Nos. 20-15398, 20-15399, 20-16045 and 20-35044

**IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

CITY AND COUNTY OF SAN FRANCISCO, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants*.

COUNTY OF SANTA CLARA, et al., *Plaintiffs-Appellees*,
v.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants-Appellants*.

STATE OF CALIFORNIA, *Plaintiff-Appellee*,
v.
ALEX M. AZAR, et al., *Defendants-Appellants.*

STATE OF WASHINGTON, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants.*

On Appeal from the United States District Courts for the
Northern District of California and the Eastern District of Washington

**SUPPLEMENTAL EXCERPTS OF RECORD
VOLUME X OF X**

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October 8, 2020

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Robert W. Ferguson

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Paul Crisalli, WSBA #40681
Lauryn K. Fraas, WSBA 53238
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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.

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

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–

56.

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

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

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

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

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

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

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

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

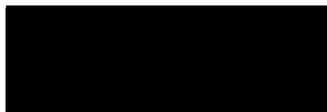
Office of the Secretary

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.

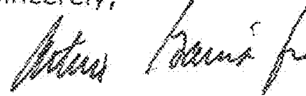
Among other things, OCR enforces Federal civil rights laws that prohibit discrimination in the delivery of health and human services because of race, color, national origin, age, disability, and, under certain circumstances, sex and religion. OCR has also been designated to receive complaints brought 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 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

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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.

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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."

Recommendations:
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,

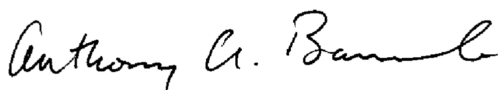

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Exhibit 7

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.

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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

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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 9

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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

[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

[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

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[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.

[illegible] *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

[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)
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

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 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

[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.

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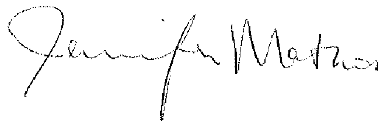
[5] National Women’s Law Center, *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.
[6] *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 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.

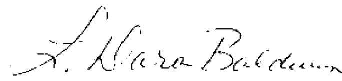
For the foregoing reasons, we urge you to revise the proposed rule to ensure that the religious refusal provisions are not interpreted to preempt civil rights protections.

Sincerely,

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

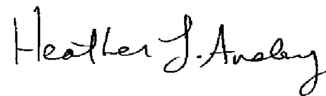


Jennifer Mathis
Bazelon Center for Mental Health Law



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 15

WASHINGTON
LEGISLATIVE OFFICE

March 27, 2018

Department of Health and Human Services
Office for Civil Rights
Attn: Conscience NPRM, RIN 0945-ZA03
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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

[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

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[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.

[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

[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

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[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

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[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.

ORIGINAL

1 UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

2

STATE OF WASHINGTON,	)	
Plaintiff,	)	Case No. 2:19-CV-00183-SAB
	)	November 7, 2019
vs.	)	Spokane, Washington
ALEX M. AZAR, II, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	Motion Hearing
	)	Pages 1 - 53
Defendants.	)	

8

9 BEFORE THE HONORABLE STANLEY A. BASTIAN
UNITED STATES DISTRICT COURT JUDGE

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25 Proceedings reported by mechanical stenography; transcript produced by computer-aided transcription.

1 (Court convened on November 7, 2019, at 9:59 a.m.)
2 THE COURTROOM DEPUTY: All rise.
3 (Call to Order of the Court)
4 THE COURT: Good morning. Please be seated.
5 THE COURTROOM DEPUTY: The matter now before the Court
6 is the *State of Washington v. Azar II, et al*., Case
7 No. 2:19-CV-183-SAB. This is the time set for a motion hearing.
8 Counsel, would you please state your presence for the Court
9 and record.
10 MR. TAKEMOTO: Benjamin Takemoto from the Department
11 of Justice on behalf of the Department of Health and Human
12 Services.
13 THE COURT: All right. Good morning.
14 MR. TAKEMOTO: Good morning.
15 MS. KOPPLIN: Rebecca Kopplin, your Honor, also from
16 the Department of Justice.
17 THE COURT: All right. Good morning.
18 MR. SPRUNG: Good morning, your Honor. Assistant
19 Attorney General Jeff Sprung on behalf of the State of
20 Washington.
21 THE COURT: All right.
22 MS. FRAAS: Lauryn Fraas from the Washington State
23 Attorney General's office.
24 THE COURT: Good morning.
25 MR. CRISALLI: Good morning, your Honor.

1 Paul Crisalli on behalf of the State of Washington.
2 THE COURT: Good morning to you, as well. Well, thank
3 you all for coming and for visiting us here in Spokane. This is
4 not my chambers so I'm -- my chair's not quite right, and I've
5 got this little thing here that keeps popping out on me. So
6 I'll try to adjust everything.
7 Let me make some remarks before we get started with our
8 argument itself; and then when I'm done, if you have any
9 questions as to -- we can deal with that.
10 In this case, the State of Washington is challenging a rule
11 recently adopted by the defendant, the US Department of Health
12 and Human Resources. That rule is called "Protecting Statutory
13 Rights in Healthcare;" and it's found, as I understand it, at
14 84 Federal Regulation 23170. It was adopted in May of 2019.
15 And it's my understanding that it was scheduled to take effect
16 on November 22nd of this year.
17 The parties have filed cross motions of summary judgment,
18 and we have both parties here. We also have briefing from four
19 amicus participants: The Institute for Policy Integrity at the
20 New York University School of Law; the scholars of the LGBT
21 population; the National Center for Lesbian Rights; and a group
22 of medical organizations, which includes the American College of
23 OB-GYN, the American Medical Association, the American Academy
24 of Pediatrics, and the American College of Emergency Physicians.
25 I want to thank the parties for the briefing that you've

1 provided. It's been very helpful. And given the nature of this
2 case, your briefs were refreshingly brief.
3 The nature of this hearing most likely, in the Court's
4 opinion, changed yesterday when Judge Paul Engelmayer from the
5 District Court of the Southern District of New York issued his
6 decision and opinion in a case I'll call the *State of New York*
7 *v. Azar*. His decision vacated the rule in its entirety and
8 across the nation.
9 Judge Engelmayer's case involved three separate lawsuits,
10 which apparently were filed in his District and then
11 consolidated in -- onto his docket. His consolidated cases
12 involved the total of 19 states, the District of Columbia, 3
13 local governments, Planned Parenthood, the National Family
14 Planning and Reproductive Health Associations were, together,
15 the plaintiffs.
16 There were also four amici participants who participated in
17 filing ten amicus briefs.
18 Judge Engelmayer's opinion was sent to me, and I do thank
19 you for sending that to me yesterday. And I was able to review
20 it yesterday evening. His opinion is 147 pages long. It's
21 comprehensive and thorough and has an excellent summary of the
22 facts, the law, and the arguments made by all of the parties
23 involved and the amicus participants involved.
24 My understanding of the rule is that Judge Engelmayer -- or
25 not the rule, the opinion -- is that Judge Engelmayer ruled in

1 favor of the plaintiffs, vacated the rule in its entirety, and,
2 in doing so, he concluded:
3 One, that it was appropriate to decide the case in front of
4 him in the context of the cross and pending motions for summary
5 judgment.
6 Second, he decided that the defendant had exceeded its
7 statutory authority in adopting the rule.
8 Third, Judge Engelmayer decided that the defendant acted
9 arbitrarily and capriciously in adopting the rule because the
10 defendants' justifications for the rule were contrary to the
11 evidence into the record. The defendant failed to supply a
12 reasoned explanation for its policy change from the previous
13 rule. I believe there was one in 2008, and then the most
14 current rule was 2011 before this one was adopted in 2019.
15 He ruled that the defendant failed to consider important
16 aspects of the problem before it, and the defendant failed to
17 properly account for the costs and benefits of the rule.
18 Finally, Judge Engelmayer ruled that the -- the rule was
19 unconstitutional in several ways, including it violated the
20 separation of powers and the spending clause; but it was my
21 understanding that he did not find it to be a violation of the
22 establishment clause.
23 So that's my understanding of what he did. I could be
24 wrong. As I said, it was 147 pages; and I went through it once.
25 So, anyway, it is what it is and that's my understanding.

