EXHIBIT 17

National
Family Planning
& Reproductive Health Association

March 27, 2018

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

Attn: Protecting Statutory Conscience Rights in Health Care NPRM, RIN 0945-ZA03

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to provide comments on the US Department of Health and Human Services' (HHS) notice of proposed rulemaking (NPRM), "Protecting Statutory Conscience Rights in Health Care," RIN 0945-ZA03.

NFPRHA is a national membership organization representing the nation's publicly funded family planning providers, including nurse practitioners, nurses, administrators, and other key health care professionals. NFPRHA's members operate or fund a network of more than 3,500 health centers and service sites that provide high-quality family planning and other preventive health services to millions of low-income, uninsured, or underinsured individuals in 50 states and the District of Columbia. Services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers and other private nonprofit organizations.

NFPRHA is deeply concerned that this NPRM ignores the needs of the patients and individuals served by HHS' programs and creates confusion about the rights and responsibilities of health care providers and entities. Because they receive Title X, Medicaid, and other HHS funds, NFPRHA members would have no choice but to comply with this rule: failure to do so could lead to termination of current or pending HHS funds, as well as return of money previously paid to NFPRHA members for services they have provided. This means hundreds of millions of dollars in federal funding are at stake for NFPRHA members if they run afoul of the rule. Without federal support, many of our members would be forced to drastically scale back the services they provide to their patients or to close completely. Because NFPRHA members represent the vast majority of Title X clinical locations that serve people who cannot afford to pay for health care on their own, this would leave many low-income and uninsured or under-insured patients without access to family planning and other critical health care services.

Although this NPRM claims the authority to interpret numerous statutes of concern and interest, NFPRHA will limit its comments primarily to the unjustified and unauthorized expansion of the Church amendments (42 USC 300a-7), Coats-Snowe amendment (42 USC 238n), and Weldon amendment (e.g. Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d)) (together, "Federal health care refusal statutes"). Because this NPRM encourages unprecedented discrimination against patients and opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program, it should be withdrawn.

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Background on the 2008 Health Care Refusal Regulations

In the decades-long history of the federal health care refusal statutes, none of which delegate rulemaking authority to HHS, regulations purporting to clarify and interpret these laws have been promulgated only once, in late 2008.

In 2008, HHS promulgated an NPRM purporting to interpret and enforce the federal health care refusal statutes claiming "concern…that there is a lack of knowledge on the part of States, local governments, and the health care industry" of the refusal rights contained within these statutes. (73 Fed. Reg. at 50, 278). Despite allowing only a 30-day comment period, HHS received more than 200,000 comments in response to the proposed rule—the vast majority of which opposed the rule as unnecessary, unauthorized, and overbroad.[1] Notably, HHS conceded, it received "no Comments indicating that there were any [federal] funding recipients not currently compliant with [the underlying statutes]" (73 Fed. Reg. at 78,095). HHS published a final rule on December 19, 2008, which did not materially differ from the NPRM and was immediately subject to legal challenge by multiple parties, including NFPRHA and seven state attorneys general.[2]

In 2011, HHS rescinded those aspects of the 2008 rule that were "unclear and potentially overbroad in scope," but maintained those parts of the rule establishing an enforcement process for the Federal health care refusal statutes and began an "initiative designed to increase the awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been violated." (76 Fed. Reg. at 9969). This rule remains in effect.

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[1] Comments to Provider Conscience Regulations, 73 Fed. Reg. 50274 (August 26, 2008) (to be codified at 45 CFR 88).

[2] *National Family Planning and Reproductive Health Association et al v. Leavitt*, No. 09-cv-00055 (Dist. Conn. Jan. 15, 2009) *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009); *Planned Parenthood Federation of America v. Leavitt*, No. 09-cv-00057 (Dist. Conn. Jan. 15, 2009); *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009).

According to the current NPRM, since 2008, "OCR [Office for Civil Rights] has received a total of forty-four complaints [related to Federal health care refusal laws], the large majority of which (thirty-four) were filed since the November 2016 election." (83 Fed. Reg. at 3886). To place that figure into context, OCR in total received approximately 30,166 complaints in fiscal year (FY) 2017.

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The NPRM overstates statutory authority and seeks to dramatically expand the reach of the underlying statutes.

For decades, federal health care refusal statutes have given specified individuals and institutions certain rights to refuse to perform, assist in the performance, and/or refer for abortion and/or sterilization services. Despite the lack of a congressional mandate to do so, the NPRM seeks to dramatically expand the scope and reach of these laws, as well as grant overall responsibility for ensuring and enforcing compliance with those statutes to OCR, using identical language to many aspects of the now-rescinded 2008 regulation that faced widespread opposition at that time.[3]

The Church amendments were enacted by Congress in the 1970s in response to debates about whether the receipt of federal funds required recipients to provide abortion or sterilization services. These provisions make clear, among other things, that:

- The receipt of federal funding under the Public Health Service Act (PHSA) (42 U.S.C. § 201 et seq.) does not itself obligate any individual to perform or assist in the performance of sterilization or abortion procedures if those procedures are contrary to the individual's religious or moral beliefs (Church (b)(1)); and,
- Health care personnel employed by certain federally funded programs and facilities cannot be discriminated against in terms of employment, promotion, or the extension of staff or other privileges for performing or assisting in the performance of sterilization or abortion services, or refusing to perform or assist in the performance of such services based on their religious or moral beliefs (Church (c)(1)).

In 1996, Congress adopted the Coats amendment in response to a decision by the accrediting body for graduate medical education to require OB/GYN residency programs to provide or permit abortion training. The Coats amendment prohibits federal, state, and local governments from discriminating against health care entities, such as "individual physicians, postgraduate physician training programs, or . . . participant[s] in a program of training in the health profession," that refuse to provide or require training in abortions or individuals who refuse to be trained to provide abortions.

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[3] Comment of the National Family Planning & Reproductive Health Association to Provider Conscience Regulations, Tracking Number 8072403d to 73 Fed. Reg. 50274 (proposed August 26, 2008) (comment dated September 25, 2008) (to be codified at 45 CFR 88).

Since 2004, Congress has attached the Weldon amendment to the annual appropriations measure that funds the Departments of Labor, Health and Human Services, and Education (Labor-HHS). That amendment prohibits federal agencies and programs and state and local governments that receive money under the Labor-HHS Appropriations Act from discriminating against individuals, health care facilities, insurance plans, and other entities because they refuse to provide, pay for, provide coverage of, or refer for abortion.

The Church, Coats-Snowe, and Weldon amendments were never intended to provide individual health care providers and/or entities with the myriad and expansive rights of refusal this NPRM seeks to achieve. Without statutory authorization, the NPRM expands the reach of the Church, Coats-Snowe, and Weldon Amendment beyond what was contemplated by Congress and is permitted by existing federal law, by expanding the categories of individuals and entities whose refusals to provide information and services are protected; expanding the types of services that individuals and entities are allowed to refuse to provide; and expanding the types of entities that are required to accept such refusals. For example:

- Despite the plain language of the Weldon amendment, the NPRM attempts to extend it to apply to funding beyond that appropriated by Labor-HHS appropriations and to non-governmental entities, as well. The statute of the Weldon amendment states:

  > "(1) None of the funds ***made available in this Act*** may be made available to ***a Federal agency or program, or to a State or local government***, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

  Yet § 88.3(c) of the NPRM adds new language that applies the Weldon amendment's prohibitions not only to federal agencies and programs and state and local governments that receive Labor-HHS funds, but also to "***[a]ny entity that receives funds through a program administered by the Secretary or under an appropriations act for the Department that contains the Weldon amendment***" [emphasis added].

  This language broadens Weldon's reach in two impermissible ways: 1) it extends the restrictions to entities that do not even receive funding via Labor-HHS appropriations, to apply to funding through any program administered by HHS; and, 2) it applies the restrictions of the Weldon amendment beyond the statutory reach of federal agencies or programs, or state or local governments, to any entity receiving certain federal funds. These extensions of Weldon's reach are clearly contrary to both the plain language of the Weldon amendment and to congressional intent.

- While the Church amendment prevents PHSA funds from being used to require individuals and institutions to, among other things, "assist in the performance" of abortions and sterilizations, and prevents employment discrimination against those who refuse to do so, § 88.3 of the NPRM

transforms this statutory shield into a sword, creating out of whole cloth a categorical right of refusal for any recipient of PHSA funds. Moreover, § 88.2 of the NPRM provides an unprecedentedly and unjustifiably broad definition of the term "assist in the performance" that runs counter to congressional intent and common sense. The NPRM would define "assist in the performance" as participating "in ***any activity*** with an ***articulable connection*** to a procedure, health service or health service program, or research activity" [emphasis added]. In other words, HHS proposes to create refusal rights for anyone who can ***simply express a connection*** between something they do not want to do and an abortion or sterilization procedure (e.g., scheduling appointments, processing payments, or treating complications). Even the sole instance of previous rulemaking under the Church amendments in 2008, which was rescinded before it ever took effect, was not so broad.

- Likewise, the NPRM's definition of referral/refer seeks to dramatically expand the scope and reach of the Coats-Snowe and Weldon amendments and runs counter to congressional intent and common sense. Section 88.2 of the NPRM defines "referral/refer for" abortion to include:

  > "the provision of any information (including but not limited to name, address, phone number, email, website, instructions, or description) by any method (including but not limited to notices, books, disclaimers, or pamphlets, online or in print), pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."

  This definition would impair the ability of health care professionals to fulfill their legal and ethical duties of providing complete, accurate, and unbiased information to their patients. For example, as discussed further below, the NPRM could be read to permit employees of Title X-funded health centers and other federally funded entities to refuse to provide information and referrals to patients, without ever addressing patient needs and in clear violation of the fundamental tenets of informed consent.

As interpreted by the NPRM, the Church, Coats-Snowe, and Weldon amendments would be radically expanded to create far-reaching protections for individuals and entities that would refuse to provide patients not only with health care services, but also the most basic information about their medical options and that seek to obstruct the ability of certain patients to access any care at all. This is impermissible and, as discussed below, would cause unprecedented harm to patients and undermine the integrity of key HHS programs.

This NPRM goes beyond HHS' statutory authority and should be withdrawn. If HHS promulgates a final rule, however, it must identify the source of its legal authority, if any at all, to promulgate these regulations and to alter and expand the meaning of the statutory language.

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The NPRM attempts to grant OCR oversight authority and enforcement discretion that is overly broad and vague; unduly punitive; and ripe for abuse.

While some of the investigative authority and enforcement powers of the current NPRM appear to comport with similar provisions in other areas subject to OCR oversight and enforcement authority, the NPRM 1) includes new, troubling provisions that are vague, overly broad, and overly punitive; and 2) as a whole, appear to impart in OCR authority and enforcement discretion that is ripe for abuse.

Indeed, while the NPRM claims to "borrow...from enforcement mechanisms already available to OCR to enforce similar civil rights laws," the NPRM contains troubling differences. For example, the NPRM states that investigations may be based on anything from 3rd party-complaints to news reports, and yet at the same time appears to give OCR the authority to withhold federal financial assistance and suspend award activities, based on "threatened violations" alone, without first allowing for the completion of an informal resolution process. (See 83 Fed. Reg. at 3891, 3930-31). By contrast, the Department of Justice (DOJ) regulations implementing Title VI of the Civil Rights Act of 1964 (prohibiting discrimination on the basis of race in federally funded programs) state that DOJ will not take such drastic steps to respond to actual or threatened violations unless noncompliance cannot first be corrected by informal means. (See 28 C.F.R. § 42.108(a)). When combined with other aspects of the NPRM, concern over the breadth and potential harm of such provisions is obvious and legitimate. For instance:

- Under § 88.6, the NPRM includes a 5-year reporting requirement that requires any recipient or sub-recipient subject to an OCR compliance review, investigation, or complaint related to the health care refusal rules to inform any current HHS "funding component" of the review/investigation/complaint, as well as to disclose that information in any application for new or renewed "Federal financial assistance or Departmental funding." Once again, this is distinct from the DOJ regulations enforcing Title VI, which only require disclosure of compliance reviews (not every investigation or complaint, regardless of whether it is unfounded) over the past two years. (28 C.F.R. § 42.406(3)). Yet the NPRM fails to explain the purpose of the vastly expanded reporting requirement and period. In light of the broad investigative authority and harsh penalties described above, this leaves affected entities with significant concern about how such information is intended to be used and whether it will unfairly prejudice consideration of applicants for federal funds or penalize currently funded entities in ways that could be extremely harmful.

The NPRM also includes very troubling language that appears to be little more than a pretext for defunding entire classes of providers, which it cannot do. The preamble text accompanying § 88.7

states, "The Director may, in coordination with a relevant Department component, restrict funds for noncompliant entities in whole or in part, including by ***limiting funds to certain programs and particular covered entities, or by restricting a broader range of funds or broader categories of covered entities***" [emphasis added]. This delegation of authority is not only far beyond the scope of the underlying laws but seems designed to grant arbitrary authority that is ripe for abuse, with no mechanism of due process or oversight to prevent entire categories of providers or programs from being penalized without cause. To the extent § 88.7 seeks to create a back door to excluding certain family planning providers from the Title X and Medicaid programs—efforts that have been repeatedly rejected by the courts—it, again, exceeds the scope of the agency's authority and will do nothing more than harm the health and well-being of patients.

Given the lack of evidence that the system currently in place cannot adequately handle complaints, as well as any sufficient justification for departing from the processes used to ensure compliance with other federal statutes, HHS must, at a minimum, adequately explain the reason for these changes, what safeguards exist to prevent abuse, and demonstrate that this language is not simply a pretext for unlawfully excluding certain categories of providers from participating in federally funded programs.

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The NPRM opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program.

