Exhibit 30

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF KATHRYN MACOMBER

I, Kathryn Macomber, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

1. I submit this Declaration in support of the State of Michigan's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through Michigan Department of Health and Human Services personnel who have assisted me in gathering this information from our institution, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Michigan Department of Health and Human Services.

2. I have worked for the Population Health Administration (PHA) for 17 years, mostly in HIV, STD, and Viral Hepatitis Epidemiology and Programs. I currently serve in an acting Administrative Deputy role with cross-cutting functions across PHA. I have a bachelor's degree in microbiology and a master's degree in Hospital and Molecular Epidemiology.

3. The MDHHS Population Health Administration has serious concerns related to the United States Department of Health and Human Services' rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the "Final Rule"). The Final Rule would significantly expand the ability of health care providers to withhold treatment, counseling, or medical information based on their religious or moral beliefs.

4. Many Population Health Administration Programs receive funding either directly from HHS or indirectly from HHS via the Centers for Disease Control and Prevention. MDHHS is a Title X funded program, and the Final Rule could jeopardize the MDHHS Family Planning Program's ability to meet the requirements of the Title X program, including providing services

without discrimination, assuring access to a broad range of contraceptive methods, and providing services to minors. MDHHS is also a Ryan White funded program. The Final Rule could also jeopardize the program's ability to meet the requirements of the program by assuring a range of HIV care including contraceptive counselling, providing services to minors, and HIV treatment.

5. HHS funding is routed to local health departments, medical providers, universities, and local clinics, among others. MDHHS has over 100 contracts to provide clinical services across HIV, STD, Family Planning, and immunizations with subcontracting service providers that would be affected by the Final Rule. These contracts fund a diverse type of clinical staff including physicians, nurse practitioners, medical assistants and RNs. Services provided include HIV care and treatment, HIV testing, STD testing, pregnancy testing and contraceptive counseling, immunizations, immunization counseling, STD treatment, and provision of HIV pre and post-exposure prophylaxis.

6. MDHHS's public health code requires essential public health services, of which HIV/STD services and vaccination is also a requirement.

7. The Final Rule would allow providers to withhold information about FDA-approved contraceptive methods, counseling and referrals to abortion services, emergency contraception information, and vaccinations such as HPV and sterilization services.

8. The Final Rule could also allow providers to deny services to entire Michigan populations, such as minors, unmarried clients, clients living with HIV/AIDS, and LGBTQ people.

9. Clients who are low-income, uninsured or under-insured, or who live in rural communities could be disproportionately affected as alternative health care providers are not readily accessible.

10. The Final Rule does not consider the needs of Michigan clients and could create confusion about the rights and responsibilities of health care providers, entities, and clients and jeopardize the trusted client-provider relationship.

11. Withholding information from clients could also impact their ability to give informed consent for some health care services.

12. The Final Rule will also have impacts for Michiganders and MDHHS in other areas, such as end-of-life care, blood transfusions, vaccinations, substance use disorders, civil rights laws related to employers, and likely many more.

13. Given that health care institutions owned and operated by Michigan will have limited notice, or possibly no notice, if one of their staff objects to the provision of a particular service or activity, those institutions will have to dramatically increase the staff available to serve patients in order to ensure that care is delivered.

14. In order to comply with the Final Rule, undue burden would be put upon the PHA. The PHA would be required to educate our subcontracting service providers concerning compliance with the Final Rule. The PHA would also be required to create written materials explaining the Final Rule to clients who may experience a denial of service in health care, as a result of the Final Rule, and also create a referral network to ensure such clients are still able to receive services from a different provider. In many parts of Michigan there is a single service provider for free, confidential health department services like HIV testing, STD testing and treatment, HIV care, and immunizations. Creating additional access points for Michiganders in need of health services would put undue burden on the State of Michigan.

15. The cost of this parallel staff will be unduly burdensome to the State institutions and to Michigan itself.

16. This is especially true in areas in which there are few other health care providers, such as rural areas, and in areas in which other providers are more likely to be religious and have objections of their own to the provision of certain types of care.

Executed on this 11 day of June, 2019

Kathryn Macomber, MPH

Exhibit 31

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA,

Defendants.

Case No. 1:19-cv-04676

DECLARATION OF DR. JAMES MADARA, MD IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, James L. Madara, M.D., hereby submit the following declaration in support of the Plaintiffs' Motion for a Preliminary Injunction in the above-captioned matter:

I. Introduction

1. I am a Medical Doctor as well as the Chief Executive Officer and Executive Vice President of the American Medical Association (the "AMA"), an Illinois not-for-profit corporation. I am also an adjunct professor of pathology at Northwestern University in Chicago, Illinois.

2. This declaration is submitted on behalf of the AMA and the Litigation Center of the AMA and State Medical Societies ("Litigation Center"). It also represents my personal beliefs.

3. On March 27, 2018, on behalf of the AMA, I submitted a letter to Alex M. Azar II, Secretary of the Department of Health and Human Services describing the AMA's position regarding the Notice of Proposed Rulemaking (Proposed Rule) on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," issued by the Office of Civil Rights (OCR) published in the Federal Register on January 26, 2018. That letter is available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70564.

4. The Final Rule, which is the subject of this lawsuit, to be codified at 45 C.F.R. § 88.7, would undermine patients' access to medical care and information, impose barriers to physicians' and health care institutions' ability to provide treatment, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients.

II. About the AMA and the Litigation Center

5. The AMA is an Illinois not-for-profit corporation headquartered in Chicago. It is the largest professional association of physicians, residents, and medical students in the United States. The AMA represents virtually all United States physicians, residents, and medical students through its policymaking process.

6. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. Since its founding in 1847, the AMA has played a crucial role in the development of medicine in the United States.

7. AMA members practice and reside in all States, including New York. Further, AMA members practice in all areas of medical specialization.

8. The AMA has published its *Code of Medical Ethics* since 1847. This was the first modern national medical ethics code in the world and continues to be the most comprehensive and well-

respected code for physicians, world-wide. The federal judiciary, including the United States Supreme Court, has repeatedly cited to the *AMA Code of Medical Ethics*. [1]

9. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

III. Physician Exercise of Conscience is not Unlimited

10. Physicians are members of a profession "dedicated to the wellbeing of their patients," AMA Code of Medical Ethics Opinion 1.1.2 *Prospective Patients*, yet "they are moral agents in their own right." AMA Code of Medical Ethics Opinion 1.1.7. *Physician Exercise of Conscience*. "Physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities." *Id.* But the exercise of a physician's own beliefs must be balanced against the fundamental obligations of the medical profession and physicians' paramount responsibility and commitment to serving the needs of their patients. AMA Code of Medical Ethics Opinion 1.1.1. *Patient-Physician Relationships*.

11. AMA Code of Medical Ethics Opinion 1.1.7. *Physician Exercise of Conscience* offers guidance on how physicians must weigh their responsibility to deliver competent medical care that could conflict with the physician's own deeply held beliefs.

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[1] *See, e.g., Lilly v. Commissioner*, 343 U.S. 90, 97 n.9 (1952); *Roe v. Wade*, 410 U.S. 113, 144 n.39 (1973); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 369 n.20 (1977); *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 288 & 308 (1990) (O'Connor, J., concurring & Brennan, J., dissenting); *Rust v. Sullivan*, 500 U.S. 173, 214 (1991) (J. Blackmun dissenting); *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997); *Vacco v. Quill*, 521 U.S. 793, 800 n.6 & 801 (1997); *Ferguson v. City of Charleston*, 532 U.S. 67, 81 (2001); *Baze v. Rees*, 553 U.S. 35, 64 & 112 (2008) (Alito, J., concurring); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 592-93 (2012) (Ginsburg, J., dissenting).

12. The *AMA Code of Medical Ethics* instructs physicians who anticipate a conflict of their personal beliefs with the duties to their patients to:

> "(a) Thoughtfully consider whether and how significantly an action (or declining to act) will undermine the physician's personal integrity, create emotional or moral distress for the physician, or compromise the physician's ability to provide care for the individual and other patients.
>
> (b) Before entering into a patient-physician relationship, make clear any specific interventions or services the physician cannot in good conscience provide because they are contrary to the physician's deeply held personal beliefs, focusing on interventions or services a patient might otherwise reasonably expect the practice to offer.
>
> (c) Take care that their actions do not discriminate against or unduly burden individual patients or populations of patients and do not adversely affect patient or public trust.
>
> (d) Be mindful of the burden their actions may place on fellow professionals.
>
> (e) Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.
>
> (f) In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer. When a deeply held, well-considered personal belief leads a physician also to decline to refer, the physician should offer impartial guidance to patients about how to inform themselves regarding access to desired services.
>
> (g) Continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethics guidance."

AMA Code of Medical Ethics Opinion 1.1.7. *Physician Exercise of Conscience.*

13. The Final Rule, through overly broad definitions, which rest on a piecemeal foundation of statutory provisions, frustrates these carefully considered ethical principles and allows physicians and other health care personnel an unconsidered, one-size-fits-all right to decline to *any* part of a health service or program if that guidance conflicts with a moral or religious belief. This represents a reckless indifference to how medicine is practiced and is contrary to the basic precept of the medical profession of beneficence to the patient. AMA Code of Medical Ethics Opinion 1.1.1. *Patient-Physician Relationships.* ("The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering."); *see also* AMA Code of Medical Ethics Opinion 1.1.7. *Physician Exercise of Conscience* ("Physicians' freedom to act according to conscience is not unlimited, however. Physicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient.").

14. For example, the Final Rule's expansive definition of "referral", 84 Fed. Reg. at 23,266-67 (to be codified at 45 C.F.R. § 88.3(h)), which would allow a physician to decline to provide any information whatsoever about an objected-to service, is inconsistent with the term as it is understood in medical practice (*i.e.* to provide the patient with the name of another provider). Refusing to provide any information about an objected-to service goes against the *AMA Code of Ethics*, particularly the physician's duty to uphold the standards of informed consent.

15. Under the ethical mandate of informed consent, "[p]atients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care." AMA Code of Medical Ethics Opinion 2.1.1 *Informed Consent.* And "withholding information without the patient's knowledge or consent is ethically unacceptable."

AMA Code of Medical Ethics Opinion 2.1.3 *Withholding Information from Patients.* Any rule that interferes with this obligation not only would jeopardize patient safety and trust in the medical profession, it also could expose providers to legal discipline.

IV. Physicians Have an Obligation to Ensure Patient Safety

16. Physicians, "as professionals dedicated to promoting the well-being of patients…individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable." AMA Code of Medical Ethics Opinion 1.1.6. *Quality.*

17. And "[a]s professionals uniquely positioned to have a comprehensive view of the care patients receive, physicians must strive to ensure patient safety and should play a central role in identifying, reducing, and preventing medical errors." AMA Code of Medical Ethics Opinion 8.6. *Promoting Patient Safety.*

18. According to the Final Rule, "assist in the performance" means "to take an action that has a specific, reasonable, and articulable connection to furthering a procedure," which "may include counseling, referral, . . . or otherwise making arrangements for the procedure . . . depending on whether aid is provided by such actions." 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

19. The Final Rule's blanket waiver for health care professionals to decline to "assist in the performance" of *any* procedure that might conflict with a personal belief would create unsafe gaps in the delivery of care, contrary to physicians' ethical and legal responsibilities to their patients.

20. Furthermore, the lack of clarity in the Final Rule regarding the types of procedures that constitute "assistance" or "referrals" would prevent physician and hospital employers from knowing how to appropriately staff treatment and how to institute effective accommodations for employees.

21. In order for medical procedures to run smoothly, and for patient safety to be optimized, physicians must be able to trust the other members of their healthcare team to provide essential

information and services. The Final Rule, which prohibits employers from posing questions to applicants about their willingness to perform particular services prior to hire, and allows providers to opt-out of providing emergency care, impedes the ability to assemble a reliable team. *See* 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

22. Physicians who practice in small medical clinics, offices, and labs may be particularly vulnerable. In order to deliver effective care with limited resources, physicians rely on staff to perform many functions, including scheduling follow up appointments, and, under appropriate supervision, providing counseling and referrals. Small practices may not have the resources to hire redundant personnel for the sole purpose of making sure at least one member of staff is available to provide necessary care to a patient.

V. The Final Rule Undermines the Patient-Physician Relationship

23. The patient-physician relationship is built upon trust, "which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare." AMA Code of Medical Ethics Opinion 1.1.1 *Patient-Physician Relationships.*

24. Not only does the Final Rule throw this relationship out of balance by placing the health care professional's interest above all else, but it permits health care professionals to do so based on personal characteristics that are outside of their patients' control. The Final Rule would allow medical personnel to discriminate at will and refuse service once they find out that a person may be interested in a particular procedure or is part of a particular protected class.

25. This is ethically unacceptable. Physicians are "ethically …called on to provide the same quality of care to all patients without regard to medically irrelevant personal characteristics." AMA Code of Medical Ethics Opinion 8.5 *Disparities in Health Care.* Furthermore, physicians must act to

decrease disparities in health care caused by bias, stereotypes, and other circumstances beyond the patient's control. AMA Code of Medical Ethics Opinion 8.5 *Disparities in Health Care* ("[P]hysicians should [p]rovide care that meets patient needs and respects patient preferences…[a]void stereotyping patients…[and e]xamine their own practices to ensure that inappropriate considerations about race, gender identify, sexual orientation, sociodemographic factors, or other nonclinical factors, do not affect clinical judgment.").

* * *

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

Executed on June 13th, 2019, in Chicago, Illinois.

James L. Madara, M.D.

Exhibit 32

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF DR. SANDRA MARTELL

1. I, Dr. Sandra Martell, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the State of Illinois's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through Winnebago County Health Department ("WCHD") personnel who have assisted me in gathering this information from our institution, or on the basis of documents I have reviewed.

3. I am the Public Health Administrator at WCHD located in Rockford, Illinois. I have a Doctor of Nursing Practice and a Master of Science Degree in Public Health Nursing/Family Nurse Practitioner from the University of Illinois at Chicago, as well as a Bachelor of Science degree in Nursing from Loyola University of Chicago. I have been the Public Health Administrator at WCHD since August 2014. Prior to taking that position, I worked in various roles for the Cook County Department of Public Health for 27 years.

4. WCHD provides services designed to protect, promote, and maintain the health of Winnebago County residents. Services address three primary goals: improving the length of useful life, reducing health disparities, and assuring access to preventive health services for every person in Winnebago County.

5. WCHD receives the following HHS funding in subgrants through the Illinois Department of Public Health:

a. $640,015 since July 1, 2017 for diagnosis and treatment of breast and cervical cancer;

b. $161,581 since July 1, 2018 as part of the Title X Family Planning Program to provide voluntary comprehensive family planning services to low-income individuals of reproductive age;

c. $167,588 since July 1, 2018 for Public Health Emergency Preparedness to prevent, mitigate, and recover from the top hazards to the public health;

d. $45,000 since July 1, 2018 for the Dental Sealant Grant Program to provide preventive oral health care, oral health education, and case management to dental homes;

e. $4,035,588 since April 1, 2017 for the Ryan White program to provide lead agency coordination of medical and support services to individuals in Illinois living with HIV/AIDS; and

f. $24,000 since July 1, 2018 to evaluate local Vaccines For Children enrolled-providers to ensure compliance with program requirements.

6. WCHD receives the following HHS funding in subgrants through the Illinois Department of Human Services:

a. $243,585 since July 1, 2018 to address the increasing level of opioid use-related problems among residents of Winnebago County;

b. $150,000 since July 1, 2018 for youth substance abuse prevention programs;

c. $222,300 since July 1, 2018 for refugee health services, including health screenings, health education, promotion, outreach, case management, and interpretation services;

d. $107,544 since July 1, 2018 for the Maternal, Infant and Early Childhood Home Visiting Grant Program to provide intensive home visitation services to new and expectant families;

e. $214,880 since July 1, 2018 for the Maternal & Child Health Program to provide intensive prenatal case management and care coordination services for high-risk pregnant women; and

f. $201,700 since July 1, 2018 to provide case management and care coordination services to high risk infants and children ages 0 – 2 with the goal of reducing infant mortality and morbidity rates.

7. HHS funds are essential to support many of the fundamental services provided by WCHD to the community and to maintaining public health across the state of Illinois.

8. I have been made aware of the Final Rule and believe it may cause significant, immediate impact upon WCHD.

II. HHS Investigation

9. On January 16, 2018, Noel Sterett of Mauck & Baker, LLC filed a complaint of religious discrimination against WCHD on behalf of Sandra Rojas ("Complaint"). Attachment A. The Complaint alleged that WCHD, as a recipient of federal funding, discriminated against Rojas in violation of the Church Amendments, Public Health Service Act, and/or the Weldon Amendment. *Id.* at 1. The Complaint attached a complaint that Rojas filed in Illinois state court against WCHD alleging WCHD discriminated against Rojas for her refusal to participate in abortion or contraception as a nurse at WCHD. *Id.* at Ex. 1.

10. On January 18, 2018, the Winnebago County State's Attorney responded to the Complaint on behalf of WCHD ("Response"). Attachment B. Our Response clarified that WCHD does not provide abortion services and did not terminate Rojas from employment, but rather, she resigned. *Id.* at 1.

11. On March 19, 2019, Luis E. Perez, the Deputy Director of the Conscience and Religious Freedom Division in the HHS Office for Civil Rights, sent an Initial Discovery Request to WCHD about the Complaint. Attachment C. The Initial Discovery Request stated that it was a "notice of an investigation" into allegations that "Ms. Rojas was subjected to unlawful discrimination by [WCHD] for refusing to participate in the provision of abortion-related services in accordance with her religious beliefs." *Id.* at 1. The Initial Discovery Request further stated that HHS's investigation was proceeding under authority granted by the Weldon Amendment, Coats-Snowe Amendment, and Church Amendments. *Id.*

12. The HHS investigation described in the Initial Discovery Request relies on the same federal statutes wielded in the Final Rule. . *See* 84 Fed. Reg. at 23,170, *passim* (to be codified at 45 C.F.R. § 88.2). Thus, HHS could revoke any or all of WCHD's HHS funding under the Final Rule if it goes into effect for any alleged violation found in HHS's investigation described in the Initial Discovery Request.