1 So I'd like to start off today first by indicating: Do we
2 have any of the amicus participants in court with us today? I
3 don't think so. Okay. I was going to ask if any of them wanted
4 to present, but I guess the answer to that is "No."
5 I think that we can -- once I turn it over to you, we can
6 limit our arguments to 30 minutes or less. But I have two
7 questions that I'd like you both to address, which I think you
8 can probably anticipate. I'd like you to address if there are
9 any differences between the case that I have and that we're here
10 for today and the case that Judge Engelmayer had in New York,
11 whether there's any factual differences or any legal
12 differences.
13 And, secondly, I'd like to hear from both of you regarding
14 whether we have a case. Judge Engelmayer has vacated the rule
15 in its entirety; and, as a matter of judicial economy, do we
16 need to proceed?
17 So who would like to start? I believe that the State of
18 Washington challenged the rule so it seems appropriate that you
19 would start, but --
20 MR. SPRUNG: Thank you, your Honor.
21 THE COURT: -- these are cross motions.
22 MR. SPRUNG: Jeff Sprung, again, your Honor; and it's
23 an honor to be in your courtroom again today. And we have three
24 lawyers from our office whom you've met who may be presenting
25 some argument. Myself. We have a new lawyer in our office,

1 Lauryn Fraas. And then she -- she may address some of the
2 arbitrary and capricious issues. And Assistant Attorney General
3 Paul Crisalli may address some of the constitutional issues.
4 I'd like to turn first to the second point that you raised
5 whether there is a case still remaining to be decided, and there
6 are -- there are two issues that that raises: One is a mootness
7 question and the other is whether there is a case of
8 controversy, whether there is a dispute between the parties.
9 The short answer is, your Honor, that it is important for
10 the Court still to rule on the cross motions.
11 And the reason for that, first, under the mootness
12 doctrine, if -- clearly this is a circumstance, if
13 Judge Engelmayer's decision was reversed on appeal, that the
14 problems here would be capable of repetition. Yet, if the Court
15 refused -- or declined to address, it would be -- would evade
16 review.
17 And, second, for similar reasons, there continues to be a
18 live case or controversy between the parties for the same
19 reason. If the Second Circuit reversed Judge Engelmayer,
20 then -- then we still would be injured as we laid out
21 previously -- as we've laid out extensively in our briefs by the
22 rule.
23 So there are -- there is precedent as recently as the
24 Title X case, which this Court was involved in, where there were
25 both limited and nationwide injunctions issued. And in those

1 cases, each of the judges continued in order to be able to
2 present a case to the Court of Appeals regardless of an
3 injunction having been entered in another case. And --
4 THE COURT: Is this -- I should have asked my third
5 question. Are these the only two cases? The case -- or the
6 consolidated cases in New York and the case here or are there
7 other cases pending?
8 MR. SPRUNG: There's a case pending in California, as
9 well. And I get my cases mixed up. I believe that's two
10 consolidated cases pending in California. The State of
11 California is representing several states along with California
12 itself. So there's -- yeah, there's another case.
13 In the California case, there was oral argument in that
14 case two or three days ago.
15 THE COURT: All right. Thank you.
16 MR. SPRUNG: And the *California v. Azar* case in the
17 Ninth Circuit really anticipates the question that you're
18 asking, your Honor. The Court in *California v. Azar* -- this was
19 in the contraception case, a case involving the Administration's
20 rule dealing with employer exemptions from the contraceptive
21 mandate that the Court of Appeals chastised the District Court
22 for not having, once an injunction was issued -- it's a little
23 different circumstance. Once the injunction was issued, the
24 District Court allowed the parties to stay the proceedings
25 before the -- the Court of -- before it while the preliminary

1 injunction was on appeal. And the Court of Appeals chastised
2 the District judge and said proceedings have to go on because
3 it's important for the Courts of Appeals to have multiple
4 decisions. That's how the -- the process for developing law in
5 the way our system works percolating upwards works.
6 And that same principle applies here. Once one ruling has
7 issued, the Court of Appeals still want to have multiple views,
8 multiple judges for them to be able to develop the -- the law
9 and the rulings that they are trying to develop in anticipation
10 of the Supreme Court.
11 So we would say that it is important for the Court to
12 continue to hear these motions.
13 The -- the only other thing I'd like to address and then
14 I'm going to preserve almost everything that I've prepared for
15 rebuttal in case it's useful, but I do want to point out a few
16 areas where we diverge from -- either diverge from
17 Judge Engelmayer or issues Judge Engelmayer didn't address.
18 And the first one is we do diverge from Judge Engelmayer on
19 a narrow point as to whether the rule encompasses moneys that
20 are issued to the State of Washington by the Department of Labor
21 and the Department of Education. And I don't know if the Court
22 recalls that, but there is this -- it is our position that
23 these -- what we termed the "draconian penalty provisions,"
24 which -- which could potentially dock all $10 billion that
25 Washington receives from HHS for its -- for Washington's own or

1 even vicarious liability for a subgrantee's violation of the
2 rule. That -- there is one provision that not only would dock
3 moneys coming to Washington from -- from HHS but also moneys
4 that come from two other federal agencies, Department of Labor
5 and Department of Education. Judge Engelmayer did not interpret
6 the rule in that way.
7 And I just want to point out to the Court the statutory --
8 or the rules section that makes clear that those two funding
9 streams also are encompassed by the rule. Not a critical point,
10 frankly, your Honor, because, as Judge Engelmayer found, even
11 the idea of docking all of -- or penalizing Washington with the
12 loss of all of its Medicaid and all of its HHS funding streams
13 was unconstitutional beyond statutory authority.
14 But it is -- if the Court looks at 40 -- at the rule
15 provision at 88.7(i)(3) and then under that the -- the penalty
16 provisions are listed. And there are five or six different
17 subsections, and the first of those refers to federal funds by
18 itself. The rest of them refer to federal funds from the
19 Department of Health and Human Services.
20 So it is, you know, under -- under rules of regulatory
21 interpretation the fact that in the very next three or four
22 sections the rules specifically constrain the definition of --
23 or the term "federal funds" to federal funds from the Department
24 while the first one does not. It -- it indicates the intent by
25 HHS that they were being broader than they were in the

1 subsequent ones. We made that argument in our briefs. The
2 Department of Health and Human Services has never denied that
3 that is their intent. That's the scope of the rule.
4 And the reason that HHS has that view -- and, you know,
5 we'd be thrilled if counsel for HHS today in this courtroom
6 said, "No, that's not our view."
7 But the reason that we believe HHS has that view is
8 twofold: One, if one looks at the definition of "federal funds"
9 or "federal financial assistance," it's -- the term as defined
10 in the rule, it has no limitation to funds from HHS alone. So
11 that's in the definition Section 88.2 of the rule.
12 And then the second point is that what HHS seems to believe
13 is its authority to penalize stems from the funding streams --
14 in the huge funding streams of the -- of the conscience statutes
15 and several of the amendments are in that -- that HHS believes
16 gives it this broad authority apply not just to HHS but to
17 Department of Labor and Department of Education, too.
18 So they say, "Well, that authority was created in this
19 provision where Congress was defining limits on funding for
20 these three agencies. So we get to penalize funds coming from
21 those three -- three agencies."
22 That's -- that's the source of our disagreement with
23 Judge Engelmayer on that point.
24 Judge Engelmayer doesn't address ripeness, your Honor. I'm
25 happy to address that on rebuttal if that's something that's

1 worth addressing.
2 And the final point I want to address is Judge Engelmayer
3 doesn't address the impact of the rule on transgender patients.
4 And the only thing I want to do is point the Court to the
5 regulatory section that applies the rule to transgender patients
6 because it is a really important point in this case. The scope
7 of the rule and HHS's silence about whether they intend to apply
8 this to transgender patients is alarming for those of us in the
9 State of Washington where we have very strong protections
10 against discrimination against transgender patients.
11 And so I direct the Court to the rule-making section, 88 --
12 88.3(a)(2)(vi), and that is the section that applies the rule to
13 transgender patients. And what that says, your Honor, is that
14 there are some -- there's a narrow provision in the Church
15 Amendment that doesn't tie the antidiscrimination provision to a
16 particular type of treatment, whether it be abortion, end of
17 life, those other things.
18 That provision, the Church Amendment, which is
19 42 USC § 300a-7(d) -- that provision says any discrimination
20 against someone on the basis of their religious beliefs is
21 prohibited. HHS is interpreting that to apply their expanded
22 provisions in this rule not just to abortion, not just to end of
23 life; but this, they say, gives them kind of a roaming authority
24 to apply it to anywhere someone has a religious or moral
25 objection.

