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 14, 18 n.8 (1989) (plurality opinion) (invalidating sales tax exemption for religious periodicals, in part because the exemption "burden[e]d nonbeneficiaries markedly" by increasing their tax bills). The Department should withdraw the Rule to avoid its violation of the Establishment Clause.

VIII. The Proposed Enforcement Scheme Is Excessive and Fails to Adequately Protect the Due Process and Other Rights of Grantees.

As explained above, the Refusal Statutes carve out specific, narrow exemptions that are only relevant and applicable to certain entities and individuals in certain circumstances. Even with its unfounded expansion of the referenced Refusal Statutes, the Department forecasts only

10-50 complaint investigations or compliance reviews arising under the Refusal Statutes each year, all concerning objections to providing certain health care. 83 FR 3915, 3922. As such, these statutes are quite unlike the various provisions of the Civil Rights Act of 1964, or other civil rights or anti-discrimination statutes that provide broad protection against discrimination to the public or across a wide range of society. Despite these differences, the Proposed Rule claims to model its compliance and enforcement mechanisms on those broad "civil rights laws, such as Title VI and Section 504 of the Rehabilitation Act." 83 FR 3896, 3898. Yet, the Rule's enforcement provisions exceed the ones in place for civil rights laws and, notably, this proposed rulemaking does not anywhere reference basic constitutional limits or specify important due process protections against overzealous enforcement. Taken together, these provisions are ripe for abuse.

The following provisions, which are not an exhaustive list of the serious enforcement scheme issues, appear particularly problematic:

- Funded entities must disclose any complaints or compliance reviews under the Refusal Statutes or Rule from the last five years in any funding application or renewal request, even if the complaint did not warrant an investigation or the investigation or review closed with no finding of any violation, 83 FR 3930;

- The Rule permits onerous remedies for a "failure or threatened failure to comply," including withholding or terminating funding or referral to the Attorney General for "enforcement in federal court or otherwise" without waiting for any attempts at voluntary compliance or resolution through informal means, 83 FR 8330-31;

- The Rule allows the Department to employ the full array of punishments against funding recipients for infractions by sub-recipients, no matter how independent those sub-recipients' actions and no matter how vigorous the recipients' compliance efforts;[27]

- The Rule creates violations for failure to satisfy *any* information requests, and grants access to "complete records," providing especially expansive access with more stringent enforcement than in the Department's Title VI regulations, without any reference to the Fourth Amendment protections developed under Title VI and other similar laws, 83 FR 3829-30; and

- The Rule's enforcement scheme also appears to lack the robust administrative review process, including proceedings before a hearing officer and required findings on the

[27] As proposed subsection 88.6(a) provides, if a sub-recipient violation is found, the recipient "from whom the sub-recipient received funds shall be subject to the imposition of funding restrictions and other appropriate remedies available under this part." 83 FR 3930. This language lacks clarity as to whether imposing a penalty is mandatory or an option, but regardless, not every violation by a sub-recipient should open the recipient to the possibility of sanctions. Moreover, fund termination under the Proposed Rule does not appear to be restricted by the "pinpointing" concept that applies under Title VI, which ensures against vindictive, broad funding terminations and excessive harms to program beneficiaries. Neither this proposed subsection nor the other new enforcement provisions should be added to Part 88, but if they are, subsection 88.6(a) should, like the Proposed Rule's other unfounded enforcement expansions, be clarified and much more strictly limited.

record, that must precede any suspension or termination of federal funding under, for example, Title VI's enforcement regulations. *See* 45 C.F.R. Part 81. If the Rule is not withdrawn, the Department should make clear that those same rigorous protections apply here.

In addition, while claiming such vast, unauthorized enforcement powers, the Department also repeatedly states that it proposes to uphold "the maximum protection" for the rights of conscience and "the broadest prohibition on" actions against any providers acting to follow their own beliefs. 83 FR 3899, 3931. This combination of a pre-ordained inclination in favor of refusers and excessive enforcement powers further threatens to undermine federal health programs by harming funding recipients who are serving patients well.

If the Rule is not withdrawn, it should be modified in accordance with these comments to ensure that providers of health care are not subjected to unduly broad inquiries or investigations, unfairly penalized, or deprived of due process, all to the detriment of focusing on care for their patients.

IX. The Department Has Not Shown the Need for Expanded Enforcement Authority and Requirements, Uses Faulty Regulatory Impact Analyses, and Proposes a Rule That Will Only Add Compliance Burdens and Significant Costs to Health Care.

Finally, the Department itself estimates hundreds of millions of dollars in cost, almost all imposed on entities providing health care, to undertake the elaborate compliance and enforcement actions the Rule contemplates. But the Proposed Rule's regulatory impact analysis severely underestimates the cost and other burdens it would impose. At virtually every step of its purported tallying of costs, the Department grossly underestimates the time that a covered institution's lawyers, management and employees will have to spend to attempt to understand the Rule, interpret its interplay with other legal and ethical requirements, train staff, modify manuals and procedures, certify and assure compliance, and monitor the institution's actions on an ongoing basis. For example, the Rule considers a single hour by a single lawyer enough for covered entities to "familiarize themselves with the content of the proposed rule and its requirements." 83 FR 3912. It allocates 10 minutes per Refusal Statute, for the roughly two dozen laws referenced, for an entity to execute the assurance and certification of compliance—thus allocating no time for actually reviewing an entity's records or operations in order to do so. 83 FR 3913. Similarly, the impact analysis mentions the time necessary to disclose investigations or compliance reviews, but not the much more significant amount of time needed to respond to and cooperate in those processes. Moreover, the Department does not factor into cost *at all* the cost to the institution when employees refuse to perform care or provide information, or the costs to the refused patients, who must seek help elsewhere and suffer harms to their health.

In estimating benefits, the analysis does not demonstrate barriers to entry for health professionals, or exits from the health profession that are occurring, nor does it substantiate the contention that the medical field does not already include professionals with a wide diversity of religious and other beliefs. As discussed above, it claims benefits to provider-patient

communication and relationships that are non-existent. The Proposed Rule offers no evidence that either greater protection for refusals or expanded enforcement mechanisms are needed.

The Department's prior rulemaking, which emphasized outreach and enforcement, remains in effect and makes clear that OCR has sufficient enforcement authority, consistent with the specific governing statutes, to address any meritorious complaints or other violations. 45 C.F.R. Part 88; 76 FR 9968. In fact, the Department itself estimates that, even with adoption of the Proposed Rule, it would initiate only 10-50 OCR investigations or compliance reviews per year. Since 2008, the number of Refusal Statute complaints per year has averaged 1.25, with 34 complaints filed in the recent November 2016 to mid-January 2018 period.[28] The Proposed Rule contemplates an enormous outlay of funds to implement an elaborate and unnecessary enforcement system that will only divert resources away from enforcing patients' civil rights protections and the provision of high-quality health care to those who need it most.

Thus, the Rule's analysis of economic impacts, including under Executive Orders 12866 and 13563, is seriously flawed and fails to demonstrate that any benefits of the Proposed Rule justify its enormous costs, many of which go unacknowledged. In addition, the Secretary proposes to falsely "certify that this rule will not result in a significant impact on a substantial number of small entities." 83 FR 3918. Small health care entities will have to bear the same regulatory analysis and ongoing compliance costs as larger entities, will face the same loss of employee time and effort from religious and other refusals, and yet have fewer resources and other employees to fall back on. While some small entities may be relieved of routinely certifying their compliance in writing, that compliance is still required – and the compliance itself imposes the much more significant cost and interference with its operations. Similarly, the Secretary erroneously "proposes to certify that this proposed rule … will not negatively affect family well-being," 83 FR 3919, when expanded refusals of medical information and health care by federally funded providers would significantly affect the stability, disposable income, and well-being of low-income families.

The Rule's regulatory impact analyses utterly fail to support its adoption. This expansive rulemaking exceeds any statutory authority and overwhelms any need, and would leave health care institutions, patients, and their families suffering.

* * *

For all these reasons, the Department should withdraw the Proposed Rule.

Sincerely,

Louise Melling
Deputy Legal Director

Faiz Shakir
National Political Director

[28] For context, in FY 2017, OCR received a total of 30,166 complaints under all of the federal statutes it enforces.

Exhibit 16

March 27, 2018

Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted Electronically

Attention: Comments in Response to Department of Health and Human Services, Office for Civil Rights, Conscience NPRM, RIN 0945-ZA03

Dear Secretary Azar,

The National Women's Law Center ("the Center") is writing to comment on the Department of Health and Human Services' ("the Department") and the Office for Civil Rights' ("OCR") proposed rule "Protecting Statutory Rights in Health Care" ("Proposed Rule").[1] Since 1972, the Center has worked to protect and advance the progress of women and their families in core aspects of their lives, including income security, employment, education, and reproductive rights and health, with an emphasis on the needs of low-income women and those who face multiple and intersecting forms of discrimination. To that end, the Center has long worked to end sex discrimination and to ensure all people have equal access to the full range of health care, including abortion and birth control, regardless of income, age, race, sex, sexual orientation, gender identity, ethnicity, geographic location, or type of insurance coverage.

Despite the Department's claims, the Proposed Rule is unnecessary. It is also illegal. The Proposed Rule attempts to create new rights for individuals and entities to refuse to provide patient care by expanding existing, harmful religious exemption laws in ways that exceed and conflict with both the plain language of the statutes and Congressional intent. The Proposed Rule also asserts authority over other federal laws, attempting to create new refusals to provide care. In creating these new rights and expanding its reach, the Proposed Rule conflicts with federal law thereby fostering confusion and chaos.

The Proposed Rule emboldens discrimination. By making it easier for institutions and individuals to refuse to provide comprehensive health care, the Proposed Rule endangers the health and lives of women and lesbian, gay, bisexual, transgender, and queer ("LGBTQ") people across the country. While the Center's comments focus in particular on the harm to women and access to reproductive health care, it is clear that the Proposed Rule will undermine the provision of health care and exacerbate health disparities for many patient populations, as other commentators will discuss. And yet the Department fails to take this harm into account. Contrary

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88) [hereinafter *Rule*].

to the Department's claims, the Proposed Rule harms rather than helps the provider-patient relationship and burdens providers who want to provide comprehensive care.

For all of these reasons, explained in more detail below, the Center is strongly opposed to the Proposed Rule and calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

I. Despite the Department's Claims, the Proposed Rule is Unnecessary, Emboldens Discrimination in Health Care, and Goes Far Beyond the 2008 Rule.

The Department claims that the Proposed Rule is necessary to protect individuals and health care providers from "discrimination, coercion, and intolerance."[2] But there is no need to address the so-called discrimination the Department purports to protect against. There are already ample religious exemptions in federal law, including in Title VII,[3] the Americans with Disabilities Act,[4] and the "ministerial exception" courts have read into the U.S. Constitution.[5] In addition, there are already a number of existing federal religious exemption laws that unfortunately allow individuals and entities to opt of providing critical health care services, in particular abortion and sterilization.[6] The Proposed Rule claims that more authority and enforcement of the religious exemption laws is needed, but the Notice of Proposed Rulemaking cites only forty-four complaints in ten years, which OCR is capable of handling without additional resources or authority.[7] Moreover, OCR already has authority to investigate complaints and, where appropriate, either collect funds wrongfully given while the entity was not in compliance or terminate funding altogether, and already educates providers about their rights under these laws.[8]

The reality is that the Department is seeking not to enforce existing laws but to expand them and create new rights under these laws. As explained below, this is unlawful and creates conflicts with other federal laws. Further, the Proposed Rule does not merely expand rights under existing refusal of care laws. Instead, it pulls in a host of new laws over which OCR has never before had authority, creating new rights and enforcement powers under these laws as well.

In so doing, the Proposed Rule does not address discrimination in health care, it emboldens it. The Proposed Rule intends to change existing law in order to allow any individual or entity involved in a patient's care – from a hospital's board of directors, to an insurance company, to the receptionist that schedules procedures – to use their personal beliefs to determine a patient's access to care. The Proposed Rule would further entrench discrimination against women and

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[2] *Id.* at 3903.
[3] 42 U.S.C. § 2000e-2 (1964).
[4] 42 U.S.C. § 12101 (1990).
[5] *See* Hosanna-Tabor Evangelical Lutheran Church v. Equal Emp't. Opportunity Comm'n, 132 S. Ct. 694, 704 (2012) (holding for the first time that the First Amendment requires a "ministerial exception").
[6] "Weldon Amendment", Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018); "Church Amendments" 42 U.S.C. § 300a-7 (2018); "Coats Amendment" 42 U.S.C. § 238n (2017).
[7] *Rule, supra* note 1, at 3886.
[8] *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 45 C.F.R. pt. 88 (2011).

LGBTQ patients who already face high rates of discrimination in health care, including as a result of providers' religious beliefs. As explained in more detail below, this not only harms individuals and subjects them to discrimination, it is unlawful.

The Department tries to hide how far-reaching and dramatic this Proposed Rule is by claiming it is merely a reinstatement of the rule promulgated by the Bush Administration in 2008 and later rescinded by the Obama Administration in 2011.[9] Even if this was the case, the Proposed Rule would be dangerous. The 2008 rule was the subject of widespread opposition, including from 28 U.S. Senators and 131 Members of the U.S. House of Representatives, 14 state attorneys general, 27 state medical societies, the American Medical Association (AMA), American Hospital Association, National Association of Community Health Centers, American College of Emergency Physicians, and commissioners on the Equal Employment Opportunity Commission.[10] In fact, the AMA and several leading medical organizations argued the 2008 Rule would "seriously undermine patients' access to necessary health services and information, negatively impact federally-funded biomedical research activities, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions."[11] But, the Proposed Rule reaches much further than the 2008 Rule. When compared to the 2008 Rule, the Proposed Rule seeks to allow more individuals and more entities to refuse care to patients and allow more services, or even information, to be refused, forces more entities to allow their employees to refuse care, imposes additional, unnecessary notice and compliance requirements, and invites states to further expand refusal laws.

II. The Proposed Rule Unlawfully Creates and Expands Rights to Refuse to Provide Care.

Under the Proposed Rule the Department intends to extend the reach of already harmful religious exemption laws so that any individual or entity, no matter how attenuated their involvement, can refuse to provide, participate in, or give information about any part of any health care service based on the assertion of a religious or moral belief. Furthermore, the Proposed Rule hamstrings the ability of an enormous range of entities to ensure that patients get the care they need. These expansions represent unlawful overreach by the Department and contradict the plain language of underlying federal law and Congressional intent.

a. The Proposed Rule Expands Existing Harmful Religious Exemption Laws

Although the Proposed Rule purports to merely interpret existing harmful federal laws that allow health care providers to refuse to treat an individual seeking an abortion and/or sterilization –

[9] *Rule, supra* note 1, at 3885. *See also* Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law 73 Fed. Reg. 78,071(Dec. 19, 2009) (2008 Rule) (rescinded in large part by 76 Fed. Reg. 9,968 (Feb. 23, 2011)(codified at 45 C.F.R. pt. 88)).
[10] Comment Letters on Proposed Rule Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law 73 Fed. Reg. 50,274 (Aug. 26, 2008) (on file with National Women's Law Center).
[11] American Medical Assoc. et al. Comment Letter on Proposed Rule 73. Fed. Reg. 50,274 (Aug. 26, 2008)(on file with National Women's Law Center).

namely the so-called Church, Coats, and Weldon Amendments – in fact it creates new rights that are not specifically and currently enumerated in those laws.

It does this in part by redefining words in harmful, expansive ways that belie common understandings of the terms in order to create new rights. For example:

- The Proposed Rule's definition of "assist in the performance" greatly expands not only the types of services that can be refused, but also the individuals who can refuse. It includes those merely making "arrangements for the procedure" no matter how tangential and could be read to include individuals such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees. In fact, the definition includes participation "in any program or activity with an *articulable connection* to a procedure…" (emphasis added).[12] While what is meant by "articulable connection" is not clear, the use of the term in case law indicates an intention for it to be interpreted broadly – a mere connection that one can articulate may suffice.[13]
- Through a broad definition of "entity" the Proposed Rule attempts to expand the individuals and types of entities covered by religious exemption laws and allow an even broader swath of individuals within those entities to refuse to do their jobs.[14] For example, under the Proposed Rule a Department grantee that provides health care transportation services for individuals with disabilities could attempt to claim a right to refuse to provide that service to a person who needs a sterilization procedure. Or an employee at a research and development laboratory could claim the right to refuse to accept the delivery of biomedical waste donated from a hospital with an obstetrics and gynecology practice that performs abortions.
- The Proposed Rule's definition of "referral" goes beyond any common understanding of the term, allowing refusals to provide any information that could help an individual to get the care they need. [15] The Proposed Rule does not even require that patients be informed of the individual's or entity's refusal to provide care, information, referrals, or other services, leaving patients unaware that their health care providers is not providing the care or information they need.
- The Proposed Rule's definition of "workforce" attempts to expand refusals of care to an even broader range of people and would allow almost all staff levels within an entity, including volunteers or trainees, to assert a new right to refuse to do their job.[16] For example, a volunteer at a hospital could claim a right to refuse to deliver medicine to a patient's room or even deliver meals to a patient who is recovering from a surgery to which the volunteer objects.

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[12] *Rule, supra* note 1, at 3923.
[13] *Cf.* Jamerson v. Runnels, 713 F.3d 1218, 1229 (9th Cir. 2013) (describing the standard for evaluating whether a peremptory challenge was impermissibly based on race as "require[ing] only that the prosecutor express a believable and *articulable connection* between the race-neutral characteristic identified and the desirability of a prospective juror…"(emphasis added)).
[14] *Rule, supra* note 1, at 3924.
[15] *Id.*
[16] *Id.*

b. These New Rights are Contrary to Existing Law and Congressional Intent

The expansions and new and unwarranted definitions exceed and conflict with the existing federal laws the Proposed Rule seeks to enforce. For example, the Proposed Rule expands the definition of "health care entity" under existing law to include plan sponsors and third-party administrators.[17] Adding plan sponsors to the definition of "health care entity" under the Weldon Amendment is a blatant attempt to add words that plainly do not exist in the underlying federal law.[18] Indeed, just two years ago, OCR determined that the Weldon Amendment – according to its plain text – does not apply to plan sponsors.[19] This also holds true for the other ways in which the Proposed Rule attempts to expand the definition of "health care entity." Under the Coats and Weldon Amendments, "health care entity" is defined to encompass a limited and specific range of individuals and entities.[20] The Proposed Rule attempts to create a new definition of this term by combining statutory definitions of "health care entity" found in different statutes and applicable in different circumstances. Such an attempt to expand the meaning of a statutory term Congress already took the time to define goes directly against Congressional intent.[21]

The legislative history of the existing federal refusal of care laws reinforces that the Proposed Rule violates Congressional intent. For example, Congress adopted the Coats Amendment in response to a decision by the accrediting body for graduate medical education to rightfully require obstetrics and gynecology residency programs to provide abortion training. The legislative history of Coats states, "[p]roviders will continue to train the management of complications of induced abortion as well as train to handle [a] situation involving miscarriage and still birth or a threat to the life of the mother. The amendment requires no change in the practice of good obstetrics and gynecology."[22] The attempted expansion under the Proposed Rule to allow anyone to refuse to provide abortion regardless of the circumstances was clearly not intended. Similarly, proponents of the Weldon Amendment made "modest" claims about the Amendment, suggesting that the additional language was necessary only to clarify existing "conscience protections" not for it to be the sweeping license to refuse the Proposed Rule attempts to create.[23]

The Proposed Rule's expanded use of sections (c)(2) and (d) of the Church Amendments also violates Congressional Intent. These two sections were passed under Title II of the National Research Services Act in 1974, which specifically dealt with biomedical and behavioral research.[24] This Act was designed to ensure that research projects involving human subjects are

[17] *Id.*
[18] *See* Weldon Amendment, *supra* note 6.
[19] *See* Letter from Jocelyn Samuels, Director of Office for Civil Rights, to Catherine W. Short, Esq. et al. (June 21, 2016), *available at* http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf.
[20] Weldon Amendment, *supra* note 6; Coats Amendment, *supra* note 6.
[21] The doctrine of *expressio unius est exclusion alterius* (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[22] 141CONG. REC. S17293 (June 27, 1995) (statement of Rep. Coats).
[23] 150 CONG. REC. H10090 (Nov. 20, 2004) (statement of Rep. Weldon).
[24] National Research Services Act of 1974, Pub. L. No, 93-348, 88 Stat. 348 § 214.

performed in an ethical manner.[25] Congress did not intend, as the Proposed Rule implies, to allow health care personnel to refuse to participate in any health care service. Such an expansion of the meaning of the Church Amendment was clearly not intended by Congress in the passage of the statute and would turn Congress' intent to protect patients on its head.

In other words, in greatly expanding the existing federal refusal laws relating to treating an individual seeking abortion or sterilization or refusing in the biomedical or behavioral research context, the Proposed Rule exceeds the scope of federal law and conflicts with congressional intent. It is therefore unlawful.

c. The Proposed Rule Overreaches Into Other Federal Laws, Undermining Congressional Intent

However, the Department does not limit its overreach to the aforementioned laws. Instead, under the Proposed Rule, the Department has unlawfully asserted authority over a greater number of federal statutes in an attempt to create new refusal provisions and to give the Department authority it previously did not have. For example, the Proposed Rule would prohibit a State agency that administers a Medicaid managed care program from requiring an organization "to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects."[26] However, the underlying Medicaid statute merely provides a rule of statutory construction which states that nothing in the statute should be construed to require a state agency that administers a Medicaid managed care program to use its funds for such purposes.[27] By misrepresenting the limited scope of this provision in order to create a new refusal provision, the Proposed Rule directly contradicts Congressional intent.

By attempting to create new refusal provisions, the Department also seeks to give OCR unlawful enforcement authority over these provisions. For many of these, Congress already established an enforcement scheme in the statute at issue. The Department should be reminded that "regardless of how serious the problem an administrative agency seeks to address … it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'"[28] Not only is it unlawful for the Department to alter the enforcement mechanisms contemplated by the statute, in many cases it would be nonsensical. For example, the Proposed Rule is attempting to re-delegate oversight of youth suicide early intervention and prevention strategies to OCR, despite the specific existing authority held by the Center for Substance Abuse Treatment.[29] Congress specifically created a "Center for Substance Abuse Treatment," the director of which is already charged with administering block grants and ensuring compliance with applicable law for development of youth suicide early intervention and prevention strategies.[30] The Department's attempt to alter this statutory scheme by attempting to give OCR

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[25] *See, e.g.*, Todd W. Rice, *The Historical, Ethical, and Legal Background of Human-Subjects Research*, 53 RESPIRATORY CARE 2325 (2008), http://rc.rcjournal.com/content/respcare/53/10/1325.full.pdf.
[26] *Rule, supra* note 1, at 3926.
[27] *See* 42 U.S.C. § 1395w-22 (2010).
[28] *See* Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125-26 (2000).
[29] *See Rule, supra* note 1, at 3927.
[30] *See* Center for Substance Abuse Treatment, 42 U.S.C. § 290bb (2016); Youth Suicide Early Intervention and Prevention Strategies, 42 U.S.C. § 290bb-36 (2004).

authority to enforce certain provisions of the block grant is unlawful. Moreover, this change is nonsensical, given that the provision of statutory construction found within the statute outlining the program's requirement was never intended to be used to create a right to refuse.[31]

III. The Proposed Rule Conflicts with Federal Laws.

The Proposed Rule generates conflict and confusion, creating chaos with existing federal laws. It appropriates language from landmark civil rights laws while entirely failing to even mention important laws that protect patients from discrimination and unreasonable barriers to health care access, that already govern employment discrimination based on religious belief, and that ensure patients get the care they need, particularly in emergency situations. By unilaterally attempting to broaden existing refusal of care laws, the Department jettisons the careful balance present in existing federal law. The Department attempts to upset this existing federal balance without legitimate statutory authority or even a reasoned explanation.

a. The Proposed Rule Would Subvert Civil Rights Statutes by Attempting to Appropriate their Language

The Department has exceeded its authority by appropriating language from civil rights statutes and regulations that were intended to improve access to health care and applying that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only unlawful, but is nonsensical and affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce. They will place a significant and burdensome requirement on health care providers, taking resources away from patient care without adding any benefit.