13. The Initial Discovery Request contains 37 requests for documents and information. Generally, the Initial Discovery Request asks WCHD to provide the following information:

a. Documents related to and the identities of individuals with knowledge of the allegations in the ongoing discrimination lawsuit filed by Rojas against WCHD;

b. How WCHD would respond to various hypothetical scenarios involving Rojas's employment with WCHD had she not resigned;

c. Documents related to any other allegations of religious discrimination made against WCHD at any point in time;

d. WCHD's "understanding of what [HHS] required in 2015 of the [WCHD] as a condition of participating in programs authorized under Title X of the Public Health Service Act." Attachment C at 3;

e. Information related to WCHD's understanding that certain laws mandate "counseling to pregnant women, for which termination of pregnancy is provided as an option, abortion referrals, or contraception." *Id.*;

f. "[T]he legal relationship[s] between the State of Illinois and Winnebago County" and "the State of Illinois and [WCHD]." *Id.* at 6;

g. "[A]ny Federal financial assistance you…have been a recipient or sub-recipient of from HHS in the last four calendar years" *Id.*;

h. "[A]n approximate total of any reimbursements you received from Medicare[,]…Medicaid[,] and the Children's Health Insurance Program[.]" *Id.*;

i. Descriptions of HHS funding that WCHD has received through the Preventive Health and Health Services Block Grant and the Maternal & Child Health Services Block Grant.

14. WCHD received an extension in responding to the Initial Discovery Request. WCHD's response is due to HHS on June 18, 2019.

15. I believe that if the Final Rule goes into effect, HHS will swiftly move to strip WCHD of HHS funding provided through various state agencies in light of the Initial Discovery Request and HHS's ongoing investigation into alleged religious discrimination by WCHD. Thus, WCHD faces a real and imminent threat of loss of over $6 million in HHS funding should the Final Rule go into effect.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 7th day of June, 2019

Dr. Sandra Martell

Public Health Administrator for the Winnebago County Health Department

Exhibit 32
Attachment A

MAUCK & BAKER, LLC

RICHARD C. BAKER
WHITMAN H. BRISKY
JOHN W. MAUCK
NOEL W. STERETT

SORIN A. LEAHU

MICHAEL P. MOSHER,
OF COUNSEL

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WWW.MAUCKBAKER.COM
TEL: 312.726.1243 FAX: 866.619.8661

January 16, 2018

Via E-Mail and U.S. Mail: OCRComplaint@hhs.gov

Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHH Bldg.
Washington, DC 20201

Re: Complaint of Discrimination in Violation of Federal Statutes

Dear Sir or Madam:

Mauck & Baker, LLC, represents Sandra Rojas (also known as Sandra Mendoza), a licensed practical nurse ("LPN") who was subjected to unlawful discrimination by the Winnebago County Health Department, a state agency subject to the Church Amendments (42 U.S.C. § 300a-7), the Public Health Service (PHS) Act (§ 245 (42 U.S.C. § 238n)), and/or the Weldon Amendment (Continuing Appropriations Resolution, Pub. L. No. 113-164, Sec. 101(a) (Sept. 19, 2015)) by virtue of its status as a recipient of federal funding.

Sandra is a pediatric nurse with forty years of experience. She serves as a nurse in furtherance of and in conformance with her religious convictions to care for children. Her religious convictions also prohibit her from performing, assisting in, referring for, or participating in any way with abortion or abortion-causing drugs. Her right to serve as a pediatric nurse without violating her conscience or compromising her religious convictions relating to abortion or abortion-causing drugs are protected by the First Amendment to the United States Constitution, the Constitution of the State of Illinois, the Illinois Religious Freedom Restoration Act, 775 ILCS 35/15, and the Illinois Healthcare Right of Conscience Act, 745 ILCS 70/1 *et seq*, in addition to the federal conscience clauses named above.

For nearly eighteen years, Sandra served as a pediatric nurse at the Winnebago County Health Department and until 2015 was never forced to participate in abortion related services. However, in the summer of 2015, the county's new Public Health Administrator, Dr. Martell, informed Sandra that she could no longer work in the health department clinics if she was unwilling to participate in the provision of abortion related

services. Her termination had nothing to do with her performance as Sandra had recently received the "Employee of the Week" and "Employee of the Quarter" awards.

The attached First Amended Complaint, *Sandra Rojas v. Dr. Martell, et al.*, Case No. 2016 L 160, (attached as Exhibit 1), contains the factual and legal descriptions of specific violations of our clients' rights. The letter from Dr. Martell to Sandra dated June 30, 2015 (Ex. B to the First Amend. Compl.) shows that Dr. Martell informed Sandra that she was basing her decision to terminate Sandra from the clinic environment on account of Sandra's religious convictions and conscientious objections and also on account of the terms of the federal grants the health department receives. The Defendants' "Third Affirmative Defense" (attached as Exhibit 2) shows how the Health Department has tried to justify its unlawful discrimination against Sandra by referring to the terms of Title X and the federal funds it receives. But as the aforementioned federal conscience clauses make plain, Title X and the terms of the federal grants actually *prohibited* Sandra's termination on account of her religious and conscientious objections.

Sandra's state court case is pending before the Circuit Court of Winnebago County in Rockford, Illinois. On February 15, 2018, the court will hold a status hearing at which the judge may rule on the parties' cross-motions for summary judgment.

Please promptly inform us of the actions your office plans to take regarding this violation. Thank you for your attention to this matter.

Sincerely yours,

/s/ Noel W. Sterett
Noel W. Sterett, Esq.

cc: Client
Charlotte LeClercq, Assistant Deputy States Attorney for Winnebago County

EXHIBIT 1

IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT
WINNEBAGO COUNTY, ILLINOIS

SANDRA ROJAS, LPN, formerly and also known as SANDRA MENDOZA, Plaintiff, v. DR. SANDRA MARTELL, Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the Winnebago County Board of Health, in his official capacity and WINNEBAGO COUNTY, ILLINOIS, Defendants.	Case No. 2016-L-160 TRIAL BY JURY DEMANDED

AMENDED VERIFIED COMPLAINT FOR DAMAGES AND DECLARATORY RELIEF

NOW COMES Plaintiff, SANDRA ROJAS, LPN, formerly and also known as Sandra Mendoza (hereinafter "Ms. Mendoza"), by and through her undersigned attorneys, for her Amended Verified Complaint for Damages and Declaratory Relief against the Defendants Dr. Sandra Martell, the Acting Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the WinnebagoCounty Board of Health, in his official capacity, and WINNEBAGO COUNTY, Illinois alleges as follows:

INTRODUCTION

1. This case is about how the Winnebago County Health Department unlawfully discriminated against Ms. Mendoza, a Licensed Practical Nurse ("LPN") with eighteen years of service in pediatrics with the Health Department, because of Ms. Mendoza's conscientious refusal to participate in any way in abortions or the provision of abortifacient or contraceptive drugs.

2. Damages and declaratory relief are sought under the Illinois Healthcare Right of Conscience Act, 745 ILCS 70/1 *et seq.*; the Illinois Religious Freedom Restoration Act, 775 ILCS 35/1 *et seq.*; and the Illinois Human Rights Act, 775 ILCS 1/1-101 et seq.

PARTIES

3. Plaintiff Sandra Rojas, formerly and also known as Sandra Mendoza, is a resident of Winnebago County, Illinois.

4. The Defendants are Dr. Sandra Martell, RN, DNP, acting Public Health Administrator for the Winnebago County Health Department headquartered at 401 Division St., Rockford, IL 61110, sued in her official capacity; James Powers, acting chair of the Winnebago County Board of Health, in his official capacity; and WINNEBAGO COUNTY, ILLINOIS, the municipal government of which the Winnebago County Health Department is a part.

5. Venue is proper in the Circuit Court of the Seventeenth Judicial Circuit, Winnebago County, Illinois under the pertinent statutes.

MS. MENDOZA'S HEALTHCARE BACKGROUND

6. Ms. Mendoza has been a licensed practical nurse since July 20, 1990.

7. Ms. Mendoza began working for the Winnebago County Health Department on June 6, 1996, and until July 31, 2015, provided nursing services as a nurse in the Pediatric Immunization Clinic including, *inter alia,* immunizations, screenings for blood lead levels, access to medical records, and assessments for the risk of tuberculosis.

8. On May 11, 2014, Ms. Mendoza also began serving in Health Protection and Promotion by providing adult immunization, hearing and vision testing for children, and TB testing for employees.

9. Ms. Mendoza has also worked part-time as a nurse at the Walter Lawson Children's home since 1978 and for Addus Home Health since 2011.

MS. MENDOZA'S RELIGIOUS AND CONSCIENCE-BASED OBJECTIONS TO ABORTION AND CONTRACEPTION

10. Ms. Mendoza is a lifelong, practicing Catholic who seeks to adhere to the commands and Word of God as revealed in the Holy Scriptures and to the teachings of the Catholic Church.

11. The Scriptures and the Church teach that human life is created in the image of God (Genesis 1:27, *Imagio Dei*), begins at conception (Psalms 139:13-16, Didache, 2:2), and should not, therefore, be destroyed (Exodus 20:1, 13, 21:22-25). Catholic doctrine (Humanae Vitae 14) also teaches against contraception by declaring it sinful to participate in "direct sterilization, whether perpetual or temporary, whether of the man or of the woman. Similarly excluded is every action which, either in anticipation of the conjugal act, or in its accomplishment, or in the development of its natural consequences, proposes, whether as an end or as a means, to render procreation impossible."

12. Current and standard human-embryology texts also confirm that the union of a sperm and ovum creates a new and distinct organism—a whole, though developmentally immature, member of the human species. See, e.g. Moore and Persaud's "The Developing Human," Larsen's "Human Embryology," Carlson's "Human Embryology & Developmental Biology," and O'Rahilly and Mueller's "Human Embryology & Teratology."

13. An abortion is the "induced termination of pregnancy, involving destruction of the embryo or fetus." The American Heritage Science Dictionary. Boston: Houghton Mifflin. 2005.

14. Both the U.S. Food and Drug Administration ("FDA") and the manufacturer of "Plan B" acknowledge that it can prevent an already-fertilized egg from implanting in the womb.

15. Ms. Mendoza has religious beliefs, as well as moral and ethical objections, which are in accord with the Word of God, the teachings of the Catholic Church and current science, which prevent her as a matter of conscience from participating in any way in abortions or the provision of abortifacient and contraceptive drugs—including but not limited to the provision of the "Plan B" pill (also known as the "morning after pill"), referrals to abortion providers, and birth control.

16. In 2001, while working for the Health Department Ms. Mendoza, after consultation with her pastor and priest Fr. William Collins of St. Patrick Parrish, informed the Health Department that she could not as a matter of religious practice and conscience participate in any way in the provision of Plan B, contraception, or abortion referrals.

17. Thereafter, Ms. Mendoza continued to work for the Health Department as a nurse in the Health Department's Pediatric Immunization Clinic and did not participate, in any way, in the provision of Plan B, contraception, or abortion referrals.

DEFENDANT'S UNLAWFUL DISCRIMINATION

18. In late 2014, Dr. Sandra Martell was employed by Winnebago County, Illinois, under the supervision of the Winnebago County Board of Health.

19. In or about March 2015, Dr. Martell began to integrate certain clinical services, including integrating the pediatric services with the women's health services.

20. In or about May 2015, Ms. Mendoza informed human resources and Dr. Martell that she could not participate in the provision of birth control, referrals to abortion clinics, or Plan B.

21. On or about July 14, 2015, Dr. Martell sent an e-mail asking Ms. Mendoza for her "...decision regarding the accommodation that is being offered in response to your request outlined in the letter to [Ms. Mendoza] dated June 30, 2015 so that we can implement it as soon

as possible with minimal impact to clients and collcagues...." July 14, 2015 E-mail attached as Exh. A.

22. Since Ms. Mendoza had not received the letter referenced in the e-mail, Ms. Mendoza contacted Ms. Martell on or about July 14, 2015 to inquire about the letter and the e-mail.

23. Ms. Mendoza was then provided a copy of the June 30, 2015 letter (attached as Exhibit B) which had been sent to the wrong address.

24. The letter acknowledges that Ms. Mendoza "conveyed that [her] religious beliefs would not permit [her] to perform a number of the required duties at the combined clinics" but that the Health Department could not "accommodate [Ms. Mendoza] within the clinic environment at the Health Department."

25. The defendant's letter than offered Ms. Mendoza "alternatives outside of the clinics" which consisted of demotion/transfer to a position as a County temporary/part time food inspector or employee at River Bluff nursing home.

26. Ms. Mendoza declined the demotions to temporary, part time food inspector and employee at River Bluff and was therefore forced to resign.

27. Ms. Mendoza could not work at the River Bluff nursing home because, as she informed Dr. Martell, her son Daniel Ortega was employed there as a Registered Nurse and the nursing home had a rule prohibiting working with family members.

28. As a direct and proximate result of defendants' actions as described herein, Ms. Mendoza has suffered damages including loss of income and benefits, pain and suffering, mental anguish, inconvenience, loss of enjoyment of life and other economic and noneconomic losses.

COUNT I

Violation of the Illinois Health Care Right of Conscience Act, 745 ILCS 70/1 *et seq.*

29. Plaintiff incorporates by reference herein all preceding paragraphs.

30. The Health Care Right of Conscience Act states the following:

> It is the public policy of the State of Illinois to respect and protect the right of conscience of all persons who refuse to obtain, receive, or accept, *or who are engaged in, the delivery of, arrangement for, or payment of health care services and medical care whether acting individually, corporately, or in association with other persons*; and to *prohibit all forms of discrimination, disqualification, coercion, disability or imposition of liability upon such persons or entities* by reason of their refusing to act contrary to their conscience or conscientious convictions *in refusing to obtain, receive, accept, deliver, pay for, or arrange for the payment of health care services and medical care.*

745 ILCS 70/2 (emphasis added).

31. Under the Act, "health care" is defined as "any phase of patient care, including but not limited to, … instructions; family planning, counseling, referrals, or any other advice in connection with the use or procurement of contraceptives and sterilization or abortion procedures; [or] medication…." 745 ILCS 70/3.

32. In addition, "health care professional" is defined as "any nurse, nurse's aide, medical school student, professional, paraprofessional or any other person who furnishes, or assists in the furnishing of, health care services." *Id.*

33. "Conscience" is defined as "a sincerely held set of moral convictions arising from belief in and relation to God, or which, though not so derived, arises from a place in the life of its possessor parallel to that filled by God among adherents to religious faiths." *Id.*

34. Section 5 of the Act states the following:

> It shall be unlawful for any person, public or private institution, or public official to discriminate against any person in any manner, including but not limited to, licensing, hiring, promotion, transfer, staff appointment, hospital, managed care entity, or any other privileges, because of such person's conscientious refusal to receive, obtain,

> accept, perform, assist, counsel, suggest, recommend, refer or participate in any way in any particular form of health care services contrary to his or her conscience.

745 ILCS 70/5.

35. Section 7 of the Act states that it is unlawful for any public or private employer, entity, or agency to "... orally question about, to impose any burdens in terms or conditions of employment on, or otherwise discriminate against any applicant, in terms of employment" or to "discriminate in relation thereto, in any other manner" on account of the applicant's refusal to "perform, counsel, suggest, recommend, refer, assist, or participate in any way in any forms of health care services contrary to his or her conscience." 745 ILCS 70/7.

36. Section 9 of the Act states the following:

> No person, association, or corporation, which owns, operates, supervises, or manages a health care facility shall be civilly or criminally liable to any person, estate, or public or private entity by reason of refusal of the health care facility to permit or provide any particular form of health care service which violates the facility's conscience as documented in its ethical guidelines, mission statement, constitution, bylaws, articles of incorporation, regulations, or other governing documents.

745 ILCS 70/9.

37. Section 10 of the Act states the following:

> It shall be unlawful for any person, public or private institution or public official to discriminate against any person, association or corporation attempting to establish a new health care facility or operating an existing health care facility, in any manner, including but not limited to, denial, deprivation or disqualification in licensing, granting of authorizations, aids, assistance, benefits, medical staff or any other privileges, and granting authorization to expand, improve, or create any health care facility, by reason of the refusal of such person, association or corporation planning, proposing or operating a health care facility, to permit or perform any particular form of health care service which violates the health care facility's conscience as documented in its existing or proposed ethical guidelines, mission statement, constitution, bylaws, articles of incorporation, regulations, or other governing documents.

745 ILCS 70/10.

38. Section 12 of the Act provides that "[a]ny person ... injured by any public or private person, association, agency, entity, or corporation by reason of any action prohibited by this Act may commence a suit therefore...." 745 ILCS 70/12.

39. Section 14 of the Act states, "This Act shall supersede all other Acts or parts of Acts to the extent that any Acts or parts of Acts are inconsistent with the terms or operation of this Act." 745 ILCS 70/14.

40. The actions of the defendants, as described herein, violated the rights of Ms. Mendoza under the Illinois Healthcare Right of Conscience Act which also provides that any person injured by reason of an action prohibited by the Act may commence suit and recover treble damages, attorney's fees, and costs.

WHEREFORE, the Plaintiff respectfully requests that:

A) This Court render a Declaratory Judgment, adjudging and declaring that Defendants violated the Illinois Health Care Right of Conscience Act, 745 ILCS 70/1 *et seq.*;

B) This Court and a jury award Plaintiff treble damages, attorney fees, and costs against the Defendants pursuant to, at least, Section 12 of the Health Care Right of Conscience Act; and

C) This Court award such other and further relief as it deems equitable and just.

COUNT II

Violation of the Illinois Religious Freedom Restoration Act, 775 ILCS 35/1 *et seq.*

41. Plaintiff incorporates by reference herein all preceding paragraphs.

42. Section 15 of the Illinois Religious Freedom Restoration Act of 1998, 775 ILCS 35/15 provides that:

> Free exercise of religion protected. Governments may not substantially burden a person's free exercise of religion, even if the burden results from a rule of general applicability, unless it demonstrates that application of the burden to the person (i) is in furtherance of a

compelling governmental interest and (ii) is the least restrictive means of furthering that compelling governmental interest.