1 Of course, there are people in our country who have
2 religious and moral objections to transgender patients, to
3 transgender individuals. So -- so it really creates a very
4 broad authority for a provider to discriminate against a
5 transgender person because of their religious or moral beliefs.
6 There's another element, which is the sterilization point.
7 That comes up in -- in the Church Amendments. That would --
8 that could also capture transgender patients because the hormone
9 treatment -- a by-product of hormone treatments that are
10 resolved -- that are prescribed for gender transition purposes,
11 a by-product of that can be sterilization. Just like a
12 by-product of chemotherapy for a cancer patient could be
13 sterilization.
14 So HHS views, as an additional reason to apply this rule to
15 transgender patients, the -- that sterilization provision in the
16 Church Amendment.
17 That's all I have for your Honor.
18 THE COURT: All right. Thank you, Mr. Sprung.
19 MR. SPRUNG: Thank you.
20 THE COURT: Did we want to hear from your colleagues
21 then or --
22 MR. SPRUNG: I -- I'd like to --
23 THE COURT: Yes, okay.
24 MR. SPRUNG: -- give them the chance.
25 THE COURT: Yes. So Ms. Fraas? Is that --

1 MS. FRAAS: Yes, your Honor.
2 THE COURT: All right.
3 MS. FRAAS: Good morning, your Honor.
4 THE COURT: Good morning.
5 MS. FRAAS: Just very briefly. When I had put
6 together my presentation on what I planned to talk to the Court
7 about today, they were exactly the issues that Judge Engelmayer
8 addressed in arbitrary and capricious in terms of the -- the
9 factual -- the administrative record with regard to the
10 complaints, failure to put forth good reasons for the policy,
11 ignoring the comments of leading medical organizations, and
12 failure to address the abandonment of the serious reliance on
13 the Title VII framework.
14 Our briefing puts forth additional reasons, your Honor; and
15 I would be happy to address any of those. We are also, however,
16 comfortable resting on the arguments set forth in the briefing
17 and just reiterating that -- that we believe that
18 Judge Engelmayer's decision really does go -- covers the -- the
19 crux of our arguments with respect to the arbitrary and
20 capricious issues.
21 THE COURT: Well, since we have a little bit of time,
22 how -- what arguments are you making that Judge Engelmayer
23 didn't cover?
24 MS. FRAAS: Okay. Additional issues that we put forth
25 were with respect to medical ethics. We -- we talked about, in

1 our briefing, which is also very well covered by the amicus
2 brief of -- of leading medical organizations, about how the rule
3 is -- is irreconcilable with medical ethics as -- as the amicus
4 brief explains, because it permits refusals to provide necessary
5 services even in cases of emergency; it fails to protect the
6 continuity of care for all patients; and it permits individuals
7 without medical training to -- to impede patient treatment.
8 Our main argument on those was just that the rules fuel a
9 few boiler-point sentences on the issue; did not -- did not
10 address the concerns.
11 We also talked about vulnerable populations and that the
12 rule failed to -- ignored the impact that it would have on
13 those -- on those groups. The comments are insufficient in that
14 regard. Judge Engelmayer's rule does discuss access to care and
15 a lot of the -- a lot of our argument centers around access to
16 care.
17 So that is in some ways encapsulated within that, but our
18 briefing sets forth additional reasons.
19 THE COURT: All right. Thank you.
20 MS. FRAAS: Thank you.
21 THE COURT: And, Mr. Crisalli, did you have some
22 comments, as well?
23 MR. CRISALLI: I have nothing else to add unless the
24 Court has questions.
25 THE COURT: No, I don't.

1 MR. CRISALLI: Thank you.
2 THE COURT: All right. All right. Let's turn our
3 attention to the -- to the Government. Are you going to divide
4 your -- your time up with the issues?
5 MS. KOPPLIN: Yes.
6 THE COURT: Okay. So is it Kopplin?
7 MS. KOPPLIN: It's Kopplin. Yes, your Honor.
8 THE COURT: Thank you. All right.
9 MS. KOPPLIN: Thank you, your Honor. So I just wanted
10 to start by addressing the questions that your Honor just posed
11 and then, perhaps, turn to the merits. And I wanted to just
12 clarify before I did that.
13 Obviously, we do have this opinion in SDNY. It's still our
14 hope to present argument and explain, you know, some of the
15 issues as we see them and, perhaps, have the chance of you
16 reaching an independent decision. But I just wanted to make
17 sure that's something that you're opening to hearing right now
18 also.
19 THE COURT: Well, I am, yes. I mean, I recognize,
20 though, that whether I agree or disagree with Judge Engelmayer,
21 it's a -- it's a comprehensive Order and opinion that he
22 developed. I certainly assume that there's going to be appeals
23 just as I assume there'll be appeals from whatever I do, whether
24 I rule in favor of the US Government or the State of Washington.
25 So that's why I was wondering do we really have to proceed

1 with this case. The State has given us some reasons why we
2 should, but the basis of my question is I -- I recognize this
3 ultimately will be decided by the Court of Appeals or maybe even
4 the Supreme Court. And they've got a pretty good decision that
5 lays out all the issues, most of them anyway, from New York.
6 So --
7 MS. KOPPLIN: All right. That makes sense.
8 THE COURT: That's why I started the way I did.
9 MS. KOPPLIN: That makes sense. And I think --
10 THE COURT: Okay.
11 MS. KOPPLIN: -- with your Honor's permission, then,
12 we'll answer the questions --
13 THE COURT: Sure.
14 MS. KOPPLIN: -- and then we will also address the
15 substance; and we do plan to divide the issues between myself
16 and Mr. Takemoto.
17 THE COURT: Very good.
18 MS. KOPPLIN: So your first -- taking them in the same
19 order that Washington did, first, the question whether this case
20 is moot, we -- maybe surprisingly but we agree with Washington
21 on this point that the Court should still continue to consider
22 the motion for summary judgment and reach its own decision. As
23 plaintiffs note, there's been other cases in the Ninth Circuit
24 recently where the Ninth Circuit has indicated that it is the
25 preferred course to let District Courts percolate and reach

1 their own independent decisions on motions for summary judgment
2 even if appeals are pending.
3 Here, of course, the Order in SDNY is not yet final in that
4 it may be appealed. It may be narrowed on appeal. It may be
5 overturned on appeal. As a practical matter, it may make some
6 difference if that happens --
7 (Interruption by the reporter)
8 MS. KOPPLIN: I'm sorry, ma'am.
9 (Interruption by the reporter)
10 MS. KOPPLIN: As a practical matter, if that happens
11 and it's overturned or narrowed, it may make a difference to the
12 plaintiffs here what the scope of the relief, if any, that your
13 Honor feels appropriate would be.
14 So we would also believe that this case should be --
15 continue to be decided on the motions for summary judgment.
16 To the first question: What the differences are, I
17 somewhat defer to plaintiffs, obviously, as they're the --
18 they're the masters of their case. I know you just heard from
19 plaintiff's counsel that they raise an argument about medical
20 ethics that was not in the SDNY case. I also note they have an
21 argument about the possibility that the rule contradicts with
22 the ACA's preventive care requirement that I do not believe was
23 encompassed in the SDNY decision.
24 I think their case may also be somewhat narrower than the
25 SDNY case in a few ways. For example, in SDNY there was a large