The NPRM ignores the reality that some individuals and entities are opposed to the essential health services that are the foundation of longstanding, critical HHS programs like Title X. In the arena of health care, and particularly family planning and sexual health, HHS-funded programs cannot achieve their fundamental, statutory objectives if grantees, providers, and contractors have a categorical right to refuse to provide essential services, such as non-directive pregnancy options counseling.

The Title X family planning program was created by Congress in 1970 "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services" (42 USC 300). Title X projects are designed to "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59).

In 2014, more than 20.2 million women in the United States were in need of publicly funded contraceptive services. Women in need of publicly funded family planning services is defined as follows: "1) they were sexually active (estimated as those who have ever had voluntary vaginal intercourse, 2) they were able to conceive (neither they nor their partner had been contraceptively sterilized, and they did not believe they were infecund for any other reason); 3) they were neither intentionally pregnant nor trying to become pregnant; and, 4) they have a family income below 250% of the federal poverty level. In addition, all women younger than 20 who need contraceptive services, regardless of their family income are assumed to need publicly funded care because of their heightened need—for reasons of

confidentiality—to obtain care without depending on their family's resources or private insurance."[4] In the face of this widespread need, publicly funded family planning and sexual health care provides a crucial safety net for women and families. The impact of these services cannot be underestimated. Without publicly funded family planning services, there would be 67% more unintended pregnancies (1.9 million more) annually than currently occur.[5]

Congress has specifically required that "all pregnancy counseling shall be non-directive" (Public Law 110-161, p. 327), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)). Despite the incredible success of the Title X program and the critical services it provides, Title X has been chronically underfunded, with no new service dollars allocated in nearly a decade. It is a testament to the dedication of the existing Title X network to meeting the goals of the program that, despite limited resources, these providers still serve more than four million patients per year.[6]

However, in addition to the overly broad definitions of "referral" and "assist in the performance" discussed above, by proposing a definition of "discrimination" that appears to jettison the longstanding framework that balances individual conscience rights with the ability of health care entities to continue to provide essential services to their patients, the NPRM seems designed to allow entities that refuse to provide women with the basic information, options counseling, and referrals required by law to compete on the same footing for federal money with family planning providers who adhere to the law and provide full and accurate information and services to patients. The NPRM thus threatens to divert scarce family planning resources away from entities that provide comprehensive family planning services to organizations that refuse to provide basic family planning and sexual health care services. Diverting funds away from providers offering the full range of family planning and sexual health services would not only seriously undermine public health, especially for the low-income, uninsured, and under-insured, but would also be contrary to congressional intent and explicit statutory requirements of the Title X family planning program.

The NPRM likewise creates confusion about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. To the extent that the rule seeks to immunize subrecipients who refuse to provide essential services and complete information about all of a woman's pregnancy options, it undermines the very foundation of the Title X program and the health of the patients who rely on it.

In addition to potential issues with the selection of grantees and subrecipients, the proposed definition of "discrimination" also poses significant employment issues for all Title X-funded health centers. As

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[4] Jennifer Frost et al, *Contraceptive Needs and Services, 2014 Update* (New York: Guttmacher Institute, 2016).
[5] Jennifer Frost et al, *Publicly Funded Contraceptive Services at U.S. Clinics, 2015* (New York: Guttmacher Institute, April 2017).
[6] Christina Fowler, *Family Planning Annual Report: 2016 national summary* (Research Triangle Park, NC: RTI International, 2017).

discussed further below, the language in the NPRM could put Title X-funded health centers in the position of being forced to hire people who intend to refuse to perform essential elements of a position. For example, the rule provides no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the individual refuses to provide non-directive options counseling. Furthermore, the NPRM does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician out of the health department's family planning project to a unit where pregnancy counseling is not done.

Because the NPRM threatens to undermine the integrity of key HHS programs, including the Title X family planning program, HHS must, at a minimum, clarify that any final rule does not conflict with preexisting legal requirements for and obligations of participants in the Title X program, or of employers, as set forth under Title VII of the Civil Rights Act of 1964, discussed below.

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The NPRM fails to sufficiently address patient needs or achieve the careful balance struck by existing civil rights laws and encourages unprecedented discrimination against patients that will likely impede their access to care and harm their health.

The stated mission of HHS is "to enhance and protect the health and well-being of all Americans." Yet, the NPRM elevates the religious and moral objections of health care providers over the health care needs of the patients who HHS is obligated to protect. The NPRM appears to allow individuals to refuse to provide health care services or information about available health care services to which they object on religious or moral grounds, with virtually no mention of the needs of the patient who is turned away. Patients should not be forced to bear the brunt of the objector's religious or moral beliefs, particularly to the detriment of their own health. In fact, legal and ethical principles of informed consent require health care providers to tell their patients about all of their treatment options, including those the provider does not offer or favor, so long as they are supported by respected medical opinion. As such, health care professionals must endeavor to give their patients complete and accurate information about the services available to them.

Furthermore, the NPRM fails to address serious questions as to whether its purpose is to upset the careful balance struck in current federal law between respecting employee's religious and moral beliefs and employers' ability to provide their patients with health care services. Title VII provides a balance between health care employers' obligations to accommodate their employees' religious beliefs and practices (including their refusal to participate in specific health care services to which they have religious objection) with the needs of the patients they serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs, unless doing so places an "undue hardship" on the employer. This law provides protection for individual belief while still ensuring patient access to health care services. The NPRM provides no guidance about how, if at all, health care

employers are permitted to consider patients' needs when faced with an employee's refusal to provide services.

The NPRM ignores the needs of patients and fails to consider whether an employer can accommodate such a refusal without undue hardship. In so doing, the NPRM invites health care professionals to violate their legal and ethical duties of providing complete, accurate, and unbiased information necessary to obtain informed consent. The failure of health care professionals to provide such information threatens patients' autonomy and their ability to make informed health care decisions.

Title VII is an appropriate standard that protects the needs of patients and strikes an appropriate balance. At a minimum, HHS should clarify that any final rule does not conflict with Title VII.

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The NPRM vastly underestimates the financial burden it would impose on federally funded health care providers who already operate with limited resources.

NFPRHA is particularly well positioned to comment upon the extremely burdensome effect the NPRM will have on the variety of public and private entities awarded federal dollars to provide health services to underserved communities.

As an initial matter, for a non-lawyer to simply read and understand the regulatory language and the lengthy preamble of the NPRM requires numerous hours – much longer than the roughly "10 minutes per law" estimated by HHS. (See 83 Fed. Reg. at 3913). A Final Rule, which would respond to prior comments and provide explanation and commentary elaborating on the Regulation, would require the same at minimum. Moreover, given the magnitude of funds at stake, the complexity and ambiguity of the NPRM's employment provisions, and the diverse staffing arrangements among recipients of federal funds, many NFPRHA members will need to pay for the time of legal counsel to review and consult with them on how to adjust their policies and practices prior to certifying compliance. This will also require time and cost for legal counsel to research and advise how, or if, it is possible for an entity to achieve compliance with the rule as well as with potentially conflicting obligations under State or other Federal laws. A reasonable estimate of these tasks alone would include at least several hours of attorney as well as multiple hours of executive and management staff time – not just the average of 4 hours (total) per year of lawyer and staff time estimated by HHS. (See 83 Fed. Reg. at 3913).

In particular, it appears that policies and practices to comply with the Department's articulated standard will be different than those necessary to comply with existing federal laws such as Title VII. Thus, in estimating an average of 4 hours (total) per year to update policies and procedures *and* retrain staff (see 83 Fed. Reg. at 3913), the NPRM utterly fails to account for:

- Time and cost for legal and human resources or executive staff to review and revise job postings, job descriptions, job application materials, interview and hiring policies and practices, and other employment recruitment and hiring materials.

- Time and cost for legal and human resources or executive staff to review and revise employee manuals and handbooks, and other employment related policies and documents.

- Time and cost to devise and provide trainings for managers and other supervisory staff on interviewing, hiring, and responding to accommodation requests from employees and volunteers who object to participating in the provision of certain health care services.

- Time and cost of hiring and training additional employees and/or paying and retraining existing employees for additional hours to accommodate other employees who refuse to provide services.

While these comments do not attempt to identify and detail each of the likely costs that NFPRHA members and other regulated entities would face if the NPRM was finalized, they demonstrate the qualitatively and quantitatively substantial costs overlooked by HHS in its NPRM. In light of these burdens and the HHS's inability to demonstrate a countervailing need for the rule, NFPRHA strongly urges HHS to withdraw the NPRM. Failure to do so will result in substantial resources being diverted away from providing critical health care to patients in an already underfunded family planning safety net.

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NFPRHA appreciates the opportunity to comment on the NPRM, "Protecting Statutory Conscience Rights in Health Care." If you require additional information about the issues raised in these comments, please contact Robin Summers at rsummers@nfprha.org or 202-552-0150.

Sincerely,

Clare M. Coleman

Clare Coleman
President & CEO

EXHIBIT 18

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

March 27, 2018

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

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

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

Dear Director Severino:

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

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

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

Recommendations

Our recommendations are as follows:

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

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

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

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

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

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

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

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

Sincerely,

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

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

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

Issue:

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

Recommendation:

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

Rationale:

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

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

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

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

Issue:

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

Recommendation:

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

Rationale:

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

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

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

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

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

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

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

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

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

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

Issue:

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

Recommendation:

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

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

Rationale:

The Preamble to the Proposed Rule states:

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

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

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

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

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

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

The Department further explained:

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

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

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

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

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

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

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

83 Fed. Reg. 3880, 3892.

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

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

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

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

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

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

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

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

Issue:

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

Recommendation:

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

Rationale:

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

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

83 Fed. Reg. 3880, 3924.

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

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

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

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

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

V. Written Assurance and Certification (Proposed § 88.4)

Issue:

The requirements for written assurances and certification are unnecessarily duplicative.

Recommendation:

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

Rationale:

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

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

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

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

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

VI. Notice (Proposed § 88.5)

Issue # 1:

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

Recommendation:

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

Rationale:

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

Issue # 2:

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

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

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

Recommendation:

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

Rationale:

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

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

VII. Effective Date

Issue:

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

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

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

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

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

Recommendation:

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

Rationale:

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

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

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

Other areas of communication that require review and revision include:

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

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

EXHIBIT 19

STATE OF CALIFORNIA
Dave Jones, Insurance Commissioner

DEPARTMENT OF INSURANCE
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Submitted via www.regulations.gov

March 27, 2018

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

SUBJECT: Comments on Proposed Rule RIN 0945–ZA03: "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"

Dear Secretary Azar:

As California's Insurance Commissioner, I lead the largest consumer protection agency in the state and am responsible for regulating California's insurance market, which is the nation's largest. The California Department of Insurance implements and enforces consumer protections such as essential health benefits requirements, anti-discrimination protections, and laws pertaining to timely access to medical care.

Your proposed rule, *Protecting Statutory Conscience Rights in Health Care,* would result in delays in timely access to medical care, denials of access to medically necessary basic health care services, and would likely result in widespread discrimination in our health care system. Simply put, it undermines patient care.

Existing state and federal law provide health care provider conscience protections, but do not allow them to interfere with patient access to care or civil rights protections that prohibit discrimination. I strongly object to the proposed rule *Protecting Statutory Conscience Rights in Health Care* ("Rule"), which encourages discrimination that will harm patients and urge that it be withdrawn by your Department.

Impacts of the Proposed Rule

Under the ostensible claim of protecting religious beliefs and moral convictions, the Rule instead would give providers free rein to discriminate against people on the basis of race, sex, sexual orientation, gender, gender identity, and almost any other kind of bias. The very individuals whose rights the Office of Civil Rights ("OCR") was created to protect would now be subject to discrimination under the Rule. A provider could, ostensibly, refuse under this Rule to provide medical care to a biracial couple seeking a medically necessary health service on the grounds

that doing so would be contrary to his or her religious beliefs or moral convictions. A medical facility, provider or insurer – by action of a scheduling assistant, intake personnel, board of directors, or medical provider – could deny treatment to a patient seeking gender reassignment surgery on the basis that he or she finds it morally objectionable. Similarly, under the proposed Rule, a woman could be denied timely access to abortion services; a provider could refuse to treat a child because her parents are lesbians and the doctor objects to their sexual orientation. In this Rule, HHS improperly pits the beliefs of providers, insurers, and other health care entities against the rights of patients.

Additionally, the Rule attacks a fundamental aspect of federalism by preventing the application of state law and consitutional protections. The U.S. Department of Health and Human Services ("HHS") cannot interfere with a state's ability to protect the civil rights of its residents. California law requires health insurance coverage for a comprehensive set of basic health care services, including reproductive health services. California's Unruh Civil Rights Act explictly prohibits discrimination:

> All persons within the jurisdiction of this state are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments of every kind whatsoever.[1]

State law further requires that medical providers and others whose licenses are granted by the state under the provisions of the Business and Professions Code are subject to disciplinary action for refusing to provide services based on characteristics protected under the Unruh Civil Rights Act.

The right of health care providers, and entities, to hold private beliefs does not and should not trump the rights of patients to obtain the care to which they are legally entitled. Licensure as a health care provider, facility, or insurer does not provide license to discriminate. Although HHS points to some law in support of this rule, there is a substantial, contrary body of law that supports a woman's right to choose, as well as the right to not be discriminated against on the basis of a person's sex, gender, gender identity, or sexual orientation. For example, California's Supreme Court ruled that the religious freedom of a medical provider does not exempt them from complying with the anti-discrimination protections in Unruh (*North Coast Women's Medical Group, Inc. v. San Diego County Superior Court* (2008) 44 Cal.4th 1145).

[1] California Civil Code section 51, subdivision (b).