43. As set forth above, the Defendants substantially burdened Ms. Mendoza's free exercise of religion and will be unable to bear the burden of proving that the substantial burden is justified by a compelling governmental interest and is the least restrictive means of furthering that compelling governmental interest.

WHEREFORE, the Plaintiff respectfully requests that:

A) This Court render a Declaratory Judgment, adjudging and declaring that Defendants violated the Illinois Religious Freedom Restoration Act, 775 ILCS 35/1 *et seq.*;

B) This Court and a jury award Plaintiff damages, attorney fees, and costs against the Defendants pursuant to Section 20 of the Illinois Religious Freedom Restoration Act.

C) This Court award such other and further relief as it deems equitable and just.

Respectfully submitted this 13th day of July, 2016.

Noel W. Sterett, Ill. Bar No. 6292008
Mauck & Baker, LLC

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Counsel for Plaintiffs

VERIFICATION BY CERTIFICATION

Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certifies that she is authorized to make this verification by certification, that the statements set forth in the Amended Verified Complaint for Damages and Declaratory Relief are true and correct, except as to matters therein stated to be on information and belief, and that as to such matters the undersigned certifies as foresaid that she verily believes the same to be true.

As to paragraphs 1, 3, 6 to 10, 15 to 28 in this Amended Verified Complaint for Damages and Declaratory Relief, Plaintiff verifies these statements to be true.

Sandra Rojas

Plaintiff Sandra Rojas, LPN formerly and also known as Sandra Mendoza

July 13, 2016

EXHIBIT A

Sandra Mendoza

From:	Sandra Martell
Sent:	Tuesday, July 14, 2015 8:07 AM
To:	Sandra Mendoza
Cc:	Kimberly Ponder; Charlotte LeClercq
Subject:	Accommodation Decision

Sandra,

Please inform me of your decision regarding the accommodation that is being offered in response to your request as outlined in the letter to you dated June 30, 2015 so that we can implement it as soon as possible with minimal impact to clients and colleagues. I also left you a voice mail message as well.

Best,

Sandra Martell, RN, DNP
Public Health Administrator
Winnebago County Health Department
P.O. Box 4009
401 Division Street
Rockford, IL 61110-0509
PH: 815.720.4200 FAX: 815.720.4002

EXHIBIT B

WCHD Winnebago County Health Department

Promoting a Safer and Healthier Community Since 1854

Sandra Martell, RN, DNP
Public Health Administrator

June 30, 2015

Sandra Mendoza, LPN
1721 South Main Street
Rockford, IL 61102

Dear Ms. Mendoza:

On June 24, 2015, you approached management at the Health Department requesting a religious accommodation due to the consolidation of duties at the various Health Department clinics which is to occur on July 1, 2015. You are currently working in the Pediatric Immunization Clinic and indicated a preference to stay with pediatrics. You conveyed that your religious beliefs would not permit you to perform a number of the required duties at the combined clinics. Unfortunately, business necessity has compelled the consolidation of the clinics, including the Pediatric Immunization Clinic, requiring cross-training of all employees.

We have diligently considered your request for an accommodation and have determined that we cannot accommodate you within the clinic environment at the Health Department. The terms of the grants that we work under require the nursing staff in the clinics to utilize a non-directed approach with our clients. Frequently this will involve job duties that you have indicated are objectionable to you. We have determined that we cannot segregate you, as the only full-time Licensed Practical Nurse (LPN), from these job duties without creating an undue hardship for the other employees in the clinics and the Health Department as a whole.

While we cannot accommodate you in the Health Department clinics, we can offer some alternatives outside of the clinics. The first position would be as a temporary part-time food inspector for the Health Department. The second would be as an LPN at River Bluff Nursing Home, which is owned by the County of Winnebago. Should you have any questions or be interested in either of these positions, please let me know and we can assist you or direct you to the appropriate personnel to assist you.

I realize that you have a lot to consider. We will continue to make a temporary accommodation for you for the next fourteen (14) days to give you time to decide what you would like to do. I look forward to your response within that time frame.

Sincerely,

Sandra Martell, RN, DNP
Public Health Administrator

Cc: Lisa Gonzalez – Center Director, Family Health Services
Kim Ponder - Winnebago County, Director of Human Resources
Charlotte LeClercq – State's Attorney

EXHIBIT 2

STATE OF ILLINOIS
IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT
WINNEBAGO COUNTY, ILLINOIS

SANDRA ROJAS, LPN, formerly and also known as SANDRA MENDOZA, Plaintiff, v. DR. SANDRA MARTELL, Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the Winnebago County Board of Health, in his official capacity, and WINNEBAGO COUNTY, ILLINOIS, Defendants.	)	2016 L 160

DEFENDANTS' VERIFIED ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S AMENDED VERIFIED COMPLAINT FOR DAMAGES AND DECLARATORY RELIEF

NOW COME the Defendants, DR. SANDRA MARTELL, Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the Winnebago County Board of Health, in his official capacity, and WINNEBAGO COUNTY, ILLINOIS, by and through their attorney, Assistant Deputy State's Attorney Charlotte A. LeClercq, and for their Answer to Plaintiff's Amended Complaint, respectfully state as follows:

1. This case is about how the Winnebago County Health Department unlawfully discriminated against Ms. Sandra Mendoza, a Licensed Practical Nurse ("LPN") with eighteen years of service in pediatrics with the Health Department, because of Ms. Mendoza's

conscientious refusal to participate in any way in abortions or the provision of abortifacient or contraceptive drugs.

ANSWER: Defendants admit that Plaintiff was employed by the Winnebago County Health Department for eighteen years as a Licensed Practical Nurse. Defendants deny the remaining allegations contained in Paragraph 1 of Plaintiff's Complaint.

2. Damages and declaratory relief are sought under the Illinois Healthcare Right of Conscience Act, 745 ILCS 70/1 *et seq.*; the Illinois Religious Freedom Restoration Act, 775 ILCS 35/1 *et seq.*; and the Illinois Human Rights Act, 775 ILCS 1/1-101 et seq.

ANSWER: Defendants admit that Plaintiff's Complaint seeks damages and declaratory relief under the Illinois Health Care Right of Conscience Act and the Illinois Religious Freedom Restoration Act. Defendants deny that Plaintiff's Complaint seeks damages and declaratory relief under the Illinois Human Rights Act. Defendants deny they in any way violated Plaintiff's rights under any of these acts.

3. Plaintiff Sandra Rojas, formerly and also known as Sandra Mendoza, is a resident of Winnebago County, Illinois.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 3 of Plaintiff's Complaint, and therefore deny the same.

4. The Defendants are Dr. Sandra Martell, RN, DNP, acting Public Health Administrator for the Winnebago County Health Department headquartered at 401 Division St., Rockford, IL 61110, sued in her official capacity; James Powers, acting chair of the Winnebago County Board of Health, in his official capacity; and WINNEBAGO COUNTY, ILLINOIS, the municipal government of which the Winnebago County Health Department is a part.

ANSWER: Defendants admit that Dr. Sandra Martell, RN, DNP, is the current Public Health Administrator for the Winnebago County Health Department located at 401 Division Street, Rockford, Illinois. Defendants admit that James Powers was the President of the Winnebago County Board of Health until May of 2016, but deny that he is the current President. Defendants deny that Winnebago County, Illinois, is a municipal government, but admit that it is a county government of which the Winnebago County Health Department is a part.

5. Venue is proper in the Circuit Court of the Seventeenth Judicial Circuit, Winnebago County, Illinois under the pertinent statutes.

ANSWER: Defendants admit the allegations contained in Paragraph 5 of Plaintiff's Complaint.

6. Ms. Mendoza has been a licensed practical nurse since July 20, 1990.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 6 of Plaintiff's Complaint, and therefore deny the same.

7. Ms. Mendoza began working for the Winnebago County Health Department on June 6, 1996, and until July 31, 2015, provided nursing services as a nurse in the Pediatric Immunization Clinic including, *inter alia*, immunizations, screenings for blood lead levels, access to medical records, and assessments for the risk of tuberculosis.

ANSWER: Defendants admit that Plaintiff worked for the Winnebago County Health Department from June 6, 1996 to July 31, 2015. Defendants further admit that the nursing services listed were provided by Plaintiff during her employment with the Health Department. Defendants lack knowledge or information sufficient to form as belief as to

whether these were the only services provided by Plaintiff during her employment, and therefore deny the same.

8. On May 11, 2014, Ms. Mendoza also began serving in Health Protection and Promotion by providing adult immunization, hearing and vision testing for children, and TB testing for employees.

ANSWER: Defendants deny that Plaintiff began serving in Health Protection and Promotion on May 11, 2014, but affirmatively state that Plaintiff began working in Health Protection and Promotion on August 11, 2014. Defendants admit that Plaintiff worked part-time for Health Protection and Promotion, providing adult immunizations and TB testing for employees from August 11, 2014 to July 31, 2015, and providing hearing and vision testing for children from August 11, 2014 to December 31, 2014. Defendants affirmatively state that Plaintiff stopped providing hearing and vision testing because she did not pass the required examination to do the testing.

9. Ms. Mendoza has also worked part-time at the Walter Lawson Children's home since 1978 and for Addus Home Health since 2011.

ANSWER: Defendants admit that documentation submitted by Plaintiff to the Winnebago County Health Department indicates that Plaintiff worked part-time at the Walter Lawson Children's home since 1978. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 9 of Plaintiff's Complaint, and therefore deny the same.

10. Ms. Mendoza is a lifelong, practicing Catholic who seeks to adhere to the commands and Word of God as revealed in the Holy Scriptures and to the teachings of the Catholic Church.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 10 of Plaintiff's Complaint, and therefore deny the same.

11. The Scriptures and the Church teach that human life is created in the image of God (Genesis 1:27, *Imagio Dei*), begins at conception (Psalms 139:13-16, Didache, 2:2), and should not, therefore, be destroyed (Exodus 20:1, 13, 21:22-25). Catholic doctrine (Humanae Vitae 14) also teaches against contraception by declaring it sinful to participate in "direct sterilization, whether perpetual or temporary, whether of the man or of the woman. Similarly excluded is every action which, either in anticipation of the conjugal act, or in its accomplishment, or in the development of its natural consequences, proposes, whether as an end or as a means, to render procreation impossible."

ANSWER: No answer to Paragraph 11 of Plaintiff's Complaint is necessary as the referenced documents speak for themselves.

12. Current and standard human-embryology texts also confirm that the union of a sperm and ovum creates a new and distinct organism – a whole, though developmentally immature, member of the human species. See, e.g. Moore and Persaud's "The Developing Human," Larsen's "Human Embryology," Carlson's "Human Embryology & Developmental Biology," and O'Rahilly and Mueller's "Human Embryology & Teratology."

ANSWER: No answer to Paragraph 12 of Plaintiff's Complaint is necessary as the referenced documents speak for themselves.

13. An abortion is the "induced termination of pregnancy, involving destruction of the embryo or fetus." The American Heritage Science Dictionary. Boston: Houghton Mifflin. 2005.

ANSWER: No answer to Paragraph 13 of Plaintiff's Complaint is necessary as the referenced dictionary speaks for itself.

14. Both the U.S. Food and Drug Administration ("FDA") and the manufacturer of "plan B" acknowledge that it can prevent an already-fertilized egg from implanting in the womb.

ANSWER: Defendants admit that the package insert for "plan B" indicates that it "may inhibit implantation." Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 14 of Plaintiff's Complaint, and therefore deny the same.

15. Ms. Mendoza has religious beliefs, as well as moral and ethical objections, which are in accord with the Word of God, the teachings of the Catholic Church and current science, which prevent her as a matter of conscience from participating in any way in abortions or the provision of abortifacient and contraceptive drugs – including but not limited to the provision of the "Plan B" pill (also known as the "morning after pill"), referrals to abortion providers, and birth control.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 15 of Plaintiff's Complaint, and therefore deny the same.

16. In 2001, while working for the Health Department Ms. Mendoza, after consultation with her pastor and priest Fr. William Collins of St. Patrick Parrish, informed the Health Department that she could not as a matter of religious practice and conscience participate in any way in the provision of Plan B, contraception, or abortion referrals.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 16 of Plaintiff's Complaint, and therefore deny the same.

17. Thereafter, Ms. Mendoza continued to work for the Health Department as a nurse in the Health Department's Pediatric Immunization Clinic and did not participate, in any way, in the provision of Plan B, contraception, or abortion referrals.

ANSWER: Defendants admit that Plaintiff worked as a nurse for the Health Department after 2001. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 17 of Plaintiff's Complaint, and therefore deny the same.

18. In late 2014, Dr. Sandra Martell was employed by Winnebago County, Illinois, under the supervision of the Winnebago County Board of Health.

ANSWER: Defendants admit that on or about September 8, 2014, Dr. Sandra Martell began her employment as Administrator of the Winnebago County Health Department. Defendants deny that Dr. Martell was employed by Winnebago County, Illinois, but affirmatively state that Dr. Martell was employed by the Winnebago County Board of Health.

19. In or about March 2015, Dr. Martell began to integrate certain clinical services, including integrating the pediatric services with the women's health services.

ANSWER: Defendants admit that in early 2015, Dr. Martell began working with the staff at the Health Department to prepare for integrating clinical services with a target date to open the fully integrated clinic at the end of June, 2015.

20. In or about May 2015, Ms. Mendoza informed human resources and Dr. Martell that she could not participate in the provision of birth control, referrals to abortion clinics, or Plan B.

ANSWER: Defendants deny Plaintiff informed human resources and Dr. Martell of her religious objections in May of 2015, but admit that Plaintiff advised human resources of her objections in June of 2015 and Dr. Martell of her objections on or about June 24, 2015. Defendants deny that the allegations contained in Paragraph 20 of Plaintiff's Complaint are the full extent of the conversations referenced.

21. On or about July 14, 2015, Dr. Martell sent an e-mail asking Ms. Mendoza for her "...decision regarding the accommodation that is being offered in response to your request outlined in the letter to [Ms. Mendoza] dated June 30, 2015 so that we can implement it as soon as possible with minimal impact to clients and colleagues...." July 14, 2015 E-mail attached as Exh. A.

ANSWER: Defendants admit that Dr. Martell sent the referenced email on or about July 14, 2015, and that the quoted language was contained in that email.

22. Since Ms. Mendoza had not received the letter referenced in the e-mail, Ms. Mendoza contacted Ms. Martell on or about July 14, 2015 to inquire about the letter and the e-mail.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegation contained in Paragraph 22 of Plaintiff's Complaint that Ms. Mendoza had not received the referenced letter, and therefore deny the same. Defendants admit that after receiving the follow up email from Dr. Martell, Plaintiff contacted Dr. Martell on or about July 14, 2015, to inquire about the letter.

23. Ms. Mendoza was then provided a copy of the June 30, 2015 letter (attached as Exhibit B) which had been sent to the wrong address.

ANSWER: Defendants admit that on or about July 14, 2015, Ms. Mendoza was provided with another copy of the June 30, 2015 letter. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegation that the letter was sent to the wrong address, and therefore deny the same. Defendants affirmatively state that the letter was sent to the address for Plaintiff that was on file with the Health Department Finance Office.

24. The letter acknowledges that Ms. Mendoza "conveyed that [her] religious beliefs would not permit [her] to perform a number of the required duties at the combined clinics" but that the Health Department could not "accommodate [Ms. Mendoza] within the clinic environment at the Health Department."

ANSWER: Defendants admit the quoted language is contained in the referenced letter. Defendants affirmatively state, however, that the allegation contained in Paragraph 24 of Plaintiff's Complaint is not a complete recitation of that letter. Defendants deny that this

allegation is a full and accurate recitation of the contents of that letter. Defendants affirmatively state that, with respect to the language in question, the letter provides:

> "We have diligently considered your request for an accommodation and have determined that we cannot accommodate you within the clinic environment at the Health Department. The terms of the grants that we work under require the nursing staff in the clinics to utilize a non-directed approach with our clients. Frequently this will involve job duties that you have indicated are objectionable to you. We have determined that we cannot segregate you, as the only full-time Licensed Practical Nurse (LPN), from these job duties without creating an undue hardship for the other employees in the clinics and the Health Department as a whole."

25. The defendant's letter than [*sic*] offered Ms. Mendoza "alternatives outside of the clinics" which consisted of demotion/transfer to a position as a County temporary/part time food inspector or employee at River Bluff nursing home.

ANSWER: Defendants admit the quoted language is contained in the referenced letter. Defendants deny that the letter indicated that either position would be a demotion. Defendants further deny that this allegation is a full and accurate recitation of the contents of that letter.

26. Ms. Mendoza declined the demotions to temporary, part time food inspector and employee at River Bluff and was therefore forced to resign.

ANSWER: Defendants admit that Plaintiff chose to resign from her position at the Health Department and that she did not accept the positions offered as either a temporary part-time food inspector or a licensed practical nurse at River Bluff Nursing Home. Defendants deny the allegations that they sought to demote Plaintiff and that Plaintiff was forced to resign. Defendants affirmatively state that the position offered as a licensed practical nurse at River Bluff Nursing Home, which is owned by Winnebago County, would not have been a demotion as that position would have utilized Plaintiff's skills as a

licensed practical nurse and would have paid Plaintiff at least as much as, if not more than, she was making as a licensed practical nurse at the Winnebago County Health Department.

27. Ms. Mendoza could not work at the River Bluff nursing home because, as she informed Dr. Martell, her son Daniel Ortega was employed there as a Registered Nurse and the nursing home had a rule prohibiting working with family members.

ANSWER: Defendants admit that Plaintiff's son, Daniel Ortega, is employed as a Registered Nurse at River Bluff Nursing Home. Defendants deny that Plaintiff could not work at River Bluff Nursing Home due to her son working at the nursing home. Defendants deny that River Bluff Nursing Home had a rule which prohibited family members from working at the nursing home. Defendants affirmatively state that the only employee-related "family member" rule at River Bluff Nursing Home was that one family member could not directly supervise another family member.