1 decision about -- a large discussion of reliance interests and
2 of whether the rule was a logical outgrowth of the definitions
3 that were in the proposed rule that I do not believe have been
4 argued here.
5 I apologize for not being, perhaps, totally comfortable
6 with this as my colleague and I were on a plane for many hours
7 yesterday when this was coming out; but we did look at it last
8 night and that's kind of our first -- our first pass at the
9 answer to that question.
10 And then the last thing I wanted to say on that question
11 was just -- you'd asked my colleague on the other side what the
12 other cases were -- to just provide a little bit more
13 information about that.
14 So there's the case in SDNY or the three cases. Then
15 there's three cases in the Northern District of California that
16 are related but not consolidated, and those are the cases that
17 were just recently argued.
18 Then there's also one case in Baltimore that has motions
19 for summary judgment and a PI pending, and argument in that case
20 has been scheduled for later this month. So just to round out
21 the summary on that.
22 THE COURT: So the three cases in California. Are
23 they in front of the same judge? You said they're not
24 consolidated, but --
25 MS. KOPPLIN: They are. They're not technically

1 consolidated, but they're in front of the same judge,
2 Judge Alsup. The arguments all happened together. We've been
3 filing things on just one of the dockets.
4 THE COURT: All right. Thank you.
5 MS. KOPPLIN: All right. So from that I would like to
6 turn briefly to the substance, and I'll just let you know that
7 how we had planned to divide it was that my colleague would talk
8 about the statutory authority for the rules and the question of
9 whether the rule's contrary to law and I would discuss whether
10 the rule's arbitrary and capricious and the constitutional
11 issues.
12 If I could possibly just get a notice when I have about
13 15 minutes left, I'd like to make sure that he has plenty of
14 time to say what he needs to say.
15 THE COURT: Sure. We just need to be wrapping things
16 up by about quarter to 12:00 for staff purposes. But other than
17 that, I want to make sure that you have a chance to make the
18 points you want me to consider. And I'm a notoriously bad time
19 keeper as Mr. Durkin back there can tell you. So --
20 MS. KOPPLIN: Well, I just -- I certainly don't want
21 to short him. So I'll -- I'll do my best, too. But any kind of
22 heads up, I'll --
23 THE COURT: All right.
24 MS. KOPPLIN: -- try to respect that; and then I'll
25 wrap things up so that he can speak.

1 THE COURT: Okay.
2 MS. KOPPLIN: So, first, turning to the question of
3 whether the rule's arbitrary and capricious, I just want to
4 remind the Court this should be a very lenient review where the
5 Court is not instructed to substitute its judgment for the
6 judgment of the Agency. The Court's merely checking to see if
7 it can reasonably discern the path that the Agency took, and
8 that's been more than met here.
9 There is one thing that I just wanted to turn to right at
10 the top because this came up a lot in the SDNY decision, and
11 that's this question of what remedies the rule provides for and
12 whether it provides for new remedies that are not otherwise
13 existing in HHS's various statutes, like, the UAR and the FAR
14 that determine how HHS can handle its grants and contracts. And
15 I just wanted to point to, your Honor, to several places in the
16 rule where this issue was actually discussed at length.
17 For example, on Page 23183 to 23184 of the preamble, the
18 rule explicitly says: (Reading) The Department, therefore, will
19 enforce such terms and conditions, et cetera, et cetera, in
20 accordance with existing statutes, regulations, and policies
21 that govern such instruments, such as the Federal Acquisition
22 Regulation; the Uniform Administrative Requirements, Cost
23 Principles, and Audit Requirements for HHS Awards, 45 CFR
24 Part 75; regulations applicable to CMS programs; the associated
25 regulations relating to the suspension and disbarment (sic); as

1 well as any other regulations or procedures that govern the
2 Department's ability to impose and enforce terms and conditions
3 on funding recipients to comply with Federal requirements.
4 And there's a similar discussion in the rule at Page 23221
5 to 23223 where the Agency again makes explicit that enforcement
6 of the rule happens through the existing regulations and
7 existing statutes that HHS uses to control the funds that it
8 handles.
9 Those are both in the preamble. In the rule itself, in the
10 text of the rule, at 88.7(i)(3), the rule before it lists kind
11 of a menu of options and that menu kind of covers everything
12 that could possibly happen. It's not saying each of these
13 things will for certain happen. And before it lists that menu,
14 the rule actually says that these steps will be taken, quote,
15 ... taken in coordination with the relevant Department
16 component, and pursuant to statutes and regulations which govern
17 the administration of contracts (e.g., Federal Acquisition
18 Regulation), grants (e.g., 45 CFR part 75) and CMS funding --
19 CFR part 75 -- oh, sorry -- and CMS funding arrangements (e.g.,
20 the Social Security Act), end quote.
21 So even in the text of the rule itself, it's clear that
22 each of these enforcements actions is meant to be taken pursuant
23 to the existing statutes and regulations that HHS is otherwise
24 following. I think that's important to note when you're reading
25 the SDNY decision.

1 Turning back to the reasons that the Agency had for taking
2 this course, first, I want to start with the question of the
3 complaints the Agency received because this is something that
4 plaintiffs really want to make a big deal out of and they're
5 kind of getting really into this minutiae of "Let's double check
6 the Agency's home work; and let's sort of count up each
7 complaint and see if we can attribute whether we think each
8 complaint was or was not correctly counted by the Agency."
9 THE COURT: Well, that's kind of the point of
10 administrative -- or judicial review of administrative action,
11 isn't it?
12 MS. KOPPLIN: I have the utmost respect for judicial
13 review. My point here is simply that the Agency is using these
14 complaints to say, "Look, we got many complaints." So it's more
15 using them for the fact that it got these complaints.
16 THE COURT: Six.
17 MS. KOPPLIN: Not six. I think --
18 THE COURT: Did you get more than six?
19 MS. KOPPLIN: Well, they got 343. And I think --
20 THE COURT: Six. You got six.
21 MS. KOPPLIN: Well, we attached six, I believe, but
22 even --
23 THE COURT: You got more than six?
24 MS. KOPPLIN: Um-hum.
25 THE COURT: And you only attached six?

1 MS. KOPPLIN: Well, we didn't want to bury your Honor
2 in papers.
3 THE COURT: Well, I can -- I can deal with paper. But
4 the record before me is that you got six complaints, and the
5 record before Judge Engelmayer is that you got six complaints
6 that relate to the issue of conscientious objectors.
7 MS. KOPPLIN: I hear -- I hear what you're saying.
8 THE COURT: Did you get more than six than that? I
9 just -- I just want to know. Did the US Government --
10 MS. KOPPLIN: Yes.
11 THE COURT: -- get more than six?
12 MS. KOPPLIN: Yes, your Honor.
13 THE COURT: How many did you get?
14 MS. KOPPLIN: So of the 343, plaintiffs try to kind of
15 shuffle many aside by saying --
16 THE COURT: How many did you get?
17 MS. KOPPLIN: I -- can I -- can I finish my
18 explanation because I think it does really relate to the
19 question you're asking?
20 THE COURT: All right.
21 MS. KOPPLIN: Plaintiffs are trying to say that these
22 complaints about vaccines would, for example, not be counted
23 because they say that there's not a statute that would be
24 violated by the conduct that's being described in those. So
25 none of the federal conscience statutes was violated.