The Rule Exceeds Legal Authority

Existing law provides sufficient protection to health care entities that refuse to participate in certain health care services, including abortion, where they find such services to be religiously or morally objectionable, as evidenced by section 88.3 of the Rule, subdivisions (a) through (d), which are largely a restatement of existing law. The Department is wrong to expand the statutory protections already provided, and has no clear authority to do so.

By providing new definitions for long-existing terms in the law, the Rule expands and distorts the meaning of these terms. The Rule attempts to redefine "assist in the performance" to include participating in "any program or activity with an articulable connection to a procedure, health services, health program, or research activity…" including, but not limited to "counseling, referral, training, and other arrangements" for the health care service. This definition is so broad as to include even the provision of basic information for a lawful or necessary health care procedure or service. As a result, a provider could refuse to tell a pregnant woman about a health care service that is vital to her health, including her future fertility.

The Rule is so broad that it makes no exception for emergency treatment, meaning that despite a woman's very life being at risk due to a miscarriage, a provider could refuse to even disclose the risk to her life on the basis of the provider's own religious beliefs or moral convictions. This is contrary to the ethical duties owed by physicians to patients, and is contrary to federal law, which allows federal funds to be used to pay for abortions in the cases where the woman's life is in danger. These duties include the doctrine of informed consent which requires a provider to inform a patient of the risks and benefits associated with a health care service or procedure, as well as available alternatives to that service or course of treatment. Informed consent is a legal obligation due from a physician to a patient; failure to receive informed consent constitutes negligence.

The Rule would expand the scope of existing federal refusal laws to almost any entity associated with health care. The Rule's broad definition of "health care entity" expands this term to include "a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan." Such an expansion of the law would allow an employer to deny coverage of abortion or any number of other health care services to their employees even if otherwise required by law.

The Rule also adds a definition for "referral" where one did not exist. By including public "notices" within this definition, the Rule will prevent the enforcement of California's Reproductive FACT Act, which requires facilities specializing in pregnancy-related care to disseminate notices to all clients about the availability of public programs that provide free or subsidized family planning services, including prenatal care and abortion. This Act is currently subject to ongoing court cases, including a case before the Supreme Court of the United States (*National Institute of Family and Life Advocates v. Becerra*, (9th Cir. 2016) 839 F.3d 823, *cert.*

granted (2017) 138 S.Ct. 464) in which the Court heard oral arguments on March 20th, 2018. HHS should allow the litigation process to conclude and permit the courts to decide whether state laws requiring these type of notices comply with the United States Constitution and federal law.

Similarly, this Rule would to allow a pharmacist to refuse to fill a birth control prescription or refer such a prescription to another pharmacist because they find it objectionable. HHS is attempting to circumvent settled case law, which has held that a pharmacy may not deny any lawful drug, including emergency contraceptives, to any customer for religious reasons. (*Storman's, Inc. v. Wiesman*, (9th Cir. 2015) 794 F.3d 1064, *cert. denied* (2016) 136 S.Ct. 2433). As in many other areas of the Rule, HHS has failed to narrowly tailor the Rule to apply to the specific conscience objections allowed under existing law. Failure to narrowly tailor the Rule will lead to confusion, denial of access to medically necessary care, and increase the likelihood of discrimination against patients.

Weldon Amendment Overreach

In addition to the above noted expansions, the Rule contradicts OCR's previous interpretation of the Weldon Amendment in an attempt to increase its application. As the Rule notes, in 2016 OCR issued a determination on three complaints brought against the California Department of Managed Health Care ("CDMHC") on the basis that the CDMHC required coverage of voluntary abortions as mandated by California law. In its determination in favor of CDMHC, OCR specifically noted that

> "[a] finding that CDMHC had violated the Weldon Amendment might require the government to rescind all funds appropriated under the Appropriations Act to the State of California – including funds provided to the State not only by HHS, but also by the Departments of Education and Labor…such a rescission would raise substantial questions about the constitutionality of the Weldon Amendment."

This determination was made after consultation with the U.S. Department of Justice. In making this determination, OCR pointed to the Court's reasoning in *National Federation of Independent Business v. Sebelius*, (2012) 567 U.S. 519, "that the threat to terminate significant independent grants was so coercive as to deprive States of any meaningful choice whether to accept the condition attached to receipt of federal funds."

With this proposed Rule, however, HHS now specifically intends to apply just such coercion, contrary to its prior, considered findings. HHS is reversing its position with scant legal basis for doing so. In essence, HHS seeks to confer upon health insurers a newly-created ability to make a claim of discrimination against the State of California if they refuse to cover abortions if, for example, they simply don't want to pay for this basic health care service. The Rule's frontal attack on this fundamental aspect of federalism puts the State of California in the impossible

position of either enforcing its state constitution[2] and law, with the loss of federal funding for many programs, or allowing a state-regulated health insurer to flout the state law specifically requiring coverage for all reproductive services, including abortion and sterilization. California will enforce state law. If this Rule is finalized rather than withdrawn, it will result in litigation.

The plain language of the Weldon Amendment allows providers to recuse themselves from participating in or facilitating an abortion. Similarly, existing law in California protects a health care provider who refuses to participate in training for, the arranging of, or the performance of an abortion. The proposed rule, however, goes far beyond these limited accommodations and, in conflict with the state Constitution, instead threatens already-obligated federal funding upon which vital health programs depend.

Adverse Impact on Consumers

The Rule's overlap and conflict with existing state and federal law will have a chilling effect on those seeking essential health care services. It will cause confusion for patients as they attempt to exercise their right to access the full range of medically appropriate care, as well as confusion for the very health care entities that the Rule purports to protect. This Rule is evidence of the continuing attempts by HHS to enshrine discrimination against women, LGBTQ individuals, and their families. It is so broad in scope that, under the guise of protecting the personal beliefs of corporations and other health care entities, it condones discrimination based only on a financial objection to providing services, rather than upon actual religious or moral convictions.

In November 2017, I submitted a declaration in the case of *State of California v. Wright* (subsequently renamed on appeal *State of California et al. v. Alex Azar)* regarding federal regulations that implicate both religious and moral exemptions regarding contraceptive coverage. Those rules would allow employers to exclude contraceptive coverage mandated by the Affordable Care Act from their employees' health insurance policies. A preliminary injunction was granted enjoining enforcement of the rule, which is currently under appeal. In my declaration I provided evidence that demonstrated the harm to women if the rule denying women access to contraceptives was permitted to remain in effect. Similarly, on December 15, 2017, the United States District Court for the Eastern District of Pennsylvania granted a preliminary injunction in *Commonwealth of Pennsylvania v. Trump*, a related case. At issue in this proposed Rule is the same grim burden presented by these cases: that the Rule would impose harm to women's health.

[2] *See e.g.* Defend Reproductive Rights v. Myers, (1981) 29 Cal.3d 252 (the California Constitution, on numerous occasions, has been construed to provide greater protection than that afforded by parallel provisions of the United States Constitution. In this case the California Supreme Court held that the California state constitution requires abortion benefits to be provided under MediCal, the state Medicaid program.)

Thanks to the Affordable Care Act, health insurance policies must cover contraceptives. Tens of millions of women across the nation benefit from the ACA provision that requires health insurance coverage of contraceptives without any co-payments or deductibles. Under this new proposed rule, women could be denied their prescribed contraception based on the moral or religious views of the pharmacy owners or employees. The Rule would permit any health care worker to interfere with a woman's constitutionally protected right to make her own reproductive health care decisions. Denying access to contraceptives and other forms of birth control (such as tubal ligation) will result in an increased number of unintended pregnancies and in abortions. Similarly, when a provider's refusal to refer a woman to a health facility where she can obtain an abortion delays the procedure, that provider is increasing health risks for that patient.

As California's Insurance Commissioner, I issued the first regulations in the nation to ensure that transgender Californians would not be discriminated against when seeking health care. We know from the 2015 U.S. National Transgender Survey that 33% of respondents who had seen a health care provider in the past year reported having at least one negative experience related to being transgender such as verbal harassment, refusal of treatment, or having to teach the health care provider about transgender people to receive appropriate care. The Rule would not only continue this significant problem, but would increase the number of patients who are refused treatment by sanctioning such actions by providers. The survey also brought to light the fact that "[i]n the past year, 23% of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person…"[3] Again, under this Rule, that problem would only worsen.

By allowing health care providers to discriminate against LGBTQ persons through this Rule, the Administration risks exacerbating existing health disparities. The Federal Office of Disease Prevention and Health Promotion has determined that LGBT persons already face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights, stating: "Discrimination against LGBT persons has been associated with high rates of psychiatric disorders, substance abuse, and suicide."[4]

The Rule Imposes a Substantial Regulatory Burden

Large portions of the Rule are essentially a restatement of existing federal law (*See e.g.* §88.3(a)-(d)). As commentators raised during the rulemaking process in 2011 and HHS acknowledged, "existing law, including Title VII of the Civil Rights Act of 1964 and the federal health care provider conscience protection statutes cited in the Rule already provide protections to

[3] James, S.E., Herman, J.L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016) *The Report of the 2015 U.S. Transgender Survey*, National Center for Transgender Equality, p.10

[4] Office of Disease Prevention and Health Promotion (ODPHP), Healthy People 2020, *Lesbian, Gay, Bisexual, and Transgender Health*, retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health

individuals and health care entities."[5] Additionally, the existing rule provides a regulatory enforcement scheme to protect and enforce the rights afforded to health care entities under these laws. The addition of an unnecessary and costly regulation is counter to the intent of Executive Order (EO) 13771. The EO promoted a policy of prudence and fiscal responsibility in the Executive Branch. This Rule satisfies neither goal. This costly Rule is unnecessary to the extent that is merely a restatement of existing law, and, because of such duplication, is likely to cause confusion.

Additionally, this Rule would unduly burden health care entities, including health insurers, states, and providers who would have to keep records to comply with a self-initiated OCR audit or rebut a complaint of discrimination; essentially, the voluminous production, retention, and production of records to prove a negative. The costs and administrative burdens associated with the assurance and certification requirements under this Rule are unnecessary given that existing law already provides sufficient protection to health care entities. Further, the compliance requirements introduce uncertainty into existing, ongoing federal grant programs, inasmuch as the requirements compel violation of state law.

In conclusion, if this rule is implemented, it would deprive women, LGBTQ individuals, their families and others of their civil rights and access to basic health care services. Patients would suffer serious and irreparable harm if this Rule was in place, with no demonstrable or justifiable benefit to providers and health care entities that are adequately protected under existing law. The proposed Rule understandably is opposed by a wide range of stakeholders. I strongly urge you to withdraw the proposed Rule.

Sincerely,

Dave Jones

DAVE JONES
Insurance Commissioner

[5] 72 Fed. Reg. at 9971

EXHIBIT 20

NYC

March 27, 2018

Via electronic submission

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Docket No.: HHS-OCR-2018-0002)

To Whom It May Concern:

The New York City Commission on Human Rights, the New York City Department of Health and Mental Hygiene, the New York City Department of Social Services, and NYC Health + Hospitals write to express our opposition to the United States Department of Health and Human Services' (HHS) proposed regulations entitled, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.

HHS' proposed rule will cause serious harm to the health and well-being of New Yorkers. It will erect barriers to the delivery and receipt of timely, high quality health care. It will foster a new standard of selective and discriminatory treatment for many of our most vulnerable populations. It will also multiply the administrative burdens that health care organizations shoulder to address time-sensitive health conditions. Finally, it will infringe on the ability of state and local governments to enforce their laws and policies. In the face of these significant harms, we urge HHS to rescind this rule.

The Proposed Rule Will Harm Patients

The proposed rule elevates healthcare providers' personal beliefs over patient health. It gives providers wide latitude in opting out of treating patients. Undoubtedly, providers will deny care to patients who need it. At a minimum, a denial will mean that patients who are turned away will experience delays and increased expenses in receiving care. But in many cases, delay will effectively mean denial, particularly where time is of the essence or locating a suitable alternate provider is not feasible. The denial of care will be the end of the road in many patients' search for treatment.

Indeed, finding an alternate provider is no simple task. Health plans have limited provider networks, caps on the number of specialty visits, and steep cost-sharing obligations. Workers have limited or no sick leave, and forcing them to visit a second provider to accommodate the first provider's beliefs means that many patients will have to decide between taking care of their health and making a living. That is no choice at all, and many patients will forego care that they otherwise would have received.

Similarly, many people live in areas with a limited number of primary care doctors, specialists, and specialty care facilities. They may be forced to travel great distances to find a provider willing to treat them. Patients who are elderly, patients with disabilities, and patients under the age of majority may be completely unable to access an alternate healthcare provider if refused

care. During an emergency such as a national disaster, there may be only one accessible provider.

The denials of care that will result if the proposed rule is adopted will have severe and often irreversible consequences: unintended pregnancies, disease transmission, medical complications and anguish in the last days of life, and death. For example:

- Post-exposure prophylaxis for HIV should be initiated within 36 hours, but not beyond 72 hours after potential exposure.
- Emergency contraception is most effective at preventing pregnancy if taken as soon as possible after sexual intercourse.
- Contraceptives and pre-exposure prophylaxis for HIV are effective only if accessed prior to a sexual encounter.
- There is a window for a safe, legal abortion, and a narrower window for medication abortion. In the case of ectopic pregnancy or other life-threatening complication, an abortion may need to be performed immediately.
- Opiate users denied methadone or buprenorphine remain at increased risk of overdose, and naloxone must be administered quickly to reverse drug overdose.
- Persons with suicidal ideation need immediate care to prevent self-harm.
- Refusing to honor a person's end-of-life wishes prolongs suffering.

In short, the proposed rule will cause long-lasting and irreparable harm to patients.