Moreover, the Proposed Rule defines "discrimination" for the first time[32] and does so in a way that subverts the language of landmark civil rights statutes to shield those who would discriminate rather than to protect against discrimination. In this context, this broad definition is inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements thereby fostering confusion.

b. The Proposed Rule Conflicts with Sections 1554 and 1557 of the Affordable Care Act

The Proposed Rule conflicts with two provisions of the Affordable Care Act.

Section 1554 of the Affordable Care Act prohibits the Secretary of Health and Human Services from promulgating any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care."[33] As discussed in more detail below, religious refusals have been used to discriminate and deny patients the care they need based on the assertion of a religious or personal belief. By expanding the reach of refusals and permitting

[31] *See* 42 U.S.C. § 290bb-36 (2004).
[32] *Id.* at 3923-924.
[33] 42 U.S.C. § 18114(1) (2010).

objecting individuals and health care entities to deny patients needed health care services, the Proposed Rule erects unreasonable barriers to medical care and impedes access to health care services such as abortion and sterilization.[34]

Section 1557 of the Affordable Care Act prohibits discrimination in health care programs or activities on the basis of race, color, national origin, sex, age, or disability.[35] Prior to Section 1557, no broad federal protections against sex discrimination in health care existed. The ACA was intended to remedy this, as evidenced not only by the robust protection provided by Section 1557 itself, but also by the ACA's particular focus on addressing the obstacles women faced in obtaining health insurance and accessing health care.[36] As discussed in more detail below, by emboldening refusals for services that women and LGBTQ patients disproportionately or exclusively need, the Proposed Rule entrenches sex discrimination in health care and undermines the express purpose of Section 1557.

c. The Proposed Rule Conflicts with Title VII

The Proposed Rule makes no mention of Title VII, the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[37] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested unless the accommodation would impose an "undue hardship" on an employer.[38] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal

[34] The Proposed Rule therefore also violates § 706(2) of the APA, which instructs a reviewing court under arbitrary and capricious standard of review to consider and hold unlawful agency action found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.
[35] 42 U.S.C. § 18116 (2010).
[36] *See* 42 U.S.C. § 300gg(a) (2015) (allowing rating based only on family size, tobacco use, geographic area, and age, but not sex); 45 C.F.R. § 147.104(e) (2015) (prohibiting discrimination in marketing and benefit design, including on the basis of sex); *see also, e.g.*, 156 CONG. REC. H1632-04 (daily ed. March 18, 2010) (statement of Rep. Lee) ("While health care reform is essential for everyone, women are in particularly dire need for major changes to our health care system. Too many women are locked out of the health care system because they face discriminatory insurance practices and cannot afford the necessary care for themselves and for their children."); 156 CONG. REC. H1891-01 (daily ed. March 21, 2010) (statement of Rep. Pelosi) ("It's personal for women. After we pass this bill, being a woman will no longer be a preexisting medical condition."); 155 CONG. REC. S12026 (daily ed. Oct. 8, 2009) (statements of Sen. Mikulski) ("[H]ealth care is a women's issue, health care reform is a must-do women's issue, and health insurance reform is a must-change women's issue because . . . when it comes to health insurance, we women pay more and get less."); 155 CONG. REC. S10262-01 (daily ed. Oct. 8, 2009) (statement of Sen. Boxer) ("Women have even more at stake. Why? Because they are discriminated against by insurance companies, and that must stop, and it will stop when we pass insurance reform."); 156 CONG. REC. H1854-02 (daily ed. March 21, 2010) (statement of Rep. Maloney) ("Finally, these reforms will do more for women's health . . . than any other legislation in my career.").
[37] *See* 42 U.S.C. § 2000e-2 (1964); Title VII of the Civil Rights Act of 1964, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.
[38] *Id.*

obligations.[39] The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both the Proposed Rule and Title VII. Indeed, when similar regulations were proposed in 2008, EEOC commissioners and the Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[40]

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician who refuses to provide non-directive options counseling to women with positive pregnancy tests even though it is an essential job function. The employer would not be required to do so under Title VII. It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

d. The Proposed Rule Conflicts with Federal Law on Treatment of Patients Facing Emergency Situations

The Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists and to stabilize the condition or, if medically warranted, to transfer the person to another facility.[41]

Because the Proposed Rule does not contain an explicit exception for situations in which an abortion – or other health service the Proposed Rule may empower individuals or entities to refuse – is needed to protect the health or life of a patient, the Proposed Rule is confusing to institutions regarding their obligations under the Proposed Rule as they relate to EMTALA. Every hospital is required to comply with EMTALA; even a religiously-affiliated hospital with an institutional objection to abortion must provide the care required in emergency situations.[42]

e. The Proposed Rule Violates the Establishment Clause

[39] *Id.*
[40] Equal Emp't. Opportunity Comm'n. Legal Counsel Comment Letter on Proposed Rule 73 Fed. Reg. 50,274 (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html; Equal Emp't Opportunity Commissioners Christine Griffiin, Stuart Ishimaru Comment Letter on Proposed Rule 73 Fed. Reg. 50,274 (on file with National Women's Law Center).
[41] *See* 42 U.S.C. § 1395dd(a)-(c) (2003).
[42] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, Shelton v. University of Medicine and Dentistry of New Jersey, 223 F.3d 220, 228 (3rd Cir. 2000); *In re* Baby K, 16 F.3d 590, 597 (4th Cir. 1994); Nonsen v. Medical Staffing Network, Inc. 2006 WL 1529664 (W.D. Wis.); Grant v. Fairview Hosp. & Healthcare Servs., No. Civ. 02–4232JNEJGL, 2004 WL 326694, at *2 (D. Minn. 2006); Brownfield v. Daniel Freeman Marina Hosp., 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); Barris v. County of Los Angeles, 972 P.2d 966, 972 (Cal. 1999).

The Proposed Rule unlawfully establishes and adopts one subset of religious views while denying health care to those with differing views. In fact, staff within the Department have indicated that the Department intends to support evangelical beliefs over others.[43] These statements are consistent with the Department's actions.[44] The Department cannot promulgate proposed rules in reliance on unconstitutional preferences such as religious beliefs. Such actions are unlawful and out of line with the Department's historical mission.[45]

IV. The Proposed Rule Will Harm Patients, and the Department Has Failed to Take This Into Account.

The Proposed Rule is contrary to the Department's stated mission: "to enhance and protect the health and well-being of all Americans." In order to achieve that mission, one of the Department's primary goals is to "eliminate[ ] disparities in health, as well as [to increase] health care access and quality."[46] In its singular focus on what the Department claims is discrimination on the basis of religious or moral beliefs, it abdicates its mission. The Department ignores the pervasive discrimination in health programs and activities that individuals face, particularly those who seek reproductive health care, or because of their sex, gender identity, or sexual orientation. The Department unlawfully ignores how this discrimination is compounded by refusals of care based on personal beliefs and how the Proposed Rule will amplify that harm.

a. Certain Groups of Patients Routinely Face Discrimination in Health Care

Women have long been the subject of discrimination in health care.[47] Despite the historic achievements of the Affordable Care Act, women are still more likely to forego care because of cost,[48] and women – particularly Black women – are far more likely to be harassed by a

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[43] Dan Diamond, *The Religious Activists on the Rise Inside Trump's Health Department*, POLITICO (Jan. 22, 2018), https://www.politico.com/story/2018/01/22/trump-religious-activists-hhs-351735.

[44] *See, e.g.*, Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding, 82 Fed. Reg. 49,300 (proposed Oct. 25, 2017); Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47, 792 (proposed Oct. 13, 2017).

[45] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[46] *See HHS Action Plan to Reduce Racial and Ethnic Health Disparities,* DEP'T OF HEALTH AND HUMAN SERVS., at 7, https://minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS_Plan_complete.pdf.

[47] Prior to the Affordable Care Act (ACA), women were charged more for health care on the basis of sex and were continually denied health insurance coverage for services that only ciswomen, transgender, and gender non-conforming patients need. *See Turning to Fairness*, NAT'L WOMEN'S L. CTR. 1, 3-4 (2012), https://nwlc.org/wp-content/uploads/2015/08/nwlc_2012_turningtofairness_report.pdf (noting that while the ACA changed the health care landscape for women in significant ways, women still face additional hurdles).

[48] *See* Shartzer, et al., *Health Reform Monitoring Survey*, URBAN INST. HEALTH POLICY CTR. (Jan. 2015), http://hrms.urban.org/briefs/Health-Care-Costs-Are-a-Barrier-to-Care-for-Many-Women.html.

provider.[49] These barriers mean women are more likely not to receive routine and preventive care than men. Moreover, when women are able to see a provider, women's pain is routinely undertreated and often dismissed.[50] And due to gender biases and disparities in research, doctors offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[51]

LGBTQ individuals encounter high rates of discrimination in health care. According to one survey, eight percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and seven percent experienced unwanted physical contact and violence from a health care provider.[52] Twenty-nine percent of transgender individuals were refused to be seen by a health care provider on the basis of their perceived or actual gender identity in the previous year.[53] Additionally, the 2015 U.S. Transgender Survey found that 23 percent of respondents did not see a provider for needed health care in the previous year because of fears of mistreatment or discrimination.[54]

And these barriers disproportionately impact those facing multiple and intersecting forms of discrimination, including women of color, LGBTQ persons of color, and individuals living with disabilities and those struggling to make ends meet. In one report, Black women disclosed that their doctors failed to inform them of the full range of reproductive health options regarding labor or delivery possibly due to stereotypes about Black women's sexuality.[55] Even though women living with disabilities report engaging in sexual activities at the same rate as women who do not live with disabilities, they often do not receive the reproductive health care they need for multiple reasons, including lack of accessible provider offices and misconceptions about their reproductive health needs.[56] These barriers also are often made worse by the complex web of

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[49] *See Discrimination in America: Experiences and Views of American Women*. NPR & HARVARD T.H. CHAN SCH. OF PUB. HEALTH (Dec. 2017), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/21/2017/12/NPR-RWJF-HSPH-Discrimination-Women-Final-Report.pdf.
[50] *See, e.g.,* Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).
[51] *See, e.g.,* Judith H. Lichtman et al., Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction, 10 J. OF THE AM. HEART ASS'N 1 (2015).
[52] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.
[53] *Id.*
[54] *The Report of the 2015 U.S. Transgender Survey*, NAT'L CTR. FOR TRANSGENDER EQUALITY 5 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.
[55] *See The State of Black Women & Reproductive Justice*, IN OUR OWN VOICE (2017), http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.
[56] RM Haynes et al., *Contraceptive Use at Last Intercourse Among Reproductive-Aged Women with Disabilities: An Analysis of Population-Based Data from Seven States*, CONTRACEPTION (2017), https://www.ncbi.nlm.nih.gov/pubmed/29253580; *see generally* Alex Zielinski, *Why Reproductive Health Can Be A Special Struggle for Women with Disabilities*, THINK PROGRESS, Oct. 1, 2015, https://thinkprogress.org/why-reproductive-health-can-be-a-special-struggle-for-women-with-disabilities-73ececea23c4/.

federal and state laws and policies that restrict access to care, particularly around certain health services like abortion.

b. Refusals of Care Based on Personal Beliefs Compound the Harm to Patients

This discrimination in health care against women, LGBTQ persons, and those facing multiple and intersecting forms of discrimination is exacerbated by providers invoking personal beliefs to deny access to health insurance and an increasingly broad range of health care services, including birth control, sterilization, certain infertility treatments, abortion, transition-related care, and end of life care.[57] For example, one woman experiencing pregnancy complications was rushed to the only hospital in her community, a religiously-affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[58] A transgender man was denied gender affirming surgery at a religiously-affiliated hospital that refused to provide him a hysterectomy.[59] A woman called an ambulance after experiencing abdominal pain, but the ambulance driver refused to take her to get the care she needed.[60]

When refusals of care happen, many patients are forced to delay or forego necessary care, which can pose a threat not only to their health, but their lives. This is particularly true for patients with limited resources and options. For many patients, such refusals do not merely represent an inconvenience but can result in necessary or even emergent care being delayed or denied outright. These refusals are particularly dangerous in situations where individuals have limited options, such as in emergencies, when needing specialized services, in rural areas, or in areas where religiously-affiliated hospitals are the primary or sole hospital serving a community. The reach of these types of refusals to provide care continues to grow with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously-affiliated entities that provide health care and related services.[61]

c. The Proposed Rule Will Further Harm Patients, Yet the Department Unlawfully Ignores that Harm

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[57] Directive 24 denies respect for advance medical directives. U.S. CONFERENCE OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES (5th ed. 2009), http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf. Moreover, religiously-affiliated individuals have challenged key provisions of the federal law and implementing regulations that prohibit discrimination on the basis of sex, gender identity, or sexual orientation in health care. *Health Care Refusals Harm Patients: The Threat to Reproductive Health Care*, NAT'L WOMEN'S LAW CTR. (May 2014), http://www.nwlc.org/sites/default/files/pdfs/refusals_harm_patients_repro_factsheet_5-30-14.pdf.; *see also Health Care Denied*, AM. CIVIL LIBERTIES UNION (May 2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[58] *See* Kira Shepherd, et al., *Bearing Faith: The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[59] *See id.* at 29.

[60] *Put Patient Health First,* NAT'L WOMEN'S LAW CENTER 1 (August 2017), https://nwlc.org/resources/continued-efforts-to-undermine-womens-access-to-health-care/.

[61] *See, e.g., Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

By stretching refusals of care far beyond their current reach, the Proposed Rule leaves patients seeking reproductive or sexual health care services facing even greater threats to their health, life, and future fertility than they did before. In addition, the expansion of refusals of care under the Proposed Rule has far reaching implications for those providing or seeking services and information in a wide range of areas including HIV, drug addiction, infertility, vaccinations, psychology, sexually transmitted infections and end-of-life care, among others. This means that the Proposed Rule will compound harm to patients in multiple new ways, imposing additional hurdles patients must overcome to get the care they need. For example, young people in federal custody, including foster youth and unaccompanied immigrant children, already face enormous hurdles to accessing health care. Yet, the Proposed Rule seeks to allow foster parents, social service agencies, and shelters that provide services to young people to refuse even minor assistance to a young person in their care who needs health services, including STI testing or treatment and abortion care.

The reach of the Proposed Rule will create a vicious cycle where those already subject to multiple forms of discrimination in the health care system may be the most likely to find themselves seeking care from a health care professional who refuses to provide it. For example, in many states women of color are more likely than white women to give birth at a Catholic hospital.[62] By expanding refusals of care, the Proposed Rule will exacerbate the barriers to health care services patients need.

Yet despite the overwhelming evidence of discrimination against patients seeking health care services and the harm of refusals of care that are based on personal beliefs, the Department issued this Proposed Rule. The Department fails entirely to consider the impact of the Proposed Rule on patients, particularly individuals seeking reproductive health care, patients of color, and LGBTQ individuals. At no point does the Proposed Rule acknowledge the many ways it will harm patients. This consideration is required by law and by the U.S. Constitution, and the Department's failure to account for these requirements renders the Proposed Rule invalid and unlawful.

III. The Proposed Rule Erodes the Core Tenants of the Medical System.

The Proposed Rule undermines the trust in the provider-patient relationship and unduly burdens those health care providers who want to fulfill their obligations to provide patients with the care they need.

a. The Proposed Rule Undermines the Provider-Patient Relationship

A strong provider-patient relationship is the foundation of our medical system. Patients rely on their providers to give full information about their treatment options and to provide medical advice and treatment in line with the standards of care established by the medical community. Yet, the Proposed Rule allows providers to do the opposite, threatening informed consent,

[62] *See* Kira Shepherd, et al., *Bearing Faith: The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

undermining standards of care, and eroding patient trust in their providers and ultimately the medical system.

Informed consent is intended to help address the knowledge and power imbalance between providers and their patients, so patients can make their own competent and meaningful decisions about their treatment options.[63] The Proposed Rule acknowledges the importance of open, honest conversations in health care, stating "open communication in the doctor-patient relationship will foster better over-all care for patients."[64] Yet, it would allow providers, including hospitals and health care institutions, to ignore the patient's right to receive information and refuse to disclose relevant and medically accurate information about treatment options and alternatives. To make matters worse, the Proposed Rule includes provisions that specifically remove statutory requirements that health care entities at least notify patients they may be refused health care services or information. For example, it omits requirements enumerated in the counseling and referral provisions of the Medicaid managed care statute. These provisions require organizations that decline to cover certain treatments to notify enrollees of the policy.[65] The Department's attempts to affirmatively remove notice requirements underscore how little it cares about patients receiving full information. Allowing refusals to provide information and then barring patients from receiving any notice that they may not be given full information makes open communication impossible.

In addition to receiving non-biased information from their providers, patients also expect to receive treatment in line with medical practice guidelines and standards of care. Yet, the Proposed Rule seeks to allow providers, including hospitals and other health care institutions, to ignore the standards of care, particularly surrounding reproductive and sexual health. This completely undermines the provider-patient relationship and will create uncertainty and doubt where there should be trust and respect.

b. The Proposed Rule Burdens Providers that Want to Uphold the Hippocratic Oath and Provide Comprehensive Care

As the American Medical Association Code of Medical Ethics states, "the relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest."[66] Yet, the Proposed Rule flips this principle on its head – attempting to expand the ability of institutions to use personal beliefs to dictate patient care. In doing so, the Department allows institutions to block providers that want to provide patients with necessary or comprehensive care.

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[63] As the AMA Code of Ethics makes clear, "Informed Consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care." *Informed Consent*, AMERICAN MED. ASSOC., https://www.ama-assn.org/delivering-care/informed-consent (last visited Mar. 23, 2018).
[64] *Rule, supra* note 1, at 3917.
[65] The requirements of 42 U.S.C. § 1396u-2(b)(3)(B)(ii) excluded from the Proposed Rule's requirements surrounding Medicaid managed care organization. *See Rule, supra* note 1, at 3926.
[66] *Code of Medical Ethics: Patient-Physician Relationships*, AMERICAN MED. ASSOC., https://www.ama-assn.org/delivering-care/code-medical-ethics-patient-physician-relationships (last visited Mar. 23, 2018).

Most providers believe they should and must treat patients according to medical standards regardless of their personal beliefs. Moreover, many providers have deeply held moral convictions that affirmatively motivate them to provide patients with certain services, including abortion, transition-related care, and end-of-life care. Existing refusal of care laws already burden these providers. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, or moral convictions of these providers. The Proposed Rule would exacerbate these problems by expanding the number and types of institutions that can bind the hands of providers and limit the types of care, or even information, they can provide.

The Proposed Rule egregiously misuses research to falsely claim that a majority of obstetrician-gynecologists are unwilling to provide abortion.[67] In fact, the survey underlying the cited study found that over 80% of obstetrician-gynecologists are willing to help a patient obtain an abortion in the vast majority of cases. The survey also found that even where providers had a moral objection to providing abortion in a particular situation, a majority would still help the patient obtain an abortion.[68] Hospitals already discriminate against health care providers by preventing them from providing certain health care services, particularly abortion, even in life-threatening situations.[69] In fact, researchers have found that over a third of obstetrician-gynecologists experience conflict with their employers over religiously based patient care policies, with a majority of obstetrician-gynecologists at Catholic institutions reporting such conflicts.[70]

The Proposed Rule's expansion of entities that can constrain their employees not only ignores the barriers facing health care professionals who are committed to providing patients with comprehensive care regardless of personal beliefs, but it also ignores the Department's duty to enforce federal law that protects those who support abortion or sterilization. The Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services. No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion. But instead of acting to protect health care providers who put patients first, the Proposed Rule allows more institutions to interfere and prevent employees from providing care.

IV. The Proposed Rule Burdens States that Want to Protect Patient Access to Care.

As the Department recognized in the preamble of the Proposed Rule, forty-seven states have laws that allow health care providers and/or institutions to refuse health care to individuals based on personal beliefs.[71] These harmful existing state laws have already undoubtedly resulted in the

[67] *Rule, supra* note 1, at 3916.
[68] Lisa Harris et al., *Obstetrician-Gynecologists' Objections to and Willingness to Help Patients Obtain an Abortion*, 118 OBSTETRICS & GYNECOLOGY 905 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4185126/.
[69] *Discrimination Against Health Care Professionals Who Provide or Support Abortion* NAT'L WOMEN'S LAW CENTER (August 2017), https://nwlc.org/resources/discrimination-against-health-care-professionals-who-provide-or-support-abortion/.
[70] Stulberg et al., *Obstetrician-Gynecologists, Religious Institutions, and Conflicts Regarding Patient Care Policies*, 73 AM. J. OF OBSTETRICS AND GYNECOLOGY e1 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3383370/
[71] *Rule, supra* note 1, at 3931; *see also Refusing to Provide Health Services*, GUTTMACHER INSTITUTE (Feb. 2018), https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.

denial of health care, and in particular have endangered women's health. Now, the Proposed Rule is inviting states to enact even more sweeping laws.[72] The Proposed Rule encourages states to pass laws that go even further than the Proposed Rule does in allowing for refusals of health care. While it is clear that federal laws generally provide a minimum level of protection and allow states to enact more substantial protections, those protections are usually for the purpose of protecting individuals from discrimination and/or ensuring access to important services or benefits. As discussed above, the Proposed Rule subverts this entirely, entrenching discrimination and taking away access to health care services and benefits.

The Proposed Rule also creates a chilling effect on the enforcement of and passage of state laws that protect patient access to health care. The Department argues that the Proposed Rule is needed in order to clarify how federal religious exemption laws interact with state and local laws. To illustrate this purported need, the preamble cites several state laws intended to protect access to care. These include laws that require anti-abortion counseling centers to provide information about the full range of reproductive health care options and inform patients if the facility employs medical providers as well as state laws that ensure that individuals have comprehensive health insurance that includes abortion coverage. The discussion implies these and other laws that protect patient access to care conflict with the Proposed Rule, particularly when read in conjunction with several of the leading questions regarding state law posed in the preamble. This puts states in the untenable position of choosing between passing laws that protect their people and potentially losing millions of dollars in critical federal funding, likely resulting in a chilling effect on states attempting to pass or enforce laws intended to protect patients.

Conclusion

The Proposed Rule is illegal and harmful. It attempts to allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores Congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, the Center unequivocally calls on the Department to withdraw the Proposed Rule.

Sincerely,

Fatima Goss Graves
President and CEO, National Women's Law Center

[72] *See e.g., Rule, supra* note 1, at 3888-89.

Exhibit 17

Elizabeth G. Taylor
Executive Director

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Ronald L. Wisor, Jr.
Hogan Lovells

Senior Advisor to the Board
Rep. Henry A. Waxman
Waxman Strategies

General Counsel
Marc Fleischaker
Arent Fox, LLP

March 27, 2018

Via Electronic Submission

The Honorable Alex M. Azar II
Secretary, U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 209F
200 Independence Avenue SW
Washington, DC 20201

Re: RIN 0945-ZA03–Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar,

On behalf of National Health Law Program, we submit these comments to the federal Department of Health and Human Services ("Department") and its Office for Civil Rights ("OCR") in opposition to the proposed regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority."

The regulations as proposed would introduce broad and poorly defined language to the existing law that already provides ample protection for the ability of health care providers to refuse to participate in a health care service to which they have moral or religious objections. While the proposed regulations purport to provide clarity and guidance in implementing existing federal religious exemptions, in reality they are vague and confusing. The proposed rule creates the potential for exposing patients to medical care that fails to comply with established medical practice guidelines, negating long-standing principles of informed consent, and undermines the ability of health facilities to provide care in an orderly and efficient manner.