1 When the Agency said that it received complaints addressing
2 issues of conscience in healthcare, it didn't necessarily mean
3 that each of those complaints at the end of a long period of
4 investigation and legal analysis stated an actionable violation
5 of one of the statutes.
6 Someone might come to HHS and say, "Hey, I have a
7 conscience-related complaint," and it might turn out that what
8 they're complaining about isn't actually covered by a statute.
9 They have a complaint, they had a problem, but it wasn't covered
10 by a statute. That's a thing that could happen. Probably does
11 happen pretty frequently. And when HHS gets those complaints --
12 THE COURT: Probably?
13 MS. KOPPLIN: -- it still looks into them.
14 THE COURT: Is the Government adopting rules because
15 "probably" there might be some problems out there?
16 MS. KOPPLIN: Well, your Honor, one of the problems
17 the rule is trying to address was a lack of information and
18 clarity among the public and among regulated entities. So --
19 THE COURT: In whose opinion?
20 MS. KOPPLIN: In the Agency's opinion, your Honor.
21 THE COURT: All right. So how many complaints did you
22 get? I totaled it up six. That's the record that the plaintiff
23 has -- has provided to this Court and that's the same record
24 that Judge Engelmayer had. So six.
25 MS. KOPPLIN: Well, my -- my Honor (sic) -- your

1 Honor, my point is that, in the 343, I think all of the
2 complaints about the vaccinations -- they tranche on this
3 question of whether conscience rights have been violated in
4 healthcare. They might not affect a violation of the statutes,
5 but HHS can still look at those and say, "Look, people are
6 confused about what the statutes cover and don't cover. People
7 think that the statutes cover this, but maybe they don't. Maybe
8 we need to clarify what the statutes do and don't cover because
9 we're getting a lot of complaints from people who think that
10 they're covered but they're not actually."
11 THE COURT: "A lot of complaints." How many?
12 MS. KOPPLIN: You know, I wish I had in front of me --
13 but I just know that -- I think it's -- of the 343, plaintiffs
14 kind of say, "Oh, you know, like, a couple hundred of them are
15 about vaccines."
16 THE COURT: They say six. I mean, I've -- I've got
17 the numbers. You say 343. The plaintiff says six. You say
18 there was more than that. How many? What's the number?
19 MS. KOPPLIN: I'm not even -- I'm sorry, your Honor.
20 I'm not even quite recalling the six. As I recall, plaintiffs
21 had come down to sort of, like, about 21 that they said they
22 thought were colorable.
23 THE COURT: Well, maybe it's six percent. Perhaps I'm
24 wrong on the number, and I'm getting a nod here. I do
25 apologize, Counsel. Six percent was the number I was using for

1 the number. So 21. I apologize for that.
2 So 343. There were 21 complaints that the plaintiff
3 indicates was relevant to this issue of conscientious -- or
4 conscience objections, and that is six percent of the number of
5 complaints that the Agency received. Are those -- is that math
6 correct?
7 MS. KOPPLIN: So our -- our position is that far more
8 than that is what's relevant to the Agency's analysis here
9 because far more than that involved conscience rights in
10 healthcare in general. Now, I think --
11 THE COURT: How many?
12 MS. KOPPLIN: -- there are a hand --
13 THE COURT: How many?
14 MS. KOPPLIN: I think it's --
15 THE COURT: That's what I'm trying to get at.
16 MS. KOPPLIN: You know, I don't have the exact number.
17 I think it's a pretty high percentage. I think plaintiffs
18 identify a handful, like, 10 or 20 that were just duplicates or
19 that maybe seemed like they were just kind of in tally with
20 something else. I'm not sure about those.
21 But of the ones that plaintiffs agree on and of the ones
22 that are about vaccines, we think these are all within the realm
23 of -- of things that the Agency looked at to decide people
24 needed more clarity about what was covered by the federal
25 statutes.

1 And I just want to also explain --
2 THE COURT: Is the Government taking the position that
3 all 343 complaints were relevant to this -- this rule?
4 MS. KOPPLIN: Like I said, I'm not taking that exact
5 position for the reason I just mentioned. I think there were,
6 perhaps, a couple duplicates in the order of, like, 10 or 20;
7 but it's our position that most of them are relevant here.
8 THE COURT: Okay. So I'm willing to allow the fact
9 that you might not have those numbers in mind, but did the
10 Government do that analysis? I mean, the State of Washington
11 did. They looked at the administrative record, and they added
12 it up. And I misstated the number, and I apologize again for
13 that. But they gave me those numbers. They gave
14 Judge Engelmayer those numbers.
15 Did your client -- whether you remember it right now as you
16 stand here or not, did your client, the US Government, do that?
17 MS. KOPPLIN: Well, our client did look at them all to
18 determine that there was 343. They did that initial analysis.
19 And I will explain -- I think plaintiffs seem to think this
20 should have been a very final analysis that says, you know, "At
21 the end of the day there's jurisdiction here. There was an
22 actionable conduct within the statute of limitations."
23 That's not really feasible for the Agency to do. I mean,
24 they did kind of a first pass. They said, "We've gotten a lot
25 of complaints. They seem to be about conscience issues in

1 healthcare. Maybe we should take a look at that."
2 Often these complaints -- also just -- just for your
3 background, these complaints often come in. They're from *pro se*
4 individuals often. They don't have counsel. They may or may
5 not provide information. It's not necessarily an easy task for
6 HHS to -- to discover right away if there's an actionable matter
7 or not. There's, you know, 25 odd statutes we're dealing with
8 here. So they have to sort of consider, which, if any, of these
9 statutes would be affected? Where's the funding stream for what
10 plaintiffs are -- for what the complainant is talking about?
11 It's not always clear what the funding stream is. You know,
12 when did this happen? So there might be factual follow up.
13 So that's why I'm saying this was kind of HHS's pass at
14 this. This doesn't mean they finished chasing down every lead
15 and then, at the end, they said, "We think there was a violation
16 of a statute." That would have taken them -- me much longer.
17 THE COURT: Isn't that their job? I mean, they're
18 proposing a rule, which, right or wrong, creates a substantial
19 change in the law and a substantial change in the provision of
20 medical care to everyone in the country and a substantial change
21 in whether people in this country will have access to medical
22 care. And you started your analysis and your comments by saying
23 one of the reasons for this rule-making endeavor was because
24 there were many, many complaints. So how many complaints were
25 there?

1 MS. KOPPLIN: I think there was probably the better
2 part of 343.
3 THE COURT: Okay. All right.
4 MS. KOPPLIN: And as I also would like to point out,
5 when we're looking at the question of an increase in complaints,
6 it's important to think of what the background for that was.
7 What was the baseline number?
8 So, in the rule, HHS said they got 10 complaints between
9 2009 and 2016. That's barely more than one complaint a year.
10 So there's seven years they're getting barely more than one
11 complaint a year. Plaintiffs don't dispute that number that I
12 know of.
13 Then between November 2016 and January 2018, they received
14 a further 34 complaints. So from barely more than 1 a year to
15 34 over the course of less than 2 years. And then we come to
16 the 343 number, which is where plaintiffs have really dug in.
17 And this is just during fiscal year 2018. This is just during
18 one year.
19 So even if we take at face value plaintiff's -- it works
20 out to about 21 total -- that is a significant increase to go
21 from barely more than 1 a year to 34 in two years to 21 in a
22 single year -- fiscal year 2018. That still does show a
23 significant increase.
24 And as I mentioned at the beginning, this is, of course,
25 only one of the reasons that HHS relied on in determining that

1 there was a need for the rule.
2 In addition, HHS was also looking at some of the data from
3 surveys that they had, comments they received during the 2011
4 rule making, comments that they received during the 2018-2019
5 rule making, and their sort of past-enforcement history and what
6 they've been seeing as they did this work.
7 Many of those comments that I just alluded to did refer to
8 a culture of hostility towards conscience in the healthcare
9 profession and a lot of concerns by people who were working in
10 the healthcare area that they had been coerced into taking
11 things that they did not want to do based on their consciences
12 that they'd otherwise been pressured.
13 Next, I'd like to address sort of the four areas where
14 plaintiff says that the Agency failed to consider the potential
15 harms of the rule. And one striking thing is that the Agency
16 actually did consider each of these potential harms and wrote
17 about each of them in their rule. So clearly they were
18 considered. Plaintiff just has a policy disagreement about the
19 outcome that HHS reached there.
20 So plaintiff talks a great deal about access to care.
21 That's discussed for many pages in the rule starting at 23180.
22 And the Agency concludes that, in light of the evidence before
23 it and in the record, they think overall the access to care will
24 increase because providing for better understanding enforcement
25 of conscience protections will allow people who might have to

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1 leave the healthcare industry to stay there will allow people
2 with religious and conscience beliefs to enter the healthcare
3 profession if they were afraid to enter before, including in
4 underserved communities.
5 THE COURT: What evidence did the Agency have to use
6 to reach its conclusion that this rule would actually lead to an
7 increase in access to care?
8 MS. KOPPLIN: So the Agency does say that they were
9 unable to find any, really, sort of conclusive studies setting
10 out either way whether it would increase or decrease the access
11 to care. But in light of the evidence they did have, including
12 the 2009 study that laid out pretty substantial percentages of
13 people in the healthcare industry, faith-based individuals in
14 the healthcare industry who had conscience concerns, I think it
15 was 40 percent of the people in that survey who were faith-based
16 healthcare professionals said that they had felt that their
17 conscience rights had been violated. They'd been discriminated
18 against because of them, which was a pretty high number.
19 THE COURT: But how would that -- let's assume that
20 number were -- was, in fact, correct and accurate. How would
21 giving them -- or how would this rule increase their ability to
22 provide more access? What they're saying is, "We don't want to
23 give access." Isn't that what they're saying? "We object to
24 this type of care. We object to caring for people from the LGBT
25 community. We object to providing information or treatment

1 regarding abortion rights."