28. As a direct and proximate result of defendants' actions as described herein, Ms. Mendoza has suffered damages including loss of income and benefits, pain and suffering, mental anguish, inconvenience, loss of enjoyment of life and other economic and noneconomic losses.

ANSWER: Defendants deny the allegations contained in Paragraph 28 of Plaintiff's Complaint.

COUNT I

Violation of the Illinois Health Care Right of Conscience Act, 745 ILCS 70/1 *et seq.*

29. Plaintiff incorporates by reference herein all preceding paragraphs.

ANSWER: Defendants incorporate herein by reference their answers to Paragraphs 1 through 28 of Plaintiff's Complaint as though fully set forth herein.

30. The Health Care Right of Conscience Act states the following:

It is the public policy of the State of Illinois to respect and protect the right of conscience of all persons who refuse to obtain, receive, or accept, *or who are engaged in, the delivery of, arrangement for, or payment of health care services and medical care whether acting individually, corporately, or in association with other persons;* and to *prohibit all forms of discrimination, disqualification, coercion, disability or imposition of liability upon such persons or entities* by reason of their refusing to act contrary to their conscience or conscientious convictions *in refusing to obtain, receive, accept, deliver, pay for, or arrange for the payment of health care services and medical care.*

745 ILCS 70/2 (emphasis added).

ANSWER: Defendants admit that the quotation alleged in Paragraph 30 of Plaintiff's Complaint is an accurate recitation (other than the italicization) of a part of the cited statutory section. Defendant deny that the quotation is a full and complete recitation of Section 2 of the Health Care Right of Conscience Act.

31. Under the Act, "health care" is defined as "any phase of patient care, including but not limited to, ... instructions; family planning, counseling, referrals, or any other advice in connection with the use or procurement of contraceptives and sterilization or abortion procedures; [or] medication...." 745 ILCS 70/3.

ANSWER: Defendants admit that the quotation alleged in Paragraph 31 of Plaintiff's Complaint is an accurate recitation of a part of the cited statutory section. Defendants deny that the quotation is a full and complete recitation of Section 3(a) of the Health Care Right of Conscience Act.

32. In addition, "health care professional" is defined as "any nurse, nurse's aide, medical school student, professional, paraprofessional or any other person who furnishes, or assists in the furnishing of, health care services." *Id.*

ANSWER: Defendants deny that Section 3 of the Health Care Right of Conscience Act defines "health care professional." Defendants affirmatively state that the alleged definition is an accurate recitation of the definition of "health care personnel" contained in Section 3(c) of the Act.

33. "Conscience" is defined as "a sincerely held set of moral convictions arising from belief in and relation to God, or which, though not so derived, arises from a place in the life of its possessor parallel to that filled by God among adherents to religious faiths." *Id.*

ANSWER: Defendants admit that the quotation alleged in Paragraph 33 of Plaintiff's Complaint is an accurate recitation of the definition of "conscience" contained in Section 3(e) of the Health Care Right of Conscience Act.

34. Section 5 of the Act states the following:

> It shall be unlawful for any person, public or private institution, or public official to discriminate against any person in any manner, including but not limited to, licensing, hiring, promotion, transfer, staff appointment, hospital, managed care entity, or any other privileges, because of such person's conscientious refusal to receive, obtain, accept, perform, assist, counsel, suggest, recommend, refer or participate in any way in any particular form of health care services contrary to his or her conscience.

745 ILCS 70/5.

ANSWER: Defendants admit that the quotation alleged in Paragraph 34 of Plaintiff's Complaint is an accurate recitation of Section 5 of the Health Care Right of Conscience Act.

35. Section 7 of the Act states that it is unlawful for any public or private employer, entity, or agency to "...orally question about, to impose any burdens in terms of conditions of employment on, or otherwise discriminate against any applicant, in terms of employment" or to "discriminate in relation thereto, in any other manner" on account of the applicant's refusal to

"perform, counsel, suggest, recommend, refer, assist, or participate in any way in any forms of health care services contrary to his or her conscience." 745 ILCS 70/7.

ANSWER: Defendants admit that the quotation alleged in Paragraph 35 of Plaintiff's Complaint is an accurate recitation of a part of Section 7 of the Health Care Right of Conscience Act. Defendants deny that the quotation is a full and complete recitation of Section 7 of the Health Care Right of Conscience Act.

36. Section 9 of the Act states the following:

No person, association, or corporation, which owns, operates, supervises, or manages a health care facility shall be civilly or criminally liable to any person, estate, or public or private entity by reason of refusal of the health care facility to permit or provide any particular form of health care service which violates the facility's conscience as documented in its ethical guidelines, mission statement, constitution, bylaws, articles of incorporation, regulations, or other governing documents.

ANSWER: Defendants admit that the quotation alleged in Paragraph 36 of Plaintiff's Complaint is an accurate recitation of a part of Section 9 of the Health Care Right of Conscience Act. Defendants deny that the quotation is a full and complete recitation of Section 9 of the Health Care Right of Conscience Act.

37. Section 10 of the Act states the following:

It shall be unlawful for any person, public or private institution or public official to discriminate against any person, association or corporation attempting to establish a new health care facility or operating an existing health care facility, in any manner, including but not limited to, denial, deprivation or disqualification in licensing, granting of authorizations, aids, assistance, benefits, medical staff or any other privileges, and granting authorization to expand, improve, or create any health care facility, by reason of the refusal of such person, association or corporation planning, proposing or operating a health care facility, to permit or perform any particular form of health care service which violates the health care facility's conscience as documented in its existing or proposed ethical guidelines, mission statement, constitution, bylaws, articles of incorporation, regulations, or other governing documents.

745 ILCS 70/10.

ANSWER: Defendants admit that the quotation alleged in Paragraph 37 of Plaintiff's Complaint is an accurate recitation of Section 10 of the Health Care Right of Conscience Act.

38. Section 12 of the Act provides that "[a]ny person ... injured by any public or private person, association, agency, entity, or corporation by reason of any action prohibited by this Act may commence a suit therefore....." 745 ILCS 70/12.

ANSWER: Defendants admit that the quotation alleged in Paragraph 38 of Plaintiff's Complaint is an accurate recitation of a part of Section 12 of the Health Care Right of Conscience Act. Defendants deny that the quotation is a full and complete recitation of Section 12 of the Health Care Right of Conscience Act.

39. Section 14 of the Act states, "This Act shall supersede all other Acts or parts of Acts to the extent that any Acts or parts of Acts are inconsistent with the terms or operation of this Act." 745 ILCS 70/14.

ANSWER: Defendants admit that the quotation alleged in Paragraph 39 of Plaintiff's Complaint is an accurate recitation of Section 14 of the Health Care Right of Conscience Act.

40. The actions of the defendants, as described herein, violated the rights of Ms. Mendoza under the Illinois Healthcare Right of Conscience Act which also provides that any person injured by reason of an action prohibited by the Act may commence suit and recover treble damages, attorney's fees, and costs.

ANSWER: Defendants deny that their actions, as described in Plaintiff's Complaint, violated Plaintiff's rights under the Illinois Health Care Right of Conscience Act.

Defendants admit that Section 12 of the Health Care Right of Conscience Act allows recovery of "threefold the actual damages," reasonable attorney's fees and costs.

WHEREFORE, the Defendants, DR. SANDRA MARTELL, Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the Winnebago County Board of Health, in his official capacity, and WINNEBAGO COUNTY, ILLINOIS, pray this Court to enter judgment as to Count I of Plaintiff's Amended Complaint in their favor, and against Plaintiff, with costs being assessed against Plaintiff, and grant such other and further relief as this Court deems reasonable and just.

COUNT II

Violation of the Illinois Religious Freedom Restoration Act, 775 ILCS 35/1 *et seq.*

41. Plaintiff incorporates by reference herein all preceding paragraphs.

ANSWER: Defendants incorporate herein by reference their answers to Paragraphs 1 through 40 of Plaintiff's Complaint as though fully set forth herein.

42. Section 15 of the Illinois Religious Freedom Restoration Act of 1998, 775 ILCS 35/15 provides that:

Free exercise of religion protected. Governments may not substantially burden a person's free exercise of religion, even if the burden results from a rule of general applicability, unless it demonstrates that application of the burden to the person (i) is in furtherance of a compelling governmental interest and (ii) is the least restrictive means of furthering that compelling governmental interest.

ANSWER: Defendants deny that the quotation alleged in Paragraph 42 of Plaintiff's Complaint is a completely accurate recitation of Section 15 of the Illinois Religious Freedom Restoration Act as the term "free" is not used in the statute.

43. As set forth above, the Defendants substantially burdened Ms. Mendoza's free exercise of religion and will be unable to bear the burden of proving that the substantial burden is

justified by a compelling governmental interest and is the least restrictive means of furthering that compelling governmental interest.

ANSWER: Defendants deny the allegations contained in Paragraph 43 of Plaintiff's Complaint.

WHEREFORE, the Defendants, DR. SANDRA MARTELL, Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the Winnebago County Board of Health, in his official capacity, and WINNEBAGO COUNTY, ILLINOIS, pray this Court to enter judgment as to Count II of Plaintiff's Amended Complaint in their favor, and against Plaintiff, with costs being assessed against Plaintiff, and grant such other and further relief as this Court deems reasonable and just.

AFFIRMATIVE DEFENSES

Defendants, DR. SANDRA MARTELL, Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the Winnebago County Board of Health, in his official capacity, and WINNEBAGO COUNTY, ILLINOIS, as affirmative defenses to Count I and Count II of Plaintiff's Amended Complaint, state as follows:

FIRST AFFIRMATIVE DEFENSE

Plaintiff is not entitled to recover under Counts I or II of Plaintiff's Complaint as Defendants attempted to accommodate Plaintiff's religious objections by offering her a full-time position within Winnebago County as a licensed practical nurse at River Bluff Nursing Home, which would have allowed Plaintiff to utilize her nursing skills and maintain the same benefits and a comparable or higher salary. Plaintiff chose to voluntarily resign rather than accept the licensed practical nurse position at River Bluff Nursing Home that was offered to her.

SECOND AFFIRMATIVE DEFENSE

Plaintiff failed to mitigate any damages she allegedly sustained in this matter as she was offered immediate transition to a full-time position within Winnebago County as a licensed practical nurse at River Bluff Nursing Home, which would have allowed Plaintiff to utilize her nursing skills and maintain the same benefits and a comparable or higher salary. Plaintiff chose to voluntarily resign rather than accept the licensed practical nurse position at River Bluff Nursing Home that was offered to her. As such, Plaintiff's damages under Count I and Count II, if any, should be reduced proportionately based upon her failure to mitigate her alleged damages.

THIRD AFFIRMATIVE DEFENSE

Plaintiff is not entitled to recover under Count I of Plaintiff's Complaint as her claims are precluded by Section 13 of the Illinois Health Care Right of Conscience Act, which provides: "Nothing in this Act shall be construed as excusing any person, public or private institution, or public official from liability for refusal to permit or provide a particular form of health care service if: …(b) the person, public or private institution or public official has accepted federal or state funds for the sole purpose of, and specifically conditioned upon, permitting or providing that particular form of health care service."

The Winnebago County Health Department is mandated, as a condition of receiving Title X federal funding, to provide certain services, including pregnancy testing, contraceptive methods and education, emergency contraceptives, and family planning options counseling. In early 2015, as a result of financial necessity given lack of funding from the State of Illinois and in conformance with the Strategic Plan adopted by the Winnebago County Board of Health in January of 2014, Dr. Martell moved forward with consolidating the various clinics at the Health Department into one clinic. The staff – including Plaintiff – was expected to be able to provide

all services in the combined clinic. Failure by any staff member to provide any of the services required under Title X could have resulted in potential liability to the Health Department and loss of funding. Therefore, Plaintiff's claims are precluded under Section 13 of the Act.

FOURTH AFFIRMATIVE DEFENSE

At all times relevant to the allegations contained in Plaintiff's Complaint, Defendant was a local public entity as defined by the Local Governmental and Governmental Employee Tort Immunity Act (745 ILCS 10/1-101 *et seq.*). Section 2-201 of the Tort Immunity Act, 745 ILCS 10/2-201, provides that "a public employee serving in a position involving the determination of policy or the exercise of discretion is not liable for an injury resulting from his act or omission in determining policy when acting in the exercise of such discretion even though abused." Section 2-109 of the Act, 745 ILCS 10/2-109, provides that "[a] local public entity is not liable for an injury resulting from an act or omission of its employee where the employee is not liable." Dr. Martell, in her position as Public Health Administrator, serves in a position involving the determination of policy and the exercise of discretion. In taking the actions alleged in Count I and Count II of Plaintiff's Complaint, Dr. Martell was engaged in policy determinations for the Winnebago County Health Department. As such, Sections 2-201 and 2-109 immunize Defendants from liability for the damages asserted by Plaintiff in Count I and Count II of her Complaint.

WHEREFORE, the Defendants, DR. SANDRA MARTELL, Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the Winnebago County Board of Health, in his official capacity, and WINNEBAGO COUNTY, ILLINOIS, pray this Court to enter judgment as to Count I and Count II of Plaintiff's

Amended Complaint in their favor, and against Plaintiff, with costs being assessed against Plaintiff, and grant such other and further relief as this Court deems reasonable and just.

Defendants, DR. SANDRA MARTELL, Public Health Administrator of the Winnebago County Health Department, in her official capacity, JAMES POWERS, Chair of the Winnebago County Board of Health, in his official capacity, and WINNEBAGO COUNTY, ILLINOIS,

Charlotte A. LeClercq

By: Charlotte A. LeClercq
Assistant Deputy State's Attorney

CHARLOTTE A. LeCLERCQ, #6283345
Assistant Deputy State's Attorney
Winnebago County State's Attorney's Office, Civil Bureau
400 West State Street, #804
Rockford, Illinois 61101
(815) 319-4799
ATTORNEY FOR DEFENDANTS

VERIFICATION

STATE OF ILLINOIS)
)
COUNTY OF WINNEBAGO)

Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certify that they have read the foregoing Verified Answer and Affirmative Defenses to Plaintiff's Complaint and that the statements set forth therein are true and correct to the best of their knowledge, information and belief. To the extent that the foregoing Verified Answer and Affirmative Defenses contain certain statements of insufficient knowledge on which to base a belief as to the truth or falsity of the allegations contained in the complaint, those allegations of insufficient knowledge are true and correct.

Dated: 7/19/2016

Dr. Sandra Martell

Dated: _____

James Powers

Dated: _____

Steven M. Chapman
County Administrator

VERIFICATION

STATE OF ILLINOIS)
)
COUNTY OF WINNEBAGO)

Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certify that they have read the foregoing Verified Answer and Affirmative Defenses to Plaintiff's Complaint and that the statements set forth therein are true and correct to the best of their knowledge, information and belief. To the extent that the foregoing Verified Answer and Affirmative Defenses contain certain statements of insufficient knowledge on which to base a belief as to the truth or falsity of the allegations contained in the complaint, those allegations of insufficient knowledge are true and correct.

Dated: _____

_____
Dr. Sandra Martell

Dated: 7-11-2016

James Powers
James Powers

Dated: _____

_____
Steven M. Chapman
County Administrator

VERIFICATION

STATE OF ILLINOIS)
)
COUNTY OF WINNEBAGO)

Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certify that they have read the foregoing Verified Answer and Affirmative Defenses to Plaintiff's Complaint and that the statements set forth therein are true and correct to the best of their knowledge, information and belief. To the extent that the foregoing Verified Answer and Affirmative Defenses contain certain statements of insufficient knowledge on which to base a belief as to the truth or falsity of the allegations contained in the complaint, those allegations of insufficient knowledge are true and correct.

Dated: _____

Dr. Sandra Martell

Dated: _____

James Powers

Dated: 7-19-16

Steven M. Chapman
County Administrator

Exhibit 32
Attachment B

JOSEPH P. BRUSCATO
WINNEBAGO COUNTY STATE'S ATTORNEY

MARILYN HITE ROSS
DEPUTY STATE'S ATTORNEY
CRIMINAL BUREAU

DAVID J. KURLINKUS
DEPUTY STATE'S ATTORNEY
CIVIL BUREAU

January 18, 2018

Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHH Bldg.
Washington, D.C. 20201

Re: Response to Complaint of Discrimination

Dear Sir or Madam,

You recently received a complaint of discrimination dated January 16, 2018, from Mauck & Baker, LLC concerning their client, Sandra Rojas, directed against the Winnebago County Health Department in Winnebago County, Illinois. The Winnebago County State's Attorney's Office represents the Health Department in a pending lawsuit filed by Ms. Rojas under the Illinois Right of Conscience Act and the Illinois Religious Freedom Restoration Act.

On behalf of the Health Department I would like to address some misperceptions which may be created by Mauck & Baker's complaint. First, the Health Department does not provide abortion services. As a recipient of funding under Title X (42 U.S.C. §300 *et seq.*), the Health Department is prohibited from providing abortion services as a method of family planning. The Health Department does dispense birth control and provides options counseling to pregnant women, which under Title X guidelines must include termination as an option.

Second, Ms. Rojas was not terminated from her employment with the Health Department. When Ms. Rojas expressed her objections to performing work that would be required of her as part of a clinic consolidation at the Health Department, she was offered, as an accommodation, a position as a licensed practical nurse at River Bluff Nursing Home, which is owned by the County of Winnebago. This position would not have entailed any loss of pay or benefits. Ms. Rojas elected not to pursue that position, but instead submitted a letter of resignation, a copy of which is attached.

Thank you for your consideration. Please let me know if you would like any additional information.