Most important, the regulations fail to account for the significant burden that will be imposed on patients, a burden that will fall disproportionately and most harshly on women, people of color, people living with disabilities, and Lesbian, Gay, Bisexual, Transgender, and Queer ("LGBTQ") individuals. These

communities already experience severe health disparities and discrimination, conditions that will be exacerbated by the proposed rule, possibly ending in in poorer health outcomes. By issuing the proposed rule along with the newly created "Conscience and Religious Freedom Division," the Department seeks to use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons, the National Health Law Program calls on the Department and OCR to withdraw the proposed rule in its entirety.

I. Under the guise of civil rights, the proposed rule seeks to deny medically necessary care

Civil rights laws and Constitutional guarantees, such as due process and equal protection, are designed to ensure full participation in civil society. The proposed rule, while cloaked in the language of non-discrimination, is designed to deny care and exclude disadvantaged and vulnerable populations. The adverse consequences of health care refusals and other forms of discrimination are well documented. As the Department stated in its proposed rulemaking for § 1557 of the Affordable Care Act ("ACA"),

> "[e]qual access for all individuals without discrimination is essential to achieving" the ACA's aim to expand access to health care and health coverage for all, as "discrimination in the health care context can often…exacerbate existing health disparities in underserved communities."[1]

The Department and OCR have an important role to play in ensuring equal health opportunity and ending discriminatory practices that contribute to health disparities. Yet, this proposed rule represents a dramatic, harmful, and unwarranted departure from OCR's historic and key mission. The proposed rule appropriates language from civil rights statutes and regulations that were designed to improve access to health care and applies that language to deny medically necessary care.

The federal government argues that robust religious refusals, as implemented by this proposed rule, will facilitate open and honest conversations between patients and physicians.[2] As an outcome of this rule, the government believes that patients, particularly those who are "minorities", including those who identify as people of faith, will face fewer obstacles in accessing care.[3] The proposed rule will not achieve these outcomes. Instead, the proposed rule will increase barriers to care, harm patients by allowing health care professionals to ignore established medical guidelines, and undermine open communication between providers and patients. The harm caused by this proposed rule will fall hardest on those most in need of care.

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[1] Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).
[2] U.S. Dep't. of Health & Human Serv., Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3917 (Jan. 26, 2018) (hereinafter "proposed rule").
[3] *Id.*

II. The expansion of religious refusals under the proposed rule will disproportionately harm communities who already lack access to care

Women, individuals living with disabilities, LGBTQ persons, people living in rural communities, and people of color face severe health and health care disparities, and these disparities are compounded for individuals who hold these multiple identities. For example, among adult women, 15.2 percent of those who identified as lesbian or gay reported being unable to obtain medical care in the last year due to cost, as compared to 9.6 percent of straight individuals.[4] Women of color experience health care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.[5] Meanwhile, people of color in rural America are more likely to live in an area with a shortage of health professionals, with 83 percent of majority-Black counties and 81 percent of majority-Latino/a counties designated by the federal Health Resources and Services Administration (HRSA) as Health Professional Shortage Areas (HPSAs).

The expansion of refusals as proposed under this rule will exacerbate these disparities and undermine the ability of these individuals to access comprehensive and unbiased health care, including sexual and reproductive health information and services. Any efforts by providers or other health care personnel to limit the information and access that patients are entitled to receive, even when the organization may not provide those services itself, is incompatible with true consumer choice and individual decision making.

a. The proposed rule will block access to care for low-income women, including immigrant women and African American women

Broadly-defined and widely-implemented refusal clauses undermine access to basic health services for all, but can particularly harm low-income women. The burdens on low-income women can be insurmountable when women and families are uninsured,[6] underinsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services nor travel to another location. This is especially true for immigrant women. In comparison to their U.S. born peers, immigrant women are more likely to be uninsured.[7] Notably, immigrant, Latina women have far higher rates of uninsurance than Latina women born in the United States (48 percent versus 21 percent, respectively).[8]

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[4] Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT'L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.
[5] In 2014, Latinas had the highest rates of contracting cervical cancer and Black women had the highest death rates. *Cervical Cancer Rates By Rates and Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm.; At the end of 2014, of the total number of women diagnosed with HIV, 60 percent were Black. *HIV Among Women,* CTRS. FOR DISEASE CONTROL & PREVENTION, Nov. 17, 2017, https://www.cdc.gov/hiv/group/gender/women/index.html.
[6] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. KAISER FAMILY FOUND., *Women's Health Insurance Coverage* 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.
[7] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf.
[8] *Id.* at 8, 16.

According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery possibly due to stereotypes about Black women's sexuality and reproduction.[9] Young Black women noted that they were shamed by providers when seeking sexual health information and contraceptive care in part, due to their age, and in some instances, sexual orientation.[10]

New research also shows that women of color in many states disproportionately receive their care at Catholic hospitals, subjecting them to treatment that does not comply with the standards of care.[11] In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[12] In New Jersey, for example, women of color make up 50 percent of women of reproductive age in the state, yet have twice the number of births at Catholic hospitals compared to their white counterparts.[13] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on wide range of hospital matters, including reproductive health care. In practice, the ERDs prohibit the provision of emergency contraception, sterilization, abortion, fertility services, and some treatments for ectopic pregnancies. Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals and as a result, women were delayed care or transferred to other facilities, risking their health.[14] The proposed rule will give health care providers a license, such as Catholic hospitals, to opt out of evidence-based care that the medical community endorses. If this rule were to be implemented, more women, particularly women of color, will be put in situations where they will have to decide between receiving compromised care or seeking another provider to receive quality, comprehensive reproductive health services. For many, this choice does not exist.

b. The proposed rule will negatively impact rural communities

The ability to refuse care to patients will leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state,[15] with

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[9] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at* https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[10] *Reproductive Injustice*, *supra* note 9, at 16-17.

[11] Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT (2018), *available at* https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[12] *Id* at 12.

[13] *Id* at 9.

[14] Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

[15] Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA, (last visited Mar. 21, 2018).

over 75 percent of chief executive officers of rural hospitals reporting physician shortages.[16] Many rural communities experience a wide array of mental health, dental health, and primary care health professional shortages, leaving individuals in rural communities with less access to care that is close, affordable, and high quality, than their urban counterparts.[17] Among the many geographic and spatial barriers that exist, individuals in rural areas often must have a driver's license and own a private car to access care, as they must travel further distances for regular checkups, often on poorer quality roads, and have less access to reliable public transportation.[18] This scarcity of accessible services leaves survivors of intimate partner violence (IPV) in rural areas with fewer shelter beds close to their homes, with an average of just 3.3 IPV shelter beds per rural county as compared to 13.8 in urban counties.[19] Among respondents of one survey, more than 25 percent of survivors of IPV in rural areas have to travel over 40 miles to the nearest support service, compared to less than one percent of women in urban areas.[20]

Other individuals in rural areas, such as people with disabilities, people with Hepatitis C, and people of color, have intersecting identities that further exacerbate existing barriers to care in rural areas. Racial and ethnic minority communities often live in concentrated parts of rural America, in communities experiencing rural poverty, lack of insurance, and health professional shortage areas.[21] People with disabilities experience difficulties finding competent physicians in rural areas who can provide experienced and specialized care for their specific needs, in buildings that are barrier free.[22] Individuals with Hepatitis C infection find few providers in rural areas with the specialized knowledge to manage the emerging treatment options, drug toxicities and side effects.[23] All of these barriers will worsen if providers are allowed to refuse care to particular patients.

Meanwhile, immigrant, Latina women and their families often face cultural and linguistic barriers to care, especially in rural areas.[24] These women often lack access to

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[16] M. MacDowell et al., *A National View of Rural Health Workforce Issues in the USA,* 10 RURAL REMOTE HEALTH (2010), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/.
[17] Carol Jones et al., *Health Status and Health Care Access of Farm and Rural Populations,* ECON. RESEARCH SERV. (2009), *available at* https://www.ers.usda.gov/publications/pub-details/?pubid=44427.
[18] Thomas A. Arcury et al., *The Effects of Geography and Spatial Behavior on Health Care Utilization among the Residents of a Rural Region*, 40 HEALTH SERV. RESEARCH (2005) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130/.
[19] Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources,* 20 J. OF WOMEN'S HEALTH (Nov. 2011) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216064/.
[20] *Id.*
[21] Janice C. Probst et al., *Person and Place: The Compounding Effects of Race/Ethnicity and Rurality on Health,* AM. J. PUB. HEALTH (2011), *available at* http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1695.
[22] Lisa I. Iezzoni et al., *Rural Residents with Disabilities Confront Substantial Barriers to Obtaining Primary Care,* 41 HEALTH SERV. RESEARCH (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1797079/.
[23] Sanjeev Arora et al., *Expanding access to hepatitis C virus treatment – Extension for Community Healthcare Outcomes (ECHO) Project: Disruptive Innovation in Specialty Care,* 52 HEPATOLOGY (2010), *available at* http://onlinelibrary.wiley.com/doi/10.1002/hep.23802/full.
[24] Michelle M. Casey et al., *Providing Health Care to Latino Immigrants: Community-Based Efforts in the Rural Midwest,* AM. J. PUB. HEALTH (2011), *available at* http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1709.

transportation and may have to travel great distances to get the care they need.[25] In rural areas, there may simply be no other sources of health and life preserving medical care. When these women encounter health care refusals, they have nowhere else to go.

c. *The proposed rule would harm LGBTQ communities who continue to face rampant discrimination and health disparities*

The proposed rule will compound the barriers to care that LGBTQ individuals face, particularly the effects of ongoing and pervasive discrimination by potentially allowing providers to refuse to provide services and information vital to LGBTQ health.

LGBTQ people continue to face discrimination in many areas of their lives, including health care, based on their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[26] LGBTQ people still face discrimination in a wide variety of services affecting access to health care, including reproductive services, adoption and foster care services, child care, homeless shelters, and transportation services – as well as physical and mental health care services.[27] In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.[28] They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.[29]

i. Discrimination against the transgender community

Discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.[30] Numerous

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[25] NAT'L LATINA INST. FOR REPROD. HEALTH & CTR. FOR REPROD. RIGHTS, NUESTRA VOZ, NUESTRA SALUD, NUESTRO TEXAS: THE FIGHT FOR WOMEN'S REPRODUCTIVE HEALTH IN THE RIO GRANDE VALLEY, 7 (2013), *available at* http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[26] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).

[27] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[28] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.

[29] *Id.*

[30] *See, e.g.*, *EEOC v. R.G. & G.R. Harris Funeral Homes*, No. 16-2424 (6th Cir. Mar. 7, 2018); *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034 (7th Cir. 2017) (Title IX and Equal Protection Clause); *Dodds v. U.S. Dep't of Educ.,* 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); Smith v. City of Salem, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *A.H. ex rel. Handling v. Minersville Area School District*, 3:17-CV-391, 2017 WL 5632662 (M.D. Pa. Nov. 22, 2017) (Title IX and Equal Protection Clause); *Stone v. Trump*, ---F.Supp.3d ---, No. 17–2459 (D. Md. Nov. 21, 2017) (Equal Protection Clause); Doe v. Trump, ---F.Supp.3d ---, 2017 WL

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federal courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination.[31] In 2012, the Equal Employment Opportunity Commission (EEOC) likewise held that "intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII."[32]

Twenty-nine percent of transgender individuals were refused to be seen by a health care provider because of their perceived or actual gender identity and 29 percent experienced unwanted physical contact from a health care provider.[33] Additionally, the 2015 U.S. Transgender Survey found that 23 percent of respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[34]
Data obtained by Center for American Progress (CAP) under a FOIA request indicates the Department's enforcement was effective in resolving issues of anti-LGBTQ discrimination. CAP received information on closed complaints of discrimination based on sexual orientation, sexual orientation-related sex stereotyping, and gender identity that were filed with the Department under § 1557 of the ACA from 2012 through 2016.

- "In approximately 30% of these claims, patients alleged denial of care or insurance coverage simply because of their gender identity – not related to gender transition."

4873042 (D.D.C. Oct. 30, 2017) (Equal Protection Clause); *Prescott v. Rady Children's Hospital-San Diego*, ---F.Supp.3d ---, 2017 WL 4310756 (S.D. Cal. Sept. 27, 2017) (Section 1557); *E.E.O.C. v. Rent-a-Center East, Inc.*, ---F.Supp.3d ---, 2017 WL 4021130 (C.D. Ill. Sept. 8, 2017) (Title VII); *Brown v. Dept. of Health and Hum. Serv.*, No. 8:16DCV569, 2017 WL 2414567 (D. Neb. June 2, 2017) (Equal Protection Clause); *Smith v. Avanti*, 249 F.Supp.3d 1194 (D. Colo. 2017) (Fair Housing Act); *Students & Parents for Privacy v. U.S. Dep't of Educ.*, No. 16-cv-4945, 2016 WL 6134121 (N.D. Ill. Oct. 18, 2016) (Title IX); *Mickens v. Gen. Elec. Co.* No. 16-603, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016) (Title VII); *Fabian v. Hosp. of Cent. Conn.*, 172 F.Supp.3d 509 (D. Conn. 2016) (Title VII); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. Jul. 5, 2016) (Section 1557); *Doe v. State of Ariz.*, No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016) (Title VII); *Dawson v. H&H Elec., Inc.*, No. 4:14CV00583 SWW, 2015 WL 5437101 (E.D. Ark. Sept. 15, 2015) (Title VII); *U.S. v. S.E. Okla. State Univ.*, No. CIV–15–324–C, 2015 WL 4606079 (W.D. Okla. 2015) (Title VII); *Rumble v. Fairview Health Serv.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (Section 1557); *Finkle v. Howard Cty.*, 12 F.Supp.3d 780 (D. Md. 2014) (Title VII); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); *Lopez v. River Oaks Imaging & Diagnostic Grp.*, Inc., 542 F.Supp.2d 653 (S.D. Tex. 2008) (Title VII); *Mitchell v. Axcan Scandipharm,* Inc., No. Civ.A. 05-243, 2006 WL 456173 (W.D. Pa. 2006) (Title VII); *Tronettiv. Healthnet Lakeshore Hosp.*, No. 03–CV–0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003) (Title VII).

[31] *See, e.g.*, *Smith v. City of Salem*, 378 F.3d 566, 572-75 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act). *See also* Statement of Interest of the United States at 14, *Jamal v. Saks*, No. 4:14-cv-02782 (S.D. Tex. Jan. 26, 2015).

[32] *Macy v. Holder*, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12 (Apr. 20, 2012).

[33] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.

[34] NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey* 5 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf [hereinafter *2015 U.S. Transgender Survey*].

- "Approximately 20% of the claims were for misgendering or other derogatory language."
- "Patients denied care due to their gender identity or transgender status included a transgender woman denied a mammogram and a transgender man refused a screening for a urinary tract infection."[35]

As proposed, the rule could allow religiously affiliated hospitals to not only refuse to provide transition related treatment for transgender people, but to also deny surgeons who otherwise have admitting privileges to provide transition related surgery in the hospital. Transition-related care is not only medically necessary, but for many transgender people it is lifesaving.

ii. Discrimination based upon sexual orientation

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences.[36] According to one survey, 8 percent of LGBQ individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.[37]

Fear of discrimination causes many LGB people to avoid seeking health care, and, when they do seek care, LGB people are frequently not treated with the respect that all patients deserve. The study "When Health Care Isn't Caring" found that 56 percent of LGB people reported experiencing discrimination from health care providers – including refusals of care, harsh language, or even physical abuse – because of their sexual orientation.[38] Almost 10 percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.[39] Delay and avoidance of care due to fear of discrimination compound the significant health disparities that affect the lesbian, gay, and bisexual population. These disparities include:

- LGB individuals are more likely than heterosexuals to rate their health as poor, have more chronic conditions, and have higher prevalence and earlier onset of disabilities.[40]

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[35] Sharita Gruberg & Frank J. Bewkes, Center for American Progress, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial* (March 7, 2018), *available at* https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.
[36] Medical schools often do not provide instruction about LGBTQ health concerns that are not related to HIV/AIDS. Jen Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S*, KAISER FAMILY FOUND.12 (2017), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.
[37] Mirza, *supra* note 33.
[38] LAMBDA LEGAL, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* 5 (2010), *available at* .http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.
[39] *Id.*
[40] David J. Lick, Laura E. Durso & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERS. ON PSYCHOL. SCI. 521 (2013), *available at*

- Lesbian and bisexual women report poorer overall physical health than heterosexual women.[41]
- Gay and bisexual men report more cancer diagnoses and lower survival rates, higher rates of cardiovascular disease and risk factors, as well as higher total numbers of acute and chronic health conditions.[42]
- Gay and bisexual men and other men who have sex with men (MSM) accounted for more than half (56 percent) of all people living with HIV in the United States, and more than two-thirds (70 percent) of new HIV infections.[43]
- Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.[44]

This discrimination affects not only the mental health and physical health of LGBTQ people, but that of their families as well. One pediatrician in Alabama reported that "we often see kids who haven't seen a pediatrician in 5, 6, 7 years, because of fear of being judged, on the part of either their immediate family or them [identifying as LGBTQ]".[45] It is therefore crucial that LGBTQ individuals, who have found unbiased and affirming providers, be allowed to remain with them. If turned away by a health care provider, 17 percent of all LGBTQ people, and 31 percent of LGBTQ people living outside of a metropolitan area, reported that it would be "very difficult" or "not possible" to find the same quality of service at a different community health center or clinic.[46]

The proposed rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBTQ persons. Refusals also implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else. The American Medical Association recommends that providers use culturally appropriate language and have basic familiarity and competency with LGBTQ issues as they pertain to any health services provided.[47] The World Professional Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care.[48] The

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http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities/.

[41] *Id.*

[42] *Id.*

[43] CTRS FOR DISEASE CONTROL & PREVENTION, *CDC Fact Sheet: HIV Among Gay and Bisexual Men* 1(Feb. 2017), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf.

[44] HUMAN RIGHTS CAMPAIGN ET AL., *Health Disparities Among Bisexual People* (2015) *available at* http://hrc-assets.s3-website-us-east-1.amazonaws.com//files/assets/resources/HRC-BiHealthBrief.pdf.

[45] HUMAN RIGHTS WATCH, *supra* note 27.

[46] Mirza, *supra* note 33.

[47] *Community Standards of Practice for the Provision of Quality Health Care Services to Lesbian, Gay, Bisexual, and Transgender Clients*, GAY LESBIAN BISEXUAL & TRANSGENDER HEALTH ACCESS PROJECT, http://www.glbthealth.org/CommunityStandardsofPractice.htm (last visited Jan. 26, 2018, 12:59 PM); *Creating an LGBTQ-friendly Practice*, A.M.A., https://www.ama-assn.org/delivering-care/creating-lgbtq-friendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018, 12:56 PM).

[48] *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, WORLD PROF. ASS'N FOR TRANSGENDER HEALTH (2011), https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf.

American College of Obstetricians and Gynecologists ("ACOG") warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.[49] LGBTQ individuals already experience significant health disparities, and denying medically necessary care based on sexual orientation or gender identity exacerbates these disparities.

In addition, LGBTQ individuals face disparities in medical conditions that may implicate the need for reproductive health services. For example, lesbian and bisexual women report heightened risk for and diagnosis of some cancers and higher rates of cardiovascular disease.[50] The LGBTQ community is significantly at risk for sexual violence.[51] Eighteen percent of LGB students have reported being forced to have sex.[52] Transgender women, particularly women of color, face high rates of HIV.[53]

Refusals to treat individuals according to medical standards of care put patients' health at risk, particularly for women and LGBTQ individuals. Expanding religious refusals will further put needed care, including reproductive health care, out of reach for many. Given the broadly written and unclear language of the proposed rule, if implemented, some providers may misuse this rule to deny services to LGBTQ individuals based on perceived or actual sexual orientation and gender identity. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care impairs the ability of patients to make a health decision that expresses their self-determination.

Finally, the proposed rule threatens to turn back the clock to the darkest days of the AIDS pandemic when same-sex partners were routinely denied hospital visitation and health care providers scorned sick and dying patients.

d. The proposed rule will hurt people living with disabilities

Many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically, people with disabilities who rely on these services have sometimes faced discrimination, exclusion, and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[54] Individuals with HIV – a recognized disability under the

[49] *Committee Opinion 512: Health Care for Transgender Individuals*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Dec. 2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.
[50] Kates, *supra* note 36, at 4.
[51] Forty-six percent of bisexual women have been raped and 47 percent of transgender people are sexually assaulted at some point in their lifetime. This rate is particularly higher for transgender people of color. Kates, *supra* note 36, at 8.; *2015 U.S. Transgender Survey*, *supra* note 34, at 5.
[52] *Health Risks Among Sexual Minority Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/healthyyouth/disparities/smy.htm (last updated May 24, 2017).
[53] More than 1 in 4 transgender women are HIV positive. Kates, *supra* note 36, at 6.
[54] See *Forziano v. Independent Grp. Home Living Prog.*, No. 13-cv-00370 (E.D.N.Y. Mar. 26, 2014) (dismissing lawsuit against group homes, including a religiously affiliated group home, that refused to allow married couple with intellectual disabilities live together). Recent regulations have reinforced protections to ensure available choice of roommates and guests. 42 C.F.R. §§ 441.301(c)(4)(vi)(B) & (D).

American Disabilities Act – have repeatedly encountered providers who deny services, necessary medications, and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[55] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy, and well-being of people with disabilities.

Many people with disabilities live or spend much of their day in provider-controlled settings where they often receive supports and services. They may rely on a case manager to coordinate necessary services, a transportation provider to get them to community appointments, or a personal care attendant to help them take medications and manage their daily activities. Under this broad new proposed language, any of these providers could believe they are entitled to object to providing a service covered under the regulation and not even tell the individual where they could obtain that service, how to find an alternative provider, or even whether the service is available to them. A case manager might refuse to set up a routine appointment with a gynecologist because contraceptives might be discussed. A personal home health aide could refuse to help someone take a contraceptive. An interpreter for a deaf individual could refuse to mediate a conversation with a doctor about abortion. In these cases, a denial based on someone's personal moral objection can potentially affect every facet of life for a person with disabilities – including visitation rights, autonomy, and access to the community.

Finally, due to limited provider networks in some areas and to the important role that case managers and personal care attendants play in coordinating care, it may be more difficult for people with disabilities and older adults to find alternate providers who can help them. For example, home care agencies and home-based hospice agencies in rural areas are facing significant financial difficulties staying open. Seven percent of all zip codes in the United States do not have any hospice services available to them.[56] Finding providers competent to treat people with certain disabilities can increase the challenge. Add in the possibility of a case manager or personal care attendant who objects to helping and the barrier to accessing these services can be insurmountable. Moreover, people with disabilities who identify as LGBTQ or who belong to a historically disadvantaged racial or ethnic group may be both more likely to encounter service refusals and also face greater challenges to receive (or even know about) accommodations.

III. The proposed rule undermines longstanding ethical and legal principles of informed consent

[55] NAT'L WOMEN'S LAW CTR., *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.
[56] Julie A. Nelson & Barbara Stover Gingerich, *Rural Health: Access to Care and Services*, 22 HOME HEALTH CARE MGMT. PRAC. (2010), *available at* http://globalag.igc.org/ruralaging/us/2010/access.pdf.

The proposed rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[57] This right relies on two factors: access to relevant and medically accurate information about treatment choices and alternatives, and provider guidance based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care.

The proposed rule purports to improve communication between patients and providers, but instead, will deter open, honest conversations that are vital to ensuring that a patient is able to be in control of their medical circumstances. For example, the proposed rule suggests that someone could refuse to offer information, if that information might be used to obtain a service to which the refuser objects. Such an attenuated relationship to informed consent could result in withholding information far beyond the scope of the underlying statutes, and would violate medical standards of care.