2 So how is this rule going to increase their willingness or

3 ability to provide access to care to the people they don't want

4 to care for?

5 MS. KOPPLIN: So first, your Honor --

6 THE COURT: I don't understand that link.

7 MS. KOPPLIN: No, let me -- I --

8 THE COURT: So if you could help me --

9 MS. KOPPLIN: I'm happy to try and clarify.

10 THE COURT: Okay.

11 MS. KOPPLIN: So, first, there -- just the -- one step

12 back from the high level here. The rule deals with individuals'

13 objections to providing certain treatment, certain procedures.

14 Nothing in the rule is about protecting someone's ability to

15 discriminate against a certain type of person. That's not

16 something the rule talks about. We're talking about objections

17 providing certain procedures --

18 THE COURT: Discrimination by another name. But how

19 is this going to increase the amount of care provided to these

20 communities?

21 MS. KOPPLIN: So image that you are, you know, a

22 doctor. You've been practicing for a number of years. Maybe

23 you have a sort of general practice in a rural area. You handle

24 a lot stuff. And you have a sincere, deeply held objection to

25 providing abortions. And for a long time you've been able to

1 make your way doing things. Maybe you refer people. I'm not
2 sure how you handle it.
3 But now someone else is coming along. Maybe it's the
4 State, maybe it's your employer, and they're saying, "We need
5 you to provide abortions. If you can't provide abortions, then
6 you're not going to have a job with us anymore." So you're
7 forced to leave the healthcare industry. Right?
8 A lot of the people in the survey -- 90 percent say they
9 would rather leave their jobs then be forced to violate their
10 consciences.
11 (Interruption by the reporter)
12 MS. KOPPLIN: Sorry, ma'am. So that's healthcare
13 opportunities that have just been missed out on.
14 We also have comments from students who are studying the
15 healthcare professions who say they feel like they are afraid to
16 enter the OB-GYN area or other areas where these things come up
17 often because, although they generally want to provide OB-GYN
18 care, they have a sincere, deeply held objection to providing an
19 abortion, for example. And so, therefore, they choose to go
20 into dermatology or something where they don't think this issue
21 will come up. Right? There's people who are being sort of
22 scared out of these certain areas of practice, even areas that
23 might be very necessary to have people practicing in.
24 THE COURT: So we'll get more dermatologists by this
25 rule.

1 MS. KOPPLIN: Well, no. I'm saying, in this status
2 quo, we're getting dermatologists. With the rule, people feel
3 their consciences will be protected. Those people might be able
4 to, you know, follow their first inclination and practice where
5 they want to practice instead of being driven out.
6 THE COURT: Okay.
7 MS. KOPPLIN: Secondly -- the other -- the other three
8 areas I'll just touch on briefly here unless your Honor has more
9 questions; but those are the emergency care aspect, medical
10 ethics, and Title VII. Each of these the Agency did certainly
11 consider and address in their rule. The Agency considered
12 emergency access at 23182 to 83, it considered issues of medical
13 ethics at 23189, and it considered Title VII at 23190 to 191.
14 And I know my colleague is going to discuss contrary to law more
15 so I might just let him get into the details there. But,
16 obviously, we briefed it; and the Agency considered it.
17 Finally, turning to plaintiff's constitutional claims, I'll
18 start with the establishment clause. I'm sure you can guess,
19 even after a brief read, but there's a lot in the SDNY opinion
20 we disagree with; but one thing --
21 (Interruption by the reporter)
22 MS. KOPPLIN: In the SDNY opinion that we disagree
23 with. One thing we don't have to disagree with is his
24 conclusion on the establishment clause. When you have here a
25 rule that is generally neutral between religion and

1 non-religion, it's very difficult to see how that could be
2 improperly promoting religion.
3 Turning to the spending clause and the separation of
4 powers, I think Judge Engelmayer's decision on this actually had
5 a lot to do with the very first issue that I raised today and
6 that's this question of: Does the rule sort of add an entirely
7 new remedy that didn't exist before? Does the rule sort of hand
8 HHS this new stick that it can hit people with that it didn't
9 used to have? And I've already addressed that so I won't return
10 to that right now.
11 But under separation of powers, our position is that,
12 because the rule does not change that substantive law and does
13 not change the substantive power that HHS has, it does not
14 violate the -- the separation of powers.
15 And similarly, on the spending clause, because the rule
16 covers the same funding streams that the statutes covered, if
17 plaintiffs really thought they had a spending clause problem,
18 then they should be here suing about the statutes. And the fact
19 that they even say in their briefing they're big fans of the
20 statutes shows that, if the statutes are constitutional, the
21 rule is, too, because it affects the same funding streams.
22 THE COURT: Isn't -- isn't their argument, though, is
23 that the statutes don't take the funding away but the rule does
24 assuming there's a violation?
25 MS. KOPPLIN: You know, I've -- I've never entirely

1 understood their argument so I'm not gonna say that it's --
2 THE COURT: Well, that's my understanding.
3 MS. KOPPLIN: That's not how I've understood it.
4 THE COURT: Okay.
5 MS. KOPPLIN: I mean, I think -- I could be wrong. I
6 think plaintiffs understand that the Weldon Amendment, Church
7 Amendments, these say, you know, HHS should not permit this
8 funding to be used in these ways. I think they will admit that
9 that has some teeth, that has some meaning, that is not a -- you
10 know, an hortatory provision floating out there that has nothing
11 to do with money. I think they know that the money is supposed
12 to be affected here.
13 They do argue, for example, that they think the rule is
14 ambiguous and, thus, the spending clause problem; but the rule
15 is less ambiguous than the statutes. The statutes don't have a
16 definition of discrimination at all. The statutes don't have a
17 definition of assistance of performance at all. It's the rule
18 that's been trying to put some more meat on the bones and say,
19 "Look, this is what we think these terms mean."
20 And the Agency here really tried to do that in the right
21 way by going through notice and comment and rule making and --
22 and kind of showing all its cards and saying, "Look, here's what
23 we think. Here's what we think discrimination means." So
24 they're trying to make it less ambiguous than it was before.
25 THE COURT: The new rule is.

1 MS. KOPPLIN: The rule is less ambiguous than the
2 federal conscience statutes, which don't even define many of
3 these provisions.
4 And, finally, on the question of what relief would be
5 appropriate, of course, our position is that there should be no
6 relief. But in the event that your Honor believes some kind of
7 relief would be appropriate, it's our position that that relief
8 should be limited to the plaintiffs because of the longstanding
9 understanding that the Court should just be remedying the
10 specific injury in fact the plaintiff has. So here our
11 plaintiff is just the State of Washington.
12 THE COURT: That's ridiculous. The rule applies
13 nationwide, does it not?
14 MS. KOPPLIN: It does, your Honor.
15 THE COURT: I mean, assuming we still have a rule.
16 MS. KOPPLIN: Correct.
17 THE COURT: How can this Court -- I'm still a federal
18 Court, at least, the last time I looked at that seal
19 (indicating). How can this Court say, "This nationwide rule is
20 improper ..." for whatever reasons I were to decide that if I go
21 down that path "... but it's invalid as to the State of
22 Washington but all the other states are fine." So the community
23 20 miles down the street, Coeur d'Alene, Idaho, good rule; but
24 here in Spokane, not a good rule.
25 MS. KOPPLIN: I mean, that is -- that is a