The breadth of the proposed rule is extraordinary, all but guaranteeing that patients will be denied essential health care. Extending protections to health plans, plan sponsors, and third-party administrators that receive federal funds may prompt health plans to cease coverage for abortion, contraceptives, health care related to gender transition, and other services. Allowing anyone "with an articulable connection to a procedure, health service, health program or research activity" to raise an alleged conscience objection, means that the myriad of participants in a healthcare encounter—from intake and billing staff to pharmacists, translators, radiology technicians, and phlebotomists—can refuse to participate in service delivery. This will cause untold disruptions and delays for patients. And the expansive definitions of "assist in the performance" and "referral" mean that healthcare providers – after refusing to care for a patient – will not even need to provide a referral or other necessary information for a patient to seek care elsewhere.

The negative health impact of denied care is profound. In the case of infectious disease, there is societal impact: delays in diagnosis, prophylaxis and treatment increase the likelihood of individual disease progression and transmission to others. The consequences of untreated substance use disorders are likewise far-reaching. Compounding matters, the harmful effects of the proposed rules will be felt most acutely by individuals and communities that already face great challenges accessing the care that they need: people of color, low-income persons, women, children, people with substance use disorders, and lesbian, gay, bisexual, transgender, queer, intersex and gender nonconforming ("LGBTQI") persons.

The Proposed Rule Will Lead to Discrimination Against Already Vulnerable Populations

The rule gives healthcare providers a free pass to discriminate based on a patient's identity and against any patient whose actions or decisions conflict with the provider's alleged conscience objection.

Discrimination by health care providers marginalizes and stigmatizes patients, driving them away from care systems. It has long-term destructive consequences for the health and well-being of patients and communities that already bear the brunt of discrimination. Women and LGBTQI people will find themselves denied care at alarming rates. Providers may refuse to prescribe contraceptives to women who are not married, fertility treatment to same-sex couples, pre-exposure prophylaxis to gay men, or counseling to LGBTQI survivors of hate or intimate partner violence. Transgender patients are likely to be refused medically necessary care like hormone therapy, and substance users may be denied medications to treat addiction or reverse drug overdose.

The impact of such discrimination extends far beyond the individual patient encounter. For example, LGBTQI youth that are denied services and psychosocial support show a lasting distrust of systems of care.[i] Concerns regarding stigma may also make patients reluctant to reach out to loved ones for support, as has been shown with women who have had abortions.[ii]

This never-before-seen license to pick and choose the type of patient and nature of care that a clinician or organization will provide runs counter to principles of comprehensiveness and inclusion that have long guided the federal government's oversight of key health care programs and the operation of the country's health care delivery system.

The Proposed Rule Creates New Administrative Burdens for a Strained Health Care System

The extraordinary breadth of the proposed rule will result in significant and costly administrative burdens on an already-strained healthcare system. The proposed rule places healthcare entities in the precarious position of having to accommodate various ethical beliefs held by thousands of staff, regardless of how tenuous those staffs' connection to the clinical encounter. Also, by prohibiting employers from withholding or restricting any title, position or status from staff that refuse to participate in care, healthcare entities are limited in being able to move staff into positions where they will not disrupt care and harm patients. Thus, doctors in private practice will be prohibited from firing any staff who refuses to assist, and thereby stigmatizes and harms, LGBTQI patients. Emergency departments, ambulance corps, mental health hotlines, and other urgent care settings may need to increase the number of shift staff to ensure sufficient coverage in case of a refusal to work with a patient. This will have a very real financial impact on healthcare facilities, including government-run and subsidized clinics and hospital systems. This is a costly proposition that flies in the face of the federal government's stated goal of reducing administrative burdens within the health care system.

The Proposed Rule Infringes on State and Local Governments' Ability to Enforce Their Laws and Policies and Conflicts with Patient Protections

The proposed rule may impact the ability of State and local governments to enforce the full scope of their health- and insurance-related laws and policies by conditioning the receipt of federal funding on compliance with the rule. Similarly, it may leave providers caught between conflicting mandates. The New York City Human Rights Law ("City Human Rights Law"), for example, like many state and local nondiscrimination laws, protects patients from discrimination based on sexual orientation, gender (including gender identity), marital status, and disability.

Protecting vulnerable populations from discrimination and misinformation is of paramount importance to New York City. The City Human Rights Law is one of the most comprehensive civil rights laws in the nation, prohibiting discrimination in health care settings based on, among other things, a patient's race, age, citizenship status, and religion. A provider's refusal to serve a patient pursuant to the proposed rule may be a violation of state and local laws, some of which are enforced through the imposition of injunctive relief and substantial financial penalties. Violations of the City Human Rights Law, for example, can lead to the imposition of penalties of up to $250,000 per violation.

We oppose regulations that allow personal beliefs to trump science at the expense of vulnerable populations' access to health care. We oppose systems that compromise our duty to protect and improve the health of City residents. We oppose actions that sanction discrimination against patients based on who they are or what health conditions they have.

We urge HHS to rescind the proposed rule.

Sincerely,

Steven Banks
Commissioner
New York City Department of
Social Services

Mary T. Bassett, MD, MPH
Commissioner
New York City Department of
Health and Mental Hygiene

Mitchell Katz, MD
President and Chief Executive Officer
New York City Health and Hospitals

Carmelyn P. Malalis
Chair and Commissioner
New York City Commission on
Human Rights

[1] Substance Abuse and Mental Health Services Administration. Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth. HHS Publication No. (SMA) 15-4928. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

[8] Shellenberg KM, Tsui AO. Correlates of perceived and internalized stigma among abortion patients in the USA: an exploration by race and Hispanic ethnicity. *Int J Gynaecol Obstet*. 2012;118(2):60015-60010.

EXHIBIT 21

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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TREASURER

Re: Proposed New 45 CFR Part 88 Regarding Refusals of Medical Care

The American Civil Liberties Union ("ACLU") submits these comments on the proposed rule published at 83 FR 3880 (January 26, 2018), RIN 0945-ZA03, with the title "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the "Proposed Rule" or "Rule").

For nearly 100 years, the ACLU has been our nation's guardian of liberty, working in courts, legislatures, and communities to defend and preserve the individual rights and liberties that the Constitution and the laws of the United States. With more than 2 million members, activists, and supporters, the ACLU is a nationwide organization that fights tirelessly in all 50 states, Puerto Rico, and Washington, D.C. for the principle that every individual's rights must be protected equally under the law, regardless of race, religion, gender, sexual orientation, gender identity or expression, disability, national origin, or record of arrest or conviction.

In Congress and in the courts, we have long supported strong protections for religious freedom. Likewise, we have participated in nearly every critical case concerning reproductive rights to reach the Supreme Court and advocated for policies that promote access to reproductive health care. The ACLU is also a leader in the fight against discrimination on behalf of those who historically have been denied their rights, including people of color, LGBT (lesbian, gay, bisexual, and transgender) people, women, and people with disabilities. Because of its profound respect for and experience defending religious liberty, reproductive rights, and principles of non-discrimination, the ACLU is particularly well positioned to comment on the Proposed Rule. We steadfastly protect the right to religious freedom. But the right to religious freedom does not include a right to harm others as this Proposed Rule contemplates. And, indeed, when the Bush Administration adopted similar rules, the ACLU challenged them in court. *See National Family Planning & Reproductive Health*

Association, Inc. v. Leavitt, *consolidated in* Case No. 3:09-cv-00054-RNC (D. Conn. 2009).[1]

The Proposed Rule grants health care providers unprecedented license to refuse to provide information and health care to patients and puts faith before patients' health. The Rule thus contravenes the core mission of the Department of Health and Human Services [the "Department"] to protect and advance the health of all. The Department's failure even to mention the impact of the rule on patients is clear evidence of its misplaced priorities. The Rule also flies in the face of the longstanding history of the Department to further our nation's health by addressing discrimination in health care, aiming instead to foster discrimination.

Tellingly, the Department justifies the Rule by citing as the "problem" cases in which patients sought remedies after being denied health care—to the detriment of their health and often for discriminatory reasons. *See* 83 FR 3888-89 & n.36. The problem, however, is not that patients want care, but that health care providers denied vital, even life-saving, medical care, discriminated, and imposed their religious doctrine to the detriment of patients' health. Tamesha Means, for example, should not have been turned away from the hospital where she sought urgent care even once, let alone three times, without even being provided with the information that her own life could be in jeopardy if she did not obtain emergency abortion care for her miscarriage.[2] Rebecca Chamorro should not have been required to undergo the additional stress, health risks, and cost of two surgical procedures, rather than a single one, when her doctor was ready, willing, and able to perform a standard postpartum tubal ligation.[3] Evan Minton's scheduled hysterectomy should not have been canceled on the eve of that procedure, despite his doctor's willingness to proceed with that routine operation, because the hospital became aware he was transgender.[4] These refusals, not the patients seeking justice, are the problem. Yet these are the types of refusals the Department seeks to make more commonplace with this Rule. 83 FR 3888-89 & n.36.

Moreover, if the Department is to adhere to its mission and to address discrimination, its focus should not be on expanding a purported right of institutions to refuse to provide care because of beliefs, but on eliminating the discrimination that continues to devastate communities in this country. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[5] Black women, for example, are three to four times more likely than white women to die during or after childbirth.[6] Women have long been the subject of discrimination in

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[1] That lawsuit was ultimately dismissed when the Obama Administration rescinded virtually all of the regulations. *See* 74 FR 10207, 75 FR 9968, 76 FR 9968, *infra* n.16.

[2] *See* Health Care Denied 9-10 (May 2016), *available at* https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied.

[3] *See id.* at 18.

[4] *See* Verified Complaint, *Minton v. Dignity Health*, Case No. 17-558259 (Calif. Super. Ct. April 19, 2017).

[5] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[6] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

health care and the resulting health disparities.[7] And due to gender biases and disparities in research, doctors offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[8] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[9] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care provider had refused to see them because of that aspect of their identity in the year before the survey.[10] The Department should be working to end, not foster, discrimination in health care.[11]

In the comments below, the ACLU details some of the specific ways in which the Proposed Rule exceeds the Department's authority and in so doing causes significant harm to patients.[12] The non-exhaustive examples of serious flaws in the Rule include:

- The Proposed Rule utterly fails to consider the harmful impact it would have on patients' access to health care.

- The Department lacks *any* legislative rule-making authority under the Church Amendments, 42 U.S.C. § 300a-7, the Coats-Snowe Amendment, 42 U.S.C. § 238n, and the Weldon Amendment, Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, Div. H, Tit. V, § 507(d) (collectively, the "Amendments"), the primary statutory authority for the Rule, and thus it cannot adopt these proposed force-of-law requirements to expand those Amendments.

- The Rule tries to expand the plain language Congress used in the Amendments and over a dozen other laws referenced by this rulemaking (collectively, the "Refusal Statutes"), proposing definitions that distort the ordinary meaning of words and otherwise impermissibly stretching these narrow provisions.

- The Rule's impact is not limited to individual health care providers; it attempts to greatly expand the Refusal Statutes to enable more institutions—e.g., hospitals,

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[7] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).

[8] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. of the Am. Heart Ass'n 1 (2015).

[9] *See, e.g.*, *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf.

[10] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

[11] The Department's Office of Civil Rights ("OCR") has a long history of combating discrimination, protecting patient access to care, and eliminating health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.

[12] Although these ACLU comments primarily focus on examples of the Proposed Rule's flaws and harms with reference to the Church, Coats and Weldon Amendments, virtually all of the problems identified in this letter extend to the Rule's similar, unfounded extension of the over a dozen other provisions encompassed within the Rule.

clinics, and other corporate entities—to deny care, even in emergency situations, and even when individual providers at the institutions have no objection to providing the care.

- The Rule is entirely unnecessary as health care providers are already shielded by Title VII's religion protections, and addressed by the Refusal Statutes, and there is no evidence that existing mechanisms are insufficient to ensure compliance with those Refusal Statutes.

- The Rule purports to seek a "society free from discrimination," but repeatedly *invites expanded discrimination – through refusals of care* – against women, LGBT patients, and other members of historically-mistreated groups.

- Likewise, the Rule purports to advance "open and honest communication," yet it *empowers providers to withhold information* from patients about their medical condition and treatment options in contravention of legal and ethical requirements and principles of informed consent.

Because the Proposed Rule harms patient health, encourages discrimination, and exceeds the Department's rulemaking authority, it should be withdrawn. If the Department refuses to do so, it must, at a minimum, revise the Proposed Rule so that it comes into alignment with the statutory provisions it purports to implement, makes clear that it is not intended to conflict with other state and federal laws that protect patients, and mitigates the harm to patients' health and well-being.

I. The Proposed Rule Fails Even to Mention Its Impact on Patients, While Inviting More Refusals of Care That Would Fall Disproportionately on Low-Income People and Other Marginalized Groups.

The Department's mission is "to enhance and protect the health and well-being of all Americans. [It] fulfill[s] that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services."[13] The Department administers more than 100 programs, which aim to "protect the health of all Americans and provide essential human services, especially for those who are least able to help themselves."[14]

It is thus extraordinary that this Notice of Proposed Rulemaking ("NPRM") is devoted solely to increasing the ability of health care entities and professionals to refuse to provide health care information and services to patients. Nowhere in the 50 pages that the NPRM spans in the Federal Register does it discuss the impact that refusals to provide information and denials of care have on patient health and well-being. In fact, patients are not even mentioned in the discussion of "affected persons and entities." 83 FR 3904. And in the Proposed Rule's flawed attempt at a cost-benefit analysis, the Department devotes a mere three paragraphs to the Rule's purported effects on patient-provider communication—and none at all to the direct harms suffered by those who are denied information and care. 83 FR 3916-17.

[13] *See* https://www.hhs.gov/about/index.html.
[14] *See* https://www.hhs.gov/programs/index.html.