In recent decades, the U.S. medical community has primarily looked to informed consent as key to assuring patient autonomy in making decisions.[58] Informed consent is intended to help balance the unequal balance of power between health providers and patients and ensure patient-centered decision-making. Moreover, consent is not a yes or no question but rather is dependent upon the patient's understanding of the procedure that is to be conducted and the full range of treatment options for a patient's medical condition. Without informed consent, patients will be unable to make medical decisions that are grounded in agency, their beliefs and preferences, and that meet their personal needs. This is particularly problematic, as many communities, including women of color and women living with disabilities, have disproportionately experienced abuse and trauma at the hands of providers and institutions.[59] In order to ensure that patient decisions are based on free will, informed consent must be upheld in the patient-provider relationship. The proposed rule threatens this principle and may very well force individuals into harmful medical circumstances.

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[57] TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

[58] BEAUCHAMP & CHILDRESS, *supra* note 58; Robert Zussman, *Sociological perspectives on medical ethics and decision-making*, 23 ANN. REV. SOC. 171-89 (1997).

[59] Gutierrez, E. R. *Fertile Matters: The Politics of Mexican Origin Women's* Reproduction, 35-54 (2008) (discussing coercive sterilization of Mexican-origin women in Los Angeles); Jane Lawrence, *The Indian Health Service and the Sterilization of Native American Women*, 24 AM. INDIAN Q. 400, 411-12 (2000) (referencing one 1974 study indicating that Indian Health Services would have coercively sterilized approximately 25,000 Native American Women by 1975); Alexandra Minna Stern, *Sterilized in the Name of Public Health*, 95 AM. J. PUB. H. 1128, 1134 (July 2005) (discussing African-American women forced to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). *See also Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, *A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century*, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization).

According to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."[60] The American Nurses Association ("ANA") similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. According to the ANA, "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[61] Similarly, pharmacists are called to respect the autonomy and dignity of each patient.[62]

Various state and federal laws require that health care professionals inform and counsel patients on specific issues such as preventing the spread of HIV/AIDS, non-directional information on family planning and abortion options, and emergency contraception to prevent pregnancy from rape.[63] In *Brownfield v. Daniel Freeman Marina Hospital*, a California court addressed the importance of patients' access to information concerning emergency contraception. The court found that:

> "The duty to disclose such information arises from the fact that an adult of sound mind has 'the right, in the exercise of control over [her] own body, to determine whether or not to submit to lawful medical treatment.' [citation omitted] Meaningful exercise of this right is possible only to the extent that patients are provided with adequate information upon which to base an intelligent decision with regard to the option available."[64]

In addition, the proposed rule does not provide any protections for health care professionals who want to provide, counsel, or refer for health care services that are implicated in this rule, for example, reproductive health or gender affirming care. The proposed rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[65] Due to the rule's aggressive enforcement mechanisms and its vague and confusing language, providers may fear to give care or information. The inability of providers to give comprehensive, medically accurate information and options that will help patients make the best health decisions violates medical principles such as,

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[60] *The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent*, 14 AM. MED. J. ETHICS 555-56 (2012), http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.
[61] *Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination*, AM. NURSES ASS'N (2001), https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html.
[62] *Code of Ethics for Pharmacists*, AM. PHARMACISTS ASS'N (1994).
[63] *See, e.g.*, *State HIV Laws*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/policies/law/states/index.html (last visited Nov. 13, 2017, 1:22PM); *Emergency Contraception*, GUTTMACHER INST. (Oct. 1, 2017), https://www.guttmacher.org/state-policy/explore/emergency-contraception.
[64] *Brownfield v. Daniel Freeman Marina Hospital*, 256 Cal. Rptr. 240 (Ct. App. 1989).
[65] *See* 42 U.S.C. § 300a-7(c).

beneficence, nonmaleficence, respect for autonomy, and justice. In particular, the principle of beneficence "requires that treatment and care do more good than harm; that the benefits outweigh the risks, and that the greater good for the patient is upheld."[66] In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable.[67] Specifically, the provision of the care should not vary due to the personal characteristics of patients and should ensure that patient values guide all clinical decisions.[68] The expansion of religious refusals as envisioned in the proposed rule may compel providers to furnish care and information that harms the health, well-being, and goals of patients.

In particular, the principles of informed consent, respect for autonomy, and beneficence are important when individuals are seeking end of life care. These patients should be the center of health care decision-making and should be fully informed about their treatment options. Their advance directives should be honored, regardless of the physician's personal objections. Under the proposed rule, providers who object to various procedures could impose their own religious beliefs on their patients by withholding vital information about treatment options— including options such as voluntarily stopping eating and drinking, palliative sedation or medical aid in dying. These refusals would violate these abovementioned principles by ignoring patient needs, their desires, and autonomy and self-determination at a critical time in their lives. Patients should not be forced to bear the brunt of their provider's religious or moral beliefs regardless of the circumstances.

IV. The regulations fail to consider the impact of refusals on persons suffering from substance use disorders (SUD)

The over breadth of this proposed rule could be devastating to people with Substance Use Disorder (SUD). Rather than promoting the evidence-based standard of care, the rule could allow anyone from practitioners to insurers to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

The opioid epidemic continues to claim too many lives. According to the Centers for Disease Control and Prevention (CDC), over 63,000 people in the U.S. died from drug overdose in 2016.[69] The latest numbers show a 2017 increase in emergency department overdose admissions of 30% across the country, and up to 70% in some areas of the Midwest.[70]

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[66] Amy G. Bryant & Jonas J. Schwartz, *Why Crisis Pregnancy Centers Are Legal but Unethical*, 20 AM. MED. ASS'N J. ETHICS 269, 272 (2018).
[67] INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 3 (Mar. 2001), *available at* http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.
[68] *Id.*
[69] Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).
[70] *Vital Signs*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioid-overdoses/.

The clear, evidence-based treatment standard for opioid use disorder (OUD) is MAT.[71] Buprenorphine, methadone, and naltrexone are the three FDA-approved drugs for treating patients with opioid use disorder. MAT is so valuable to treatment of addiction that the World Health Organization considers buprenorphine and methadone "Essential Medications."[72] Buprenorphine and methadone are, in fact, opioids. However, while they operate on the same receptors in the brain as other opioids, they do not produce the euphoric effect of other opioids but simply keep the user from experiencing withdrawal symptoms. They also keep patients from seeking opioids on the black market, where risk of death from accidental overdose increases. Patients on MAT are less likely to engage in dangerous or risky behaviors because their physical cravings are met by the medication, increasing their safety and the safety of their communities.[73] Naloxone is another medication key to saving the lives of people experiencing an opioid overdose. This medication reverses the effects of an opioid and can completely stop an overdose in its tracks.[74] Information about and access to these medications are crucial factors in keeping patients suffering from SUD from losing their jobs, losing their families, and losing their lives.

However, stigma associated with drug use stands in the way of saving lives.[75] America's prevailing cultural consciousness, after decades of treating the disease of addiction as largely a criminal justice and not a public health issue, generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use.[76] One commissioner even quoted the Bible as he voted to shut it

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[71] U.S. DEP'T HEALTH & HUM. SERV., PUB NO. (SMA)12-4214, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS (2012), https://store.samhsa.gov/shin/content/SMA12-4214/SMA12-4214.pdf; National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction.
[72] World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf
[73] OPEN SOC'Y INST., BARRIERS TO ACCESS: MEDICATION-ASSISTED TREATMENT AND INJECTION-DRIVEN HIV EPIDEMICS 1 (2009), https://www.opensocietyfoundations.org [https://perma.cc/YF94-88AP].
[74] *See* James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).
[75] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, VOX, Nov. 15, 2017, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.
[76] German Lopez, *An Indiana county just halted a lifesaving needle exchange program, citing the Bible,* VOX, Oct. 20, 2017, https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange.

down. Use of naloxone to reverse overdose has been decried as "enabling these people" to go on to overdose again.[77]

In this frame of mind, only total abstinence is seen as successful treatment for SUD, usually as a result of a 12-step or faith-based program. MAT is considered by many to be simply "substituting one drug for another drug."[78] This belief is so common that even the former Secretary of the Department is on the record as opposing MAT because he didn't believe it would "move the dial," since people on medication would be not "completely cured."[79] The scientific consensus is that SUD is a chronic disease, and yet many recoil from the idea of treating SUD with medication like any other illness such as diabetes or heart disease.[80] The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[81]

People with SUD already suffer due to stigma and have a difficult time finding appropriate care. For example, it can be difficult to find access to local methadone clinics in rural areas.[82] Other roadblocks, such as artificial caps on the number of patients to whom doctors can prescribe buprenorphine, further prevent people with SUD from receiving appropriate care.[83] Only one-third of treatment programs across the country provide MAT, even though treatment with MAT can cut overdose mortality rates in half and is considered the gold standard of care. [84] The current Secretary of the Department has noted that expanding access to MAT is necessary to save lives and that it will be "impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care.[85] This rule, which allows misinformation and personal feelings to get in

[77] Tim Craig & Nicole Lewis, *As opioid overdoses exact a higher price, communities ponder who should be saved*, WASH. POST, Jul. 15, 2017, https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.4184c42f806c.
[78] Lopez, *supra* note 75.
[79] Eric Eyre, *Trump officials seek opioid solutions in WV*, CHARLESTON GAZETTE-MAIL, May 9, 2017, https://www.wvgazettemail.com/news/health/trump-officials-seek-opioid-solutions-in-wv/article_52c417d8-16a5-59d5-8928-13ab073bc02b.html.
[80] Nora D. Volkow et al., *Medication-Assisted Therapies — Tackling the Opioid-Overdose Epidemic*, 370 NEW ENG. J. MED. 2063, http://www.nejm.org/doi/full/10.1056/NEJMp1402780.
[81] Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis, Nov. 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf
[82] Christine Vestal, *In Opioid Epidemic, Prejudice Persists Against Methadone*, STATELINE, Nov. 11, 2016, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/11/11/in-opioid-epidemic-prejudice-persists-against-methadone
[83] 42 C.F.R. §8.610.
[84] Matthais Pierce, et al., *Impact of Treatment for Opioid Dependence on Fatal Drug-Related Poisoning: A National Cohort Study in England*, 111:2 ADDICTION 298 (Nov. 2015); Luis Sordo, et al., Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies, BMJ (2017), http://www.bmj.com/content/357/bmj.j1550.; Alex Azar, Secretary, U.S. Dep't of Health & Hum. Serv., Plenary Address to National Governors Association, (Feb. 24, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html.
[85] Azar, *supra* note 84.

the way of science and lifesaving treatment, will not help achieve the goals of the administration; it will instead trigger countless numbers of deaths.

V. The proposed rule permits health care professionals to opt out of providing medical care that the public expects by allowing them to disregard evidence-based standards of care

Medical practice guidelines and standards of care establish the boundaries of medical care that patients can expect to receive and that providers should be expected to deliver. The health services impacted by refusals are often related to reproductive and sexual health, which are implicated in a wide range of common health treatment and prevention strategies. Information, counseling, referral and provisions of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Many of these conditions disproportionately affect women of color.[86] The expansion of these refusals as outlined in the proposed rule will put women, particularly women of color, who experience these medical conditions at greater risk for harm.

Moreover, a 2007 survey of physicians working at religiously-affiliated hospitals found that nearly one in five (19 percent) experienced a clinical conflict with the religiously-based policies of the hospital.[87] While some of these physicians might refer their patients to another provider who could provide the necessary care, one 2007 survey found that as many as one-third of patients (nearly 100 million people) may be receiving care from physicians who do not believe they have any obligations to refer their patients to other providers.[88] Meanwhile, the number of Catholic hospitals in the United States has increased by 22 percent since 2001, and now own one in six hospital beds across the

[86] For example, Black women are three times more likely to be diagnosed with lupus than white women. Latinas and Asian, Native American, and Alaskan Native women also are likely to be diagnosed with lupus. Office on Women's Health, *Lupus and women*, U.S. DEP'T HEALTH & HUM. SERV. (May 25, 2017), https://www.womenshealth.gov/lupus/lupus-and-women. Black and Latina women are more likely to experience higher rates of diabetes than their white peers. Office of Minority Health, *Diabetes and African Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (Jul. 13, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18; Office of Minority Health, *Diabetes and Hispanic Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (May 11, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=63. Filipino adults are more likely to be obese in comparison to the overall Asian population in the United States. Office of Minority Health, *Obesity and Asian Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (Aug. 25, 2017), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=55. Native American and Alaskan Native women are more likely to be diagnosed with liver and kidney/renal pelvis cancer in comparison to non-Hispanic white women. Office of Minority Health, *Cancer and American Indians/Alaska Natives*, U.S. DEP'T OF HEALTH & HUM. SERV. (Nov. 3, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=31.
[87] Debra B. Stulberg M.D. M.A., et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, J. GEN. INTERN. MED. 725-30 (2010) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/.
[88] Farr A. Curlin M.D., et al., *Religion, Conscience, and Controversial Clinical Practices*, NEW ENG. J. MED. 593–600 (2007) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/.

country.[89] The increase of Catholic hospitals poses a danger for women seeking reliable access to medical services, many of whom do not understand the full range of services that may be denied them. One public opinion survey found that, among the less than one-third of women who understood that a Catholic hospital might limit care, only 43 percent expected limited access to contraception, and a mere 6 percent expected limited access to the morning-after pill.[90]

a. Pregnancy prevention

The importance of the ability of women to make decisions for themselves to prevent or postpone pregnancy is well established within the medical guidelines across a range of practice areas. Millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. Denying these women access to contraceptive information and services violates medical standards that recommend pregnancy prevention for these medical conditions. For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care.[91] Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant.[92]

Moreover, women who are struggling to make ends meet are disproportionately impacted by unintended pregnancy. In 2011, 45% of pregnancies in the U.S. were unintended – meaning that they were either unwanted or mistimed.[93] Low-income women have higher rates of unintended pregnancy as they are least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy.[94] The Institute of Medicine has documented negative health effects of unwanted pregnancy for mothers and children. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors as well as low-birth weight babies and insufficient prenatal care.[95]

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[89] Julia Kaye et al., *Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives*, AM. CIVIL LIBERTIES UNION 22 (2017), *available at* https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[90] Nadia Sawicki, *Mandating Disclosure Of Conscience-Based Limitations On Medical Practice*, 42 AM. J. OF LAW & MED. 85-128 (2016) *available at* http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.

[91] AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE S115, S117 (2017), available at: http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf

[92] *Id.* at S114.

[93] *Unintended Pregnancy in the United States*, Guttmacher Inst. (Sept. 2016), https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.

[94] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in rates of unintended pregnancy in the United States, 1994 and 2001*, 38 PERSPECTIVES ON SEXUAL & REPROD. HEALTH 90-6 (2006).

[95] INSTITUTE OF MEDICINE COMMITTEE ON UNINTENDED PREGNANCY, THE BEST INTENTIONS: UNINTENDED PREGNANCY AND THE WELL-BEING OF CHILDREN AND FAMILIES (Sarah S. Brown & Leon Eisenberg eds.,1995).

b. Sexually transmitted infections (STIs)

Religious refusals also affect access to sexual health care more broadly. Contraceptives and access to preventative treatment for STIs are a critical aspect of health care. The CDC estimates that 20 million new STIs occur each year. Chlamydia remains the most commonly reported infectious disease in the U.S., while HIV/AIDS remains the most life threatening. Women, especially young women, and Black women, are hit hardest by Chlamydia—with rates of Chlamydia 5.6 times higher for Black than for white Americans.[96] Consistent use of condoms results in an 80 percent reduction of HIV transmission, and the American Academy of Pediatrics, ACOG, and the World Health Organization all recommend that providers promote condom use.[97]

c. Ending a pregnancy

While there are numerous reasons for why a person would seek to end a pregnancy, there are many medical conditions in which ending a pregnancy is recommended as treatment. These conditions include: preeclampsia and eclampsia, certain forms of cardiovascular disease, and complications for chronic conditions. Significant racial disparities exist in rates of and complications associated with preeclampsia.[98] For example, the rate of preeclampsia is 61 percent higher for Black women than for white women, and 50 percent higher than women overall.[99] ACOG and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival.[100] ACOG and American Heart Association recommend that a pregnancy be avoided or ended for certain conditions such as severe pulmonary hypertension.[101] Many medications can

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[96] *Sexually Transmitted Disease Surveillance 2016*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 2017), https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf.

[97] American Academy of Pediatrics Committee on Adolescence, *Condom Use by Adolescents*, 132 PEDIATRICS (Nov. 2013), http://pediatrics.aappublications.org/content/132/5/973; American Academy of Pediatrics, American College of Obstetricians and Gynecologists, March of Dimes Birth Defects Foundation. Guidelines for perinatal care. 6th ed. Elk Grove Village, IL; Washington, DC: American Academy of Pediatrics; American College of Obstetricians and Gynecologists; 2007; American College of Obstetricians and Gynecologists. Barrier methods of contraception. Brochure (*available at* http://www.acog.org/publications/patient_education/bp022.cfm). Washington, DC: American College of Obstetricians and Gynecologists; 2008 July; World Health Organization, UNAIDS, UNFPA, *Position statement on condoms and HIV prevention*, UNICEF (2009), https://www.unicef.org/aids/files/2009_position_paper_condoms_en.pdf.

[98] Sajid Shahul et al., *Racial Disparities in Comorbidities, Complication, and Maternal and Fetal Outcomes in Women With Preeclampsia/eclampsia*, 34 HYPERTENSION PREGNANCY (Dec. 4, 2015), http://www.tandfonline.com/doi/abs/10.3109/10641955.2015.1090581?journalCode=ihip20.

[99] Richard Franki, *Preeclampsia/eclampsia rate highest in black women*, OB.GYN. NEWS (Apr. 29., 2017), http://www.mdedge.com/obgynnews/article/136887/obstetrics/preeclampsia/eclampsia-rate-highest-black-women.

[100] AMERICAN ACADEMY OF PEDIATRICS & AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

[101] Mary M. Canobbio et al., *Management of Pregnancy in Patients With Complex Congenital Heart Disease*, 135 CIRCULATION e1-e39 (2017); Debabrata Mukherjee, *Pregnancy in Patients With Complex Congenital Heart Disease*, AM. COLL. CARDIOLOGY (Jan. 24, 2017), http://www.acc.org/latest-in-cardiology/ten-points-to-remember/2017/01/24/14/40/management-of-pregnancy-in-patients-with-complex-chd.

cause significant fetal impairments, and therefore the U.S. Food and Drug Administration and professional medical associations recommend that women use contraceptives to ensure that they do not become pregnant while taking these medications.[102] In addition, some medical guidelines counsel patients to end a pregnancy if they are taking certain medications for thyroid disease.[103]

d. Emergency contraception

The proposed rule will magnify the harm in circumstances where women are already denied the standard of care. Catholic hospitals have a record of providing substandard care or refusing care altogether to women for a range of medical conditions and crises that implicate reproductive health. For example, in a 2005 study of Catholic hospital emergency rooms by Ibis Reproductive Health for Catholics for Choice, it was found that 55 percent would not dispense emergency contraception under any circumstances.[104] Twenty three percent of the hospitals limited EC to victims of sexual assault.[105]

These hospitals violated the standards of care established by medical providers regarding treatment of sexual assault. Medical guidelines state that survivors of sexual assault should be provided emergency contraception subject to informed consent and that it should be immediately available where survivors are treated.[106] At the bare minimum, survivors should be given comprehensive information regarding emergency contraception.[107]

e. Artificial Reproductive Technology (ART)

Refusals to provide the standard of care to LGBTQ individuals because of their sexual orientation or gender identity can affect access to care across a broad spectrum of health concerns, which includes primary and specialty care settings. One example of refusals that affects LGBTQ patients, as well as non-LGBTQ patients, is refusals to educate about, provide, or cover ART procedures for religious reasons. For individuals with cancer, the

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[102] ELEANOR BIMLA SCHWARZ M.D. M.S., et al., *Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women*, 147 Annals of Internal Medicine. (Sept. 18, 2007).
[103] For example, the American College of Obstetricians and Gynecologists specifically recommends that if a woman taking Iodine 131 becomes pregnant, her physician should caution her to consider the serious risks to the fetus, and consider termination. American College of Obstetricians and Gynecologists, *ACOG Practice Bulletin No. 37: Thyroid disease in pregnancy* 100 OBSTETRICS & GYNECOLOGY 387-96 (2002).
[104] Teresa Harrison, *Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff*, 46 ANNALS EMERGENCY MED. 105-10 (Aug. 2005), http://www.annemergmed.com/article/S0196-0644(05)00083-1/pdf
[105] *Id.* at 105.
[106] *Committee Opinion 592: Sexual Assault*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Apr. 2014), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co592.pdf?dmc=1&ts=20170213T2116487879; *Management of the Patient with the Complaint of Sexual Assault*, AM. COLL. EMERGENCY MED. (Apr. 2014), https://www.acep.org/Clinical---Practice-Management/Management-of-the-Patient-with-the-Complaint-of-Sexual-Assault/#sm.00000bexmo6ofmepmultb97nfbh3r.
[107] *Access to Emergency Contraception H-75.985*, AMA (2014), https://policysearch.ama-assn.org/policyfinder/detail/emergency%20contraception%20sexual%20assault?uri=%2FAMADoc%2FHOD.xml-0-5214.xml.

standard of care includes education and informed consent around fertility preservation, according to the American Society for Clinical Oncology and the Oncology Nursing Society.[108] Refusals to educate patients about or to provide ART occur for two reasons: refusals based on religious beliefs about ART itself and refusals to provide ART to LGBTQ individuals because of their LGBTQ identity. In both situations, refusals to educate patients about ART and fertility preservation, and to facilitate ART when requested, are against the standard of care.

The lack of clarity in the rule could lead a hospital or an individual provider to refuse to provide ART to same-sex couples based on religious belief. For some couples, this discrimination would increase the cost and emotional toll of family building. In some parts of the country, however, these refusals would be a complete barrier to parenthood. More broadly, these refusals deny patients the human right and dignity to be able to decide to have children, and cause psychological harm to patients who are already vulnerable because of their health status or their experience of health disparities.

f. HIV Health

For HIV, in addition to consistent condom use, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are an important part of prevention for those at high risk for contracting HIV. ACOG recommends that PrEP be considered for individuals at high risk of contracting HIV.[109] Under the proposed rule, an insurance company could refuse to cover PrEP or PEP because of a religious belief. Refusals to promote and facilitate condom use because of religious beliefs and refusals to prescribe PrEP or PEP because of a patient's perceived or actual sexual orientation, gender identity, or perceived or actual sexual behaviors is in violation of the standards of care and harms patients already at risk for experiencing health disparities. Both PrEP and PEP have been shown to be highly effective in preventing HIV infection. Denying access to this treatment would adversely affect vulnerable, highest risk populations including gay and bisexual men.

VI. The proposed rule misinterprets statutory language governing Medicaid managed care organizations

The proposed rule misinterprets narrowly tailored language governing Medicaid managed care organizations (MCOs), and instead creates a freestanding religious exemption.[110]

[108] Alison W. Loren et al., *Fertility Preservation for Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update*, 31 J. CLINICAL ONCOLOGY 2500-10 (July 1, 2013); Ethics Committee of the American Society for Reproductive Medicine, *Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion*, 100 AM. SOC'Y REPROD. MED. 1224-31 (Nov. 2013), http://www.allianceforfertilitypreservation.org/_assets/pdf/ASRMGuidelines2014.pdf; Joanne Frankel Kelvin, *Fertility Preservation Before Cancer Treatment: Options, Strategies, and Resources*, 20 CLINICAL J. ONCOLOGY NURSING 44-51 (Feb. 2016).
[109] ACOG *Committee Opinion 595: Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (May 2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus.
[110] 83 Fed. Reg. 3926.