1 condition --
2 THE COURT: I'm a District Court in the Eastern
3 District of Washington. Arguably, I don't have -- I don't take
4 cases from Seattle, Tacoma, or Everett or Vancouver. So if --
5 if your clients' argument as to the extent of the remedy that
6 this Court -- a federal court -- can provide if your argument is
7 correct, then is my rule only good until the Cascade
8 Mountains --
9 MS. KOPPLIN: Oh, no. That's not --
10 THE COURT: -- or does it go all the way --
11 MS. KOPPLIN: That's not what we're saying at all,
12 your Honor.
13 THE COURT: -- to the Pacific Ocean?
14 MS. KOPPLIN: If -- if I could explain a little bit --
15 THE COURT: All right.
16 MS. KOPPLIN: -- I'm saying, if the State of
17 Washington as well as the states of South Carolina, North
18 Carolina, Louisiana, Alabama, Maryland, Mississippi -- if all
19 fifty states and the District of Columbia had sued in your
20 courtroom, then we're -- our argument would be different because
21 you would have all those plaintiffs before you --
22 THE COURT: Would I have --
23 MS. KOPPLIN: -- and you'd be looking at all their
24 injuries.
25 THE COURT: -- to have all 50 states? And so let's

1 say I had 49 of them. Had everybody but Hawaii. So the rule --
2 if I ruled in favor of the plaintiff, if I were to invalidate
3 the rule and declare it vacated, would it apply only to the 49
4 states I had but in -- in Hawaii it was just fine?
5 MS. KOPPLIN: So it should be --
6 THE COURT: I mean, I don't understand the reasoning.
7 MS. KOPPLIN: It should -- it should be set aside just
8 as the plaintiffs that are before you. So if the State of
9 Washington is concerned that it's going to have this rule
10 enforced against it and that would be improper and your Honor
11 agrees, then you should tell HHS "The rule is set aside as to
12 Washington. You're not going to enforce this against the State
13 of Washington. I've found they have some -- some arguments --"
14 THE COURT: What case law do you have to suggest that
15 that's the limit to the remedy that this federal Court has here
16 in Spokane, Washington?
17 MS. KOPPLIN: So one recent case would be the case
18 *California v. Azar* in the Ninth Circuit where the Ninth Circuit
19 vacated the nationwide scope of an injunction a District Court
20 had entered.
21 THE COURT: We're not talking about an injunction.
22 We're talking about a remedy. We're here on the substance. I
23 was also one of the Courts on the *Azar* -- I call it the *Azar I*
24 case, the Title X. I issued a nationwide injunction, and that
25 issue is now with the Ninth Circuit. I understand that very,

1 very clearly. I might disagree with it, but we'll see what the
2 Circuit says.
3 But we're here now to decide whether this rule is valid or
4 invalid. And so what case law do you have or constitutional
5 provision do you have that this federal Court here in the
6 Eastern District of Washington does not have the power to
7 invalidate a nationwide rule? I'm not aware of that case or any
8 case law that suggests that. But I'd like -- I know that your
9 client is making that argument. I'd like to know what that
10 argument is based on.
11 MS. KOPPLIN: Sure. So there's -- I'd point you first
12 toward the *Gill v. Whitford* case from the Supreme Court where
13 the Supreme Court said that relief should be limited to the
14 inadequacy that produced the injury in fact that plaintiff has
15 established. And it also said that a Court's constitutionally
16 prescribed rule is to vindicate the individual rights of the
17 people appearing before it. And it also said that a plaintiff's
18 remedy must be tailored to address the plaintiff's particular
19 injury.
20 THE COURT: But how can I invalidate a rule only
21 within the District in which I sit?
22 MS. KOPPLIN: So it's not a question of this being
23 tied to the District you sit. It's a question of what plaintiff
24 do you have before you. The plaintiff here is the State of
25 Washington. So our argument is that the remedy would be to

1 correct any injury the State of Washington might suffer. If
2 another plaintiff thinks they might have an injury, they can and
3 have sued somewhere else. And -- and the Courts hearing those
4 claims might want to reach their own decisions about what relief
5 should apply to those -- those entities.
6 THE COURT: All right. You can assume you'll lose on
7 that particular issue. So let's move on.
8 MS. KOPPLIN: Well, thank you for listening to me,
9 your Honor.
10 And, also, on the scope of relief, I would say the relief
11 should be limited only to the specific provisions of the rule
12 that your Honor has a problem with. There is a severability
13 clause in the rule. So if your Honor is particularly troubled
14 by a certain definition, then it's plaintiff's burden to show
15 that the rule cannot stand without that particular definition.
16 THE COURT: I'm more open to that particular argument.
17 MS. KOPPLIN: Well, I'm glad to hear it, your Honor.
18 THE COURT: All right.
19 MS. KOPPLIN: I've reached the end of what I prepared
20 here. So I will -- or, actually, I'm sorry. I thought of one
21 more thing.
22 THE COURT: Go ahead.
23 MS. KOPPLIN: This is just in response to one thing
24 that plaintiff said. Plaintiffs were discussing this issue of
25 whether or not the rule affects funding from the Departments of

1 Labor and Education.

2 THE COURT: Right.

3 MS. KOPPLIN: And they noted that as a possible

4 disagreement with the SDNY decision. We did address in our

5 briefing and I think we also generally agree with the SDNY

6 decision. Its basis, as I recall from my hasty reading, was

7 that in 88.7 the provisions for relief are limited to the

8 Department's funds; and the Department is defined as HHS. So

9 we're a little bit unclear how that would cover funds from

10 Education or Labor.

11 So with that, I'll let my colleague address the other

12 issues.

13 THE COURT: All right. Thank you, Ms. Kopplin. And I

14 apologize again for having my facts mixed up at the beginning of

15 your argument, but --

16 MS. KOPPLIN: Oh, no. Thank you.

17 THE COURT: -- I appreciate the fact that you

18 clarified that for me. Mr. Takemoto.

19 MR. TAKEMOTO: Good morning, your Honor.

20 THE COURT: Good morning.

21 MR. TAKEMOTO: As my co-counsel said, I will, at your

22 discretion, discuss the statutory authority and contrary-to-law

23 claims that plaintiffs have brought.

24 To begin -- yes?

25 THE COURT: No, no. You said at my discretion or

1 my -- that's fine. That's why we're here. So please.
2 MR. TAKEMOTO: To begin on the statutory authority
3 claims, there are, essentially, three sources of statutory
4 authority for this rule. The first concerns the explicit
5 authority that HHS has been granted, including provisions in the
6 Affordable Care Act, Medicare and Medicaid Acts, and CHIP.
7 Those are major programs, and so they're worth pointing out.
8 Another source of authority for this rule are the -- is the
9 implicit authority that HHS has been given through the
10 conscience statutes.
11 And then the last authority that HHS relies on is the
12 housekeeping authority, which my co-counsel has -- has already
13 discussed.
14 Going into some of the definitions, it's worth stepping
15 back and, you know, assessing what this rule does. It basically
16 has two key provisions. One is the definition section, which
17 defines certain terms that either aren't defined in the statutes
18 or defined through non-exhaustive lists.
19 The other key portion of the rule concerns -- basically
20 describes for regulated entities the authority that HHS has to
21 enforce the conscience statutes when recipients agree to comply
22 with them.
23 And both of these provisions are squarely within HHS's
24 authority as we set out in the briefs. We go through, you know,
25 each of the definitions and explain why they meet that *Chevron*

1 Step One, the plain language of the statutes, and then at Step
2 Two of *Chevron*, you know, why this is a reasonable construction
3 of those definitions.
4 I don't have much more to add on the contrary-to-law claims
5 other than to point out that this is a facial challenge to this
6 rule, and so identifying hypothetical scenarios that may --
7 where a statute may conflict with the rule is not sufficient to
8 vacate the rule.
9 And I would point your Honor to the Supreme Court's
10 decision in *Reno v. Flores*, which involved an undocumented
11 minor's ability to waive the right to an immigration judge. And
12 the Supreme Court said that, although that right may be invalid
13 in some circumstances because it conflicts with other -- other
14 law, if the plaintiff's -- it was the plaintiff's burden to show
15 that it was invalid in all circumstances. And that's at 507
16 United States Reports, Page 309.
17 THE COURT: Thank you.
18 MR. TAKEMOTO: With that, if your Honor has any
19 specific questions on these sections, I'm happy to answer them.
20 Otherwise, we'll rest on our briefs.
21 THE COURT: No. Okay. Thank you.
22 MR. TAKEMOTO: Thank you.
23 THE COURT: I'll give the parties a few minutes to
24 respond to each other. How about ten minutes per side? Would
25 that be sufficient?