But this failure to address the obvious consequences of giving federally-subsidized providers *carte blanche* to decide whom to treat or not treat based on religious or moral convictions—or indeed, based on any reasoning or none at all[15]—does not mean the harm does not exist. Indeed, the harms would be substantial. For example, as set forth in more detail below, the Proposed Rule:

- Appears to provide immunities for health care institutions and professionals who refuse to provide complete information to patients about their condition and treatment options;

- Would result in patients being denied, or delayed in getting, health care to the extent the Rule requires health care facilities to employ people who refuse to perform core functions of their jobs;

- Purports to create new "exemptions," that would leave patients who rely on federally-subsidized health care programs, such as Title X family planning services, unable to obtain services those programs are required by law to provide;

- Creates confusion about whether hospitals can refuse to provide, and bar its staff from providing, emergency care to pregnant women who are suffering miscarriages or otherwise need emergent abortion care; and

- Invites health care providers to discriminate against individuals based on who they are by, for example, refusing to provide otherwise available services to a patient for the sole reason that the patient is transgender.

These harms will fall most heavily on historically disadvantaged groups and those with limited economic resources. As the ACLU's own cases and requests for assistance reflect, women, LGBT individuals, and members of other groups who continue to struggle for equality are those who most often experience refusals of care. The Proposed Rule's unauthorized expansion of the Refusal Statutes will only exacerbate these disparities.

Likewise, people with low and moderate incomes will suffer most acutely under the Proposed Rule. The Refusal Statutes, and therefore the expansive Proposed Rule, are tied to federal funding. Individuals with limited income are more likely to rely on health care that is in some manner tied to federal funding and are therefore more likely to be subject to the refusals to provide care and information sanctioned by the Proposed Rule. Thus, for example, if a health care entity that, under the Proposed Rule, is now able to obtain a government contract to provide Title X family planning services despite its unwillingness to provide the required services, low-income individuals in the area are likely to have few, if any, other options for the care.

[15] Although the NPRM highlights religious freedom and rights of conscience, a number of the Refusal Statutes – and the proposed expansions of those in the Rule – do not turn on the existence of any religious or moral justification. The Proposed Rule would empower not only those acting based on the basis of belief, but others acting, for example, out of bare animus toward a patient's desired care or any aspect of their identity.

Not only will this result in the outright denial of care to the detriment of patients' health, it will also impose serious economic consequences that the Proposed Rule fails to take into account. For example, the denial of care can result not only in greater health care costs, but also in lost wages (and in some cases loss of employment), increased transportation costs and increased child care costs. For women, immigrant patients, and rural patients, these snowballing effects can be particularly acute. Yet, remarkably, the Proposed Rule finds no effect at all on the "disposable income or poverty of families and children" from expanding denials of health care. 83 FR 3919. Contrary to the Department's conclusions, this Rule would impose new costs on and create new pressures for many families, especially those with the least economic means.

Rather than seek to expand patient protections, the Proposed Rule appears to launch a direct attack on existing federal legal protections that prevent or remedy discrimination against patients. *See, e.g., infra* Part IV. The Rule raises equal concern with regard to its intended effect on state laws that aim to enhance patient protection and address discrimination. The Preamble devotes extensive discussion to "Recently Enacted State and Local health care laws" that have triggered some litigation by "conscientious objectors," 83 FR 3888, characterizing those disputes as part of the rationale for the Rule.[16] But this rulemaking provides no clarity as to preservation of other legal protections and repeatedly evidences an intent to cut back on, for example, important equality safeguards for patients. At the very least, this will create severe confusion, creating competing and contradictory requirements, and in so doing put critical federal funding for vital care at risk. At worst, it targets vulnerable patients for increased refusals of care and the harms described above.

Because it is contrary to the very mission of the Department, attempts to license widespread denials of care and harm to patients, and fosters discrimination, the Proposed Rule should be withdrawn.

II. The Department Lacks the Authority to Promulgate the Proposed Rule.

Not only does the Rule undermine patient's health, it is unauthorized. For example, the Department does not possess *any* legislative rulemaking powers under the Church, Coats-Snowe or Weldon Amendments – the Amendments that form the bases for the bulk of the Rule – and thus it lacks the authority to promulgate this Rule with respect to those statutes.

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). With this Proposed Rule, the Department clearly seeks to adopt legislative rules that will impose force-of-law, substantive requirements and compliance procedures that must be followed by covered entities. But there is no authority delegated by Church, Coats-Snowe or Weldon to undertake such rulemaking. Indeed, in prior litigation, the Department itself emphasized that "[i]n the first place, it is not clear that the Weldon Amendment can be said to delegate regulatory authority to the Executive Branch at all." Br. of

[16] *See also* 83 FR 3889 (seeking to "clarify" that conscience protections "supersede conflicting provisions of State law"; pointing to state requirements, for example, that insurers include abortion coverage in health plans as illustrations of "the need for greater clarity concerning the scope and operation" of federal rights of refusal).

Defs. at 35, *National Family Planning and Reproductive Health Association v. Gonzales*, 391 F. Supp. 2d 200 (D.D.C. 2005), *available at* 2004 WL 3633834; *see also* 76 FR 9971, 9975 (discussing that the Amendments do not provide for promulgation of regulations).

None of the Amendments includes, or references, *any* explicit delegation of regulatory authority. *Compare, e.g.,* 42 U.S.C. § 2000d-1 (expressly directing all relevant federal agencies to issue "rules, regulations, or orders of general applicability" to achieve the objectives of Title VI). Nor is there any implicit delegation of legislative rulemaking authority for these provisions. As underscored by the decades that Church, Coats-Snowe and Weldon have applied without any legislative rulemaking supplementing their content, those enactments do not give the Department the power to issue force-of-law rules under them, as the Department is now – expansively – trying to do.[17] For this reason alone, the Department cannot properly proceed to adopt the Proposed Rule or any similar variation of it.

III. The Rule Proposes Numerous Expansive Definitions That Defy the Meaning of the Statutory Terms and Would Fuel Confusion, Misinformation, and Denials of Care.

Even if the Department had the necessary rulemaking authority (which it does not), the Proposed Rule's broad definition of certain terms and expansions of the Refusal Statutes' reach would far exceed any conceivable authority. An agency cannot use rulemaking to extend the scope of a statute. *See City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 297 (2013) (agency must stay within the bounds of the statute under which it acts). Yet that is what this Rule does, through numerous proposed "definitions," including, among others, those proposed for "assist in the performance," "referral or refer for," and "discrimination."

Indeed, it is telling that the Rule's Preamble devotes four pages in the Federal Register to trying to justify its over-reaching definitions, but does not attempt to describe the Rule's proposed substantive requirements at all. Instead, the Preamble claims that the substantive requirements are simply "taken from the relevant statutory language." 83 FD 3895. But that assertion is belied by, *inter alia*, the Department's proposed expansion and re-writing of those statutes through impermissible re-definition of numerous statutory terms and other sleights of hand. Any rule-making of this kind needs to attempt to explain not only the definitions of words, but how those definitions and the Rule's substantive requirements come together to regulate conduct, which the Department utterly fails to do.

For example, the Department proposes to define "assist in the performance" of an abortion or sterilization to include not only assistance *in the performance* of those actual procedures—the ordinary meaning of the phrase—but also participation in any other activity

[17] Although the Bush Administration promulgated similar rules in December 2008, those rules did not take full effect before their reconsideration and rescission commenced. The eventual replacement regulation, which became final in 2011 and remains in force today, consists of just two provisions describing solely that OCR is designated to receive complaints under the Amendments. The Department promulgated that rule under 5 U.S.C. § 301, the Department's "housekeeping" authority for adopting regulations limited to the conduct of its own affairs. Section 301 does not authorize the promulgation of substantive regulatory requirements like those in the Proposed Rule. *See* 76 FR 9975-76. Moreover, that we here highlight the lack of regulatory rule-making authority under Section 301 and under the Amendments should not be read to imply that any such authority exists under the other Refusal Statutes referenced in this NPRM; the Proposed Rule does not specify *any* authority for legislative rulemaking.

with "an articulable connection to a procedure[.]" 83 FR 8892, 3923. Through this expanded definition, the Department explicitly aims to include activities beyond "direct involvement with a procedure" and to provide "broad protection"—despite the statutory references limited to "assist[ance] in the performance of" an abortion or sterilization procedure itself. *Id.*; *cf. e.g.,* 42 U.S.C. § 300a-7(c)(1).

This would mean, for example, that simply admitting patients to a health care facility, filing their charts, transporting them from one part of the facility to another, or even taking their temperature could conceivably be considered "assist[ing] in the performance" of an abortion or sterilization, as any of those activities could have an "articulable connection" to the procedure. As described more fully below, *see infra* Part VI, the Proposed Rule would even sanction the withholding of basic information about abortion or sterilization on the grounds that "assist[ing] in the performance" of a procedure "includes but is not limited to counseling, referral, training, and other arrangements for the procedure." 83 FD 3892, 3923.

But the term "assist in the performance" does not have the virtually limitless meaning the Department proposes ascribing to it. The Department has no basis for declaring that Congress meant anything beyond actually "assist[ing] in the performance of" the specified procedure—given that it used that phrase, 42 U.S.C. § 300a-7(c)(1). There is no basis for the Department to interpret that term to mean any activity with any connection that can merely be articulated, regardless of how attenuated the claimed connection, how distant in time, or how non-procedure-specific the activity.

Likewise, the Proposed Rule's definition of "referral or refer for" impermissibly goes beyond the statutory language and congressional intent. The Rule declares that "referral or refer for" means "the provision of *any* information … by any method … pertaining to a health care service, activity, or procedure … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" it, where the entity (including a person) doing so "sincerely understands" the service, activity, or procedure to be a "possible outcome[.]" 83 FR 3894, 3924 (emphasis added). This expansive definition could have dire consequences for patients. For example, a hospital that prohibits its doctors from even discussing abortion as a treatment option for certain serious medical conditions could attempt to claim that the Rule protects this withholding of critical information because the hospital "sincerely understands" the provision of this information to the patient may assist the patient in obtaining an abortion.[18]

But by providing a green light for the refusal to provide information that patients need to make informed decisions about their medical care, the Proposed Rule not only violates basic medical ethics, but also far exceeds congressional intent. A referral, as used in common parlance and the underlying statutes, has a far more limited meaning than providing *any* information that *could* provide *any assistance whatsoever* to a person who may ultimately decide to obtain, assist, finance, or perform a given procedure sometime in the future. The meaning of "referral or refer for" in the health care context is to *direct* a patient elsewhere for care. *See* Merriam-Webster, https://www.merriam-webster.com/dictionary/referral ("referral" is "the process of directing or redirecting (as a medical case or a patient) to an appropriate specialist or agency for definitive

[18] As explained in Part VI(B), *infra*, the Proposed Rule's overbroad interpretation of the phrase "make arrangements for," 83 FR 3895, compounds the problems with the unjustified definition of referral.

treatment"); Medicare.gov, *Glossary: Referral*, https://www.medicare.gov/glossary/r.html (defining referral as "[a] written order from your primary care doctor for you to see a specialist or get certain medical services"); HealthCare.gov, *Glossary: Referral*, https://www.healthcare.gov/glossary/referral/ (same); Ctrs. for Medicare & Medicaid Services Website, *Glossary: Referral*, https://www.cms.gov/apps/glossary/default.asp?Letter=R&Language ("Generally, a referral is defined as an actual document obtained from a provider in order for the beneficiary to receive additional services."); *id.* (a referral is a "written OK from your primary care doctor for you to see a specialist or get certain services").

In addition, the Proposed Rule's definition appears to include a subjective element not present in any of the referenced statutes or in the ordinary meaning of "referral": Under the Rule, an entity's "sincere understanding" determines whether or not a referral has occurred. 83 FR 3924; *see also* 83 FR 3894 n.46 (claiming that a "referral constitutes moral cooperation with a conscientiously objected activity"). The Proposed Rule states that it is attempting to provide "broad protection for entities unwilling to be complicit in" certain services, 83 FR 3895, but transforming "refer for" into a much looser, subjective notion of being "complicit in" is a significant departure from the actual statutory language of the Refusal Statutes and plainly exceeds the Department's authority.

These expansive definitions are all the more troubling to the extent the Proposed Rule's definition of "discrimination" purports to provide unlimited immunity for institutions or employees who refuse to perform essential care. The Rule apparently attempts to provide unlimited immunity for institutions that receive some federal funds to deny abortion care, to block coverage for such care, or to stop patients' access to information, no matter what the patients' circumstances or the mandates of state or federal law. Likewise, the definition appears aimed at providing immunity for employees who refuse to perform central parts of their job, regardless of the impact on the ability of a health care entity to provide appropriate care to its patients. This expansion of "discrimination" would apparently treat virtually any adverse action—including government enforcement of a patient non-discrimination or access-to-care law—against a health care facility or individual as *per se* discrimination. Indeed, the definition of discrimination appears designed to provide a tool to stop enforcement of state laws providing more protection of patients, particularly those seeking abortion care. But "discrimination" does not mean any negative action, and instead requires an assessment of context and justification, with the claimant showing unequal treatment on prohibited grounds under the operative circumstances. [19] *See infra* Parts IV-V.

While this comment letter does not attempt to detail all of the unfounded definitional expansions included in the Proposed Rule, other examples abound. *See e.g.*, 83 FR 3893

[19] The Rule should not be expanded even further by an unfounded "disparate impact" concept that has no place in implementing these narrowly-targeted Refusal Statutes. While the Proposed Rule does not explain its proffered "disparate impact" concept, such a concept might empower the Department, for example, to forbid *any* enforcement of a general state government policy that is contrary to a particular institution's religious dictates, or of a neutral employment rule that is contrary to some employees' beliefs (rather than accepting that an employer's obligations are at most reasonable accommodation of particular employees, if possible without undue hardship, *see infra* Part IV).