Under current law, MCOs are prohibited from restricting a provider's ability to offer counseling and information regarding treatment and care that is within the lawful scope of the provider's practice regardless of whether these services are covered by the MCO.[111] However, the MCO does not need to pay for counseling or referral related to a service to which they object on the basis of religious or moral beliefs.[112] The underlying religious exemption is intended only to qualify the statute's prohibition on interference with doctor-patient communications of Medicaid managed care enrollees. Because the underlying statutory exemption is a provision of statutory construction, Congress could not have intended this provision to be a blanket provision for Medicaid managed care organizations.[113] Moreover, the proposed rule omits enrollee protections required by the underlying statute when a Medicaid managed care organization declines to cover referral or counseling on the basis of religious of moral beliefs. Current and prospective enrollees must receive written notice and information on policies regarding counseling or referral or changes to such policies before and during enrollment and within 90 days after a change to policy has occurred.[114] The language of the proposed rule misinterprets and far exceeds the plain language of the statute and may discourage Medicaid managed care organizations from complying with notice requirements to the detriment of enrollees.

VII. The proposed rule does not take into account the law governing emergency health situations

In addition, the proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[115] Under EMTALA, every hospital is required to comply – even those that are religiously affiliated.[116] Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may

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[111] 42 U.S.C. § 1396u-2(b)(3)(A).
[112] *Id.* § 1396u-2(b)(3)(B)(i).
[113] *See e.g.*, *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 376 n.5 (1986) (stating that statutes may provide their own rules of statutory construction to ensure that the statute is read correctly). Moreover, when a general statement of policy is qualified by an exception, the exception is read narrowly to preserve the primary operation of the provision. *C.I.R. v. Clark*, 489 U.S. 726, 739 (1989) (citing *Phillips, Inc. V. Walling*, 324 U.S. 490, 493 (1945) ("To extend an exemption to other than those plainly and unmistakably within its terms and spirit is to abuse the interpretative process and to frustrate the announced will of the people").
[114] 42 U.S.C. § 1396u-2(b)(3)(B)(ii).
[115] 42 U.S.C. § 1295dd(a)-(c) (2003).
[116] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

believe they are not required to comply with EMTALA's requirements. As a result, patients experiencing medical emergencies may not receive the care they need.

VIII. The proposed rule violates the Establishment Clause

The Establishment Clause of the First Amendment bars the government from granting religious and moral exemptions that would harm any third party.[117] It requires the Department to "take adequate account of the burdens" that an exemption "may impose on nonbeneficiaries" and must ensure that any exemption is "measured so that it does not override other significant interests."[118]

The Supreme Court acknowledged the limitations imposed by the Establishment Clause in *Burwell v. Hobby Lobby Stores, Inc.*, declaring the effect on employees of an accommodation provided to employers under the Religious Freedom Restoration Act (RFRA) "would be precisely zero."[119] Justice Kennedy emphasized that an accommodation must not "unduly restrict other persons, such as employees, in protecting their own interests."[120] The proposed exemptions clearly impose burdens on, and harm others, and thus, violate the clear mandate of the Establishment Clause.

IX. The regulations are overly broad, vague, and will cause confusion in the health care delivery system

The regulations dangerously expand the application of the underlying statutes by offering an extremely broad definition of who can refuse and what they can refuse to do. Under the proposed rule, any one engaged in the health care system could refuse services or care. The proposed rule defines workforce to include "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity."[121] Under this definition, could any member of the health care workforce refuse to serve a patient in any way – could a nurse assistant refuse to serve lunch to a transgender patient, could a billing specialist refuse to help a patient who had sought contraceptive counseling?

a. Discrimination

The failure to define the term "discrimination" will cause confusion for providers, and as employers, expose them to liability. Title VII already requires that employers accommodate employees' religious beliefs to the extent there is no undue hardship on the employer.[122] The regulations make no reference to Title VII or current EEOC guidance, which prohibits discrimination against an employee based on that employee's race, color, religion, sex, and

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[117] E.g., *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Cutter v. Wilkinson*, 544 U.S.709, 720, 726 (2005*); Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989).
[118] *Cutter*, 544 U.S. at 720, 722; see also *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709-10 (1985).
[119] *Hobby Lobby*, 134 S. Ct. 2751, 2760 (2014).
[120] *Id.* at 2786-87 (Kennedy, J., concurring).
[121] 83 Fed. Reg. 3894.
[122] 42 U.S.C. § 2000e-2.; *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

national origin.[123] The proposed rule should be read to ensure that the long-standing balance set in Title VII between the right of individuals to enjoy reasonable accommodation of their religious beliefs and the right of employers to conduct their businesses without undue interference is to be maintained.

If this balance is not maintained, the language in the proposed rule could force health care providers to hire people who intend to refuse to perform essential elements of a position. For example, the proposed rule lacks clarity about whether a Title X-funded health center's decision not to hire a counselor or clinician who objected to provide non-directive options counseling as an essential job function of their position would be deemed discrimination under the rule. Furthermore, the proposed rule does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician to a unit where pregnancy counseling is not done. By failing to define "discrimination," supervisors in health care settings will be unable to proceed in the orderly delivery of health care services, putting women's health at risk. The proposed rule impermissibly muddies the interpretation of Title VII and current EEOC guidance. If implemented, health care entities may be forced to choose between complying with a fundamentally misguided proposed rule and long-standing interpretation of Title VII.

Finally, the proposed rule's lack of clarity regarding what constitutes discrimination, may undermine non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.[124] Instead, courts have held that the government has a compelling interest in ending discrimination and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes it clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the basis of race, because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal."[125] The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

b. Assist in the performance

The definition of "assist in the performance" greatly expands the types of services that can be refused beyond any reasonable stretch of the imagination. The proposed rule defines

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[123] *Id.*
[124] *See e.g.*, *Bob Jones Univ. v. United States*, 461 U.S. 574 (1983) (holding that the government's interest in eliminating racial discrimination in education outweighed any burdens on religious beliefs imposed by Treasury Department regulations); *Newman v. Piggie Park Enters., Inc.*, 390 U.S. 400 (1968) (holding that a restaurant owner could not refuse to comply with the Civil Rights Act of 1964 and not serve African-American customers based on his religious beliefs); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1392 (4th Cir. 1990) (holding a religious school could not compensate women less than men based on the belief that "the Bible clearly teaches that the husband is the head of the house, head of the wife, head of the family"); *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316 (11th Cir. 2012) (reversing summary judgment for religious school that claimed a religious right to fire teacher for becoming pregnant outside of marriage).
[125] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).

"assistance" to include participation "in any activity with an *articulable connection* to a procedure, health service or health service program, or research activity."[126] In addition, the Department includes activities such as "making arrangements for the procedure."[127] If workers in very tangential positions, such as schedulers, are able to refuse to do their jobs based on personal beliefs, the ability of any health system or entity to plan, to properly staff, and to deliver quality care will be undermined. Employers and medical staff may be stymied in their ability to establish protocols, policies and procedures under these vague and broad definitions. The proposed rule creates the potential for a wide range of workers to interfere with and interrupt the delivery of health care in accordance with the standard of care.

The regulations also leave unclear whether a worker can assert his or her moral belief in refusing to treat patients based on their identity or deny care for reasons outside of religious or moral beliefs. Even though women living with disabilities report engaging in sexual activities at the same rate as women who do not live with disabilities, they often do not receive the reproductive health care they need for multiple reasons, including lack of accessible provider offices and misconceptions about their reproductive health needs.[128] Biased counseling can contribute to unwanted health outcomes and exacerbate health disparities.[129] The proposed rule is especially alarming, as it does not articulate a definition of moral beliefs. The prejudices of a health care professional could easily inform their beliefs and consequently, serve as the basis of denying care to an individual based on characteristics alone. The proposed rule will foster discriminatory health care settings and interactions between patients and providers that are informed by bias instead of medically accurate, evidence-based, patient-centered care.

Moreover, in the preamble, the proposed rule states that the exemptions that Weldon provides is not limited to refusals of abortion care on the basis of religious or moral beliefs.[130] Due to this, health care professionals may think they can deny abortion care and other health services just because they do not want to provide the service. The preamble uses language such as "those who choose not to provide" or "Would rather not" as justification for a refusal. This is more concerning because the proposed rule contains no mechanism to ensure that patients receive the care they need if their provider refuses to furnish a service. The onus will be on the patient to question whether her hospital, medical doctor, or health care professional has religious, moral, or other beliefs that would lead them to deny services or if services were denied, the basis for refusal. This is likely to occur, as the proposed rule does not have any provisions that stipulate that patients must

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[126] 83 Fed. Reg. 3892.
[127] *Id.*
[128] RM Haynes et al., *Contraceptive Use at Last Intercourse Among Reproductive-Aged Women with Disabilities: An Analysis of Population-Based Data from Seven States*, CONTRACEPTION (2017), https://www.ncbi.nlm.nih.gov/pubmed/29253580; *See generally* Alex Zielinski, *Why Reproductive Health Can Be A Special Struggle for Women with Disabilities*, THINKPROGRESS, Oct. 1, 2015, https://thinkprogress.org/why-reproductive-health-can-be-a-special-struggle-for-women-with-disabilities-73ececea23c4/.
[129] In one study in Massachusetts, women living with intellectual and developmental disabilities, including those who were Black and Latina, faced increased risks of preterm delivery and very low and low birth weight babies. M. Mitra et al., *Pregnancy Outcomes Among Women with Intellectual and Developmental Disabilities*, AM. J. PREV. MED. (2015), https://www.ncbi.nlm.nih.gov/pubmed/25547927.
[130] 83 Fed. Reg. 3890-91.

be given notice that they may be refused certain health care services on the basis of religious or moral beliefs.

c. Referral

The definition of “referral” similarly goes beyond any understanding of the term, allowing refusals to provide any information based on which an individual could get the care they need. Any information distributed by any method, including online or print, regarding any service, procedure, or activity could be refused by an entity if the information given would lead to a service, activity, or procedure that the entity or health care entity objects. Under this definition, could a medical doctor refuse to provide a website describing the medical conditions which contraception treats? Or could an entity refuse to provide a list of LGBTQ-friendly providers? In addition, the Department states that the underlying statutes of the proposed rule permits entities to deny help to anyone who is likely to make a referral for an abortion or for other services.[131] The breadth and vagueness of this definition will possibly lead providers to refrain from providing information vital to patients out of anxiety and confusion of what the proposed rule permits them to do.

d. Health Care Entity

The proposed rule's definition of "health care entity" conflicts with federal religious refusal laws such as the Coats and Weldon Amendments, thus fostering confusion regarding which entities are required to comply with the proposed rule and existing federal religious refusals. Specifically, under the Coats and Weldon Amendments a “health care entity” is defined to encompass a limited and specific range of individuals and entities involved in health care delivery. Under the proposed rule, a plan sponsor “not primarily engaged in the business of health care” would be deemed a “health care entity.”[132] This definition would mean that an employer acting as a third party administrator or sponsor could count as a “health care entity” and deny coverage. In 2016, OCR found that religiously affiliated employers were not health care entities under the Weldon amendment.[133]

Moreover, the Department states that their definition of “health care entity” is “not an exhaustive list” for concern that the Department would “inadvertently omit[ting] certain types of health care professionals or health care personnel.”[134] Additionally, the proposed rule incorporates entities as defined in 1 U.S.C. 1 which includes corporations, firms, societies, etc.[135] States and public agencies and institutions are also deemed to be entities.[136] The Department’s inclusion of entities who are primarily not engaged in the health care delivery system highlights the true purpose of the proposed rule, to permit a greater number of entities to interfere in the provider-patient relationship and deter a patient from making the best decision based on their circumstances, preferences, and beliefs.

[131] *Id.* at 3895.
[132] *Id.* at 3893.
[133] Office for Civil Rights, Decision Re: OCR Transaction Numbers: 14-193604, 15-193782 & 15-195665, 4 (Jun. 21, 2016) (letter on file with NHeLP-DC office).
[134] 83 Fed. Reg. 3893.
[135] *Id.*
[136] *Id.*

X. The Department failed to follow procedural requirements

This proposed rule suffers from a number of additional inadequacies, including:

- The Department fails to provide "adequate reasons" or a "satisfactory explanation" for this rulemaking based on the underlying facts and data. Under the Administrative Procedures Act, an agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the fact found and the choice made."[137] As stated in the proposed rule, between 2008 and November 2016, OCR received 10 complaints alleging violations of federal religious refusal laws; OCR received an additional 34 similar complaints between November 2016 and January 2018.[138] By comparison, during a similar time period from fall 2016 to fall 2017, OCR received *over 30,000 complaints* alleging either civil rights or HIPAA violations. These numbers demonstrate that rulemaking to enhance enforcement authority over religious refusal laws is not warranted.

- The Department fails to adequately assess the costs imposed by this proposed rule, including both underestimating quantifiable costs, and completely neglecting to address the costs that would result from delayed or denied care. Under Executive Order 13563, an agency must "tailor its regulations to impose the least burden on society" and choose "approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)."[139] The Department completely neglects to address the costs that would result from delayed or denied care. This proposed rule completely fails to account for increased medical and social costs that come from delayed or denied care. Health care refusals without adequate safeguards may also have negative consequences on the long-term socioeconomic status of women. A recent study in the American Journal of Public Health found that women who were denied a wanted abortion were three times more likely to be unemployed than women who obtained abortions.[140] Thus, the health care refusals that may increase because of this rule could lead to delays or effective denials of care that would not only affect women's immediate health costs but also have fundamental negative consequences in the long term—factors that the Department completely fails to acknowledge or take into account in this proposed rule.

- The Department and Office of Management and Budget ("OMB") have failed to take the appropriate steps to ensure that the regulation does not conflict with the policies or actions of other agencies. Under Executive Order 12866, in order to ensure that each agency does not promulgate regulations that are "inconsistent, incompatible, or

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[137] *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2125 (June 20, 2016) (citing *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 103 (1983)).
[138] 83 Fed. Reg. 3886.
[139] Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Sec. 1 (b).
[140] Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. H. 407 (2018), http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304247.

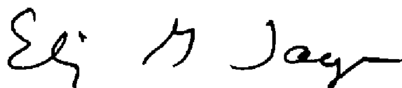
duplicative with its other regulations of those of other Federal agencies," each agency must include any significant regulatory actions in the Unified Regulatory Agenda.[141] The Department failed to include any reference to this significant regulation in its regulatory plans, and therefore failed to put impacted entities, including other federal agencies, on notice of possible rulemaking in this area. In addition, prior to publication in the Federal Register, the proposed rule must be submitted to the Office of Information and Regulatory Affairs (OIRA), within the OMB, to provide "meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order [12866] and do not conflict with the policies or actions of another agency."[142] According to OIRA's website, the Department submitted the proposed rule to OIRA for review on January 12, 2018, one week prior to the proposed rule being issued in the Federal Register. Standard review time for OIRA is often between 45 and 90 days. One week was plainly insufficient time for OIRA to review the rule, including evaluating the paperwork burdens associated with implementing this proposed rule. In addition, it is extremely unlikely that within that one-week timeframe, OIRA could or would have conducted the interagency review necessary to ensure that this proposed rule does not conflict with other federal statutes or regulations.

Conclusion

The National Health Law Program opposes the proposed rule as it expands religious refusals to the detriment of patients' health and well-being. We are concerned that these regulations, if implemented, will interfere in the patient-provider relationship by undermining informed consent. The proposed rule will allow any one in the health care setting to refuse health care that is evidence-based and informed by the highest standards of medical care. The outcome of this regulation will harm communities who already lack access to care and endure discrimination.

Thank you for your attention to our comments. If you have any questions, please reach out to Susan Berke Fogel, Director of Reproductive Health, at fogel@healthlaw.org.

Sincerely,



Elizabeth G. Taylor
Executive Director

[141] Executive Order 12866, at § 4(b),(c).
[142] *Id.* at § 6(b).

Exhibit 18

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

March 26, 2018

U.S. Department of Health and Human Services, Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, D.C. 20201

The Washington State Department of Health (DOH) appreciates the opportunity to comment on the proposed rule, “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,” printed in the Federal Register on January 26, 2018 (83 FR 3880). We are specifically responding to the request for feedback on the rule’s potential to improve or worsen health outcomes.

The proposed rule significantly broadens the criteria by which people or entities can claim conscience objections to deny patients care, the types of entities that must accommodate their employees’ or volunteers’ objections, and the types of activities to which an entity can object. This threatens to directly reduce access to essential health care services, especially for vulnerable populations—including those living in rural areas—and thereby worsen health outcomes. In addition, the proposed rule conflicts with program requirements in existing successful HHS programs (e.g., immunizations and family planning) that have been shown to improve outcomes. This change will jeopardize the integrity of and funding for these programs. This would further reduce access to care and lead to poorer health outcomes and wider inequities.

The proposed rule does not appropriately balance the conscience rights of providers with health outcomes of their patients or the public health system’s role to ensure access to health care services for *all* people.

For these reasons, we recommend HHS withdraw the proposed rule.

If not withdrawn, we strongly urge HHS to revise the language to:

- Allow entities, including states, health systems, clinics, providers, and insurers, to consider significant public health concerns, such as patient access to care, when managing conscience objections.
- Remove requirements for accommodations when they directly conflict with the statutory requirements of HHS programs as determined by the U.S. Congress.

The rule proposes definitions that broaden the type of entity who can claim a conscience objection and the types of activities for which a moral or religious objection could be made, including referrals. The proposed definitions for “assist in the performance,” “health care entity,”

and "referral/refer for," taken in conjunction with one another, significantly broaden the number of entities or persons who have a basis to file a complaint and will lead to significant unintended consequences.

First, the broadening of these definitions will make it difficult for some organizations to manage conscience objections without harming their business operations. Small clinics cannot afford multiple schedulers, billers, or assistants who may raise moral or religious objections, which previously were accommodated only for healthcare providers.

It is also our expectation these expanded definitions would create substantial gaps in access to preventive services and limit referrals to services that are provided elsewhere. These gaps could be especially harmful for vulnerable populations such as women and families with low incomes; people who are lesbian, gay, bisexual, or transgender (LGBT); people of color; and people living in rural or otherwise underserved areas. While 20 percent of the population lives in rural areas, less than 10 percent of physicians practice in rural areas. As a result, many individuals across the U.S. already have limited options to receive medical care, including preventive services such as family planning or vaccinations. If the only provider in an area does not administer vaccines because it is against his or her personal religious beliefs, for example, entire communities could be left vulnerable to devastating infectious diseases. Similarly, all women in a given community could find themselves without access to contraception or other reproductive health care if the only provider in the area asserts moral or religious objections.

Finally, the broadening of these definitions may create confusion or be interpreted in a way that facilitates discrimination against women, low-income individuals, LGBT people, or people of color, under the guise of a conscience objection. These groups already face barriers to care and experience health inequities. The proposed rule could further decrease their access to necessary health care and worsen health outcomes and disparities. This clearly runs counter to the mission of HHS "to enhance and protect the health and well-being of all Americans," and it neglects the responsibility of our public health system to ensure access to quality health services.

The proposed rule conflicts with existing requirements in HHS programs.

Definitions in the proposed rule allow for refusals that conflict with the requirements of some existing HHS programs. These programs have a documented history of providing quality preventive health care services, improving health outcomes, and saving costs. This proposed rule will jeopardize the integrity and continued success of these programs, funding for them, and the delivery of the quality services they provide.

- The Vaccines for Children program requires participating healthcare providers to offer all routinely recommended vaccines to eligible at-risk children (42 USC 1396s(c)(2)(B)(i)). Under this proposed rule change, a person or entity may object to administering a vaccine. States and health care providers may struggle to comply with federal requirements for at-risk children to access and receive the recommended standard-of-care vaccines, because of an expanded number and basis for conscience objections.

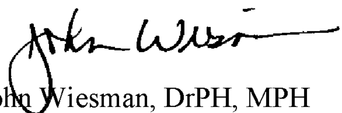
- The Title X family planning projects are designed to "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59.1). The Title X statute specifically requires that "all pregnancy counseling shall be nondirective" (Public Law 112-74, p. 1066-1067), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)).

The proposed rule protects individuals and entities who refuse to provide some essential services or provide complete information about all of a woman's pregnancy options. The proposed rule could force the Washington State Department of Health and Title X sub-recipients to choose between violating the Title X requirements or violating the proposed rule.

The Emergency Medical Treatment and Active Labor Act (EMTALA) requires emergency department to provide emergency treatment to *anyone* seeking treatment. The proposed rule could potentially conflict with EMTALA statutory requirements. For example, a hospital or provider could decline service to a woman with possible complications following an abortion. These proposed rules could jeopardize patient lives.

Preserving religious freedom in the U.S. is important, and so is our responsibility as government leaders to ensure access to health care services for all people. Existing laws have sought to preserve balance between conscience objections based on sincerely held religious beliefs and moral convictions, and the needs of patients and the public health. It is imperative to the nation's health and well-being that this rule does the same. Unfortunately, the rule as written fails to strike an appropriate balance, clearly placing the health of patients and the public at risk. I urge you to withdraw it.

Sincerely,



John Wiesman, DrPH, MPH
Secretary of Health

Exhibit 19

National
Family Planning
& Reproductive Health Association

March 27, 2018

US Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Attn: Protecting Statutory Conscience Rights in Health Care NPRM, RIN 0945-ZA03

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to provide comments on the US Department of Health and Human Services' (HHS) notice of proposed rulemaking (NPRM), "Protecting Statutory Conscience Rights in Health Care," RIN 0945-ZA03.

NFPRHA is a national membership organization representing the nation's publicly funded family planning providers, including nurse practitioners, nurses, administrators, and other key health care professionals. NFPRHA's members operate or fund a network of more than 3,500 health centers and service sites that provide high-quality family planning and other preventive health services to millions of low-income, uninsured, or underinsured individuals in 50 states and the District of Columbia. Services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers and other private nonprofit organizations.

NFPRHA is deeply concerned that this NPRM ignores the needs of the patients and individuals served by HHS' programs and creates confusion about the rights and responsibilities of health care providers and entities. Because they receive Title X, Medicaid, and other HHS funds, NFPRHA members would have no choice but to comply with this rule: failure to do so could lead to termination of current or pending HHS funds, as well as return of money previously paid to NFPRHA members for services they have provided. This means hundreds of millions of dollars in federal funding are at stake for NFPRHA members if they run afoul of the rule. Without federal support, many of our members would be forced to drastically scale back the services they provide to their patients or to close completely. Because NFPRHA members represent the vast majority of Title X clinical locations that serve people who cannot afford to pay for health care on their own, this would leave many low-income and uninsured or under-insured patients without access to family planning and other critical health care services.

Although this NPRM claims the authority to interpret numerous statutes of concern and interest, NFPRHA will limit its comments primarily to the unjustified and unauthorized expansion of the Church amendments (42 USC 300a-7), Coats-Snowe amendment (42 USC 238n), and Weldon amendment (e.g. Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d)) (together, "Federal health care refusal statutes"). Because this NPRM encourages unprecedented discrimination against patients and opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program, it should be withdrawn.

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Background on the 2008 Health Care Refusal Regulations

In the decades-long history of the federal health care refusal statutes, none of which delegate rulemaking authority to HHS, regulations purporting to clarify and interpret these laws have been promulgated only once, in late 2008.

In 2008, HHS promulgated an NPRM purporting to interpret and enforce the federal health care refusal statutes claiming "concern…that there is a lack of knowledge on the part of States, local governments, and the health care industry" of the refusal rights contained within these statutes. (73 Fed. Reg. at 50, 278). Despite allowing only a 30-day comment period, HHS received more than 200,000 comments in response to the proposed rule—the vast majority of which opposed the rule as unnecessary, unauthorized, and overbroad.[1] Notably, HHS conceded, it received "no Comments indicating that there were any [federal] funding recipients not currently compliant with [the underlying statutes]" (73 Fed. Reg. at 78,095). HHS published a final rule on December 19, 2008, which did not materially differ from the NPRM and was immediately subject to legal challenge by multiple parties, including NFPRHA and seven state attorneys general.[2]

In 2011, HHS rescinded those aspects of the 2008 rule that were "unclear and potentially overbroad in scope," but maintained those parts of the rule establishing an enforcement process for the Federal health care refusal statutes and began an "initiative designed to increase the awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been violated." (76 Fed. Reg. at 9969). This rule remains in effect.