Sincerely,

Charlotte A. LeClercq

Charlotte A. LeClercq
Assistant Deputy State's Attorney – Civil Bureau

cc: Attorney Noel Sterett
Mauck & Baker, LLC
One North LaSalle Street
Suite 600
Chicago, IL 60602

Dr. Sandra Martell
Winnebago County Health Department
555 N. Court Street
Rockford, IL 61110

Untitled

7-17-15

Mary,
Please accept this letter as my formal notice of resignation from Winn. Co. Health Dept effective on 7-31-15. I have enjoyed my employment here and appreciate all i have learned

Sincerely

Sandra Mendoza

Exhibit 32
Attachment C

DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE SECRETARY

Voice - (800) 368-1019 TDD - (800) 537-7697 Fax - (202) 619-3818
http://www.hhs.gov/ocr/

Office for Civil Rights
200 Independence Ave., SW
Washington, DC 20201

March 4, 2019

SENT VIA CERTIFIED MAIL

Charlotte A. LeClercq
Office of the State's Attorney
Winnebago County, Civil Division
400 W. State Street, Ste. 804
Rockford, IL 61101

Re: OCR Transaction Number 18-293234

Dear Ms. LeClercq:

The U.S. Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") received the attached complaint from Mauck & Baker, filed on behalf of Sandra Rojas (also known as Sandra Mendoza, hereinafter "Ms. Rojas"), on January 16, 2018. The complaint alleges Ms. Rojas was subjected to unlawful discrimination by the Winnebago County Health Department for refusing to participate in the provision of abortion-related services in accordance with her religious beliefs. If you do not represent the Winnebago County Health Department and Winnebago County in this matter, please notify OCR at your earliest convenience.

Federal regulations designate OCR to receive and handle complaints based on the Federal laws that protect conscience and prevent coercion, including the Weldon Amendment,[1] the Coats-Snowe Amendment,[2] and the Church Amendments.[3] OCR has reviewed the complaint and has determined that it has sufficient authority and cause to investigate the allegations under one or more of these laws.

Accordingly, OCR requests that you respond to the attached Initial Discovery Request, in accordance with the instructions, **within 30 days of the date of this letter,** by mail or e-mail sent to Mandi Ancalle, 200 Independence Avenue, S.W., Washington, D.C. 20201, Mandi.Ancalle@hhs.gov. You should not destroy, modify, remove, transfer, or make inaccessible documents that are potentially responsive to the discovery request, or that appear to be related to this complaint. OCR requests that you take all necessary steps to ensure that individuals who file

[1] *E.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, Div. B, Tit. V, § 507(d), 132 Stat 2981, 3118 (September 28, 2018).
[2] 42 U.S.C. § 238n.
[3] *Id.* § 300a-7.

complaints or participate in the investigation of complaints are free from harassment, intimidation, and retaliation, in accordance with Federal law.

This letter is notice of an investigation and does not constitute a finding of violation. We look forward to your cooperation with the investigation and are providing you with a full opportunity to respond to the allegations in the complaint on the merits and to proffer any relevant information and documents for OCR to consider in determining your compliance status. Section 1001 of title 18 of the U.S. Code makes it a crime for any person to knowingly and willfully make any materially false, fictitious, or fraudulent statements or representations to a department or agency of the United States as to any matter within its jurisdiction.

If you have any questions, please do not hesitate to contact Mandi Ancalle, Civil Rights Analyst, by phone at 202-205-9244, or by e-mail at Mandi.Ancalle@hhs.gov.

Sincerely,

Luis E. Perez
Deputy Director
Conscience and Religious Freedom Division

INITIAL DISCOVERY REQUESTS AND INSTRUCTIONS
OCR Transaction No: 18-293234

INITIAL DISCOVERY REQUESTS

1. Please provide a substantive response to the allegations contained in the complaint (attached), and please identify any persons with personal knowledge and information that supports the Winnebago County Health Department's responses to these allegations.

2. Please identify persons who are or have been employed by the Winnebago County Health Department who are likely to have information related to Ms. Rojas having expressed her objections to counseling to pregnant women, for which termination of pregnancy is provided as an option, abortion referrals, or contraception; the Winnebago County Health Department's response to Ms. Rojas expressing her objection; or Ms. Rojas's departure from the Winnebago County Health Department, along with the subject matter of the information.

3. Please identify persons who are or have been employed by the Winnebago County Health Department who may have personal knowledge of the circumstances that provide the basis of Ms. Rojas's allegations or who provide information that you use in responding to the allegations or these discovery requests, along with the subject matter of the information.

4. In Charlotte LeClercq's letter to the U.S. Department of Health and Human Services, dated January 18, 2018, she alleges the Winnebago County Health Department "does dispense contraception and provides options counseling to pregnant women, which under Title X guidelines must include termination as an option." Please explain your understanding of what the U.S. Department of Health and Human Services required in 2015 of the Winnebago County Health Department as a condition of participating in programs authorized under Title X of the Public Health Service Act. In your response, please explain your understanding of the degree of discretion, if any, the Winnebago County Health Department had in 2015 in implementing these conditions. Please produce all related documents that support or memorialize your understanding.

5. Other than Title X of the Public Health Service Act, please identify any Federal, state, or local law, regulation, or sub-regulatory guidance in effect in 2015 that you understood to mandate the Winnebago County Health Department's provision of counseling to pregnant women, for which termination of pregnancy is provided as an option, abortion referrals, or contraception. Please produce all related documents that support or memorialize your understanding.

6. Please produce any training materials, policies, procedures, written scripts, talking points, instructions or similar guidance that the Winnebago County Health Department had available for staff in 2015 regarding the provision of abortion referrals, contraception, or counseling to pregnant women, for which termination of pregnancy is provided as an option. For documents produced in response to this question, please identify which documents were made available to staff to demonstrate compliance with any Federal, state or local law, regulation, or sub-regulatory guidance. Please be sure to provide an

explanation linking the materials, policies, procedures, written scripts, talking points, instructions or similar guidance with the associated Federal, state or local law, regulation, or sub-regulatory guidance.

7. Please produce Ms. Rojas's applicant and employment record. If not otherwise notated in her record, please explain why she received "employee of the week," "employee of the quarter," and other awards she received.

8. Please explain why the Winnebago County Health Department could not accommodate Ms. Rojas's religious beliefs by her remaining employed in her position at the Winnebago County Health Department. Please produce all related documents.

9. Had Ms. Rojas remained employed with you, please indicate who would have fulfilled the duties of Ms. Rojas when she was unavailable, out sick, on personal leave, or on vacation, the job title of that person, his or her duties, and whether he or she objected to abortion, counseling to pregnant women for which termination of pregnancy is provided as an option, abortion referrals, or the provision of contraception. Please produce all related documents.

10. Please explain the duties Ms. Rojas would have been required to fulfill had she remained employed by the Winnebago County Health Department, in her position, during and after the clinic consolidation. Please produce all related documents, which may include the job posting for the vacancy Ms. Rojas left that includes job duties.

11. If Ms. Rojas remained employed by the Winnebago County Health Department during and after the clinic consolidation, would she have been required to provide counseling to pregnant women, for which termination of pregnancy is provided as an option? Please produce all related documents, which may include the job posting for the vacancy Ms. Rojas left that includes job duties.

12. If Ms. Rojas remained employed by the Winnebago County Health Department during and after the clinic consolidation, would she have been required to provide prescriptions for contraception to patients? Please produce all related documents, which may include the job posting for the vacancy Ms. Rojas left that includes job duties.

13. If Ms. Rojas remained employed by the Winnebago County Health Department during and after the clinic consolidation, would she have been required to refer patients for abortion? Please produce all related documents, which may include the job posting for the vacancy Ms. Rojas left that includes job duties.

14. Please provide a list of the "required duties at the combined clinics," as referenced in Dr. Martell's June 30, 2015, letter to Ms. Rojas, which communicated an understanding that Ms. Rojas would not be able to perform the "required duties at the combined clinics" because of her religious beliefs.

15. Please explain your understanding of Ms. Rojas's religious beliefs, which you allege would have prevented her from completing the "required duties at the combined clinics."

16. Please indicate the extent to which you were made aware of Ms. Rojas's religious convictions regarding abortion, and when you were made aware of her religious objection to providing counseling to pregnant women, for which termination of pregnancy is provided as an option, abortion referrals, and contraception. Please produce all related documents.

17. Please produce the names and contact information of any individuals who filled the position Ms. Rojas left vacant when she resigned on July 17, 2015, and please indicate whether these individuals have prescribed contraception or participated in counseling pregnant women that termination of pregnancy is an option, or referrals for abortion in fulfilling their official duties, and if so, on what dates.

18. Please produce a list of pediatrics-related positions at the Winnebago County Health Department in 2015. Please include whether in 2015 the Health Department sought applicants for each of those positions. Please produce documents that support your response, such as position descriptions.

19. Please explain how you made the decision to offer Ms. Rojas a position as a licensed practical nurse at River Bluff Nursing Home. Please produce all related documents.

20. Please explain the differences, in terms of permanency, salary, and benefits, between Ms. Rojas's position at the Winnebago County Health Department as of June 1, 2015, and those of the River Bluff Nursing Home LPN position Ms. Rojas was offered as an accommodation in the June 30, 2015, letter from Dr. Martell. Please produce documents that support your response, such as position descriptions or vacancy announcements.

21. Please explain how you made the decision to offer Ms. Rojas a position as a temporary, part-time food inspector. Please produce all related documents.

22. Please explain the differences, in terms of permanency, salary, and benefits, between Ms. Rojas's position at the Winnebago County Health Department as of June 1, 2015, and those of the food inspector position Ms. Rojas was offered as an accommodation in the June 30, 2015, letter from Dr. Martell. Please produce documents that support your response, such as position descriptions or vacancy announcements.

23. Please produce your policies regarding family members working at the same facility or location.

24. Please produce all documents regarding claims of discrimination related to the views of an applicant, employee, trainee, volunteer, or other worker about abortion or sterilization, or refusal to perform or assist in the performance of abortion or sterilization. Claims include verbal and written internal complaints, lawsuits, complaints filed with Federal or State agencies, and other means by which you have been notified of allegations of discrimination based on religion or conscience. For any such claim, please note whether and how it was resolved, and please identify the names of staff involved in reviewing, investigating, or resolving the claims.

25. Please identify each accommodation request from staff members resulting from objections to providing or participating in the provision of contraception, including sterilization; counseling for pregnant women, for which termination of pregnancy is provided as an option; or abortion referrals from January 2015 through the present. Please identify the duration of time that each request was pending, the final disposition of each request, and other pertinent information relevant to OCR's inquiry.

26. Please provide a list of all open positions within the Winnebago County Health Department and its affiliates from June 1, 2015, to August 1, 2015, including the dates the positions became open and when the positions were ultimately filled.

27. Please produce all policies pertaining to terms of employment at the Winnebago County Health Department and policies pertaining to non-discrimination in hiring.

28. Please explain the legal relationship between the State of Illinois and the Winnebago County Health Department. Please produce related documents, such as organizational charts, charters, or statutes.

29. Please explain the legal relationship between the State of Illinois and Winnebago County. Please produce related documents, such as organizational charts, charters, or statutes.

30. Please describe the types of health services you provide.

31. Please provide your National Provider Identifier (NPI), issued by the Centers for Medicaid & Medicare Services.

32. Please describe any Federal financial assistance you, or your subdivision or affiliate, have been a recipient or sub-recipient of from HHS in the last four calendar years. Please describe the awarding HHS component (or non-Federal organization receiving Federal financial assistance from HHS), dates the financial assistance was received, and the dollar amount of the assistance.

33. Please provide an approximate total of any reimbursements you received from Medicare programs Part A, Part C, and Part D, respectively, and when the reimbursements first began, to the best of your knowledge.

34. Please provide an approximate total of any reimbursements you received from Medicaid and the Children's Health Insurance Program, respectively, and when the reimbursements first began, to the best of your knowledge.

35. For the following grant programs, if you receive Federal financial assistance, please provide the amount received, the date received and when it first began, to the best of your knowledge, and any associated grant, grantee, or provider numbers:

PROGRAM NAME	U.S.C.	CFDA #
Preventive Health and Health Services Block Grant	42 U.S.C. 300w-7	93.991
Maternal & Child Health Services Block Grant	42 U.S.C. 708	93.994

36. Please produce all documents relied upon or used in responding to the preceding requests.

37. Please provide any other information or documentation you believe is relevant to the allegations set forth in the attached complaint.

INSTRUCTIONS AND DEFINITIONS FOR RESPONDING TO OCR DISCOVERY REQUESTS

In responding to the discovery requests, please apply the following instructions and definitions:

INSTRUCTIONS

1. In complying with this request, you should produce all responsive documents that are in your possession, custody, or control or otherwise available to you, regardless of whether the documents are possessed directly by you.

2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to OCR.

3. In the event that any entity, organization, or individual named in the request has been, or is currently, known by any other name, the request should be read also to include such other names under that alternative identification.

4. Each document that is not electronic should be produced in a form that may be copied by standard copying machines.

5. When you produce documents, you should identify the paragraph(s) or clause(s) in OCR's request to which each document responds.

6. Documents produced pursuant to this request should be produced in the order in which they appear in your files and should not be rearranged. Any documents that are stapled, clipped, or otherwise fastened together should not be separated. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. Indicate the office or division and person from whose files each document was produced.

7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph(s) or clause(s) of the request to which the documents are responsive, should be provided in an accompanying index.

8. Responsive documents must be produced regardless of whether any other person or entity possesses non-identical or identical copies of the same document.

9. OCR requests electronic documents in addition to paper productions. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, back up tape, or removable computer media such as thumb drives, flash drives, memory cards, and external hard drives), you should immediately consult with OCR staff to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above.

10. If any document responsive to this request was, but no longer is, in your possession, custody, or control, or has been placed into the possession, custody, or control of any third party and cannot be provided in response to this request, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control, or was placed in the possession, custody, or control of a third party.

11. If any document responsive to this request was, but no longer is, in your possession, custody or control, state:
    a. how the document was disposed of;
    b. the name, current address, and telephone number of the person who currently has possession, custody or control over the document;
    c. the date of disposition; and,
    d. the name, current address, and telephone number of each person who authorized said disposition or who had or has knowledge of said disposition.

12. If any document responsive to this request cannot be located, describe with particularity the efforts made to locate the document and the specific reason for its disappearance, destruction or unavailability.

13. If a date or other descriptive detail set forth in this request referring to a document, communication, meeting, or other event is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.

14. The request is continuing in nature and applies to any newly discovered document, regardless of the date of its creation. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.

15. All documents should be Bates stamped sequentially and produced sequentially. In a cover letter to accompany your response, you should include a total page count for the entire production, including both hard copy and electronic documents.

16. The documents should be delivered to Mandi Ancalle (contractor), 200 Independence Avenue, S.W., Washington, D.C. 20201.

17. In the event that a responsive document is withheld on any basis, including a claim of privilege, you should provide a privilege log containing the following information concerning any such document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; (e) the relationship of the author and addressee to each other; and (f) any other description necessary to identify the document and to explain the basis for not producing the document. If a claimed privilege applies to only a portion of any document, that portion only should be withheld and the remainder of the document should be produced. As used herein, "claim of privilege" includes, but is not limited to, any claim that a document either may or must be withheld from production pursuant to any statute, rule, or regulation.

18. If the request cannot be complied with in full, it should be complied with to the extent possible, which should include an explanation of why full compliance is not possible.

19. For all responses, please provide any facts, contentions, narrative responses, or documents you believe are relevant to OCR's inquiry.

20. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; (2) documents responsive to the request have not been destroyed, modified, removed, transferred, or otherwise made inaccessible to OCR since the date of receiving OCR's request or in anticipation of receiving OCR's request, and (3) all documents identified during the search that are responsive have been produced to OCR, identified in a privilege log provided to OCR, as described in (17) above, or identified as provided in (10), (11) or (12) above.

DEFINITIONS

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail ("email"), instant messages, calendars, contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, power point presentations, spreadsheets, and work sheets. The term "document" includes all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments to the foregoing, as well as any attachments or appendices thereto.

2. The term "document" also means any graphic or oral records or representations of any kind (including, without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotapes, recordings, and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, back up tape, memory sticks, recordings, and removable computer media such as thumb drives, flash drives, memory cards, and external hard drives), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, electronic format, disk, videotape or otherwise. A document bearing any notation not part of the original text is considered to be a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

3. The term "documents in your possession, custody or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that have been placed in the possession, custody, or control of any third party.

4. The term "communication" or "correspondence" means each manner or means of disclosure, transmission, or exchange of information, in the form of facts, ideas, opinions, inquiries, or otherwise, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, email, instant message, discussion, release, personal delivery, or otherwise.

5. The terms "and" and "or" should be construed broadly and conjunctively as necessary to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes the plural number, and vice versa.

6. The terms "person" or "persons" mean natural persons, firms, partnerships, associations, limited liability corporations and companies, limited liability partnerships, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, other legal, business or government entities, or any other organization or group of persons, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

7. The terms "referring," "refers," "relating," "related," "regards," or "regarding," with respect to any given subject, mean anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.

8. The terms "you" or "your" mean and refer to Winnebago County and the Winnebago County Health Department, and any of their agencies, offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on their behalf or under their control or direction.

Exhibit 33

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF THE PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Pursuant to 28 U.S.C. § 1746(2), I, Teresa D. Miller, declare that the following is true and correct:

1. I am the Secretary for the Pennsylvania Department of Human Services ("PADHS") and have held that position since August 21, 2017.

2. Before being appointed Secretary, I served as the Commissioner for the Pennsylvania Insurance Department for two and a half years.

3. Before coming to Pennsylvania, I worked at the Centers for Medicare & Medicaid Services ("CMS") in the United States Department of Health and Human Services. While at CMS, I served as the acting director of the State Exchanges Group, the Oversight Group, and the Insurance Programs Group in the Center for Consumer Information and Insurance Oversight.

4. At CMS, I helped develop and implement regulations and guidance related to the private market reforms of the Affordable Care Act and state-based exchanges.

5. I previously served as the administrator of the Oregon Insurance Division, where I implemented early stages of the Affordable Care Act at the state level and reformed Oregon's health insurance rate review process.

6. I submit this Declaration in support of the Commonwealth of Pennsylvania's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of HHS, and the United States of America regarding the recently issued rule, entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) ("Final Rule"). I have compiled the information in the statements set forth below through personal knowledge or through information that PADHS personnel assisted me in collecting. I have also familiarized myself with the Final Rule in order to understand its immediate impact on PADHS.