(proposing to define "health care entity" to include those employers and others who sponsor health plans but "are *not* primarily in the business of health care") (emphasis added), 3894 (proposing to define "workforce" to include volunteers and contractors, despite those individuals' independence from any corporate or public entities employing workers), 3894 (erroneously expanding definition of "health service program"), 3923-24.[20] The Department has no authority to expand the Refusal Statutes in this way, and these irrational definitions that are contrary to both the Refusal Statutes and congressional intent should be explicitly rejected.

IV. The Proposed Rule Threatens to Upend the Appropriate Balance Struck by Long-Standing Federal Laws.

A. The Proposed Rule Ignores the Careful Balance Title VII Strikes Between Protecting Employees' Religious Beliefs and Ensuring Patients Can Obtain the Health Care They Need.

The Proposed Rule is not only unauthorized and harmful to patients, it is also unnecessary as federal law already amply protects individuals' religious freedom—freedom the ACLU has fought to protect throughout its nearly 100-year history.

For example, for more than four decades, Title VII has required employers to make reasonable accommodations for current and prospective employers' religious beliefs so long as doing so does not pose an "undue hardship" to the employer. 42 U.S.C. §§ 2000e(j), 2000e-2(a).[21] An "undue hardship" occurs under Title VII when the accommodation poses a "more than *de minimis* cost" or burden on the employer's business. *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); EEOC Guidelines, 29 C.F.R. § 1605.2(e)(1). Thus, Title VII—while protecting employees' freedom of religion—establishes an essential balance. It recognizes that an employer cannot subject an employee to less favorable treatment solely because of that employee's religion and that generally an employer must accommodate an employee's religious practices. However, it does not require accommodation when the employee objects to performing core job functions, particularly to the extent those objections harm patients, depart from standards of care, or otherwise constitute an undue hardship. *Id.*; *see also Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985). This careful balance between the needs of employees, patients, and employers is critical to ensuring that health care employers are able to provide quality health care.

Despite this long-standing balance, nowhere does the Proposed Rule mention these basic legal standards or the need to ensure patient needs are met. Instead, by presenting a seemingly unqualified definition of what constitutes "discrimination," 83 FR 3923-24, the Department

[20] Moreover, the Proposed Rule not only re-defines words and phrases from the Refusal Statutes, but also adds words. For example, Section 1303 of the Patient Protection and Affordable Care Act ("ACA"), 42 U.S.C. § 18023(b)(1)(A)(i), refers to "abortion services"; the Proposed Rule expands that to "abortion or abortion-related services," without defining what that added term – found nowhere in the statute – purports to cover. 83 FR 3926; *see also, e.g.,* 83 FR 3924 (defining "health program or activity" without any apparent use of phrase in a Refusal Statute though it is used to protect patients in Section 1557 of the ACA).

[21] For purposes of Title VII, religion includes not only theistic beliefs, but also non-theistic "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." Equal Employment Opportunity Commission ("EEOC") Guidelines, 29 C.F.R. §1605.1.

appears to attempt to provide complete immunity for religious refusals in the workplace, no matter how significantly those refusals undermine patient care, informed consent, or the essential work of health care institutions. Indeed, the Rule is explicit in seeking an unlimited ability to "be[] free not to act contrary to one's beliefs," regardless of the harm it causes others. 83 FR 3892. This definition thus raises real concerns that the Proposed Rule could be invoked by employees or job applicants who refuse to perform core elements of the job. For example, job applicants may attempt to claim that a family planning provider is required to hire them as pregnancy options counselors even though they refuse to provide any information about the option of abortion and even where the provision of such information is required by the provider's federal funding.

However, neither the Refusals Statutes, nor any other federal law, permits such an unprecedented re-definition of "discrimination." When Congress prohibited discrimination in certain Refusal Statutes, it did not *sub silentio* create an absolute right to a job even if the employee refuses to perform essential job functions, as that has never been the meaning, legal or otherwise, of "discrimination." *See, e.g., McDonnell Douglas Corp. v. Green*, 411 U.S. 793, 802 (1973) (employment discrimination claim requires proof that employee was qualified for the position, and employer may articulate a legitimate, non-discriminatory job-related reason to defeat such a claim). Such an unfounded definitional shift for "discrimination" improperly expands narrow congressional enactments and attempts to reinterpret federal laws, all long construed to be harmonious, to instead be conflicting and contradictory. It turns the Department's mission on its head. If the Department does not withdraw the entire Rule, it should explicitly limit its reach and attempt to clarify how Title VII's balance can continue to have full force and effect in the workplace.

B. Rather than Ensuring Patients Can Get Care in an Emergency, the Proposed Rule Describes the Obligation to Provide Critical Care as Part of the "Problem."

The Proposed Rule puts patients at risk by ignoring the federal Emergency Medical Treatment and Labor Act ("EMTALA") and hospitals' obligations to care for patients in an emergency. As Congress has recognized, a refusal to treat patients facing an emergency puts their health and, in some cases, their lives at serious risk. Through EMTALA, Congress has required hospitals with an emergency room to provide stabilizing treatment to any individual experiencing an emergency medical condition or to provide a medically beneficial transfer. 42 U.S.C. § 1395dd(a)-(c).

The Refusal Statutes do not override the requirements of EMTALA or similar state laws that require health care providers to provide abortion care to a patient facing an emergency. *See, e.g., California v. U.S.*, Civ. No. 05-00328, 2008 WL 744840, at *4 (N.D. Cal. March 18, 2008) (rejecting notion "[t]hat enforcing [a state law requiring emergency departments to provide emergency care] or the EMTALA to require medical treatment for emergency medical conditions would be considered 'discrimination' under the Weldon Amendment"). Indeed, after a challenge to the Weldon Amendment was filed on the ground that it could inhibit the enforcement of statutes requiring hospitals to provide emergency abortion care, Representative

Weldon emphasized that his amendment did not disturb EMTALA's requirement that critical-care facilities provide appropriate treatment to women in need of emergency abortions.[22]

It is particularly troubling, therefore, to have the Department include the long-standing legal and ethical obligation to provide emergency care to patients in the Rule's Preamble as *justification* for expanding the Refusal Statutes – in other words, as justification to *relieve* hospitals or hospital personnel of any obligation, for example, to perform an emergency abortion when a patient is in the midst of a miscarriage, or even to "refer" a patient whose health is deteriorating for an emergency abortion. 83 FR 3888, 3894. But the ethical imperative is the opposite: "In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." 83 FR 3888 (quoting American Congress of Obstetricians and Gynecologists ("ACOG") ethics opinion and describing it as part of the problem the Proposed rule is meant to address).

Tragically, such concerns are far from hypothetical. As noted above, Tamesha Means was turned away from critical care three times, exposing her to serious risk and putting her life in jeopardy, and in the midst of being discharged the third time, was finally helped only when she started to deliver. Another miscarrying patient collapsed at home and almost bled to death after being turned away three different times from the only hospital in her community which refused to provide her the emergency abortion she needed.[23] Refusals such as these disproportionately affect women of color who are more likely than other women to receive their care at Catholic hospitals, which follow directives that can keep providers from following standards of care and governing law.[24]

The Proposed Rule suggests that hospitals that fail to provide patients like these with appropriate emergency care should be given a free pass. Any such license to refuse patients emergency treatment, including emergency abortions, however, would not only violate EMTALA, but also the legal, professional, and ethical principles governing access to health care in this country. For that reason, if not withdrawn in its entirety, the Proposed Rule should, as one of many necessary limitations, clarify that it does not disturb health care providers' obligations to provide appropriate care in an emergency.

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[22] *See* 151 Cong. Rec. H176-02 (Jan. 25, 2005) (statement of Rep. Weldon) ("The Hyde-Weldon Amendment is simple. It prevents federal funding when courts and other government agencies force or require physicians, clinics, and hospitals and health insurers to participate in *elective* abortions.") (emphasis added); *id.* (Weldon Amendment "ensures that in situations where a mother's life is in danger a health care provider must act to protect a mother's life"); *id.* (discussing that the Weldon Amendment does not affect a health care facility's obligations under EMTALA). Nor were the other Refusal Statutes intended to affect the provision of emergency care. *See*, e.g., 142 Cong. Rec. S2268-01, S2269 (March 19, 1996) (statement of Senator Coats in support of his Amendment) ("a resident needs not to have [previously] performed an abortion … to have mastered the procedure to protect the health of the mother if necessary"); *id.* at S2270 (statement of Senator Coats) ("[T]he similarities between the procedure which [residents] are trained for, which is the D&C procedure, and the procedures for performing an abortion are essentially the same and, therefore, [residents] have the expertise necessary, as learned in those training procedures, should the occasion occur and an emergency occur to perform an abortion.").

[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[24] *Id.* at 12 (2018).

C. The Proposed Rule Fosters Discrimination.

The Proposed Rule also puts patients at risk by ignoring the federal Patient Protection and Affordable Care Act ("ACA"), which explicitly confers on patients the right to receive nondiscriminatory health care in any health program or activity that receives federal funding. 42 U.S.C. § 18116. Incorporating the prohibited grounds for discrimination described in other federal civil rights laws, the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. *Id.* at § 18116(a).

The Refusal Statutes must be read to coexist with the nondiscrimination requirements of the ACA and similar state nondiscrimination laws. If a nondiscrimination requirement has any meaning in the healthcare context, it must mean that patients cannot be refused care simply because of their race, color, national origin, sex, age, or disability. And as courts have recognized, the prohibition on sex discrimination under the federal civil rights statutes should be interpreted to prohibit discrimination against transgender people. *See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017) (discrimination against transgender students violates Title IX, which is the basis for the ACA's prohibition on sex discrimination); *see also EEOC v. R.G. & G.R. Funeral Homes, Inc.*, __ F.3d __, 2018 WL 1177669 at *5-12 (6th Cir. Mar. 7, 2018) (Title VII); *Glenn v. Brumby*, 663 F.3d 1312, 1316-19 (11th Cir. 2011) (Title VII); *Rosa v. Park W. Bank & Tr. Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187, 1201-03 (9th Cir. 2000) (Gender Motivated Violence Act).

Notwithstanding these protections, as well as explicit statutory protections from discrimination based on gender identity and sexual orientation in many states, the Proposed Rule invites providers to discriminate against LGBT patients, particularly transgender people. The Department includes as a *justification* for expanding the Refusals Statutes a California lawsuit—*Minton v. Dignity Health*—in which a transgender patient is suing under the state nondiscrimination law, alleging that he was denied care a religiously-affiliated hospital routinely provided to other patients, simply because he is transgender. 83 FR 3888-89 & n.36. The Proposed Rule thus suggests that discrimination against a patient simply because he is transgender is permissible—in violation not only of California's nondiscrimination law, but also of the ACA. For that reason, if not withdrawn in its entirety, the Proposed Rule should, as one of many necessary limitations, clarify that it does not disturb health care providers' obligations to provide nondiscriminatory care.

D. The Proposed Rule Creates Confusion That Threatens to Deprive Title X Clients of Services That the Underlying Statutes and Regulations Require.

Finally, the Proposed Rule threatens to undermine the Title X program, which for more than four decades has provided a safety net upon which millions of low-income, under-insured, and uninsured individuals rely each year for family planning essential to their health and the promise of equality. For example, Congress requires that all pregnancy counseling within the Title X program be neutral and "nondirective." *See, e.g.*, Pub. L. No. 115-31 at 521. The Department's own regulations also require that pregnant women receive "neutral, factual

information" and "referral[s] upon request" for prenatal care and delivery, adoption, and/or abortion. 42 C.F.R. § 59.5(a)(5). Yet the Proposed Rule's unauthorized expansion of the Weldon Amendment, *see infra* Part V(C), creates confusion about whether health care entities that refuse to provide non-directive options counseling (which includes discussion of abortion) and abortion referrals may seek to claim an exemption from these requirements and therefore a right to participate in the Title X program despite their refusal to provide the services to which Title X clients are entitled. The Department cannot promulgate a rule that conflicts with federal law in this manner and if it is not withdrawn, the Department should make explicit that it does not provide an exemption to the Title X requirements.

* * *

None of the Refusal Statutes was intended or designed to disrupt the balance between existing federal laws—such as Title VII, EMTALA, Title X and also later-in-time statutes, such as Section 1557 of the ACA—or to create categorical and limitless rights to refuse to provide basic health care, referrals, and even information. Thus, even if the Department had the authority to promulgate the Proposed Rule (which it does not), the Proposed Rule is so untethered to congressional language and intent that it must be withdrawn or substantially modified.

V. The Rule Attempts Impermissibly Transform the Referenced Statutes Into Shields for Inadequate or Discriminatory Care.

The Proposed Rule not only distorts the definitions of words in the statutes, but also alters their substantive provisions in other ways to attempt to expand the ability of entities and individuals to deny care in contravention of legal and ethical requirements and to the severe detriment of patients. Some of these additional statutory expansions, are highlighted below.

A. Examples of Impermissible Church Amendment Expansions.

Subsection (b) of the Church Amendments, for example, specifies only that the receipt of Public Health Service Act funding *in and of itself* does not permit a court or other public authority to require that an individual perform or assist in the performance of abortion or sterilization, or require that an entity provide facilities or personnel for such performance. *See, e.g.*, 42 U.S.C. 300a-7(b) ("The receipt of any grant, contract or loan guarantee under the Public Health Service Act . . . by any individual does not authorize any court or any public official or other public authority to require . . . such individual to perform or assist in the performance of any sterilization procedure or abortion if [doing so] would be contrary to his religious beliefs or moral convictions."). The Proposed Rule, however, attempts to transform that limited prohibition – that receipt of certain federal funds alone does not create an obligation to provide abortions or sterilizations – into an across-the-board shield that forbids any public entity from determining that *any* source of law requires that the entities provide these services. 83 FR 3924-25. If the Rule is not withdrawn, the Department should modify the Rule so that it does not exceed the statute.