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[1] Comments to Provider Conscience Regulations, 73 Fed. Reg. 50274 (August 26, 2008) (to be codified at 45 CFR 88).

[2] *National Family Planning and Reproductive Health Association et al v. Leavitt*, No. 09-cv-00055 (Dist. Conn. Jan. 15, 2009) *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009); *Planned Parenthood Federation of America v. Leavitt*, No. 09-cv-00057 (Dist. Conn. Jan. 15, 2009); *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009).

According to the current NPRM, since 2008, "OCR [Office for Civil Rights] has received a total of forty-four complaints [related to Federal health care refusal laws], the large majority of which (thirty-four) were filed since the November 2016 election." (83 Fed. Reg. at 3886). To place that figure into context, OCR in total received approximately 30,166 complaints in fiscal year (FY) 2017.

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The NPRM overstates statutory authority and seeks to dramatically expand the reach of the underlying statutes.

For decades, federal health care refusal statutes have given specified individuals and institutions certain rights to refuse to perform, assist in the performance, and/or refer for abortion and/or sterilization services. Despite the lack of a congressional mandate to do so, the NPRM seeks to dramatically expand the scope and reach of these laws, as well as grant overall responsibility for ensuring and enforcing compliance with those statutes to OCR, using identical language to many aspects of the now-rescinded 2008 regulation that faced widespread opposition at that time.[3]

The Church amendments were enacted by Congress in the 1970s in response to debates about whether the receipt of federal funds required recipients to provide abortion or sterilization services. These provisions make clear, among other things, that:

- The receipt of federal funding under the Public Health Service Act (PHSA) (42 U.S.C. § 201 et seq.) does not itself obligate any individual to perform or assist in the performance of sterilization or abortion procedures if those procedures are contrary to the individual's religious or moral beliefs (Church (b)(1)); and,
- Health care personnel employed by certain federally funded programs and facilities cannot be discriminated against in terms of employment, promotion, or the extension of staff or other privileges for performing or assisting in the performance of sterilization or abortion services, or refusing to perform or assist in the performance of such services based on their religious or moral beliefs (Church (c)(1)).

In 1996, Congress adopted the Coats amendment in response to a decision by the accrediting body for graduate medical education to require OB/GYN residency programs to provide or permit abortion training. The Coats amendment prohibits federal, state, and local governments from discriminating against health care entities, such as "individual physicians, postgraduate physician training programs, or . . . participant[s] in a program of training in the health profession," that refuse to provide or require training in abortions or individuals who refuse to be trained to provide abortions.

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[3] Comment of the National Family Planning & Reproductive Health Association to Provider Conscience Regulations, Tracking Number 8072403d to 73 Fed. Reg. 50274 (proposed August 26, 2008) (comment dated September 25, 2008) (to be codified at 45 CFR 88).

Since 2004, Congress has attached the Weldon amendment to the annual appropriations measure that funds the Departments of Labor, Health and Human Services, and Education (Labor-HHS). That amendment prohibits federal agencies and programs and state and local governments that receive money under the Labor-HHS Appropriations Act from discriminating against individuals, health care facilities, insurance plans, and other entities because they refuse to provide, pay for, provide coverage of, or refer for abortion.

The Church, Coats-Snowe, and Weldon amendments were never intended to provide individual health care providers and/or entities with the myriad and expansive rights of refusal this NPRM seeks to achieve. Without statutory authorization, the NPRM expands the reach of the Church, Coats-Snowe, and Weldon Amendment beyond what was contemplated by Congress and is permitted by existing federal law, by expanding the categories of individuals and entities whose refusals to provide information and services are protected; expanding the types of services that individuals and entities are allowed to refuse to provide; and expanding the types of entities that are required to accept such refusals. For example:

- Despite the plain language of the Weldon amendment, the NPRM attempts to extend it to apply to funding beyond that appropriated by Labor-HHS appropriations and to non-governmental entities, as well. The statute of the Weldon amendment states:

  > "(1) None of the funds ***made available in this Act*** may be made available to ***a Federal agency or program, or to a State or local government***, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

  Yet § 88.3(c) of the NPRM adds new language that applies the Weldon amendment's prohibitions not only to federal agencies and programs and state and local governments that receive Labor-HHS funds, but also to "***[a]ny entity that receives funds through a program administered by the Secretary or under an appropriations act for the Department that contains the Weldon amendment***" [emphasis added].

  This language broadens Weldon's reach in two impermissible ways: 1) it extends the restrictions to entities that do not even receive funding via Labor-HHS appropriations, to apply to funding through any program administered by HHS; and, 2) it applies the restrictions of the Weldon amendment beyond the statutory reach of federal agencies or programs, or state or local governments, to any entity receiving certain federal funds. These extensions of Weldon's reach are clearly contrary to both the plain language of the Weldon amendment and to congressional intent.

- While the Church amendment prevents PHSA funds from being used to require individuals and institutions to, among other things, "assist in the performance" of abortions and sterilizations, and prevents employment discrimination against those who refuse to do so, § 88.3 of the NPRM

transforms this statutory shield into a sword, creating out of whole cloth a categorical right of refusal for any recipient of PHSA funds. Moreover, § 88.2 of the NPRM provides an unprecedentedly and unjustifiably broad definition of the term "assist in the performance" that runs counter to congressional intent and common sense. The NPRM would define "assist in the performance" as participating "in ***any activity*** with an ***articulable connection*** to a procedure, health service or health service program, or research activity" [emphasis added]. In other words, HHS proposes to create refusal rights for anyone who can ***simply express a connection*** between something they do not want to do and an abortion or sterilization procedure (e.g., scheduling appointments, processing payments, or treating complications). Even the sole instance of previous rulemaking under the Church amendments in 2008, which was rescinded before it ever took effect, was not so broad.

- Likewise, the NPRM's definition of referral/refer seeks to dramatically expand the scope and reach of the Coats-Snowe and Weldon amendments and runs counter to congressional intent and common sense. Section 88.2 of the NPRM defines "referral/refer for" abortion to include:

> "the provision of any information (including but not limited to name, address, phone number, email, website, instructions, or description) by any method (including but not limited to notices, books, disclaimers, or pamphlets, online or in print), pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."

This definition would impair the ability of health care professionals to fulfill their legal and ethical duties of providing complete, accurate, and unbiased information to their patients. For example, as discussed further below, the NPRM could be read to permit employees of Title X-funded health centers and other federally funded entities to refuse to provide information and referrals to patients, without ever addressing patient needs and in clear violation of the fundamental tenets of informed consent.

As interpreted by the NPRM, the Church, Coats-Snowe, and Weldon amendments would be radically expanded to create far-reaching protections for individuals and entities that would refuse to provide patients not only with health care services, but also the most basic information about their medical options and that seek to obstruct the ability of certain patients to access any care at all. This is impermissible and, as discussed below, would cause unprecedented harm to patients and undermine the integrity of key HHS programs.

This NPRM goes beyond HHS' statutory authority and should be withdrawn. If HHS promulgates a final rule, however, it must identify the source of its legal authority, if any at all, to promulgate these regulations and to alter and expand the meaning of the statutory language.

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The NPRM attempts to grant OCR oversight authority and enforcement discretion that is overly broad and vague; unduly punitive; and ripe for abuse.

While some of the investigative authority and enforcement powers of the current NPRM appear to comport with similar provisions in other areas subject to OCR oversight and enforcement authority, the NPRM 1) includes new, troubling provisions that are vague, overly broad, and overly punitive; and 2) as a whole, appear to impart in OCR authority and enforcement discretion that is ripe for abuse.

Indeed, while the NPRM claims to "borrow...from enforcement mechanisms already available to OCR to enforce similar civil rights laws," the NPRM contains troubling differences. For example, the NPRM states that investigations may be based on anything from 3rd party-complaints to news reports, and yet at the same time appears to give OCR the authority to withhold federal financial assistance and suspend award activities, based on "threatened violations" alone, without first allowing for the completion of an informal resolution process. (See 83 Fed. Reg. at 3891, 3930-31). By contrast, the Department of Justice (DOJ) regulations implementing Title VI of the Civil Rights Act of 1964 (prohibiting discrimination on the basis of race in federally funded programs) state that DOJ will not take such drastic steps to respond to actual or threatened violations unless noncompliance cannot first be corrected by informal means. (See 28 C.F.R. § 42.108(a)). When combined with other aspects of the NPRM, concern over the breadth and potential harm of such provisions is obvious and legitimate. For instance:

- Under § 88.6, the NPRM includes a 5-year reporting requirement that requires any recipient or sub-recipient subject to an OCR compliance review, investigation, or complaint related to the health care refusal rules to inform any current HHS "funding component" of the review/investigation/complaint, as well as to disclose that information in any application for new or renewed "Federal financial assistance or Departmental funding." Once again, this is distinct from the DOJ regulations enforcing Title VI, which only require disclosure of compliance reviews (not every investigation or complaint, regardless of whether it is unfounded) over the past two years. (28 C.F.R. § 42.406(3)). Yet the NPRM fails to explain the purpose of the vastly expanded reporting requirement and period. In light of the broad investigative authority and harsh penalties described above, this leaves affected entities with significant concern about how such information is intended to be used and whether it will unfairly prejudice consideration of applicants for federal funds or penalize currently funded entities in ways that could be extremely harmful.

The NPRM also includes very troubling language that appears to be little more than a pretext for defunding entire classes of providers, which it cannot do. The preamble text accompanying § 88.7

states, “The Director may, in coordination with a relevant Department component, restrict funds for noncompliant entities in whole or in part, including by ***limiting funds to certain programs and particular covered entities, or by restricting a broader range of funds or broader categories of covered entities***” [emphasis added]. This delegation of authority is not only far beyond the scope of the underlying laws but seems designed to grant arbitrary authority that is ripe for abuse, with no mechanism of due process or oversight to prevent entire categories of providers or programs from being penalized without cause. To the extent § 88.7 seeks to create a back door to excluding certain family planning providers from the Title X and Medicaid programs—efforts that have been repeatedly rejected by the courts—it, again, exceeds the scope of the agency’s authority and will do nothing more than harm the health and well-being of patients.

Given the lack of evidence that the system currently in place cannot adequately handle complaints, as well as any sufficient justification for departing from the processes used to ensure compliance with other federal statutes, HHS must, at a minimum, adequately explain the reason for these changes, what safeguards exist to prevent abuse, and demonstrate that this language is not simply a pretext for unlawfully excluding certain categories of providers from participating in federally funded programs.

***

The NPRM opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program.

The NPRM ignores the reality that some individuals and entities are opposed to the essential health services that are the foundation of longstanding, critical HHS programs like Title X. In the arena of health care, and particularly family planning and sexual health, HHS-funded programs cannot achieve their fundamental, statutory objectives if grantees, providers, and contractors have a categorical right to refuse to provide essential services, such as non-directive pregnancy options counseling.

The Title X family planning program was created by Congress in 1970 “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” (42 USC 300). Title X projects are designed to “consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children” (42 CFR 59).

In 2014, more than 20.2 million women in the United States were in need of publicly funded contraceptive services. Women in need of publicly funded family planning services is defined as follows: “1) they were sexually active (estimated as those who have ever had voluntary vaginal intercourse, 2) they were able to conceive (neither they nor their partner had been contraceptively sterilized, and they did not believe they were infecund for any other reason); 3) they were neither intentionally pregnant nor trying to become pregnant; and, 4) they have a family income below 250% of the federal poverty level. In addition, all women younger than 20 who need contraceptive services, regardless of their family income are assumed to need publicly funded care because of their heightened need—for reasons of

confidentiality—to obtain care without depending on their family's resources or private insurance."[4] In the face of this widespread need, publicly funded family planning and sexual health care provides a crucial safety net for women and families. The impact of these services cannot be underestimated. Without publicly funded family planning services, there would be 67% more unintended pregnancies (1.9 million more) annually than currently occur.[5]

Congress has specifically required that "all pregnancy counseling shall be non-directive" (Public Law 110-161, p. 327), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)). Despite the incredible success of the Title X program and the critical services it provides, Title X has been chronically underfunded, with no new service dollars allocated in nearly a decade. It is a testament to the dedication of the existing Title X network to meeting the goals of the program that, despite limited resources, these providers still serve more than four million patients per year.[6]

However, in addition to the overly broad definitions of "referral" and "assist in the performance" discussed above, by proposing a definition of "discrimination" that appears to jettison the longstanding framework that balances individual conscience rights with the ability of health care entities to continue to provide essential services to their patients, the NPRM seems designed to allow entities that refuse to provide women with the basic information, options counseling, and referrals required by law to compete on the same footing for federal money with family planning providers who adhere to the law and provide full and accurate information and services to patients. The NPRM thus threatens to divert scarce family planning resources away from entities that provide comprehensive family planning services to organizations that refuse to provide basic family planning and sexual health care services. Diverting funds away from providers offering the full range of family planning and sexual health services would not only seriously undermine public health, especially for the low-income, uninsured, and under-insured, but would also be contrary to congressional intent and explicit statutory requirements of the Title X family planning program.

The NPRM likewise creates confusion about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. To the extent that the rule seeks to immunize subrecipients who refuse to provide essential services and complete information about all of a woman's pregnancy options, it undermines the very foundation of the Title X program and the health of the patients who rely on it.

In addition to potential issues with the selection of grantees and subrecipients, the proposed definition of "discrimination" also poses significant employment issues for all Title X-funded health centers. As

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[4] Jennifer Frost et al, *Contraceptive Needs and Services, 2014 Update* (New York: Guttmacher Institute, 2016).
[5] Jennifer Frost et al, *Publicly Funded Contraceptive Services at U.S. Clinics, 2015* (New York: Guttmacher Institute, April 2017).
[6] Christina Fowler, *Family Planning Annual Report: 2016 national summary* (Research Triangle Park, NC: RTI International, 2017).

discussed further below, the language in the NPRM could put Title X-funded health centers in the position of being forced to hire people who intend to refuse to perform essential elements of a position. For example, the rule provides no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the individual refuses to provide non-directive options counseling. Furthermore, the NPRM does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician out of the health department's family planning project to a unit where pregnancy counseling is not done.

Because the NPRM threatens to undermine the integrity of key HHS programs, including the Title X family planning program, HHS must, at a minimum, clarify that any final rule does not conflict with preexisting legal requirements for and obligations of participants in the Title X program, or of employers, as set forth under Title VII of the Civil Rights Act of 1964, discussed below.

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The NPRM fails to sufficiently address patient needs or achieve the careful balance struck by existing civil rights laws and encourages unprecedented discrimination against patients that will likely impede their access to care and harm their health.

The stated mission of HHS is "to enhance and protect the health and well-being of all Americans." Yet, the NPRM elevates the religious and moral objections of health care providers over the health care needs of the patients who HHS is obligated to protect. The NPRM appears to allow individuals to refuse to provide health care services or information about available health care services to which they object on religious or moral grounds, with virtually no mention of the needs of the patient who is turned away. Patients should not be forced to bear the brunt of the objector's religious or moral beliefs, particularly to the detriment of their own health. In fact, legal and ethical principles of informed consent require health care providers to tell their patients about all of their treatment options, including those the provider does not offer or favor, so long as they are supported by respected medical opinion. As such, health care professionals must endeavor to give their patients complete and accurate information about the services available to them.

Furthermore, the NPRM fails to address serious questions as to whether its purpose is to upset the careful balance struck in current federal law between respecting employee's religious and moral beliefs and employers' ability to provide their patients with health care services. Title VII provides a balance between health care employers' obligations to accommodate their employees' religious beliefs and practices (including their refusal to participate in specific health care services to which they have religious objection) with the needs of the patients they serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs, unless doing so places an "undue hardship" on the employer. This law provides protection for individual belief while still ensuring patient access to health care services. The NPRM provides no guidance about how, if at all, health care

employers are permitted to consider patients' needs when faced with an employee's refusal to provide services.

The NPRM ignores the needs of patients and fails to consider whether an employer can accommodate such a refusal without undue hardship. In so doing, the NPRM invites health care professionals to violate their legal and ethical duties of providing complete, accurate, and unbiased information necessary to obtain informed consent. The failure of health care professionals to provide such information threatens patients' autonomy and their ability to make informed health care decisions.

Title VII is an appropriate standard that protects the needs of patients and strikes an appropriate balance. At a minimum, HHS should clarify that any final rule does not conflict with Title VII.

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The NPRM vastly underestimates the financial burden it would impose on federally funded health care providers who already operate with limited resources.

NFPRHA is particularly well positioned to comment upon the extremely burdensome effect the NPRM will have on the variety of public and private entities awarded federal dollars to provide health services to underserved communities.

As an initial matter, for a non-lawyer to simply read and understand the regulatory language and the lengthy preamble of the NPRM requires numerous hours – much longer than the roughly "10 minutes per law" estimated by HHS. (See 83 Fed. Reg. at 3913). A Final Rule, which would respond to prior comments and provide explanation and commentary elaborating on the Regulation, would require the same at minimum. Moreover, given the magnitude of funds at stake, the complexity and ambiguity of the NPRM's employment provisions, and the diverse staffing arrangements among recipients of federal funds, many NFPRHA members will need to pay for the time of legal counsel to review and consult with them on how to adjust their policies and practices prior to certifying compliance. This will also require time and cost for legal counsel to research and advise how, or if, it is possible for an entity to achieve compliance with the rule as well as with potentially conflicting obligations under State or other Federal laws. A reasonable estimate of these tasks alone would include at least several hours of attorney as well as multiple hours of executive and management staff time – not just the average of 4 hours (total) per year of lawyer and staff time estimated by HHS. (See 83 Fed. Reg. at 3913).

In particular, it appears that policies and practices to comply with the Department's articulated standard will be different than those necessary to comply with existing federal laws such as Title VII. Thus, in estimating an average of 4 hours (total) per year to update policies and procedures *and* retrain staff (see 83 Fed. Reg. at 3913), the NPRM utterly fails to account for:

- Time and cost for legal and human resources or executive staff to review and revise job postings, job descriptions, job application materials, interview and hiring policies and practices, and other employment recruitment and hiring materials.

- Time and cost for legal and human resources or executive staff to review and revise employee manuals and handbooks, and other employment related policies and documents.

- Time and cost to devise and provide trainings for managers and other supervisory staff on interviewing, hiring, and responding to accommodation requests from employees and volunteers who object to participating in the provision of certain health care services.

- Time and cost of hiring and training additional employees and/or paying and retraining existing employees for additional hours to accommodate other employees who refuse to provide services.

While these comments do not attempt to identify and detail each of the likely costs that NFPRHA members and other regulated entities would face if the NPRM was finalized, they demonstrate the qualitatively and quantitatively substantial costs overlooked by HHS in its NPRM. In light of these burdens and the HHS's inability to demonstrate a countervailing need for the rule, NFPRHA strongly urges HHS to withdraw the NPRM. Failure to do so will result in substantial resources being diverted away from providing critical health care to patients in an already underfunded family planning safety net.

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NFPRHA appreciates the opportunity to comment on the NPRM, "Protecting Statutory Conscience Rights in Health Care." If you require additional information about the issues raised in these comments, please contact Robin Summers at rsummers@nfprha.org or 202-552-0150.

Sincerely,

Clare Coleman
President & CEO

Exhibit 20

NATIONAL CENTER FOR LESBIAN RIGHTS

WASHINGTON DC OFFICE
1776 K Street NW, Suite 852
Washington, D.C. 20006

March 26, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Protecting Statutory Conscience Rights in Health Care (RIN 0945-ZA03)

The National Center for Lesbian Rights (NCLR) writes to urge that the above-referenced Proposed Rule be withdrawn in its entirety, as it would endanger patient health and encourage widespread discrimination in health care delivery.

NCLR is a non-profit, public interest law firm that litigates precedent-setting cases at the trial and appellate court levels, advocates for equitable public policies affecting the lesbian, gay, bisexual, and transgender (LGBT) community, provides free legal assistance to LGBT people and their advocates, and conducts community education on LGBT issues. NCLR has been advancing the civil and human rights of LGBT people and their families across the United States through litigation, legislation, policy, and public education since its founding in 1977. We also seek to empower individuals and communities to assert their own legal rights and to increase public support for LGBT equality through community and public education. NCLR recognizes the critical importance of access to affordable health care for all people, and is concerned about the increasing use of religious exemptions to undercut civil rights protections and access to services for our community.

Our overarching objections to this Proposed Rule are twofold. First, it strays far from the primary mission of the Department of Health & Human Services. Our nation's premier public health agency should always maintain a focus on protecting the health of all, rather than seeking to empower health care providers to withhold care, in contravention of the core principles of informed consent and adherence to accepted standard of care. Second, it exceeds the agency's authority and was promulgated in violation of the Administrative Procedure Act. We provide further detail below.

I. The Proposed Rule disregards HHS's core mission

The Proposed Rule disregards the health care needs of patients and the core mission of the Department of Health & Human Services (HHS). The purpose of our nation's health care delivery system is to deliver health care to the people of this country. As the nation's largest public health agency, and one that is charged with furthering the health of all Americans, HHS is primarily charged with assisting patients in accessing care and health care providers in

delivering high-quality, culturally-competent care to everyone. Access to care, rather than denials of care, should be the goal. This Proposed Rule, in addition to being on questionable legal ground, focuses exclusively on purported rights of health care providers to turn patients away, with virtually no mention of the impact on patient health and well-being or on how access to care will be ensured. The priorities reflected in the Rule represent a sharp departure from the missions of HHS and its Office for Civil Rights (OCR) and should be withdrawn.

A. HHS should be trying to broaden access, not encourage denials of care

The HHS web site states: "It is the mission of the U.S. Department of Health & Human Services (HHS) to enhance and protect the health and well-being of all Americans. We fulfill that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services" (emphasis added).[1] The Proposed Rule departs significantly from that vision as well as the Office for Civil Rights (OCR's) mission to address health disparities and discrimination that harm patients.[2] Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended, proposing a regulatory scheme that would be affirmatively harmful to many patients seeking care.

HHS, through OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[3] If finalized, however, the Proposed Rule will undermine HHS's mission of combating discrimination, protecting patient access to care, and eliminating health disparities. Through enforcement of civil rights laws, OCR has in the past worked to reduce discrimination in health care by ending discriminatory practices such as segregation in health care facilities based on race or disability, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[4]

[1] *See* https://www.hhs.gov/about/index.html.

[2] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[3] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity, which would eventually become OCR, would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws, including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has in the past worked to reduce discrimination in health care.

[4] *See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy*

Despite this past progress, there is still much work to be done, and the Proposed Rule would divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[5] Black women are three to four times more likely than are white women to die during or after childbirth.[6] And the disparity in maternal mortality is growing rather than decreasing,[7] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resultant health disparities. Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care (we discuss this further below).

There is an urgent need for OCR to address these disparities, yet the Proposed Rule seeks instead to prioritize the expansion of existing religious refusal laws beyond their statutory requirements to create new religious exemptions. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.

B. The evidence does not support the existence of the problem the Proposed Rule purports to address

Rather than focusing on the overarching aim of ensuring that all people in this country have access to the health care they need, the Proposed Rule seeks to empower health care providers, whose very jobs are to deliver health care, to instead deny not only health care services but even information about services to which they might personally object. It would create additional barriers to care in a health care system already replete with obstacles, particularly for people with limited incomes or those who are LGBT.