The Pennsylvania Department of Human Services

7. PADHS is the state agency that, through seven program offices, administers services "that provide care and support to Pennsylvania's most vulnerable individuals and families." *About DHS*, Pennsylvania Dep't of Human Servs.[1] The mission of PADHS is to improve the quality of life for individuals and families and to promote opportunities for independence through services and supports while demonstrating accountability for taxpayer resources.

8. Among other work, as the state Medicaid agency, PADHS administers the Pennsylvania Medical Assistance Program for more than 2.3 million Pennsylvania residents through managed care and fee-for-services delivery systems as well as home- and community-based waiver programs.

9. PADHS also administers the Children's Health Insurance Program ("CHIP") through contracts with managed care organizations to 171,281 children who do not qualify for Medical Assistance but whose families cannot afford commercial insurance.

10. In addition to administering services for Medical Assistance and CHIP beneficiaries, PADHS is responsible for enrolling providers that deliver Medical Assistance services, establishing fee-for-service payment rates, processing provider claims, entering into agreements with and monitoring managed care organizations, and ensuring the integrity of all Medical Assistance programs.

11. Through its many programs, PADHS serves low-income individuals, including persons with physical disabilities and senior citizens; individuals with intellectual disabilities or

[1] http://www.dhs.pa.gov/learnaboutdhs/index.htm

autism; individuals with mental health or substance use disorders; and dependent and delinquent children.

12. PADHS also serves low-income Pennsylvanians through cash assistance programs such as Temporary Assistance to Needy Families ("TANF"); employment and training programs; the Supplemental Nutrition Assistance Program ("SNAP"), formerly known as food stamps; home heating assistance; subsidized child care; and assistance for refugees and individuals experiencing homelessness.

13. In addition to administering the multiple programs outlined above, among others, PADHS licenses and regulates thousands of facilities that care for the populations it serves as well as child care centers, assisted living residences, and personal care homes.

14. PADHS relies heavily on federal funding to administer virtually all of its programs and carry out its mission, which includes access to quality health care. In calendar year 2018, PADHS received $20,144,458,957 in federal funding for Medical Assistance Program and CHIP service and administration costs alone.

15. Of that amount, PADHS received $556,290,260 for administrative activities, which include ensuring compliance with existing state and federal laws that facilitate the accommodation of religious or moral objections, and that balance conscience protection rights with patients' right to access health care.

16. The federal funding that PADHS received in 2018 is consistent with the amounts it received in previous years. Specifically, PADHS received the following amounts in federal funding for the Medical Assistance Program and CHIP in the previous two calendar years:

(i) For calendar year 2017, $17,408,765,420

(ii) For calendar year 2016, $18,570,792,819

17. The Governor's proposed executive budget for fiscal year 2019-2020 relies on $19,607,306,000 in federal funding from HHS for the Medical Assistance Program and CHIP.

18. These billions of dollars in federal funds have improved the quality of, and access to, health care for individuals and families in Pennsylvania. Without these funds, many Pennsylvanians would go without health care.

Impact of the Final Rule on PADHS

19. The Final Rule expands the definitions of the terms "assist in the performance," "discrimination," "health care entity," and "referral or refer for," 84 Fed. Reg. at 23,263–64 (45 C.F.R. § 88.2), and is unclear about who or what falls under these terms. Nevertheless, PADHS and the providers, managed care organizations, and licensed facilities with which it conducts business must prepare to comply with them.

20. Because HHS has asserted the authority to terminate all federal funding from states that HHS finds to be noncompliant with the Final Rule, 84 Fed. Reg. at 23,272 (45 C.F.R. § 88.7(i)(3)), PADHS reasonably believes that a finding of noncompliance with the enforcement and compliance provisions of the Final Rule could jeopardize all or a significant portion of the federal funding PADHS receives from HHS.

21. Likewise, if any of the providers or managed care organizations with which PADHS conducts business fails to comply with the enforcement and compliance provisions of the Final Rule, PADHS reasonably believes that HHS could attempt to terminate all or a significant portion of the federal funding PADHS receives from HHS. 84 Fed. Reg. at 23,270 (45 C.F.R. § 88.6(a)).

22. The termination of billions of dollars in federal funds from PADHS would have a devastating impact on the Pennsylvanians whom PADHS serves with those funds, which includes the Commonwealth's most vulnerable populations.

23. Pennsylvanians who rely on PADHS's programs could lose their only access to health care and the many other supportive services they currently receive. Even if the populations PADHS serves would still receive health care under its programs, the Final Rule threatens to diminish the quality of, and access to, the health care and other services they receive. Patients will receive less comprehensive information about their health care options, in addition to delayed access if their current health care provider objects to treating them under the Final Rule.

Conclusion

24. The Final Rule may result in direct financial harm to PADHS, and thus direct financial harm to the Pennsylvanians it serves.

25. The Final Rule will allow for unprecedented discrimination and refusal of services and will increase mistreatment, which undermines the intent and integrity of health and human services programs, and even runs contrary to HHS's own mission. It will invite health and human services professionals to ignore existing law and medical standards, and it will go against person-centered approaches and evidence-based practices that have been at the core of social service and public health delivery for decades.

26. For these reasons, I believe that an injunction of the Final Rule is necessary to prevent immediate and irreparable harm in Pennsylvania and around the country.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

Date: 6/13/19

Teresa D. Miller
Secretary
Pennsylvania Department of Human Services

Exhibit 34

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF ANDREW W. NICHOLS, M.D.

1. I, Andrew W. Nichols, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the State of Hawaii's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through the University of Hawai'i at Mānoa personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the University of Hawai'i Student Health Center at my campus.

3. I am the Director of University Health Services at the University of Hawai'i at Mānoa located in the State of Hawai'i. My educational background includes a B.S. in Biological Sciences from Stanford University, M.D. from Wake Forest University School of Medicine, and Family Medicine Residency and Sports Medicine Fellowship training at UCLA. I have been employed as an Associate Professor/Professor/Clinical Professor of Family Medicine and Community Health since 1994, and Specialist and Director since 2011.

4. The University of Hawai'i is the only state university in Hawai'i and has 10 campuses across the Hawaiian Islands, which include three universities and seven community colleges. The University of Hawai'i at Mānoa and the University of Hawai'i at Hilo both have student health centers which provides health related services to approximately 20,000 students; 16,806 for the University of Hawai'i at Mānoa and 3,204 for the University of Hawai'i at Hilo.

5. The Student Health Center at the University of Hawai'i at Mānoa provides health services including vaccinations, HIV/STD prevention and contraception, and abortion referrals.

6. The University of Hawai'i received $56,358,106.00 in contracts and grants from the HHS from July 1, 2017 to June 30, 2018.

7. If the University of Hawai'i is deemed to be in non-compliance with the Final Rule, this financial assistance from HHS is threatened and could be terminated.

8. In addition, the Student Health Center will need to expend time and effort in training staff on what behavior is now permissible from objectors and how to work around objections not planned for in advance.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 29th day of May, 2019.

Andrew W. Nichols, M.D.
Director, University Health Services
University of Hawai'i at Mānoa

Exhibit 35

PRIVILEGED & CONFIDENTIAL
COMMON INTEREST PROTECTED

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF M. NORMAN OLIVER, MD

1. I, M. Norman Oliver, MD, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct.

2. I submit this Declaration in support of the Commonwealth of Virginia's litigation against the United States Department of Health and Human Services (HHS); Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services; and the United States of America regarding the recently issued rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (Final Rule). I have compiled the information in the statements set forth below either through personal knowledge, through Virginia Department of Health (VDH) personnel who have assisted me in gathering this information, or on the basis of documents that have been provided to and/or reviewed by me. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon VDH.

3. I am the State Health Commissioner at VDH located at 109 Governor Street, Richmond, Virginia. My educational background includes Doctor of Medicine and Masters in Anthropology. I have been employed as the State Health Commissioner since May 2018. Prior to this appointment, I served as the Deputy Commissioner for Population Health for VDH. Before accepting the Deputy Commissioner position, I was the Walter M. Seward Professor and Chair of the Department of Family Medicine at the University of Virginia School of Medicine.

Background

4. The Virginia Department of Health (VDH) serves as the leader and coordinator of Virginia's public health system, with approximately 3,300 salaried employees and an annual budget of $730 million. Generally, VDH services are delivered to the public by local health departments (LHDs) or by VDH field offices. Each city & county in Virginia is required to establish and maintain a LHD. Pursuant to statutory authority, VDH has organized these 119 LHDs into 35 health districts.

Local health districts provide a variety of services, including Title X family planning services, screenings for sexually transmitted diseases, the provision of treatment as appropriate, primary care referrals, adult and childhood immunizations, HIV testing and tuberculosis testing and treatment. Some local health districts also provide physical exams and prenatal and post-partum care.

5. In 2018, 38,021 patients received Title X services through VDH, ultimately preventing 8,170 unintended pregnancies. Of these patients,

a. 34,805 (92%) were living at or below 200% of the federal poverty level;

b. 25,586 (67%) were uninsured;

c. 5,603 (15%) were teens;

d. 12,152 received cervical cancer screenings (pap tests);

e. 7,333 received breast cancer screenings (clinical breast exams); and

f. 12,904 were tested for chlamydia, the most commonly reported infectious disease in the United States.

6. Virginia received over $6.7 billion in federal health-care funding from the HHS in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system, including $4.5 million in Title X Family Planning funds for the 2020 grant year (April 1, 2019 through March 31, 2020).

7. In the course of offering services/executing duties as regulator, VDH receives/passes through/grants to others the following funds from HHS, and for the following purposes: over $160 million (based on Fiscal Year 2018 data) to undertake efforts in all hazards preparedness and response; chronic disease prevention; clinical services/consumer care; environmental health; data analytics and disease surveillance; laboratory services; communicable disease prevention (including general communicable disease, HIV/STD and tuberculosis); immunization services; injury and

violence prevention; food safety;; opioid use prevention/harm reduction; newborn screening; home visiting; reproductive health planning; nutrition; and expanding insurance coverage access and assuring quality and access to health services such as rural health programs and primary care supportive functions. Of the $160 million; $33M was passed through to non-state entities such as health care providers, medical schools, charitable organizations, non-profits, as well as to counties and cities; $8M was transferred to state institutions of higher education; and $409k was received as pass through funding to the VDH from non-state entities.

8. These funds are essential to the functioning of VDH and the maintenance of public health within our jurisdiction.

Impact

9. The Final Rule's substantial expansion of the terms "assist in the performance," "discrimination," and "health care entity" has required VDH to re-evaluate existing staffing and may ultimately require VDH to hire additional staff to ensure consistent coverage for all patients at all times, particularly in emergency situations.

10. The Final Rule, if implemented, will also require VDH to modify hiring and training practices to accommodate the expanded range of religious, moral, ethical, or other objections to care permissible by the Final Rule.

11. In addition, under the Final Rule, VDH will be required to allocate personnel and resources to determine—with limited advance notice—the veracity of religious, moral, ethical, or other objections made by a much-expanded universe of potential objectors.

12. Under the Final Rule, VDH must also review contractual and other relationships with subcontractors used to deliver health services, for VDH will be responsible under the Final Rule for non-compliance by subcontractors who receive HHS funding through VDH.

13. The Final Rule will also have the effect of displacing existing state law in ways that affect VDH's existing operations, including but not limited to:

a. 18 Va. Admin. Code 85-20-28, which prohibits medical practitioners from "terminat[ing] the relationship or mak[ing] his [or her] services unavailable without documented notice to the patient that allows for a reasonable time to obtain the services of another practitioner."

b. Virginia Code Ann. § 38.2-3445, which requires all health carriers "providing individual or group health insurance coverage" who provide "any benefits with respect to services in an emergency department of a hospital" to provide such coverage "[w]ithout the need for any prior authorization determination, regardless of whether the emergency services are provided on an in-network or out-of-network basis."

c. Va. Code Ann. § 38.2-3407.5:1, which requires insurers who otherwise provide prescription drug coverage to offer coverage for "any prescribed drug or device approved by the United States Food and Drug Administration for use as a contraceptive."

d. Virginia Code Ann. § 54.1-2957.21, which allows genetic counselors to opt out of "counseling that conflicts with their deeply-held moral or religious beliefs" and protects such objectors from liability "provided [the counselor] informs the patient that he [or she] will not participate in such counseling and offers to direct the patient to the online directory of licensed generic counselors maintained by the Board."

14. If VDH fails to comply with the new requirements of the Final Rule, it risks losing HHS funding, which the agency relies on for ongoing operations.

15. For these reasons, the Final Rule, if implemented, will have a significant impact on VDH's funding and operations.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 6th day of June, 2019

M. Norman Oliver, MD, MA
State Health Commissioner

Exhibit 36

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF DR. DAVID PREZANT

1. I, David Prezant, MD, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the City of New York's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and the United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, the Fire Department of the City of New York (herein after "FDNY" or "Agency") personnel who have assisted me in gathering this information from our Agency, or on the basis of documents that have been provided to and/or reviewed by me. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon FDNY.

3. I am the Chief Medical Officer at FDNY, located in New York City at 9 Metrotech Center, Brooklyn NY 11201. I am a graduate of Columbia College and Albert Einstein College of Medicine and completed a residency in internal medicine at the Harlem Hospital. I have been employed as the Chief Medical Officer since 2006 and have been working for the FDNY as a Medical Officer since 1986. I am also a Professor of Medicine at the Albert Einstein College of Medicine, Montefiore Medical Center, and Pulmonary Division.

The Fire Department of the City of New York;
Receipt and Use of HHS Funds

4. The FDNY is the largest Fire Department in the United States and is universally recognized as one of the world's busiest and most highly skilled emergency response agencies. As first responders to fires, primary medical emergencies, and public safety incidents including disasters and terrorist acts, the FDNY is responsible for providing critical public safety and emergency medical services to residents and visitors across New York City's five boroughs. We

are committed to making New York City the safest big city in the nation; to that end, FDNY members are sworn to serve and protect life and property.

5. With an annual budget of $2 billion and more than 16,000 members, FDNY is tasked with, among other things, using these resources to respond to more than one million emergencies every year. While a large part of FDNY's budget comes directly from the City of New York, many emergency transports are reimbursed through the Medicare and Medicaid program billed through NYC Health + Hospitals.

6. In accordance with existing medical protocols, the FDNY EMS ("emergency medical services") Command responds to 911 requests for emergency medical assistance by, depending upon the type of medical emergency, dispatching ambulances staffed with two emergency medical technicians ("EMTs") or two paramedics ("Medics").

7. Requests for emergency medical assistance are forwarded to FDNY through New York City's 911 System. Call-receiving operators obtain relevant information and, using established algorithms, determine the priority of the call and whether an EMT- or Medic-staffed ambulance shall be dispatched. Ambulance dispatchers, using a computer-aided dispatch system, then assign an ambulance to respond to the request for emergency medical assistance. Generally, the ambulance with the shortest anticipated response time is assigned to the call. FDNY dispatches both FDNY-staffed ambulances and private ambulances that operate in the New York City 911 System pursuant to agreements with hospitals in New York City, regardless of affiliation. The computer-aided dispatch system does not differentiate between the FDNY-staffed ambulances and the private ambulances. Ambulance personnel, regardless of their affiliation, are required to work under the protocols approved by the 911 System and transport patients to the closest, appropriate hospital emergency department.

8. Response time is critical for life-threatening emergencies, including pregnancy-related complications, cardiac arrest, ischemic heart disease, strokes, choking, asthma/COPD attacks, difficult breathing regardless of diagnosis, and major trauma. Reductions in response time (responding faster) for these illnesses/injuries are often the difference between life and death. For this reason, our computerized triage system sorts EMS calls into segments and call types so that response times and assets (EMT versus Medics) can be matched to the severity of the call. Segment 1 (choking and cardiac arrest) receives the fastest response times and Segment 7 (for example, an emotionally disturbed person in no obvious danger to themselves or others) receives the lowest priority. Any delay in initiating the appropriate care—including CPR, oxygen, compression to stop bleeding, for example—increases the potential for an untoward patient outcome, up to and including the death of the patient.

Policies Addressing Religious Objections

9. FDNY does not have policies in place to address religious or moral objections to providing EMS-related duties. This is because our EMTs and Medics are tasked with the singular mission of providing pre-hospital emergency medical care in response to all requests for such assistance to which they are assigned, regardless of race, religion, ethnicity, sex, sexual orientation, or any other factor, including their personal beliefs or those of the ill or injured persons to whom they are responding. EMTs and Medics are physician extenders and must by law and regulation operate according to written protocols matched to each call type. They cannot add or omit items or actions as dictated by the protocols because they operate as physician extenders without the ability to determine on their own the appropriate actions. Furthermore, I cannot imagine any protocol that includes any action that would possibly evoke a

religious objection since every protocol and every action has only one mission—to save the life of the patient being treated.

Immediate Impact of the Final Rule on FDNY

10. It is FDNY's understanding that the Final Rule expands definitions of certain terms in ways that may affect how we function, specifically: "assist in the performance," "discriminate or discrimination," "health care entity," and "referral or refer for."

11. There is a lack of clarity as to whom and what falls under these terms, particularly in the first-responders context. FDNY would be unable to prepare for compliance with the Final Rule in a meaningful way.

12. In a congested and densely-populated city with over 8.5 million residents and millions of visitors, it is financially and operationally impracticable for our Agency to procure additional ambulances and equipment, or to double-staff a sufficient number of first responders to be on standby in the event a member of our Agency or employee of a non-FDNY staffed ambulance, refuses to provide care at the scene of an emergency. Nor would it seem reasonable to have to screen our response staff and the staff of the privately operated ambulances within the 911 System and their possible actions under each protocol for any potential religious objection. We dispatch by call type and by nearest ambulance; we do not dispatch by which particular person is staffing an ambulance. It would be unreasonable for us to do so. The delay in care that would result should an objection be made to treating a patient could result in great harm or death to the patient.