Similarly, the Proposed Rule apparently aims to vastly expand the prohibitions contained in subsection (d) of the Church Amendments in a manner that is contrary to the legislative language, the statutory scheme, and congressional intent. Congress enacted Subsection (d) of the Church Amendment in 1974 as part of Public Law 93-348, a law that addressed biomedical and behavioral research, and appended that new Subsection (d) to the pre-existing subsections of Church from 1973, which all are codified within 42 U.S.C. § 300a-7: the "Sterilization or Abortion" section within the code subchapter that relates to "Population Research and Voluntary Family Planning Programs."

Despite this explicit and narrow context for Subsection (d), the Proposed Rule attempts to transform this Subsection into a much more general prohibition that would apply to *any* programs or services administered by the Department, and that would assertedly prevent any entity that receives federal funding through those programs or services from requiring individuals to perform or assistance in the performance of *any* actions contrary to their religious beliefs or moral convictions. *See* 83 FR 3894, 3906, 3925. This erroneous expansion of Church (d) could prevent health care institutions from ensuring that their employees provide appropriate care and information: It would purportedly prevent taking action against members of their workforce who refuse to provide any information or care that they "sincerely understand" may have an "articulable connection" to some eventual procedure to which they object, no matter what medical ethics, their job requirements, Title VII or laws directly protecting patient access to care may require.

The ACLU is particularly concerned that the Proposed Rule's erroneous expansion of Church (d) could be used to deny services because of the identity of the individual seeking help. To name a few of the many possibilities that could result from the Proposed Rule's emboldening of personal-belief-based care denials:

- A nurse could deny access to reproductive services to members of same-sex or inter-racial couples, because her religious beliefs condemn them;

- A physician could refuse to provide treatment for sexually transmitted infections to unmarried individuals, because of her opposition to non-marital sex;

- Administrative employees could refuse to process referrals or insurance claims, just as health care professionals could deny care itself, because they object to recognizing transgender individuals' identity and medical needs.

This inappropriately expanded conception of Church Subsection (d) conflicts with statutory language, the anti-discrimination protections of Section 1557 of the ACA, the requirements of EMTALA, and the balance established by Title VII, and otherwise manifestly overreaches in a number of respects. Instead, the Department should clarify that the Church Amendments are limited to what the statute provides and Congress intended.

B. Examples of Impermissible Coats-Snowe Amendment Expansions.

The Proposed Rule similarly stretches the Coats-Snowe Amendment beyond its language and Congress' clear intent. In 1996, Congress adopted the Coats-Snowe Amendment, entitled "Abortion-related-discrimination in governmental activities regarding training and licensing of physicians," in response to a decision by the Accrediting Council for Graduate Medical Education to require obstetrician-gynecologist residency programs to provide abortion training. The Proposed Rule, however, entirely omits that context.

Rather than being confined to training and licensing activities as the statute is, the Proposed Rule purports to give all manner of health care entities, including insurance companies and hospitals, a broad right to refuse to provide abortion and abortion-related care. In addition, the Rule's expansion of the terms "referral" and "make arrangements for" extends the Coats-Snowe Amendment to shield any conduct that would provide "any information … by any method … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" an abortion or that "render[s] aid to anyone else reasonably likely" to make such an abortion referral. 83 FR 3894-95, 3924 (emphasis added). This expansive interpretation not only goes far beyond congressional intent and the terms of the statute, it also could have extremely detrimental effects on patient health. For example, it would apparently shield, against any state or federal government penalties, a women's health center that required any obstetrician-gynecologist practicing there who diagnosed a pregnant patient as having a serious uterine health condition to refuse even to provide her with the name of an appropriate specialist, because that person "is reasonably likely" to provide the patient with information about abortion.

Again, if the Proposed Rule is not withdrawn, it should be pared back and clarified so as to be faithful to both the statutory text and congressional intent.

C. Examples of Impermissible Weldon Amendment Expansions.

The Department attempts the same sort of improper regulatory expansion of the Weldon Amendment, which is not a permanent statutory provision but a rider that Congress has attached to the Labor, Health and Human Services and Education Appropriations Act annually since 2004. As written, the Weldon Amendment is no more than a bar on particular appropriated funds flowing to federal agencies or programs, or state or local government, if any of those government institutions discriminate on the basis that a health care entity does not provide, pay for, provide coverage of, or refer for abortion. But the Proposed Rule attempts to vastly increase the Amendment's reach in multiple ways. First, the Proposed Rule explicitly extends the reach of the Weldon Amendment beyond the appropriations act to which it is attached, by stating that it also applies to any entity that receives any other "funds through a program administered by the Secretary," which would include, for example, Medicaid. 83 FR 3925. Second, although the terms of the Amendment itself bind only federal agencies and programs and state and local governments, the Rule expands Weldon's reach to also proscribe the behavior of any person, corporation, or public or private agency that receives any of this newly enlarged category of funds. *Id.*

The Rule then provides that no one of this greatly expanded universe of parties may subject any institutional or individual health care entity[25] to discrimination for refusal to provide, pay for, provide coverage for, or refer for abortions. Such unauthorized expansions of limited appropriations language seem designed to encourage broad and harmful denials of care. For example, under the expanded definitions contained in the Proposed Rule, an employer, even one with no religious or moral objection to abortion, may attempt to claim that it has a right to deny its employees' insurance coverage for abortion irrespective of state law. Or a private health care network that receives Medicaid reimbursement could face employees asserting not only the ability to refuse to participate in certain abortion-related care, but also to remain in their positions without repercussions. This is not implementation of the Weldon Amendment; this is a new scheme. If the Rule is not withdrawn, the Department should modify the Rule so that it does not exceed the statute.[26]

VI. The Proposed Rule Appears Intended to Provide a Shield for Health Care Providers Who Fail to Provide Complete Information to Patients in Violation of Both Medical Ethics and Federal Law.

The Proposed Rule also appears to allow providers to let their own personal preferences distort provider-patient communications and deprive patients of critical health care information about their condition and treatment options. The Proposed Rule's Preamble suggests the Rule will improve physician-patient communication because it will purportedly "assist patients in seeking counselors and other health-care providers who share their deepest held convictions." 83 FR 3916-17. But patients are already free to inquire about their providers' views and providers must already honor patients' own expressions of faith and decisions based on that faith. *Cf. id.* Allowing *providers* to decide what information to share—or not share—with patients, as the Rule would do, regardless of the requirements of informed consent and professional ethics would gravely harm trust and open communication in health care.

As the American Medical Association's Code of Medical Ethics ("AMA Code") explains, the relationship between patient and physician "gives rise to physicians' ethical responsibility to place patients' welfare about the physician's own self-interest[.]" AMA Code § 1.1.1. Even in instances where a provider opposes a particular course of action based on belief, the AMA states that the provider must "[u]phold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects." *Id.* § 1.1.7(e). Similarly, ACOG emphasizes that "the primary duty" is to the patient, and that without exception "health care providers must impart accurate and unbiased information so that patients can make informed decisions about their health care." ACOG Committee Opinion No. 385, Recommendations 1-2 (Nov. 2007) (Reaffirmed 2016). Therefore, under well-established principles of informed consent and medical ethics, health care providers must provide patients with all of the information they need to make their own decisions; providers

[25] Although the Weldon Amendment itself defines "health care entity" to include individual health care professionals or "any other kind of health care facility, organization or plan," the Proposed Rule's definitions, as discussed above, try to further extend "health care entity" to also encompass companies or associations whose primary purpose is *not* health care, but who happen to sponsor a health care plan. This appears to reach employers.
[26] Moreover, for any promulgated Rule, the Department must explain its practical operation in detail, so that any affected public or private actors can ascertain the Department's meaning.

may not allow their own religious or moral beliefs to dictate whether patients receive full information about their condition, the risks and benefits of any procedure or treatment, and any available alternatives.

By erroneously expanding the meaning of "assist in the performance of," "refer for" and "make arrangements for," as described above, however, the Proposed Rule purports to allow health care providers to refuse to provide basic information to patients in ways that were never contemplated by the underlying statutes. As described above, these broad definitions may be used to immunize the denial of basic information about a patient's condition as well as her treatment options. Protecting health care professionals when they withhold this vital information from patients violates fundamental legal and ethical principles, deprives patients of the ability to make informed decisions and leads to negligent care. If the Department moves forward with the Proposed Rule, it should modify it to make clear that it does not subvert basic principles of medical ethics and does not protect withholding information from a patient about her condition or treatment options.

VII. The Rule Would Violate the Establishment Clause Because It Authorizes Health Care Providers to Impose their Faith on their Patients, to the Detriment of Patient Health.

The Proposed Rule imposes the significant harms on patients identified above in service of institutional and individual religious objectors. It purports to mandate that their religious choices take precedence over the health care needs of patients. But the First Amendment forbids government action that favors the free exercise of religion to the point of forcing unwilling third parties to bear the burdens and costs of someone else's faith. As the Supreme Court has emphasized, "[t]he principle that government may accommodate the free exercise of religion does not supersede the fundamental limitation imposed by the Establishment Clause." *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *accord Bd. of Educ. of Kiryas Joel Village School Dist. v. Grumet*, 512 U.S. 687, 706 (1994) ("accommodation is not a principle without limits").

Because the Rule attempts to license serious patient harms in the name of shielding others' religious conduct, it is incompatible with our longstanding constitutional commitment to separation of church and state. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708-10 (1985) (rejecting, as Establishment Clause violation, law that freed religious workers from Sabbath duties, because the law imposed substantial harms on other employees); *see also Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 14, 18 n.8 (1989) (plurality opinion) (invalidating sales tax exemption for religious periodicals, in part because the exemption "burden[e]d nonbeneficiaries markedly" by increasing their tax bills). The Department should withdraw the Rule to avoid its violation of the Establishment Clause.

VIII. The Proposed Enforcement Scheme Is Excessive and Fails to Adequately Protect the Due Process and Other Rights of Grantees.

As explained above, the Refusal Statutes carve out specific, narrow exemptions that are only relevant and applicable to certain entities and individuals in certain circumstances. Even with its unfounded expansion of the referenced Refusal Statutes, the Department forecasts only

10-50 complaint investigations or compliance reviews arising under the Refusal Statutes each year, all concerning objections to providing certain health care. 83 FR 3915, 3922. As such, these statutes are quite unlike the various provisions of the Civil Rights Act of 1964, or other civil rights or anti-discrimination statutes that provide broad protection against discrimination to the public or across a wide range of society. Despite these differences, the Proposed Rule claims to model its compliance and enforcement mechanisms on those broad "civil rights laws, such as Title VI and Section 504 of the Rehabilitation Act." 83 FR 3896, 3898. Yet, the Rule's enforcement provisions exceed the ones in place for civil rights laws and, notably, this proposed rulemaking does not anywhere reference basic constitutional limits or specify important due process protections against overzealous enforcement. Taken together, these provisions are ripe for abuse.

The following provisions, which are not an exhaustive list of the serious enforcement scheme issues, appear particularly problematic:

- Funded entities must disclose any complaints or compliance reviews under the Refusal Statutes or Rule from the last five years in any funding application or renewal request, even if the complaint did not warrant an investigation or the investigation or review closed with no finding of any violation, 83 FR 3930;

- The Rule permits onerous remedies for a "failure or threatened failure to comply," including withholding or terminating funding or referral to the Attorney General for "enforcement in federal court or otherwise" without waiting for any attempts at voluntary compliance or resolution through informal means, 83 FR 8330-31;

- The Rule allows the Department to employ the full array of punishments against funding recipients for infractions by sub-recipients, no matter how independent those sub-recipients' actions and no matter how vigorous the recipients' compliance efforts;[27]

- The Rule creates violations for failure to satisfy *any* information requests, and grants access to "complete records," providing especially expansive access with more stringent enforcement than in the Department's Title VI regulations, without any reference to the Fourth Amendment protections developed under Title VI and other similar laws, 83 FR 3829-30; and

- The Rule's enforcement scheme also appears to lack the robust administrative review process, including proceedings before a hearing officer and required findings on the

[27] As proposed subsection 88.6(a) provides, if a sub-recipient violation is found, the recipient "from whom the sub-recipient received funds shall be subject to the imposition of funding restrictions and other appropriate remedies available under this part." 83 FR 3930. This language lacks clarity as to whether imposing a penalty is mandatory or an option, but regardless, not every violation by a sub-recipient should open the recipient to the possibility of sanctions. Moreover, fund termination under the Proposed Rule does not appear to be restricted by the "pinpointing" concept that applies under Title VI, which ensures against vindictive, broad funding terminations and excessive harms to program beneficiaries. Neither this proposed subsection nor the other new enforcement provisions should be added to Part 88, but if they are, subsection 88.6(a) should, like the Proposed Rule's other unfounded enforcement expansions, be clarified and much more strictly limited.

> record, that must precede any suspension or termination of federal funding under, for example, Title VI's enforcement regulations. *See* 45 C.F.R. Part 81. If the Rule is not withdrawn, the Department should make clear that those same rigorous protections apply here.

In addition, while claiming such vast, unauthorized enforcement powers, the Department also repeatedly states that it proposes to uphold "the maximum protection" for the rights of conscience and "the broadest prohibition on" actions against any providers acting to follow their own beliefs. 83 FR 3899, 3931. This combination of a pre-ordained inclination in favor of refusers and excessive enforcement powers further threatens to undermine federal health programs by harming funding recipients who are serving patients well.

If the Rule is not withdrawn, it should be modified in accordance with these comments to ensure that providers of health care are not subjected to unduly broad inquiries or investigations, unfairly penalized, or deprived of due process, all to the detriment of focusing on care for their patients.