Through prior rulemaking in this area, HHS has already created mechanisms by which any provider who believes they have been subject to discrimination in violation of any of the federal health care refusal statutes may file a complaint with OCR and seek redress. Complaints have been filed and resolved through this process. And HHS has the ability to decline to fund entities that engage in violations of these laws. Individual health care providers who wish to exercise a conscientious objection to participating in certain health care services have the ability to do so and HHS, through OCR, already has the tools it needs to protect those rights. Rather than seeking to engage in a sweeping new rulemaking effort that would inappropriately

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Rights of People Living with HIV/AIDS, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[5] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[6] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

[7] *See id.*

shift the balance too far in the direction of care denial, the agency should instead devote its resources to expanding access to health care for all.

1. Discrimination against LGBT people in health care is pervasive

LGBT people, women, and other vulnerable groups already face significant barriers to getting the care they need.[8] The Proposed Rule will compound the barriers to care that LGBT individuals face, particularly the effects of ongoing and pervasive discrimination, by inviting providers to refuse to provide services and information vital to LGBT health.

As a civil rights organization that has been advocating for the LGBT community for over four decades, we at NCLR see firsthand the negative effects of stigma and discrimination on LGBT people seeking care. Despite significant gains in societal acceptance and legal protections, we still face hostility and ill treatment simply for being who we are, and sometimes the consequences are fatal. For example, NLCR currently represents the parents of a transgender youth who died by suicide after being denied appropriate care and discharged prematurely by a hospital in southern California.[9]

LGBT people of all ages continue to face discrimination in health care on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes that "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[10] This surfaces in a wide variety of contexts, including physical and mental health care services.[11] In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.[12] They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access.[13]

There is a growing body of research documenting how LGBT people encounter barriers in the health care system and suffer disproportionately from a variety of conditions due to health care

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[8] *See, e.g.,* Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care; Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), www.ustranssurvey.org/report; Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring.
[9] *See* http://www.nclrights.org/cases-and-policy/cases-and-advocacy/case-prescott-v-rchsd/.
[10] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).
[11] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.
[12] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.
[13] *Id.*

access issues compounded by stigma and discrimination. In 2010, Lambda Legal found that fifty-six percent of lesbian, gay, and bisexual survey respondents (out of 4,916 total respondents) experienced health-care discrimination in forms such as refusal of health care, excessive precautions used by health-care professionals, and physically rough or abusive behavior by health-care professionals. Seventy percent of transgender and gender nonconforming respondents experienced the same, and sixty-three percent of respondents living with HIV/AIDS had experienced health-care discrimination. In addition, low-income LGBT people and LGBT people of color experienced increased barriers to health care. Approximately seventeen percent of low-income lesbian, gay, and bisexual respondents and twenty-eight percent of low-income transgender respondents reported harsh language from health-care providers compared to under eleven percent of LGB respondents and twenty-one percent of transgender respondents, overall.[14] The 2015 U.S. Transgender Survey found that 23 percent respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[15]

A recent survey conducted by the Center for American Progress found that among lesbian, gay, bisexual, and queer (LGBQ) respondents who had visited a doctor or health care provider in the year before the survey:

- 8 percent said that a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation;
- 6 percent said that a doctor or other health care provider refused to give them health care related to their actual or perceived sexual orientation;
- 7 percent said that a doctor or other health care provider refused to recognize their family, including a child or a same-sex spouse or partner;
- 9 percent said that a doctor or other health care provider used harsh or abusive language when treating them;
- 7 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).[16]

Among transgender people who had visited a doctor or health care providers' office in the past year:

- 29 percent said a doctor or other health care provider refused to see them because of their actual or perceived gender identity;

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[14] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination against LGBT People and People with HIV*, 2010, https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isntcaring.pdf.

[15] NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey* 5 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.

[16] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

- 12 percent said a doctor or other health care provider refused to give them health care related to gender transition;
- 23 percent said a doctor or other health care provider intentionally used the wrong name;
- 21 percent said a doctor or other health care provider used harsh or abusive language when treating them;
- 29 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).[17]

When LGBT patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In the CAP study, nearly one in five LGBT people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBT people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[18] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

Health-care disparities in general are often more pronounced in rural areas in the United States, and this is further compounded for LGBT individuals, often due to a lack of cultural competency. This hinders physical and mental health providers from meeting the health needs of rural communities.[19] The lack of connection to positive, affirming resources also isolates LGBT youth, making them more susceptible to self-destructive behavior patterns.[20] Isolation continues into adulthood, when LGBT populations are more likely to experience depression and engage in high-risk behaviors.[21]

NCLR has been holding convenings of LGBT people in rural communities for the past several years, and we hear consistently about difficulties in accessing adequate health care. The challenges our community faces in these rural settings include having few providers with LGBT competency, difficulty maintaining health insurance coverage due to employment challenges, transportation difficulties to get to what medical providers there are, food deserts, and specific health conditions that are often more prevalent among LGBT people because of having to live with discrimination and social isolation, including poor eating habits, smoking, and substance abuse.

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[17] *Id.*

[18] *Id.*

[19] Cathleen E. Willging, Melina Salvador, and Miria Kano, "Pragmatic Help Seeking: How Sexual and Gender Minority Groups Access Mental Health Care in a Rural State," *Psychiatric Services* 57, no. 6 (June 2006): 871–4, http://doi.org/10.1176/ps.2006.57.6.871.

[20] Colleen S. Poon and Elizabeth M. Saewyc, "Out Yonder: Sexual-Minority Adolescents in Rural Communities in British Columbia," *American Journal of Public Health* 99, no. 1 (January 2009): 118–24, http://doi.org/10.2105/AJPH.2007.122945.

[21] Trish Williams et al., "Peer Victimization, Social Support, and Psychosocial Adjustment of Sexual Minority Adolescents," *Journal of Youth and Adolescence* 34, no. 5 (October 2005): 471–82, https://doi.org/10.1007/s10964-005-7264-x.

In rural areas, if care is denied for religious reasons, there may be no other sources of health and life-preserving medical care.[22] The ability to refuse care to patients would therefore leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state,[23] with over 75 percent of chief executive officers of rural hospitals reporting physician shortages.[24] Many rural communities experience a wide array of mental health, dental health, and primary care health professional shortages, leaving individuals in rural communities with less access to care that is close, affordable, and high quality, than their urban counterparts.[25]

In addition to geographic challenges, the problems for patients presented by the expansion of refusal provisions in both federal and state law have been exacerbated by the growth in health care systems owned and operated by religious orders. Mergers between Catholic and nonsectarian hospitals have continued as hospital consolidation has intensified. Catholic hospitals and health systems must follow the church's Ethical and Religious Directives for Catholic Health Care Services ("Directives"), which prohibit a wide range of reproductive health services, such as contraception, sterilization, abortion care, and other needed health care.[26] Nonsectarian hospitals must often agree to comply with these Directives in order to merge with Catholic hospitals.[27]

Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women's care was delayed or they were transferred to other facilities at great risk to their health.[28] The reach of this type of religious refusal of care is growing with the proliferation of religiously affiliated entities that provide health care and related services.[29] New research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than are white women to give birth in Catholic hospitals.[30]

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[22] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.
[23] Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA, (last visited Mar. 21, 2018).
[24] M. MacDowell et al., *A National View of Rural Health Workforce Issues in the USA,* 10 RURAL REMOTE HEALTH (2010), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/.
[25] Carol Jones et al., *Health Status and Health Care Access of Farm and Rural Populations,* ECON. RESEARCH SERV. (2009), *available at* https://www.ers.usda.gov/publications/pub-details/?pubid=44427.
[26] U.S. CONF. OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH SERVICES 25 (5th ed. 2009), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf.
[27] Elizabeth B. Deutsch, *Expanding Conscience, Shrinking Care: The Crisis in Access to Reproductive Care and the Affordable Care Act's Nondiscrimination Mandate*, 124 Yale L. J. 2470, 2488 (2015).
[28] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[29] *See, e.g., Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.
[30] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

Refusals in the context of reproductive health care sometimes run in both directions – they prevent access to contraception and abortion, but also to assisted reproductive technologies (ART) to enable pregnancy. Not only does this infringe on individuals' right to information and care, for those with certain medical conditions it directly contravenes the standard of care. For individuals with cancer, for example, the standard of care includes education and informed consent around fertility preservation, according to the American Society for Clinical Oncology and the Oncology Nursing Society.[31] Refusals to educate patients about or to provide ART, or to facilitate ART when requested, are contrary to the standard of care.

While religiously-based objections to contraception and abortion are well known and have posed access barriers for years, less evident is how these types of refusals can also affect the LGBT community. Not only are LGBT people affected by denials of reproductive health care, other types of medically necessary care, such a transition-related care, are also frequently refused.

Many religious health care providers are opposed to infertility treatments altogether or are opposed to providing it to certain groups of people such as members of the LGBT community.[32] Health care providers have even sought exemptions from state antidiscrimination laws to avoid providing reproductive services to lesbian parents.[33] For example, in one case, an infertility practice group subjected a woman to a year of invasive and costly treatments only to ultimately deny her the infertility treatment that she needed because she is a lesbian.[34] When doctors at the practice group recognized that the woman needed in vitro fertilization to become pregnant, every doctor in the practice refused, claiming that their religious beliefs prevented them from performing the procedure for a lesbian.[35] Because this was the only clinic covered by her health insurance plan, the woman had to pay out-of-pocket for the treatment at another clinic, which subjected her to serious financial harm.

The lack of clarity in the Proposed Rule could lead a hospital or an individual provider to refuse to provide ART to same-sex couples based on religious belief. For some couples, this

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[31] Alison W. Loren et al., *Fertility Preservation for Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update*, 31 J. CLINICAL ONCOLOGY 2500-10 (July 1, 2013); Ethics Committee of the American Society for Reproductive Medicine, *Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion*, 100 AM. SOC'Y REPROD. MED. 1224-31 (Nov. 2013), http://www.allianceforfertilitypreservation.org/_assets/pdf/ASRMGuidelines2014.pdf; Joanne Frankel Kelvin, *Fertility Preservation Before Cancer Treatment: Options, Strategies, and Resources*, 20 CLINICAL J. ONCOLOGY NURSING 44-51 (Feb. 2016).

[32] U.S. CONF. OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH SERVICES 25 (5th ed. 2009), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf. (Directive 41 of the Ethical and Religious Directives for Catholic Health Care states: "Homologous artificial fertilization is prohibited when it separates procreation from the marital act in its unitive significance.")

[33] Douglas Nejaime et al., *Conscience Wars: Complicity-Based Conscience Claims in Religion and Politics*, 124 Yale L.J. 2516, 2518 (2015). *See*, e.g., *N. Coast Women's Care Med. Grp., Inc. v. San Diego Cnty. Superior Court*, 189 P.3d 959 (Cal. 2008) (on the potential impact of healthcare refusal laws on same-sex couples).

[34] *Benitez v. N. Coast Women's Care Med. Grp., Inc.*, 106 Cal. App. 4th 978 (2003); *see also* LAMBDA LEGAL, BENITEZ V. NORTH COAST MEDICAL GROUP (Jul. 1, 2001), http://www.lambdalegal.org/in-court/cases/benitez-v-north-coast-womens-care-medical-group.

[35] *Id.*

discrimination would increase the cost and emotional toll of family building. In some parts of the country, however, these refusals would be a complete barrier to parenthood. More broadly, these refusals deny patients the human right and dignity to be able to decide to have children, and cause psychological harm to patients who are already vulnerable because of their health status or their experience of health disparities.

Religiously-based refusals can also result in the denial of other medically necessary care to LGBT people, particularly those who are transgender and in need of gender-affirming services. The following is one example that we learned about through a call to our Legal Help Line:

- Carl,[36] a transgender man, needed to undergo a hysterectomy and oophorectomy as part of his medically-supervised transition. Working with his healthcare providers, Carl obtained insurance coverage for the procedure. His surgeon, who had privileges at several hospitals in the area, scheduled the procedure at the hospital that was nearest to Carl and the surgeon. That hospital happened to be a religiously-affiliated facility. A few days before the procedure was scheduled to occur, Carl was informed that he could not have the procedure done at the hospital. According to the surgeon, the decision was made by the hospital's Ethics Committee. The reason Carl was given for the decision was that "the hospital does not perform that type of hysterectomy." Due to the short notice of the cancellation, the surgeon was unable to get the procedure moved to another hospital.

The foregoing barriers and challenges are evident in the stories we are hearing from NCLR supporters who are alarmed by the prospect of this Rule, including the following comments that have been submitted already to HHS:[37]

- I and many of my community members struggle to afford healthcare as it is, even with full time jobs. I live in a rural area and even if you do have health insurance, access to healthcare is very difficult. I do not see how my sexual orientation, religion, or other parts of me that one might disagree with at a personal level has anything to do with my right to receive healthcare. This regulation, whatever its intentions, will give those who are discriminatory the ability to act on this in a way that can harm the community and disproportionately provide support based on personal differences. I fear this will only further drive people apart.

- As a retired nurse educator I find this proposed rule unethical, immoral, unconscionable & inhumane. All health professionals essentially take an oath to treat & or take care of any person regardless of their race/religion/age/sexual orientation/ethnic background. And women have a right to choose their own reproduction health care. I strongly oppose this rule which promotes discrimination & urge HHS to withdraw it.

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[36] This incident was reported to NCLR Legal Help Line attorneys; the name has been changed to protect the caller's privacy.

[37] Some have been edited slightly for length and clarity.

- If this rule is allowed to exist, it will allow emergency room staff to turn away people maimed by car accidents, mass shootings and terrorist attacks. Do you really want to be waiting for life saving care as you are interviewed (interrogated) to determine that you are the "right" sort of person who aligns with a hospital staff member's religious beliefs? You could easily die as you try to prove that you are "worthy" of their care.

- I happen to be a health care provider and I see LGBT people in my practice regularly. I understand the disadvantages they face every day as they go to work, to school, and even at home in their families and communities. Access to health care is a critical problem for many people, and HHS should not be making the problem worse by inviting health care institutions and providers to turn people away based on religious or moral reasons.

- I am a US citizen, I am also Romani Hindu. I am an intersex female and lesbian. I greatly oppose any rules or laws that would allow any person to establish their personal religious views as a means to hold others as a lesser person. This archaic way of thinking does not create a peaceful and free nation. I live in America that is said to be a free nation. Yet I am not free simply because of who I am. I have a difficult time finding the heath care I need because of discrimination. I am a senior citizen of America and have been denied medical care. Giving any person the right to discriminate for any purpose does great harm to an entire country.

- I am an LBGTX woman, married and the mother of two adult children. I travel frequently for work and have paid into my company's health insurance system for over 40 years. While I'm fairly confident that wouldn't be refused treatment locally, the thought that I might be refused treatment during an emergency while I'm traveling because I am a gay woman is both appalling and frightening.

- I am a 75 year-old lesbian living in San Francisco. As an R.N. and an LCSW, I have worked in the healthcare field for my entire adult life. The proposed rule entitled "Protecting Statutory Conscience Rights in Health Care" would give permission to mistreat or not treat an entire group of citizens. This is outrageous! This would be against any oath that a healthcare provider has taken to provide healthcare to all - without exception. An individual's personal opinions or biases have no place in the healthcare field. HHS should not promote discrimination of any kind. I am sure this proposed rule would prove to be unconstitutional if tested in our courts - and it surely would be. This proposed rule should be withdrawn immediately! It's shocking that it's even been suggested.

- In many small communities there is a limited number of health care providers. Allowing this kind of bigotry and prejudice could be life-threatening to any number of people. I know of no religion that preaches withholding life-saving care from anyone. The whole idea of government sponsored bigotry is outrageous and about as un-American as you can get.

- In the last year alone, I had to be taken by ambulance to Emergency Rooms in Northern and Southern California due to a heart issue. I also had to go to an Emergency Room in

Rochester, NY. I dare to think what might have happened to me if the health care providers refused service because my same sex spouse was with me and they "objected" to our relationship.

- I fear we will return to the days where we could be refused health care because of who we love. In 2008, I had to carry legal papers with me to the emergency room so that my partner, before marriage was legal, could be informed about my illness and be involved in making decisions. We were lucky to have a nurse who was also lesbian and while she was on duty I had excellent care. One of my care givers was not happy that I had a female partner and excused himself from the room to send in another therapist a few hours later. We cannot go back, lives are at stake.

- I have personally known people who have come within inches of death from complications due to HIV/AIDS because of the neglect of a doctor based on that doctor's personal beliefs. Discrimination and personal beliefs should not factor in to medical treatment, ever.

- In our community there is a shortage of health care providers to begin with, and if you reduce the number of providers that LGBT people can use, people will die.

- My children (one of whom is still a minor) are part of the LGBTQ community, and your rule would allow physicians to deny them lifesaving medical treatment, should they fall ill or have a medical emergency, such as a car accident or appendicitis, because they are gay or trans. They could die in the waiting area of the ER while someone who would be willing to treat them is located, and brought to the hospital, or in transit to a hospital where someone would treat them. It would allow doctors providing preventative care like pap smears to turn away my trans son, so that he wouldn't be able to find out if he had ovarian cancer until it was too late. Or to deny them vaccines for preventable diseases, or even just the flu. It would allow pharmacists to deny my children a prescription for antibiotics, because they feel morally or religiously opposed to their "lifestyle choices." It could have allowed one of my best friends to die from the heart attack he had a few years ago, because he's married to another man - because he was taken to a Catholic hospital by the ambulance crew. If it happened again, and your rule is in place, that hospital, one of the largest and most comprehensive in coverage in our area, could start turning people away en mass, for simply not being Catholic. In a predominantly Mormon state, that means about half the population.

The fear expressed throughout these comments is palpable. LGBT people are all too familiar with discrimination and hostile treatment, including in health care settings, and inviting health care institutions and providers to turn away people and deny them care would exacerbate the widespread mistreatment experienced by many LGBT people in the health care system today.

2. The Proposed Rule fits a troubling pattern at HHS

We are concerned that this overemphasis on the right to deny care rather than the right to receive it reflects a broader orientation on the part of the agency. In 2017, HHS adopted rules – with no prior public comment – vastly expanding existing religious exemptions from the

ACA's requirement of birth control coverage. This was followed by a Request for Information (RFI) regarding supposed barriers to participation in health care by religious entities, a puzzling choice given the proliferation of religiously affiliated health care systems in this country. The FY 2018 – 2022 HHS Strategic Plan also overemphasized accommodating religious beliefs and moral convictions of health care providers, while failing to mention key populations (like LGBT people) or include any measurable goals, as such a document is supposed to do. Taken together, these issuances from HHS signal an alarming approach to public health, one that elevates the personal religious beliefs of some health care providers far above patients' well-being.

C. The Proposed Rule fails completely to address its impact on patients

The Proposed Rule is silent with regard to the needs of patients and the impact that expanding religious refusals can have on their health. It includes no limitations to its sweeping exemptions that would protect patients' rights under the law and ensure that they receive medically necessary treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs remain paramount, and that they are able to receive both accurate information and quality health services.

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care.[38] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions to bind the hands of providers and attempt to limit the types of care they can provide. This has profound implications for the core medical ethical precept of informed consent, and for the ability of health care providers to follow accepted standards of care for their patients.

1. Informed consent

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment.[39] This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally

[38] *See, e.g.*, Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf; *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report;.

[39] TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality care.

According to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."[40]The American Nursing Association similarly maintains that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[41] Pharmacists are also expected to respect the autonomy and dignity of each patient.[42]

The Proposed Rule purports to improve communication between patients and providers,[43] but in reality it will have the opposite effect, deterring open, honest conversations that are vital to ensuring that a patient is able to be in control of their medical circumstances. Informed consent is intended to address the unequal balance of power between health providers and patients and ensure patient-centered decision-making. Moreover, consent is not a "yes or no" question but rather is dependent upon the patient's understanding of the procedure that is to be conducted and the full range of treatment options for a patient's medical condition. [44] Without informed consent, patients will be unable to make medical decisions that are grounded in agency, their beliefs and preferences, and that meet their personal needs. This is particularly problematic as many communities, including women of color and women living with disabilities, have disproportionately experienced abuse and trauma at the hands of providers and institutions.[45]

In order to ensure that patient decisions are based on free will, informed consent is essential to the patient-provider relationship. The Proposed Rule threatens this principle by inviting

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[40] *The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent*, 14 AM. MED. J. ETHICS 555-56 (2012), http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.

[41] *Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination*, AM. NURSES ASS'N (2001), https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html.

[42] *Code of Ethics for Pharmacists*, AM. PHARMACISTS ASS'N (1994).

[43] 83 Fed. Reg. 3917.

[44] BEAUCHAMP & CHILDRESS, *supra* note 39; Robert Zussman, *Sociological perspectives on medical ethics and decision-making*, 23 ANN. REV. SOC. 171-89 (1997).

[45] Gutierrez, E. R. *Fertile Matters: The Politics of Mexican Origin Women's* Reproduction, 35-54 (2008) (discussing coercive sterilization of Mexican-origin women in Los Angeles); Jane Lawrence, *The Indian Health Service and the Sterilization of Native American Women*, 24 AM. INDIAN Q. 400, 411-12 (2000) (referencing one 1974 study indicating that Indian Health Services would have coercively sterilized approximately 25,000 Native American Women by 1975); Alexandra Minna Stern, *Sterilized in the Name of Public Health*, 95 AM. J. PUB. H. 1128, 1134 (July 2005) (discussing African-American women forced to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). *See also Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, *A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century*, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization).

institutions and individual providers to withhold information about services to which they personally object, without regard for the patient's needs or wishes.

2. Standards of care

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are not only important services in their own right, they are also part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer.[46] Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them. It is alarming that a public health agency would actively encourage compromising patient health by facilitating departures from accepted standards of care.

A 2007 survey of physicians working at religiously-affiliated hospitals found that nearly one in five (19 percent) experienced a clinical conflict with the religiously-based policies of the hospital.[47] While some of these physicians might refer their patients to another provider who could provide the necessary care, another survey found that as many as one-third of patients (nearly 100 million people) may be receiving care from physicians who do not believe they have any obligations to refer their patients to other providers.[48] Meanwhile, the number of Catholic hospitals in the United States has increased by 22 percent since 2001, and they now control one in six hospital beds across the country.[49] The increase of Catholic hospitals poses a danger for women seeking reliable access to medical services, many of whom do not understand the full range of services that may be denied them. One public opinion survey found

[46] For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

[47] Debra B. Stulberg M.D. M.A., et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, J. GEN. INTERN. MED. 725-30 (2010) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/.

[48] Farr A. Curlin M.D., et al., *Religion, Conscience, and Controversial Clinical Practices*, NEW ENG. J. MED. 593–600 (2007) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/.

[49] Julia Kaye et al., *Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives*, AM. CIVIL LIBERTIES UNION 22 (2017), *available at* https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

that, among the less than one-third of women who understood that a Catholic hospital might limit care, only 43 percent expected limited access to contraception, and a mere 6 percent expected limited access to the morning-after pill.[50]

As outlined below, there are significant questions regarding the authority of HHS to enforce the statutes cited in the Proposed Rule in the manner suggested. But even if the types of care denials this rule encourages are ultimately found to contravene federal law, we have grave concerns that the very promulgation of this Rule in its current form will encourage some health care providers and institutions to improperly restrict access to care for LGBT people, those seeking reproductive health care, and others, with harmful consequences. The ability to seek legal redress at a later date is cold comfort to a patient denied essential, even life-saving, care.

II. HHS has failed to establish its authority to issue the Proposed Rule

It is incumbent upon HHS to set forth with specificity the source of its purported authority to engage in this rulemaking, through which it seeks to reinterpret the scope of over two dozen federal statutes by, among other things, redefining key terms and adopting a wider array of enforcement tools. Absent such a detailed showing, the Proposed Rule should be withdrawn because, in addition to representing misguided and dangerous public health policy, it goes well beyond the authority of HHS and is therefore unlawful.