13. As discussed, FDNY first responders operate under tight response times to emergencies due to the life-or-death nature of our work. For each ambulance dispatched, there is a host of challenges and uncertainties that our EMTs and Medics encounter, including the types

of services to be provided or persons to be stabilized. Accounting for a possible refusal of care for a particular dispatch while ensuring another EMS Team is available is impracticable.

14. Even if there were an appropriately staffed ambulance available to be dispatched following an objection to the provision of care, because rapid response time is critical to successful patient outcome, an alternate dispatch will likely lead a less successful or possibly catastrophic outcome, including the death of the patient.

15. Dispatching an alternate EMS Team to replace a private hospital's ambulance team is even more difficult given the additional time required to communicate the objection to the FDNY.

16. This is especially so when sufficient advanced notice of an objection is not required, either by our own personnel or those of hospital-affiliated personnel operating within the 911 System.

17. It has been a stated goal of the FDNY, City Hall, and City Council to respond faster to 911 calls involving the most life-threatening conditions (Segments 1–3), rather than to respond slower.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 6 day of June, 2019

David Prezant, MD
FDNY Chief Medical Officer

Exhibit 37

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF KARYL T. RATTAY, M.D., M.S.

1. I, Karyl T. Rattay, M.D., M.S., Director of the Delaware Department of Health and Social Services, Division of Public Health, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of Delaware's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, or on the basis of documents that have been provided to and reviewed by me. I have also familiarized myself with the Final Rule.

3. I have served as the Director of the Division of Public Health (DPH or the Division) within the Delaware Department of Health and Social Services (DHSS) and as Delaware's State Health Officer since May, 2009 and lead 630 employees. I received my Medical Doctorate from the Medical University of Ohio in 1992 and then completed residencies in pediatrics and preventive medicine at Georgetown University and the University of Maryland. I am board-certified in Pediatrics. I have a Master's of Science in Epidemiology. .

4. In this Declaration, I will use Title X statistics, by and large, as examples of the impact of the Final Rule.

5. The Final Rule will prejudice certain patient populations; for example, women seeking family planning counseling and lesbian, bisexual, gay and transgender persons (LBGT), especially in rural areas, where alternative locations are limited. Based on the Final Rule's expanded definition of health care provider (adding non-clinical personnel to clinical personnel, discussed in paragraphs 7 and 8 below) as applied to conscience protection, patients falling into these categories (which are

already at risk for denial of services) are more likely to be refused medical care and denied referral information for appropriate medical providers for prohibited services.

6. The Delaware DPH provides patient care through its State Health Centers, which are also Title X recipients. In 2017, the seven State Health Centers provided nearly 30,000 services to almost 5,400 clients. Services included, among other things, sexual and reproductive health, child health, and immunizations. The State Health Centers are located throughout the State, with at least one clinic in each county. These centers serve people in almost all income levels. State Health Centers see insured, under-insured and uninsured patients. The centers bill their patients on a sliding fee scale, based on the household income.

7. There are a total of 152 personnel servicing State Health Centers statewide, including six (6) Clinic Managers; twenty-one (21) Administrative Support; (23) twenty three Registered Nurses (RN); eight (8) RN Supervisors; twenty two (22) Nutritionists; forty eight (48) Social Security Service Technicians /Social Security Specialists; nine (9) Disease Intervention Specialists; ten (10) Advanced Practice Nurse RNs; four (4) Lab Techs; and one (1) Physician.

8. These numbers are significant as the Final Rule expands the definition of a "health care entity" beyond clinical personnel (e.g., doctors and nurses, etc.) to non-clinical personnel (e.g., facility managers, administrative support, etc.) This will increase facilities' exposure for care/referral denials given the greater number of individuals in each facility covered by conscience protections under the Final Rule.

9. DPH provides patient care described above in its State Health Centers. As noted in the Complaint, the Final Rule would expand the scope of provider conscience protection rights beyond the underlying existing conscience protection statutes. These facilities serve patients eligible for Title X grants, which is the only federal program devoted solely to the provision of

family planning and reproductive health care. Title X is designed to provide access to contraceptive supplies and information to all who want and need them with priority given to low-income persons. A broad range of effective and acceptable family planning methods and services are available on a voluntary and confidential basis.

10. In addition to contraceptive services and related counseling, Title X supports clinics which provide a number of preventive health services, such as patient education and counseling; breast and pelvic examinations; cervical cancer, and STD and HIV screenings. Under Title X, DPH partners with agencies that provide reproductive health services and pregnancy diagnosis and counseling. However, no Delaware state facilities provide abortions.

11. In 2017, Delaware's Title X providers served 19,132 patients. To the extent Delaware's Title X funding were to be interrupted and/or withheld due to the application of the Final Rule, the adverse impact on the health of Delawareans would be significant.

12. For example, a May 2018 *Guttmacher Institute*[1] study noted that "contraceptive use is a key predictor of whether a woman will have an abortion. In 2011, the very small group of American women who were at risk of experiencing an unintended pregnancy, but were not using contraceptives, accounted for the majority of abortions." *State Facts about Abortion and Delaware*, at https://www.guttmacher.org/fact-sheet/state-facts-about-abortion-delaware#7.

13. Again, among other things, Title X funded facilities provide access to contraceptive supplies and information to all who want and need them with priority given to low-income persons. Any reduction of the provision of contraceptives in Delaware based on the Final Rule which purports to create the expanded provider "exemptions" referenced herein, will leave Delawareans and in particular low income Delawareans who rely on federally subsidized health care programs, at

[1] The Guttmacher Institute is a leading research and policy organization committed to advancing sexual and reproductive health and rights in the United States and globally.

risk in terms of the access to the contraceptives these programs provide which serve to lower abortion rates.

14. Furthermore, given the statistics that unintended pregnancy rates are "highest among low-income women (i.e., women with incomes less than 200% of the federal poverty level), women aged 18–24, cohabiting women and women of color", access to contraceptives and education regarding their use in Title X funded programs is imperative. Guttmacher Institute, January 2019 Fact Sheet "Unintended Pregnancy in the United States," at https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.

The Title X Program in Delaware

15. The Department of Health and Social Services is Delaware's sole Title X grantee. Delaware received $1.1 million for fiscal year 2019 and $810,000 for fiscal year 2018 in Title X family planning service grants. *See* U.S. Department of Health & Human Services website, HHS.Gov Office of Population Affairs- "HHS Title X Family Planning Service Grants Award by State" - Fiscal Year 2019 and 2018 Grantees, found at: https://www.hhs.gov/opa/grants-and-funding/recent-grant-awards/index.html; https://www.hhs.gov/opa/grants-and-funding/archive/past-grant-awards/2018.html

16. The Title X program served over 19,000 patients in Delaware in 2017, of whom: 83% were female; 50% were female and between the ages of 18 and 29; 88% were at or below 250% of the federal poverty level; 64% were at or below 100% of the federal poverty level; 25% indicated Hispanic/Latino ethnicity; 38,441 clinic visits were provided, including, 6,163 cervical cancer screenings, 27,336 sexually transmitted infections (STI) screenings and 6,504 annual/well-woman exams.

17. Title X has never funded abortions in Delaware. Only two of Delaware's 44 Title X sub-recipient sites also provide abortions for non-Title X patients. These Planned Parenthood health centers also provided Title X services to almost 7,000 patients in 2017, more than a 1/3 of the patients in the Title X program. Delaware's Title X program is necessary and cost-effective. In 2010, the 57% rate of unintended pregnancies in Delaware was the highest in the nation at 62 per 1,000 women aged 15 to 44. In 2010, 3,300 or 71.3% of unplanned births in Delaware were publicly funded, compared with 68% nationally. That same year, the federal and state governments spent $94.2 million on unintended pregnancies; of this, $58.2 million was paid by the federal government and $36.0 million was paid by the states. In 2017, Title X funding prevented 2,900 unplanned pregnancies, saving the state and federal governments millions of dollars for the $1,135,000 allocated by HHS.

18. According to Frost, Frohwirth and Zolna's 2016 study, Title X funded centers averted 1,300 abortions in 2014 alone in Delaware by preventing unintended pregnancies.[2]

19. Title X is instrumental in turning the tide on Delaware's unplanned pregnancy rates. In 2014, Delaware launched the DECAN (Contraceptive Access Now) Initiative along with its non-profit partner, Upstream. The DECAN Initiative's goal is to provide contraception to every woman who does not want to become pregnant by "providing training and technical assistance to all publicly funded healthcare providers and the largest private healthcare providers in the state to ensure their patients are offered the full range of contraceptive methods in a single appointment." According to a Child Trends report, between 2014 -2017, Long Acting Reversible Contraceptive (LARC) use increased from 13.7 to 31.5 percent among Delaware Title X family planning clients ages 20-39. Notably, this resulted in a simulated 24% decrease in the unintended pregnancy rate

[2] Frost, J., Frohwith, L and Zolna, M. Contraceptive Needs and Services, 2014 Update, *available at* https://www.guttmacher.org/report/contraceptive-needs-and-services-2014-update

among this population during 2014-2017. The Title X Family Planning Program is the backbone of the sustainability plan for the DECAN Initiative and the Final Rule jeopardizes the progress Delaware has made in preventing thousands of unplanned pregnancies.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 11th day of June, 2019

KARYL T. RATTAY, M.D., M.S.
Director, Division of Public Health,
Delaware Department of Health and Social Services

Exhibit 38

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE DECLARATION OF LINDA ROSEN, M.D., M.P.H.

DECLARATION OF LINDA ROSEN, M.D., M.P.H.

Pursuant to 28 U.S.C. § 1746(2), I, Linda Rosen, M.D., M.P.H., hereby declare as follows:

1. I am the Chief Executive Officer ("CEO") for Hawaii Health Systems Corporation ("HHSC"), a body corporate and politic and an instrumentality and agency of the State of Hawai'i.

2. I make this declaration based on my professional knowledge of HHSC matters as CEO, my function as the Chief Medical Officer of HHSC, my knowledge of hospital operations as an emergency and critical care physician, and my experience in health care systems operations in public health. In my past experience as the Hawai'i State Director of Health, Hawai'i's Chief of Emergency Medical Services and Injury Prevention System Branch, and as Medical Director for Pediatric Emergency Medical Services and Family Health Services for the State of Hawai'i, I have established comprehensive systems of care, including Hawai'i's statewide trauma system, Hawai'i's statewide stroke system of care, a statewide emergency medical system including 911 ambulance services, and a systematic public health approach to illness and injury that focuses on prevention, risk reduction, and equitable access to quality health care services.

3. For patients, hospital operations can be life-saving. Patients are the center of hospital planning, delivery, and assessments of care. Hospitals work tirelessly to define and outline safety measures, quality service expectations, and patient engagement efforts that result in positive patient experiences and outcomes from hospital services. Successful hospital operations and patient safety are sourced in the hospital's workforce. To avoid life-threatening errors, staff must be qualified and well-trained in a professional environment conducive to focusing on the specialized task-oriented, critically important work of saving the lives and preserving the good health of patients.

4. For trauma systems, stroke systems, and emergency systems, time is of the essence for patients requiring immediate and appropriate care. In a medical crisis, where every

minute can matter to the life of the patient, every patient must have access to timely and undeterred healthcare.

5. I submit this Declaration in support of the State of Hawai'i's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through HHSC personnel who have assisted me in gathering this information from our institution, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon HHSC.

6. HHSC is a public hospital system comprised of a network of hospitals and clinics within its regional health care systems on the islands of Oahu, Kauai, and Hawaii (which is divided into two regions, East Hawai'i, and West Hawai'i due to the size of the island). HHSC is dedicated to providing high quality health care services to residents and visitors in the State of Hawai'i regardless of their ability to pay. In this regard, HHSC serves as a vital component of the State of Hawai'i health care safety net. HHSC facilities include in East Hawai'i: Hilo Medical Center ("HMC"), Yukio Okutsu State Veterans Home, Hale Ho'ola Hamakua ("HHH"), and Ka'u Hospital ("Ka'u"); in West Hawai'i: Kona Community Hospital ("KCH") and Kohala Hospital ("Kohala"); on Oahu: Leahi Hospital and Maluhia (both of which are long term care facilities); and on Kauai: Kauai Veterans Memorial Hospital ("KVMH") and Samuel Mahelona Memorial ("SMMH") Hospital, and all related outpatient and ancillary facilities.

7. In fiscal year 2018 (July 1, 2017-June 30, 2018) HHSC received the following amounts of reimbursements from the federal government:

A.	Federal Payments	$64,141,112
B.	Medicare Payments	$75,080,367
C.	Medicaid Quest Payments	$93,847,351

8. I am aware that in fiscal year 2018, HHSC facilities provided a total of 13,016 acute care admissions, 575 long-term care admissions, delivered 1,872 babies, handled 75,456 emergency department visits, and employed a total of 2,526 full time equivalent personnel. In fiscal year 2018, HHSC facilities provided approximately 12% of all acute care discharges and 16% of all emergency department visits statewide, approximately 69% of all acute care discharges and 84% of all emergency department visits in Hawai'i County (of which HHSC operates four of the five hospitals) on the island of Hawai'i and approximately 19% of acute care discharges and 37% of all emergency department visits in Kauai County, on the island of Kauai (of which HHSC operates two of the three hospitals). Not only are the Hawaiian Islands one of the most isolated archipelagos in the world, each the State's five (5) counties are separated from one another by ocean, further isolating our State's rural areas.

9. In fiscal year 2018, the East Hawai'i emergency department visits for HMC, Ka'u, and HHH were 48,715, 2,022, and 2,992 respectively; the West Hawai'i emergency department visits for KCH and Kohala were 22,661 and 1,745 respectively; the Kauai region emergency department visits for KVMH and SMMH were 6,820 and 6,259 respectively. The Oahu region facilities provide long term care and do not have emergency departments.

10. HHSC facilities protect an employee's right to not participate in the treatment of a patient where that treatment presents a conflict with the sincerely held religious beliefs of the

employee, provided that the employee submits a request not to participate in treatment prior to the need for the employee to participate in any such treatment and the employee is willing to be reassigned to another department. Reassignment to a unit the employee was not originally scheduled to work in is commonly known as "floating."

11. The absence of advance notice of a conflict or ambiguity about whether a particular treatment causes a conflict may have an immediate and damaging impact on HHSC and the rural communities that it serves. This requirement of prior notice is essential for the HHSC emergency departments to effectively provide the necessary services in the State's many rural areas. Rural hospitals provide the only emergency and hospital care available to a large geographic area while having a limited pool of employees. If these hospitals are unable to ascertain in advance whether an employee can perform the necessary duties of the employee's position, and determine whether they can make reasonable accommodations, the health of all individuals in that community is potentially affected, and the health of some individuals will be compromised.

12. The unforeseen refusal of an employee to participate in care will likely result in failure to meet the standard of care due to the limits of staffing that do not allow for the rapid substitution of another employee.

13. It is important for an employee to be willing to "float" to another department or take another patient assignment. While floating requires an action on the employee's part in that they would leave the area where the objected to actions are taking place and report to work in another area, the "float" is necessary for hospitals to be able to staff various patient care settings on a 24/7/365 basis, and all staff on duty have responsibilities. To provide the needed patient care, if an employee declines to provide care because of objections and that employee also

declines to float to another position, that employee must be replaced by another employee whose previous responsibilities must be still be covered. Pulling alternate staff to provide the objected to care can compromise the care of those patients the alternate staff were previously assigned to if their duties cannot be covered by others. For example, in the hospital intensive care unit (ICU), if a patient has advanced directives requiring the discontinuation of treatments, which a nurse may have a religious objection to, it may be reasonable to reassign the patient to another nurse or assign the nurse to another unit to avoid the conflict depending on the staffing available and the frequency of such a conflict arising. But if the nurse refuses to be reassigned, the need to provide alternate staffing may leave a void in staffing elsewhere. This scenario has the potential to frequently arise, especially in HHSC's small rural facilities where the number of on duty staff is usually limited. Prohibiting hospitals from making reasonable accommodations with their staffing would lead to compromises in the standard of care delivered. This is especially a concern where a conflict is likely to occur, but cannot be identified in advance, such as the need to provide blood transfusions in the emergency department, or provide anesthesia in emergency ectopic surgery. In situations like those, a nurse who objects to participating in such treatment would definitely cause unacceptable compromises to patient care as the substitution of staff would take time when time is of the essence and cannot be spared for the sake of the patient.

14. It is of great concern that while the Final Rule seeks to protect employees from discrimination in certain "fields of practice" it may be narrowly interpreted and lead to guarantees of employment in areas where allowing such objections would cause a failure to meet the standards of medical care. There are specialty areas of practice, such as the examples for nurses in the emergency department as previously described, where the objection of the employee may effect enough of the professional requirements of that position that it makes the

area of practice an unreasonable setting to work in. And yet, the current practice does not restrict an individual who objects to some medical procedures from entering an entire field of practice such as nursing.

15. The number of staff available to cover for an employee who objects to participating in certain care is not the only significant variable. The training, competencies, and required experience of healthcare professionals varies significantly from one department in a hospital to another even when comparing employees with the same job titles. For example, a nurse in the OB unit may not have the necessary competencies to work as a nurse in ICU or behavioral health. The availability of an employee to cover for the objecting employee with same or similar competencies cannot be planned for in advance in the absence of prior notice. And, while being able to staff a hospital to provide care to all residents and visitors 24/7/365 is of the first priority, our hospitals are also subject to complex and rigorous regulations regarding patient privacy. These regulations require our hospitals to follow strict security protocols when providing employees access to a patient's electronic health record. As a result, access to all or some of a patient's medical record may be limited to employees who regularly work in the department caring for the patient. For example, even if a nurse working in the emergency department has the competencies to cover for an objecting employee in OB, he or she may not be provisioned to access an OB patient's chart. Providing such access is rarely possible on demand; there is almost always a delay between the time a request is made and when the access is actually granted. This too may add time to replacing an objecting employee when the patient may not have time to spare.

16. Without advance notice, if an employee refuses to provide care and the hospital cannot get another employee in place, which is likely due to the nurse shortage and long

distances that employees may commute, particularly in rural areas, patient care and in turn the public health of the communities that HHSC serves will suffer severe impacts.