1 MR. SPRUNG: Yeah. Yes.
2 THE COURT: Okay.
3 MR. SPRUNG: That is, your Honor.
4 THE COURT: Okay. Let's take a little break right
5 now. Then you can gather your thoughts and you can start making
6 your thoughts for a quick reply. And so let's take ten minutes
7 and then we'll get back together and wrap this up. Thank you.
8 (Court recessed at 10:58 a.m.)
9 (Court reconvened at 11:13 a.m.)
10 THE COURT: All right. Thank you. Please be seated.
11 All right. Let's have a brief rebuttal to each other, and we'll
12 start with the State. And I'll try to limit it to about ten
13 minutes each side so that we can get done on time.
14 MR. SPRUNG: Your Honor, we just have two points to
15 make; and I'm going to ask Ms. Fraas to begin.
16 THE COURT: Okay. Thank you. Excuse me.
17 MS. FRAAS: Thank you, your Honor. Just on the issue
18 of complaints, on Pages 31 to 34 of our motion for summary
19 judgment, we carefully walked through our analysis of the
20 administrative record. And we explained there, you know, how we
21 went from 334 complaints in the record down to the arguably at
22 most 21 percent -- at 21 complaints or 6 percent of the
23 administrative record --
24 THE COURT: And that's what I flipped around in my
25 mind, and I again apologize for that.

1 MS. FRAAS: Absolutely. No, there's a lot of numbers
2 in this case.
3 And I would just note that, in their opposition, the
4 Government did not take any issue with our analysis of -- of the
5 complaints there.
6 To the -- to their point that -- you know, that the Agency
7 properly considered more than just the conscience violations
8 complaints, I would just direct the Court to Page 23175 of the
9 rule where the Government -- where the Agency says, and I quote,
10 Since November 2016, there has been a significant increase in
11 complaints filed with OCR alleging violations of the laws that
12 were the subject of the 2011 rule.
13 And the 2011 rule, your Honor, only related to the three --
14 the three statutes dealing with abortion and sterilization, not
15 vaccinations and not all those other issues. So, clearly, I
16 think that statement indicates that the Agency's belief that
17 there was a substantial increase in complaints on the conscience
18 statutes.
19 Thank you.
20 THE COURT: Thank you, Ms. Fraas.
21 MR. SPRUNG: Your Honor, the only point that I would
22 be happy to address is the severability point. I'm happy to
23 walk through the analysis of the severability issue if the Court
24 would find that helpful.
25 THE COURT: I don't think I need it, but I'm certainly

1 willing to listen if you'd like to make those arguments.
2 MR. SPRUNG: No. Thank you, your Honor.
3 THE COURT: All right. Thank you. From the
4 Government, which I realize they're both government entities
5 here; but I'm just used to calling the United States Government
6 "the Government." And I think that's probably from the criminal
7 docket. But go ahead.
8 MR. TAKEMOTO: The other government doesn't have
9 anything to add.
10 THE COURT: "The other." All right. Thank you.
11 Thank you.
12 All right. Well, I want to, again, thank all of you for
13 the briefing that you did. It was helpful. And maybe you hear
14 that all the time. I don't know. But -- but I maybe need to
15 put it into context. We don't always get briefing from parties
16 on cases that are this good. So I'm not just saying that. I
17 really did appreciate the -- the good briefing that both parties
18 and the amicus participants provided to the Court. It was
19 helpful for us to understand the complex and, you know, large
20 issue that needs to be decided.
21 I also want to thank you for your comments today. I think
22 they were well organized and were helpful, and I realize that
23 all of us were struggling with sort of a change in the -- in the
24 terrain that occurred yesterday with the ruling out of the
25 Southern District of New York. But I think you all responded to

1 it adequately and well and you were helpful to the Court.
2 So I'm looking for my notes here, and I'm getting close to
3 where -- there they are.
4 All right. So I am going to grant the motion for the
5 plaintiff, State of Washington, and deny the motion for the US
6 Government. I'm going to rule that Judge Engelmayer has
7 approached the issue in the way that -- that I was approaching
8 it, as well; but he did it in a very thorough and comprehensive
9 way. And I don't intend to plow the same ground that he plowed.
10 So I will accept his ruling.
11 I will have a written decision later that will address some
12 of the additional issues the parties have asked this Court to
13 address, but I don't intend to go into extensive detail on the
14 issues that Judge Engelmayer handled so well.
15 But I agree with his conclusions that, first, it's
16 appropriate for this Court to decide this issue on summary
17 judgment; second, that the US Government and the Department of
18 Health and Human Services exceeded its statutory authority in
19 adopting this rule; third, that it acted arbitrarily and
20 capriciously in adopting this rule for the reasons that he
21 stated and that I summarized in my opening remarks; and,
22 finally, that the rule is unconstitutional in several respects.
23 Again, my written order will address, hopefully, all of the
24 issues that you've identified that -- that you think still need
25 to be addressed and that Judge Engelmayer didn't address.

1 We -- and, generally, this Court gets its written decisions
2 out fairly quickly; but -- and we will try in this case, as
3 well. This case is a little bit more complex than most.
4 However, I don't feel the pressure -- and I guess if you
5 want to argue with me I'll give you a chance. I don't feel the
6 pressure that we necessarily need to get a written order out by
7 November 22nd, because whatever happens to Judge Engelmayer's
8 order, ultimately nothing will happen to it most likely between
9 now and the 22nd. So I think he took that -- that particular
10 time deadline away from the other courts, me and Northern
11 California and Baltimore that are deciding this issue.
12 If you want to address that, you can; but I don't feel that
13 that's really a deadline that needed to be met. As of yesterday
14 when I was preparing, I thought it was a deadline that needed to
15 be met.
16 Am I wrong on that? I'm not asking you to agree or
17 disagree with Judge Engelmayer. I think I know where you're
18 headed with an appeal, but I doubt anything's going to happen to
19 his order by the 22nd of November.
20 MR. TAKEMOTO: Your Honor, the Government -- the
21 United States Government doesn't have anything to add to what
22 you said.
23 THE COURT: All right. So, again, it's possible that
24 we'll get our -- my decision out by -- before that; but if we
25 can't do it, we can't do it. And I don't feel that that's a

1 particular deadline that we have to meet.
2 So are there any other issues that we need to deal with on
3 this case this morning?
4 MR. SPRUNG: No, your Honor.
5 MR. TAKEMOTO: No, your Honor.
6 THE COURT: All right. Well, thank you again for
7 visiting with me here today and in -- in -- not Yakima, in
8 Spokane. I hope you enjoyed your visit, and safe travels back
9 home.
10 MR. TAKEMOTO: Thank you.
11 MS. FRAAS: Thank you, your Honor.
12 THE COURT: Thank you.
13 (Court adjourned at 11:20 a.m.)
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1 C E R T I F I C A T E

2

3 I, RONELLE F. CORBEY, do hereby certify:

4 That I am an Official Court Reporter for the United States

5 District Court for the Eastern District of Washington in

6 Spokane, Washington;

7 That the foregoing proceedings were taken on the date and

8 at the time and place as shown on the first page hereto; and

9 That the foregoing proceedings are a full, true and

10 accurate transcription of the requested proceedings, duly

11 transcribed by me or under my direction.

12 I do further certify that I am not a relative of, employee

13 of, or counsel for any of said parties, or otherwise interested

14 in the event of said proceedings.

15 DATED this 19th day of November, 2019.

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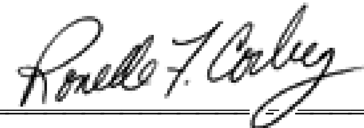

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