A. HHS has exceeded its rulemaking authority

The Proposed Rule exceeds HHS's authority under the various federal refusal statutes it references and seeks to enforce. An agency may not promulgate regulations that purport to have the force of law without delegated authority from Congress.[51] Yet none of the 25 statutory provisions cited by the Proposed Rule delegates authority to HHS to engage in rulemaking as contemplated in the Proposed Rule. Specifically, nothing within the 25 statutes cited by the Proposed Rule gives HHS the authority to require healthcare entities to provide assurances or certifications, to post the extensive notice included as Appendix A of the Proposed Rule, or to keep and make records available for review.[52] Nor does it give HHS the authority to conduct periodic compliance reviews or to subject healthcare entities to the full investigative process described in Section 88.7 of the Proposed Rule.[53]

The Department draws this purported authority not from the cited statutes but from its desire to implement a regulatory scheme "comparable to the regulatory schemes implementing other civil rights laws."[54] This desire arises from HHS's belief that the 25 cited statutes provide rights

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[50] Nadia Sawicki, *Mandating Disclosure Of Conscience-Based Limitations On Medical Practice*, 42 AM. J. OF LAW & MED. 85-128 (2016) *available at* http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.
[51] *Gonzales v. Oregon*, 546 U.S. 243, 274–75 (2006); *United States v. Mead*, 533 U.S. 218, 229–30 (2001); *Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 801 (D.C. Cir. 2002); *Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1371 (D.C. Cir. 1990)*Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 39–40 (D.D.C. 2014).
[52] *See* 83 Fed. Reg. at 3928–30.
[53] *Id.* at 3930–31.
[54] 83 Fed. Reg. 3904.

"akin to other civil rights to be free from discrimination on the basis of race, national origin, disability, etc."[55] Both the plain text and legislative history of these "other civil rights laws" distinguish them from the 25 statutes cited by the Proposed Rule, however. Each of the "other civil rights laws" cited by the Proposed Rule expressly authorizes HHS to promulgate regulations for their uniform implementation.

Title VI of the Civil Rights Act of 1964,[56] for example, which prohibits discrimination on the basis of race, color, or national origin in federal funding, states that "[e]ach Federal department and agency which is empowered to extend Federal financial assistance to any program or activity . . . is authorized and directed to effectuate the provisions of [Title VI] with respect to such program or activity by issuing rules, regulations, or orders of general applicability."[57] Title VI soon became the model for other nondiscrimination laws.[58]

Most recently, in Section 1557 of the Patient Protection and Affordable Care Act of 2009 (ACA), Congress clarified that the protections of Title VI, Title IX, the Age Discrimination Act, and Section 504 of the Rehabilitation Act of 1973 apply to all health programs or activities that receive federal financial assistance.[59] Congress explicitly granted HHS the authority to promulgate regulations to implement Section 1557.[60] Section 1553 of the ACA, which contains one of the refusal provisions cited by the Proposed Rule, does *not* contain such a grant.[61] Rather, Section 1553 gives HHS the authority to "receive complaints of discrimination" based on its provisions.[62] When Congress has explicitly granted an agency rulemaking authority in one section of a statute, the lack of such a grant in another section of the statute clearly indicates that Congress did not intend the agency to exercise rulemaking authority over that section.[63] The ACA conforms to the pattern Congress has followed for the past half-century: When it intends to grant HHS the kind of rulemaking authority claimed by the Proposed Rule, it does so expressly. The lack of such an explicit grant in any of the 25 cited statutes is

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[55] *Id.* at 3903.
[56] 42 U.S.C. 2000d *et seq*.
[57] Pub. L. No. 88-352, Title VI, § 602, 78 Stat. 252 (1964) (codified at 42 U.S.C. § 2000d-1).
[58] Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA) of 1990, both of which prohibit disability discrimination, explicitly refer to Title VI's enforcement provisions. *See* 29 U.S.C. § 794a(a)(2) (Section 504); 42 U.S.C. § 12133 (ADA). The Age Discrimination Act of 1975 not only permitted but required the Department to promulgate regulations to carry out its nondiscrimination provisions. 42 U.S.C. § 6103(a)(1). Title IX of the Education Amendments Act of 1972, which prohibits sex discrimination in education, contained delegation language that exactly mirrors that of Title VI. 20 U.S.C. § 1682.
[59] *See* Pub. L. 111-148, Title I, § 1557 (2010) (codified at 42 U.S.C. § 18116(a)). Congress did not include conscience protections in Section 1557, strongly implying that it does not see them as being "akin to," 83 Fed. Reg. at 3904, or "on an equal basis" with "other civil rights laws," *id.* at 3896. See *Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004) (noting that relationship with other federal statutes can be useful in statutory interpretation).
[60] 42 U.S.C. § 18116(c). The Department did so on May 18, 2016. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376 (May 18, 2016) (to be codified at 45 C.F.R. part 92). The final rule contains no mention of conscience protections.
[61] *See* 42 U.S.C. § 18113.
[62] *Id.*
[63] *See Amalgamated Transit Union*, 894 F.2d at 1371 ("[O]n the few occasions when Congress intended to give UMTA broad rulemaking authority . . . it did so expressly.").

therefore clear evidence that HHS does not have congressional authority to promulgate the Proposed Rule.

B. The Proposed Rule violates the Administrative Procedure Act

Even if HHS could promulgate a rule such as this based on its general authority to engage in rulemaking, that authority is not without limits. Under the Administrative Procedure Act (APA), "agency action, findings, and conclusions found to be… arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to a constitutional right," or "in excess of statutory jurisdiction, authority, or limitations" shall be held unlawful and set aside.[64] An agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the fact found and the choice made."[65] In addition, an agency can only change an existing policy if it provides a "reasoned explanation" for disregarding or overriding the basis for the prior policy.[66]

1. The Proposed Rule is arbitrary and capricious

In promulgating this Proposed Rule, HHS acted in an arbitrary and capricious manner in violation of the APA, and as a result the rule should be withdrawn in its entirety. The Proposed Rule is arbitrary and capricious on a number of grounds.

HHS fails to provide "adequate reasons" or a "satisfactory explanation" for this rulemaking based on the underlying facts and data. As stated in the Proposed Rule itself, between 2008 and November 2016, the Office of Civil Rights received ten complaints alleging violations of federal religious refusal laws; OCR received an additional 34 such complaints between November 2016 and January 2018. By comparison, during a similar time period from fall 2016 to fall 2017, OCR received *over 30,000 complaints* alleging either civil rights or HIPAA violations. These numbers demonstrate that rulemaking to enhance enforcement authority over religious refusal laws is not warranted.

HHS also fails to adequately assess the costs imposed by this Proposed Rule, both by underestimating quantifiable costs, and by neglecting to address the costs that would result from delayed or denied care. Under Executive Order 12866, when engaging in rulemaking, "each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs."[67] Under Executive Order 13563, an agency must "tailor its regulations to impose the least burden on society" and choose "approaches that maximize net benefits (including

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[64] 5 U.S.C. § 706(2)(A), (B), (C).
[65] *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2125 (June 20, 2016) (citing *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 103 (1983)).
[66] *Id.* at 2125-26.
[67] Executive Order 12866 on Regulatory Planning and Review (September 30, 1993).

potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)."[68]

HHS has failed to take the appropriate steps to ensure that the Proposed Rule is consistent with applicable law and does not conflict with the policies or actions of other agencies. Under Executive Order 12866, in order to ensure that agencies does not promulgate regulations that are "inconsistent, incompatible, or duplicative with its other regulations of those of other Federal agencies," each agency must include any significant regulatory actions in the Unified Regulatory Agenda.[69] HHS failed to include any reference to this significant regulation in its regulatory plans, and therefore failed to put impacted entities, including other federal agencies, on notice of possible rulemaking in this area. In addition, prior to publication in the Federal Register, the Proposed Rule must be submitted to the Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB), to provide "meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order [12866] and do not conflict with the policies or actions of another agency."[70] According to OIRA's website, HHS submitted the Proposed Rule to OIRA for review on January 12, 2018, one week prior to the Proposed Rule being published in the Federal Register. Standard review time for OIRA is often between 45 and 90 days; one week was plainly insufficient time for OIRA to review the rule, including evaluating the paperwork burdens associated with implementing it. In addition, it is extremely unlikely that within that one week timeframe, OIRA could or would have conducted the interagency review necessary to ensure that this Proposed Rule does not conflict with other federal statutes or regulations.

The timing of the Proposed Rule also illustrates a lack of sufficient consideration. The Proposed Rule was published just two months after the close of a public comment period for a Request for Information closely related to this Rule.[71] The 12,000-plus public comments were not all posted until mid-December, one month before this Proposed Rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the Proposed Rule—namely, the refusal of care by federally funded health care institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the Request for Information and whether the Proposed Rule was developed in an arbitrary and capricious manner.

The Proposed Rule also conflicts with several key federal statutes, as well as the U.S. Constitution. It makes no mention of Title VII,[72] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[73] With respect to religion, Title VII requires reasonable accommodation of

[68] Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Sec. 1 (b).
[69] Executive Order 12866, at Sec. 4(b),(c).
[70] *Id.* at Sec. 6(b).
[71] "Removing Barriers for Religious and Faith-Based Organizations To Participate in HHS Programs and Receive Public Funding," 82 Fed. Reg. 49300 (Oct. 25, 2017).
[72] 42 U.S.C. § 2000e-2 (1964).
[73] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[74] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[75]

Furthermore, the language in the Proposed Rule could put health care entities in the untenable position of being forced to hire people who intend to refuse to perform essential elements of the job for which they are being hired. For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling. It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

The Proposed Rule also conflicts with the Emergency Medical Treatment and Active Labor Act ("EMTALA"), which requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[76] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[77] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances – such as those experiencing an ectopic pregnancy or miscarriage - not receiving necessary care. The Proposed Rule fails to explain how entities will be able to comply with the new regulatory requirements in a manner consistent with the statutory requirements of EMTALA, making the Proposed Rule unworkable.

Finally, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant

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[74] *See id.*

[75] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.

[76] *See* 42 U.S.C. s 1295dd(a)-(c)

[77] *See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

religious exemptions to existing legal requirements and, in fact, bars granting an exemption when it would detrimentally affect any third party.[78] It requires an agency to "take adequate account of the burdens" that an exemption "may impose on nonbeneficiaries" and must ensure that any exemption is "measured so that it does not override other significant interests."[79] The proposed exemptions clearly impose burdens on and harm others and thus, violate the clear mandate of the Establishment Clause.

In promulgating a regulation that is inconsistent with federal statutes and regulations, as well as the Constitution, HHS engaged in arbitrary and capricious rulemaking, and its conduct was further compounded by a failure by OIRA to engage in appropriate oversight and review. For these reasons, the Proposed Rule should be withdrawn.

2. The Proposed Rule is not in accordance with law and exceeds statutory authority

The Proposed Rule is also not in accordance with law because much of its language exceeds the plain parameters and intent of the underlying statutes it purports to enforce. It defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. Therefore, the Proposed Rule violates the APA and should be withdrawn.

For example, the Church Amendments prohibit federal funding recipients from discriminating against those who refuse to perform, or "assist in the performance" of, sterilizations or abortions on the basis of religious or moral objections, as well as those who choose to provide abortion or sterilization.[80] The statute does not contain a definition for the phrase "assist in the performance." Instead the Proposed Rule creates a definition, but one that is not in accordance with the Church Amendments themselves. The proposed definition includes participation "in any activity with an *articulable connection* to a procedure, health service or health service program, or research activity" and greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential. [81] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, could now assert a new right to refuse. As Senator Church stated from the floor of the Senate during debate on the Church Amendments: "The amendment is meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal

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[78] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
[79] *Cutter*, 544 U.S. at 720, 722; see also *Thornton*, 472 U.S. at 709-10.
[80] 42 USC 300a-7.
[81] 83 Fed. Reg. 3892.

to perform what would otherwise be a legal operation."[82] This overly broad definition opens the door for religious and moral refusals from precisely the type of individuals that the amendment's sponsor himself sought to exclude. This arbitrary and capricious broadening of the amendment's scope goes far beyond what was envisioned when the Church Amendments were enacted.

If workers in very tangential positions, such as schedulers, are able to refuse to do their jobs based on personal beliefs, the ability of any health system or entity to plan, to properly staff, and to deliver quality care will be undermined. Employers and medical staff may be stymied in their ability to establish protocols, policies and procedures under these vague and broad definitions. The Proposed Rule creates the potential for a wide range of workers to interfere with and interrupt the delivery of health care in accordance with applicable standards of care.

The definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information based on which an individual could get the care they need.[83] Any information distributed by any method, including online or print, regarding any service, procedure, or activity could be refused by an individual or entity if the information given would lead to a service, activity, or procedure to which the provider objects.

Under the Coats and Weldon Amendments, "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[84] The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[85] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but contravenes congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms HHS now attempts to insert.[86]

The Proposed Rule defines workforce to include "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity."[87] Under this definition, virtually any member of the health care workforce could ostensibly refuse to serve a patient in any way.

The Weldon Amendment is expanded under the Proposed Rule by defining "discrimination" against a health care entity broadly to include a number of activities, including denying a grant

[82] S9597, https://www.gpo.gov/fdsys/pkg/GPO-CRECB-1973-pt8/pdf/GPO-CRECB-1973-pt8.pdf (emphasis added). Senator Church went on to reiterate that "[t]his amendment makes it clear that Congress does not intend to compel the courts to construe the law as coercing religious affiliated hospitals, doctors, or nurses to perform surgical procedures against which they may have religious or moral objection." S9601 (emphasis added).
[83] 83 Fed. Reg. 3895.
[84] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[85] 83 Fed. Reg. 3893.
[86] The doctrine of expressio unius est exclusio alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[87] 83 Fed. Reg. 3894.

or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."[88] Such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion and undermining non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.[89] Instead, courts have held that the government has a compelling interest in ending discrimination and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes it clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the basis of race, because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal."[90] In seeking to craft a regulatory scheme mirroring "other civil rights laws," HHS is in fact hampering enforcement of the very civil rights laws it claims to be emulating.

Moreover, the Proposed Rule states that the exemptions that Weldon provides is not limited to refusals of abortion care on the basis of religious or moral beliefs – the denial may be for any reason at all.[91] The preamble uses language such as "those who choose not to provide" or "would rather not" as justification for a refusal. This unbounded license to deny care is made more dangerous by the fact that the Proposed Rule contains no mechanism to ensure that patients receive the care they need if their provider refuses to furnish a service. The onus will be on the patient to question whether her hospital, medical doctor, or health care professional has religious, moral, or other beliefs that would lead them to deny services, or if services were denied, the basis for refusal. The Proposed Rule does not have any provisions that stipulate that patients must be given notice that they may be refused certain health care services on the basis of religious or moral beliefs.

The Proposed Rule also purports to equip OCR with a range of enforcement tools that it in fact lacks the authority to employ, including referring matters to the Department of Justice "for additional enforcement,"[92] something not contemplated within any of the statutes referenced in the Proposed Rule. These measures, combined with the impermissibly broad definitions and other inappropriately expansive interpretations of the underlying statutes, would have a chilling effect on the provision of a range of medically necessary health care services.

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[88] 83 Fed. Reg. 3892.
[89] *See, e.g., Bob Jones Univ. v. United States*, 461 U.S. 574 (1983) (holding that the government's interest in eliminating racial discrimination in education outweighed any burdens on religious beliefs imposed by Treasury Department regulations); *Newman v. Piggie Park Enters., Inc.*, 390 U.S. 400 (1968) (holding that a restaurant owner could not refuse to comply with the Civil Rights Act of 1964 and not serve African-American customers based on his religious beliefs); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1392 (4th Cir. 1990) (holding a religious school could not compensate women less than men based on the belief that "the Bible clearly teaches that the husband is the head of the house, head of the wife, head of the family"); *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316 (11th Cir. 2012) (reversing summary judgment for religious school that claimed a religious right to fire teacher for becoming pregnant outside of marriage).
[90] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).
[91] 83 Fed. Reg. 3890-91.
[92] 83 Fed. Reg. 3898.

Conclusion

The Proposed Rule departs from the core mission of HHS, would undermine patient care, and is contrary to law. We therefore urge that it be withdrawn.

If you have any questions regarding these comments, please contact Julianna S. Gonen, PhD, JD, NCLR Policy Director, at jgonen@nclrights.org or 202-734-3547.

National Center for Lesbian Rights

Exhibit 21

Jodi Magee
President/CEO

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March 27, 2018

The Honorable Alex Azar

Secretary of Health and Human Services

U.S. Department of Health and Human Services

200 Independence Avenue, SW

Washington, DC 20201

Re: Comments on Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03

Dear Secretary Azar:

Physicians for Reproductive Health is committed to ensuring all individuals have access to health care, regardless of their gender identity, sexual orientation, and/or the type of services being requested, including abortion, contraception or sterilization. Physicians for Reproductive Health (Physicians) is a doctor-led national advocacy organization that uses evidence-based medicine to promote sound reproductive health policies. Physicians unites the medical community and concerned supporters. Together, we work to improve access to comprehensive reproductive health care, including contraception and abortion, especially to meet the health care needs of economically disadvantaged patients. Physicians believes a health care provider's personal beliefs should never determine the care a patient receives. By allowing patient care to be compromised by religious or personal beliefs without consideration of the best medical care for the patient, this rule stands to undermine the very foundation of the doctor-patient relationship. Indeed, one of the reasons cited for the proposed rule is a case—*Chamorro v. Dignity Health*—we filed in California against a Catholic

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hospital network regarding their refusal to allow doctors to provide patients with the standard of care in the form of postpartum tubal ligations. That is why we strongly oppose the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.[1]

The Proposed Rule seeks to unlawfully expand refusals to provide care by attempting to allow individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program. In addition, the Proposed Rule unlawfully attempts to create new refusals seemingly out of thin air. Such expansions exceed the Department's authority; violate the Constitution; undermine the ability of states to protect their citizens; undermine critical HHS programs like Title X; interfere with the provider-patient relationship; and threaten the health and well-being of people across the country and around the world.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department seeks to inappropriately use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons Physicians calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

The Proposed Rule Unlawfully Exceeds the Department's Authority by Impermissibly Expanding Religious Refusals to Provide Care

The Proposed Rule attempts to expand the reach not only of existing harmful refusal of care laws but also to create new refusals of care where none were intended.

a. The Proposed Rule Seeks to Allow the Refusal of any Health Service Based on Personal Belief

The Proposed Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and transition-related care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[2] Read in conjunction with

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (*to be codified at* 45 C.F.R. pt. 88) [*hereinafter* Rule].
[2] *See id.* at 12.

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the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

b. The Proposed Rule Unlawfully Expands Already Harmful Abortion/Sterilization Refusal of Care Laws

Already existing refusal of care laws are used across the country to deny patients the care they need.[3] The Proposed Rule attempts to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.[4] But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on.[5] Such an attempted expansion goes beyond what the statute enacted by Congress allows. Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things, individuals working under global health programs funded by the Department, thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be

[3] *See, e.g.*, *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[4] The Church Amendments, 42 U.S.C. § 300a-7 (2018).

[5] *See* Rule *supra* note 1, at 185.

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refused to include merely "making arrangements for the procedure" no matter how tangential.[6] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.[7]

Furthermore, the Proposed Rule's new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the Proposed Rule seeks to enforce. Specifically, under the Coats and Weldon Amendments "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[8] The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[9] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert.[10]

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination."[11] In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."[12] In a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further, such a vague and

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[6] *Id.* at 180.
[7] *Id.* at 183.
[8] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[9] *See* Rule *supra* note 1, at 182.
[10] The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[11] *See* Rule *supra* note 1, at 180.
[12] *Id.*

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inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

The Proposed Rule Carries Severe Consequences for Patients and will Exacerbate Already Existing Inequities

a. Refusals of Care Make it Difficult for Many Individuals to Access the Care They Need

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[13] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[14] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[15] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[16] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[17] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in

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[13] *See, e.g.*, *supra* note 3.
[14] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[15] *See* Julia Kaye, et al., *Health Care* Denied, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[16] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[17] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.

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the following days, the hospital did not give her full information about her condition and treatment options.[18]

b. Refusals of Care are Especially Dangerous for Those Already Facing Barriers to Care

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[19] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[20] In rural areas there may be no other sources of health and life preserving medical care.[21] In developing countries where many health systems are weak, health care options and supplies are often unavailable.[22] When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen

[18] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[19] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[20] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[21] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[22] *See* Nurith Aizenman, *Health Care Costs Push a Staggering Number of People into Extreme Poverty*, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggering-number-of-people-into-extreme-poverty; *Tracking Universal Health Coverage: 2017 Global Monitoring Report*, WORLD HEALTH ORG. & THE WORLD BANK (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.

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states, women of color are more likely than white women to give birth in Catholic hospitals.[23] These hospitals, as well as many Catholic-affiliated hospitals, must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care.[24] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[25] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[26] In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.[27]

c. In Proposing this Rule, the Agency has Abandoned its Legal Obligations to Adequately Account for Harm to Patients

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[28] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it

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[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[24] *See id.* at 10-13.
[25] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[26] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.
[27] *See The Mexico City Policy: An Explainer*, KAISER FAMILY FOUND. (June 1, 2017), https://www.kff.org/global-health-policy/fact-sheet/mexico-city-policy-explainer/.
[28] Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

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completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[29]

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[30] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[31]

The Proposed Rule Will Undermine Critical Federal Health Programs, including Title X

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.[32] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[33] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[34] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such

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[29] *See* Rule *supra* note 1, at 94-177.
[30] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
[31] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.
[32] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's Family Planning Program*, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.
[33] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[34] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

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funds are generally conditioned.[35] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[36] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[37]

The Proposed Rule Will Carry Severe Consequences for Providers and Undermine the Provider-Patient Relationship

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, or moral convictions of these providers.[38] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.[39] Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment

[35] *See, e.g.*, Rule *supra* note 1, at 180-185.
[36] *See* NFPRHA *supra* note 34.
[37] *See id.*
[38] *See* Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[39] *See* TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

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altogether.[40] By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.[41]

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer.[42] Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[43] No health care professional should face

[40] *See id.*
[41] *See* Rule *supra* note 1, at 150-151.
[42] For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).
[43] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

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discrimination from their employer because they treated or provided information to a patient seeking an abortion.

The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[44] Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce.[45] They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[46] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities,

[44] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[45] *See* Rule *supra* note 1, at 203-214.

[46] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

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segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[47]

Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[48] And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth.[49] Further, the disparity in maternal mortality is growing rather than decreasing,[50] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.[51] And due to gender biases and disparities in research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[52] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[53] Eight percent of

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[47] *See, e.g.*, *Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.
[48] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.
[49] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.
[50] *See id.*
[51] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).
[52] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. of the Am. Heart Ass'n 1 (2015).
[53] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care

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lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[54]

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed, rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[55]

The Proposed Rule Conflicts with Other Existing Federal Law

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals to care it would create. For example, the Proposed Rule makes no mention of Title VII,[56] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[57] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[58] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed

professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.

[54] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

[55] *See supra* note 46.

[56] 42 U.S.C. § 2000e-2 (1964).

[57] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[58] *See id.*

comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[59]

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling even though the employer would not be required to do so under Title VII.[60] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[61] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[62] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

[59] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.
[60] *See* Rule *supra* note 1, at 180-181.
[61] 42 U.S.C. § 1295dd(a)-(c) (2003).
[62] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

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The Proposed Rule Will Make It Harder for States to Protect their Residents

The Proposed Rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[63] Moreover, the Proposed Rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[64]

Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients, contrary to the Department's stated mission. For these reasons Physicians for Reproductive Health calls on the Department to withdraw the Proposed Rule in its entirety.

Sincerely,
Board of Directors, Physicians for Reproductive Health

[63] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[64] *See id.*

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