IX. The Department Has Not Shown the Need for Expanded Enforcement Authority and Requirements, Uses Faulty Regulatory Impact Analyses, and Proposes a Rule That Will Only Add Compliance Burdens and Significant Costs to Health Care.

Finally, the Department itself estimates hundreds of millions of dollars in cost, almost all imposed on entities providing health care, to undertake the elaborate compliance and enforcement actions the Rule contemplates. But the Proposed Rule's regulatory impact analysis severely underestimates the cost and other burdens it would impose. At virtually every step of its purported tallying of costs, the Department grossly underestimates the time that a covered institution's lawyers, management and employees will have to spend to attempt to understand the Rule, interpret its interplay with other legal and ethical requirements, train staff, modify manuals and procedures, certify and assure compliance, and monitor the institution's actions on an ongoing basis. For example, the Rule considers a single hour by a single lawyer enough for covered entities to "familiarize themselves with the content of the proposed rule and its requirements." 83 FR 3912. It allocates 10 minutes per Refusal Statute, for the roughly two dozen laws referenced, for an entity to execute the assurance and certification of compliance—thus allocating no time for actually reviewing an entity's records or operations in order to do so. 83 FR 3913. Similarly, the impact analysis mentions the time necessary to disclose investigations or compliance reviews, but not the much more significant amount of time needed to respond to and cooperate in those processes. Moreover, the Department does not factor into cost *at all* the cost to the institution when employees refuse to perform care or provide information, or the costs to the refused patients, who must seek help elsewhere and suffer harms to their health.

In estimating benefits, the analysis does not demonstrate barriers to entry for health professionals, or exits from the health profession that are occurring, nor does it substantiate the contention that the medical field does not already include professionals with a wide diversity of religious and other beliefs. As discussed above, it claims benefits to provider-patient

communication and relationships that are non-existent. The Proposed Rule offers no evidence that either greater protection for refusals or expanded enforcement mechanisms are needed.

The Department's prior rulemaking, which emphasized outreach and enforcement, remains in effect and makes clear that OCR has sufficient enforcement authority, consistent with the specific governing statutes, to address any meritorious complaints or other violations. 45 C.F.R. Part 88; 76 FR 9968. In fact, the Department itself estimates that, even with adoption of the Proposed Rule, it would initiate only 10-50 OCR investigations or compliance reviews per year. Since 2008, the number of Refusal Statute complaints per year has averaged 1.25, with 34 complaints filed in the recent November 2016 to mid-January 2018 period.[28] The Proposed Rule contemplates an enormous outlay of funds to implement an elaborate and unnecessary enforcement system that will only divert resources away from enforcing patients' civil rights protections and the provision of high-quality health care to those who need it most.

Thus, the Rule's analysis of economic impacts, including under Executive Orders 12866 and 13563, is seriously flawed and fails to demonstrate that any benefits of the Proposed Rule justify its enormous costs, many of which go unacknowledged. In addition, the Secretary proposes to falsely "certify that this rule will not result in a significant impact on a substantial number of small entities." 83 FR 3918. Small health care entities will have to bear the same regulatory analysis and ongoing compliance costs as larger entities, will face the same loss of employee time and effort from religious and other refusals, and yet have fewer resources and other employees to fall back on. While some small entities may be relieved of routinely certifying their compliance in writing, that compliance is still required – and the compliance itself imposes the much more significant cost and interference with its operations. Similarly, the Secretary erroneously "proposes to certify that this proposed rule … will not negatively affect family well-being," 83 FR 3919, when expanded refusals of medical information and health care by federally funded providers would significantly affect the stability, disposable income, and well-being of low-income families.

The Rule's regulatory impact analyses utterly fail to support its adoption. This expansive rulemaking exceeds any statutory authority and overwhelms any need, and would leave health care institutions, patients, and their families suffering.

* * *

For all these reasons, the Department should withdraw the Proposed Rule.

Sincerely,

Louise Melling
Deputy Legal Director

Faiz Shakir
National Political Director

[28] For context, in FY 2017, OCR received a total of 30,166 complaints under all of the federal statutes it enforces.

EXHIBIT 22

GREATER NEW YORK HOSPITAL ASSOCIATION
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March 27, 2018

Via Electronic Mail
http://www.regulations.gov

Roger Severino
Director, Office for Civil Rights
US Department of
Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW
Washington, D.C. 20201

Re: HHS—OCR—2018—0002, Protecting Statutory Conscience Rights in Health Care, Delegations of Authority; Proposed Rule (Vol. 83, No. 18) Jan. 26, 2018, RIN 0945-ZA03

Dear Mr. Severino:

On behalf of the 160 members of Greater New York Hospital Association (GNYHA), I am writing to comment on the Department of Health and Human Services' (the Department) proposed rule, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.

Our membership includes not-for-profit community hospitals and large academic medical centers, providing a wide range of health care services to millions of patients across New York, New Jersey, Connecticut, and Rhode Island. In many cases, our members are among the largest employers in their communities. As such, they have decades of experience protecting the conscience rights of their employees and prohibiting unlawful discrimination in all its forms. And they have done this while also upholding their primary reason for being—to provide the very best patient care to all those in need.

Health care workers' conscience rights must be balanced with patients' rights and providers' ethical duties. The detailed comments below reflect our view that the proposed rule does not give enough credence to this principle and focuses too heavily on only one side of the equation.

GNYHA

Any Regulations on Conscience Rights Must Reflect Hospitals' Obligation to Balance Health Care Workers' Rights with the Ethical Duty of Care

The Department gives as one of the reasons for the proposed rule an American Congress of Obstetricians and Gynecologists (ACOG) ethics opinion that noted,

> 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.[1]

This statement goes to the heart of the interests that must be balanced when protecting conscience rights in health care.

As set forth in the 2013 edition of *The Hastings Center Guidelines for Decisions on Life-Sustaining Treatment and Care Near the End of Life* (*The Hastings Center Guidelines*), a widely used and cited source of guidance in health care settings, health care providers have a fundamental "duty of care" to patients. This duty prohibits them from "abandoning patients and requires them to meet standards of care and honor patients' rights."[2] Policies in hospitals and other health care institutions support ethical practice by reflecting the duty of care, which is also reflected in a range of legal and regulatory obligations, e.g., the Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd, and New York State Education Law § 6530 (30) (defining patient abandonment as a form of professional misconduct for physicians and other licensed professionals).

Laws and regulations protecting conscience rights have been enacted since the 1970s. Institutional policies have long reflected these rights, including the conscience rights of individual workers and of institutions themselves. Because of this long American tradition of explicitly articulating conscience rights through institutional policy and processes, and explaining these rights in the context of the fundamental duty of care, hospitals are familiar with how to balance workers' conscience rights with patients' rights.

The *Hastings Center Guidelines* recommend that health care institutions "should aim to accommodate [providers'] requests to withdraw from a case on religious or other moral grounds without compromising standards of professional care and the rights of patients." The accommodation process should also hold the provider responsible "for maintaining his or her duty of care by assisting in the orderly transfer of the patient to another professional."[3] This appropriately balances the rights of patients and the rights of providers.

These recommendations, which reflect broad consensus in health care professions and health care ethics, are consistent with actual hospital policies and procedures. These policies generally

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[1] "The Limits of Conscientious Refusal in Reproductive Medicine," *ACOG Committee Opinion*, no. 385 (November 2007; *reaffirmed 2016*)
[2] N. Berlinger, B. Jennings, S. Wolf, *The Hastings Center Guidelines for Decisions on Life Sustaining Treatment and Care Near the End of Life* (Oxford University Press, 2013), 17.
[3] Ibid.

include the worker's duty to notify[4] the hospital on hire, or at another appropriate time, of his or her request not to participate in a particular aspect of patient care or treatment, and the basis of that request. The duty to notify is an important feature of ethical practice to ensure minimal disruption to hospital operations in evaluating and accommodating individual conscience rights. Personal convictions must be communicated and managed in a professional setting, and only the holder of those convictions can start that process. Once notified, the hospital then evaluates and makes efforts to reasonably accommodate the request, taking into account the facts and circumstances of the situation.

In rare cases where the employee notification occurs during the course of providing care to a patient, hospital policies generally require the worker to maintain appropriate standards of care until patient care responsibilities can be transferred. Patient care is the heart of hospital operations, and the duty of care applies throughout the process of finding a reasonable accommodation of the individual's conscience rights.

The Department Should Incorporate a "Reasonable Accommodation" Framework, as It Supports a Balanced Approach to Protecting Conscience Rights

Hospital conscience policies generally mirror the framework for other legally mandated requests for reasonable accommodations. Thus, as the Department revisits its enforcement model for conscience rights, it should take note of the standards developed through the body of law concerning reasonable accommodations under Title VII of the Civil Rights Act and similar models.

Title VII requires employers to grant employees' requests for reasonable accommodation based on religion, unless doing so would cause an undue hardship.[4] Employers are not required to adopt the precise accommodation requested.[5] Further, the employer is entitled to inquire into whether the employee's professed beliefs are in fact sincerely held and religious in nature.[6] Indeed, "[s]ocial, political, or economic philosophies, as well as mere personal preferences, are not 'religious' beliefs protected by Title VII."[7] This framework, shaped over years of enforcement and litigation, provides useful standards to apply in the context of the Office for Civil Rights' (OCR) evaluation and enforcement on the Federal conscience laws, and as such, the Department should explicitly adopt it.

Comments on Specific Regulatory Proposals

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[4] New York State Civil Rights Law, Sec. 79-i, prohibits discrimination against individuals who refuse to perform abortions due to conscience or religious beliefs and provides a mechanism for notifying hospitals and other entities of such refusal in writing.

[4] Reasonable accommodation without undue hardship as required by section 701(j) of Title VII of the Civil Rights Act of 1964, 29 CFR §1605.2(b)(1).

[5] Reasonable accommodation without undue hardship as required by section 701(j) of Title VII of the Civil Rights Act of 1964, 29 CFR §1605.2(c)(2).

[6] "Religious" nature of a practice or belief, 29 CFR §1605.1; see also, *United States v. Seeger,* 380 U.S. 163 (1969).

[7] "EEOC Compliance Manual, Religious Discrimination, Section 12-I(A)(1)–Definition of Religion," (July 22, 2008). https://www.eeoc.gov/policy/docs/religion.html, (accessed March 26, 2018).

"Assist in the Performance"

The Department proposes defining the term "Assist in the Performance" to mean "participate *in any activity with an articulable connection* to a procedure, health service or health service program, or research activity … [emphasis added]." Included would be "counseling, referral, training, and other arrangements for the procedure, health service, or research activity" (FR 3892).

The Department's intent appears to be to broaden the field of individuals covered by the Federal conscience laws. Putting aside whether this would be consistent with each of the underlying statutes, such a broad definition runs the risk of creating unintended consequences for patient care.

By expanding the field of individuals who may refuse to perform their duties, based solely on their ability to articulate a "connection" to the subject procedure or service, the Department runs the risk of turning what is currently a rare occurrence—direct conflicts between conscience rights and the duty of care—into a more common event. It would also make more difficult the process of predicting and planning for scenarios in which conscience rights might need to be exercised. Finally, including referral in the definition could undermine one of the core ethical principles outlined above—the requirement that providers make an appropriate referral when their values conflict with a patient's treatment choices.

"Discriminate" or "Discrimination"

The Department seeks to apply the general principles of nondiscrimination from Title VI of the Civil Rights Act and notes that being free from discrimination also includes "being free not to act contrary to one's beliefs" (FR 3892). But such freedom is not absolute in the health care context; certain rules and precepts, such as the duty of care, should not be viewed as targeting religious or conscience-motivated conduct merely because they reflect workers' and institutions' patient care obligations. And given the complexity of interests at issue, they should not be viewed through a "disparate impact" lens. It is vitally important that health care institutions have the discretion and tools to balance patient rights, including their own right not to be discriminated against, with individuals' conscience rights without fear of unreasonable enforcement action. Conscience rights should not stand above all other civil rights protected by Federal, State, and local laws.

Compliance Requirements

The Department proposes certain new compliance requirements, including that Recipients inform their Departmental funding component of any compliance review, investigation, or complaint and report any such matters brought within the prior five years in any application for new or renewed Federal Financial Assistance or Departmental funding. In addition to being extremely burdensome, these requirements are unfair in that they do not distinguish among the varieties of inquiries that a Recipient may be facing and whether they were substantiated or not. These requirements are also unnecessary because OCR will have custody of all of the relevant information, which it can make available to the Departmental funding components.

GNYHA

Enforcement Authority

The Department proposes for OCR to "[i]n coordination with the relevant component or components of the Department, take other appropriate remedial action as the Director of OCR deems necessary and as allowed by law …" (FR 3898). OCR should defer to the conscience laws, and any existing administrative regimes, on sanctioning and due process. The Departmental funding components already have such procedures in place. The Department should delineate the grounds for various types of sanctions with respect to the conscience laws.

Conclusion: The Proposed Rule is Arguably Unnecessary, and At Minimum, Should be Reframed and Streamlined

The Department cites many reasons for issuing the proposed rule, but one of its primary goals is to enhance awareness of the Federal conscience protections among the public and the health care community. This awareness-raising began when OCR recently announced the establishment of its new "Conscience and Religious Freedom Division," and certainly new regulations are not necessary for OCR to undertake additional public education efforts.

This type of rulemaking seems to be exactly what President Trump intended to thwart with the issuance of his executive order, Reducing Regulation and Controlling Regulatory Costs.[8] The proposed rule stands in contrast with the Administration's regulatory streamlining goals and should be reframed and significantly scaled back, in accordance with the foregoing comments.

Thank you for taking our comments into consideration.

Very Truly Yours,

Kenneth E. Raske
President

[8] "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs," (January 30, 2107). https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/ (accessed March 26, 2018).