17. The Final Rule presents unworkable situations for our HHSC hospitals in the following ways:

A. While accommodating employees' personal beliefs and objections is desirable, the hospital's ability to always deliver the community standard of care is the most important factor to be considered. We can make reasonable accommodations, but "reasonable" must be understood to allow for care to be delivered according to community standards which in many cases includes the timeliness or rapidity with which such care is provided.

B. Hospitals are under strict regulation and must deliver care that meets accepted professional and community standards for each condition or face lawsuits for malpractice, loss of the right to provide care from regulatory agencies, and loss of reimbursements from third party payors. The standard of care for many conditions is time-sensitive. Care delivered incompletely, or too late, may result in death or adverse outcomes that would not have occurred had the standard been met.

C. For example, when a patient injured in a car crash arrives in shock at the emergency department, blood products must be rapidly administered or the patient will die. When a woman presents with lower abdominal pain due to an ectopic pregnancy, the failure to quickly operate can result in rupture, hemorrhage, and death. Even in end-of-life situations, if a patient and family expect advance directives eschewing advanced life support to be followed and they are not, this can inflict pain and suffering on the patient and family. These outcomes are not hypothetical; they may and frequently are the result when care is untimely or inappropriate.

[*Signature appears on the following page*]

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 10th day of June, 2019

Linda Rosen

Linda Rosen, M.D., M.P.H.
Chief Executive Officer / Chief Medical Officer
Hawaii Health Systems Corporation

Exhibit 39

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF JOHN JAY SHANNON, MD

1. I, John Jay Shannon, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I am the Chief Executive Office ("CEO") of Cook County Health and Hospitals System, doing business as Cook County Health ("CCH"). I submit this Declaration in support of Cook County, Illinois's litigation against the United States Department of Health and Human Services ("HHS") regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through CCH personnel who have assisted me in gathering this information from our institution, or on the basis of documents that I have reviewed. I have also familiarized myself with the Rule in order to understand its immediate impact upon CCH.

3. I was appointed to this position on June 27, 2014. I have spent most of my professional career at John H. Stroger, Jr. Hospital of Cook County, formerly Cook County Hospital, after joining the CCH medical staff in 1990. Prior to this role, I served as Chief of Clinical Integration for CCH. Additionally, from 2007 to 2012, I served as Executive Vice President and Chief Medical Officer at Parkland Health & Hospital System in Dallas from 2007-2012. I received my B.A. from Spring Hill College, and my medical degree from Rush Medical College. I trained in Internal Medicine and was a Chief Resident at University of Texas Southwestern Affiliated Hospitals in Dallas, and later earned specialty training in Pulmonary and Critical Care Medicine at the University of Michigan Medical Center in Ann Arbor.

4. As CEO, I am charged with, among other things, full operational and management authority of CCH, the preparation and submittal of CCH budgets and strategic and financial plans, overseeing CCH expenditures, the hiring and discipline of

personnel, the negotiation of collective bargaining agreements, the provision of quarterly reports to the Cook County Board of Commissioners, and such other duties delegated by the CCH Board of Directors.

I. Background on CCH; Receipt and Use of HHS Funds

5. The County of Cook, Illinois, is the second most populous county in the United States, with a population of over five million people. The County of Cook is the owner and operator of its own public healthcare system, CCH. CCH is one of the largest public health care systems in the United States, providing a range of health care services regardless of a patient's ability to pay.

6. CCH comprises two hospitals (John H. Stroger, Jr. Hospital ("Stroger Hospital") and Provident Hospital), a robust network of more than a dozen community health centers, the Ruth M. Rothstein CORE Center, the Cook County Department of Public Health, correctional health care facilities at the Cook County Jail and the Juvenile Temporary Detention Center, and CountyCare, a Medicaid managed care health plan.

7. CCH serves approximately 500,000 individuals annually through the health system and the health plan.

8. CCH received more than $500 million in in fiscal year 2018 in federal healthcare funds. This figure includes reimbursement for direct medical services as well as grant funding. These funds are used to provide healthcare services to Cook County residents, and more than 65% of our patients are uninsured or underinsured and would otherwise lack meaningful access to medical care. These funds are received

pursuant to federal programs such as the Benefit Improvement and Protection Act, Disproportionate Share Hospital payments, Medicaid, Medicare, and Medicare/Medicaid incentive programs.

9. In addition to the direct funding CCH receives from HHS, it is also a recipient of pass-through grants of approximately $7 million from the Illinois Department of Public Health and the Illinois Department of Human Services that originate with federal funding.

10. In addition to the CCH medical facilities and healthcare services, CCH has a Department of Pharmacy. CCH pharmacies dispense approximately 1.5 million prescriptions per year among the eight out-patient pharmacies conveniently located across the Chicagoland area.

II. Final Rule Frustrates Compliance with Illinois State Law

11. CCH's current policies are tailored to comply with existing requirements of our Illinois laws on religious accommodation, which provide, among other things, that:

    a. Individuals with conscience objections are not relieved of their obligations to provide emergency medical care under 210 ILCS 70/1; 210 ILCS 80/1; 745 ILCS 70/6; Ill. Adm. Code 545.35;

    b. Abandoning a patient is grounds for disciplinary action, including license revocation under 225 ILCS 60/22(A)(16);

    c. Health care providers must give patients information concerning their condition and proposed treatment under 410 ILCS 50/3;

    d. Health care providers conducting HIV testing must first obtain informed consent from individuals undergoing testing under 410 ILCS 305/3;

e. Certain agencies must deliver specified services either directly on-site or by referral, including contraception and other reproductive health care services under 77 Ill. Adm. Code 635.90;

f. Insurers must provide coverage for contraception under 215 ILCS 5/356z.4; and

g. The Illinois Reproductive Health Act protects access to comprehensive reproductive health care.

12. The Final Rule would interfere with CCH's ability to adhere to the aforementioned Illinois laws because the Final Rule purports to preempt these laws. Therefore, under the Final Rule, CCH would be forced to choose between following Illinois law and potentially violating the Final Rule, which could lead to revocation of any or all HHS funding.

III. Immediate Impact of the Final Rule on CCH

A. Trauma and Emergency Care

13. Stroger Hospital's Trauma Unit handles almost 8,000 incidents per year (representing over 5,000 unique patients). This makes it the busiest trauma unit in the Midwest and one of the busiest in the country. In addition, its Emergency Department sees over 117,000 patients per year.

14. As a result of the Rule, and the risk that any employee may now refuse to provide patient care without advance notice to the hospital, CCH must attempt to create contingency staffing plans to ensure that more than one of each necessary professional is available at all times in its emergency rooms.

15. For example, a woman who visits the emergency room with an obstetrics problem, such as an ectopic pregnancy, will encounter a large number of staff members in her course of treatment. Each emergency care staff member is critical to ensuring the patient's safety. As a result of the Final Rule, CCH must plan for instances where a critical staff member objects on religious or moral grounds at any time to assisting in the provision of care to a woman with an emergency situation such as an ectopic pregnancy.

16. CCH would incur the burden of ensuring that additional replacement staff would always be available to perform essential functions required for a patient in emergency situations.

B. Reproductive Health Care

17. The Family Planning Title X Block Grant is an HHS program developed to provide funding for a broad range of high quality family planning services for under-served and low income individuals. Services funded with Title X dollars in Illinois include:

a. FDA-approved methods of contraception;

b. Pap tests;

c. Screening tests for sexually transmitted infections ("STI");

d. Pregnancy tests as indicated and according to nationally recognized standards of care and non-directive counseling upon a positive pregnancy test;

e. Contraceptive management, client counseling, and education;

f. Pre-conception care; and

g. Counseling and referrals for pregnancy planning, including assistance with infertility.

18. In addition to the 8,000 to 12,000 women of low income treated annually within CCH facilities under Title X, CCH also serves the population of Cook County as a whole, including the detainees housed within the Cook County Jail and Juvenile Temporary Detention Center. The services provided to our female patients include obstetric and perinatal care, basic wellness and primary care, postpartum care, gynecological care, STA management, adolescent care, basic reproductive endocrinology, counseling and contraception, and family planning services. Annually CCH hospitals and clinics have in excess of 225,000 visits from 55,000 individual women patients per year (excluding correctional health patients).

19. CCH anticipates instances of conscience objections relating to reproductive health services, including those provided under Title X funding, considering that some individuals have conscience objections to contraception, STI testing, pregnancy counseling, and pregnancy planning. One also can reasonably anticipate moral objections to providing health care services to women suffering from addictions to drugs or alcohol or who have been charged with a crime. Regardless of its basis, a CCJ employee who refuses to participate in care places an unmanageable burden on CCH and its ability to provide patients with the necessary care. Such refusals also increase the burden of work for those employees who do not object, thereby creating workload inequalities across the system and likely labor and union issues.

20. Furthermore, a health care worker's invocation of the right to refuse harms the patient and disregards her needs, as the refusal results in the need to bring in another provider or staff member, lost time, delays in treatment, prolonged pain and suffering by the patient, and a limitation of care options. The withholding of care by providers and

health care staff violates the primary purpose of healthcare. By prioritizing the rights of the employees over the rights of the patients, the end result is a diminishment of the quality of care.

C. HIV/AIDS Care

21. CCH receives approximately $14 million in HHS funding to run the Ruth M. Rothstein CORE Center, and related programs in multiple CCH clinical sites, which provide comprehensive HIV/AIDS and other infectious disease testing and treatment services to more than 10,000 patients each year. The Core Center is one of the largest HIV/AIDS clinics in the U.S. specializing in prevention, care and research of HIV/AIDS and other infectious diseases.

22. It is highly likely that some CORE Center employees will have conscience objections because some individuals hold religious or conscience objections to treating individuals living with HIV or AIDs. Additionally, we anticipate conscience objections to distributing pre-exposure prophylaxis medications ("PrEP"). Some individuals have religious or conscience objections to PrEP because they believe it condones homosexuality, and certain sexual behaviors that they may find objectionable, such as premarital sex, extramarital sex, and unprotected sex. However, the Final Rule does not explain how CCH can adequately accommodate and protect conscience objectors or how HHS OCR will assess whether a recipient of HHS funding like CCH has violated the Final Rule. Thus, CCH faces a very real risk of losing all HHS funding under the Final Rule, particularly due to an alleged violation in the context of HIV/AIDS care.

23. My understanding is that under the Final Rule, if HHS finds that CCH or any of its grantees or subgrantees are in violation of the Final Rule, CCH could lose the above-referenced HHS funding under the funding termination scheme. As a result of loss of HHS funding, thousands of Cook County residents living with HIV who have limited or no prescription drug coverage would be deprived of the life-saving drugs provided by CCH.

24. HHS has publicly committed to ending the HIV epidemic in the United States by 2030, meaning getting to a 'functional zero" of new HIV infections by maximizing the number of people living with HIV who are in care and virally suppressed, and more aggressive utilization of proven HIV prevention tools such as PrEP (see www.HIV.gov). HHS is expecting its grantees around the country to employ scientific best public health practices to achieve this goal, inclusive of widespread implementation of targeted and routine HIV/STI screening, and rapid linkage to care. The CORE Center and its CCH system-wide HIV programs are committed to achieving this goal as well. The Final Rule will interfere with healthcare entities, including CCH's, achievement of this goal.

D. Staffing and Training Costs

25. The Final Rule would require CCH to expend time, resources, and effort by: modifying hiring practices; double or triple-staffing emergency functions in light of limits the Final Rule places on requiring advance notice of objections; and training staff on what behavior is now permissible from objectors and how to work around objections not planned for in advance.

26. Hiring additional staff to act as alternate providers is impracticable for CCH. As additional staffing is costly and it is not clear whether CCH can feasibly achieve this goal and realistically avoid harm to patient care. In fiscal year 2018, CCH directly employed the equivalent of 6,588 full-time and part-time staff, of whom 6,272 staff persons provided hourly, as opposed to salaried, services. CCH salaries for fiscal year 2018 amounted to over $600,000,000.

E. Cermak Health Services of Cook County

27. Cermak Health Services (CHS), which is a service line of CCH, is the daily provider of healthcare to approximately 6,000 patients at the Cook County Jail and JTDC CHS provides a comprehensive range of healthcare services.

28. We anticipate conscience objections to providing mental health care to this justice involved population. Such objections will significantly impact CHS patients in need of mental health services, as approximately 36 percent of patients housed at the jail are on the mental health case load.

29. Additionally, as the facility provides a broad range of services to all patients, we anticipate moral and religious objections to providing HIV/AIDS care, Medication Assisted Treatment for Substance Use Disorders, reproductive health services for women, and hormone therapy to transitioning patients. As CHS patients are not able to seek medical care elsewhere, objections in this area will have grave consequences for the 6,000 people who rely on us for necessary healthcare.

30. As a result of the Final Rule, and the risk that any employee may now refuse to provide patient care without advance notice, CCHHS must attempt to create contingency staffing plans to ensure that more than one of each necessary

professional is available at all times to provide care and prevent disastrous outcomes for the our patient population at the Cook County Jail and the Juvenile Temporary Detention Center.

F. Other Areas Impacted by the Final Rule

31. CCH staff members administer multiple vaccinations, including pediatric vaccinations, on a daily basis. CCH administered 31,519 flu vaccinations alone in 2018. In light of the number of vaccines hospital and clinic staff administer, accommodating an individual's refusal to provide vaccinations on religious or moral grounds would in nearly every case significantly burden CCH.

I declare under penalty of perjury that, to the best of our knowledge, the foregoing is true and correct.

Executed on this 7th day of June, 2019

John Jay Shannon, MD

Chief Executive Office
Cook County Health and Hospitals System

Exhibit 40

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF LISA SHERYCH

I, Lisa Sherych, declare:

1. I am the Interim Administrator of the Division of Public and Behavioral Health, for the Nevada Department of Health and Human Services. (NDHHS).

2. I make this Declaration in support of Plaintiffs' Motion for Preliminary Injunction based on my personal knowledge and NDHHS records, and would testify to the following facts if called as a witness at any hearing on this Motion.

3. According to TAGGS, Nevada received over $2.6 billion in federal health care funding from the Department of Health and Human Service (Department) in the 2018 federal fiscal year.

4. For the upcoming two year Nevada budget beginning July 1, 2019, Nevada expects to spend more than $6.7 billion on federal reimbursement for medical services alone, with significant additional Department monies for additional services.

5. Nevada uses these funds to provide numerous services to its citizens that are unrelated to what the Final Rule at issue in this case purports to regulate, serving more than one million Nevadans.

6. For instance, Nevada expects to receive more than $102 million in federal funding for its Women, Infants and Children program during its upcoming two year budget. These programs serve more than 56,000 Nevadans at last count in February 2019.

7. Further, Nevada expects to receive more than $63 million in federal funding for substance abuse programs in its upcoming two year budget, which seek to address the opioid crisis facing Nevada.

8. Finally, Nevada expects to receive more than $19 million in federal funding for children's mental health services in its upcoming two year budget.

9. Implementation of the Final Rule, absent this Court's intervention, means NDHHS will have to expend more resources to ensure adequate care while attempting to avoid the risks associated with the Final Rule penalties.

I hereby declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

Executed on this 7th day of June, 2019

LISA SHERYCH
Interim Administrator
Division of Public and Behavioral Health
Nevada Department of Health and Human Services

Exhibit 41

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF KYLEEANN STEVENS, M.D.

1. I, KyleeAnn Stevens, M.D., pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the State of Minnesota, related to litigation involving the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through Minnesota Department of Human Services ("MDHS") personnel who have assisted me in gathering this information from our agency, or on the basis of documents that I reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon MDHS.

3. I am employed by MDHS as the Executive Medical Director for Behavioral Health. As the Executive Medical Director, I oversee medical services at all of MDHS's treatment programs which are within the Direct Care and Treatment division of MDHS ("DCT").

4. MDHS receives federal funds from HHS, including Medicaid and Medicare dollars, that, among other things, assist in the operation of an array of residential and treatment programs serving people with mental illness, developmental disabilities, and chemical dependency.

5. DCT understands that the Final Rule expands certain definitions, including "assist in the performance" and "discrimination" that may affect how DCT administers its programs.

6. MDHS anticipates that its employees or subcontractors could assert religious or moral objections to certain services that DCT provides to patients, or to services that are provided to DCT patients that are reimbursed by federal funds. While there is a lack of clarity as to who or what may fall under the scope of the Final Rule, DCT must make preparations in order to comply with the Final Rule.

7. For example, MDHS operates six Community Behavioral Health Hospitals ("CBHH"). CBHHs provide short-term, acute inpatient psychiatric services in 16-bed stand-alone facilities, most of which are located in rural areas, geographically separated from other health care resources. CBHHs have very limited staff, including a limited nursing staff. In fact, in all CBHHs, only one primary care nurse practitioner serves the entire facility. DCT also operates pharmacies throughout Minnesota that annually dispense approximately 3 million doses of medications to patients in our care. Given the breadth of the Final Rule, including its definition of "assist in the performance," DCT anticipates it may have issues adequately caring for patients without expending additional resources to cover instances where employees or subcontractors refuse to provide care based on religious or moral objections.

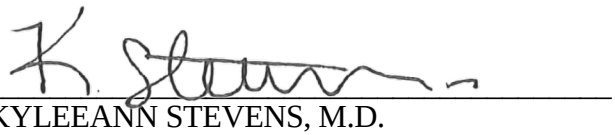
8. DCT provides care and treatment to individuals who have been civilly committed for mental illness, chemical dependence, and/or developmental disability. These individuals are often unable to care for or advocate for themselves. Limiting their ability to access health care places them at greater risk for physical and emotional harm.

9. MDHS also refers its patients for health care services to outside entities, that are reimbursed by MDHS with federal funds. MDHS may need to expend additional administrative costs to ensure its patients receive timely and appropriate care in the event an outside entity makes any religious or moral objection to a health care procedure.

10. If HHS funds cut off funding for Minnesota's state hospitals, they could not remain CMS-certified and the State would have to independently fund its health care services.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 7th day of June, 2019



KYLEEANN STEVENS, M.D.

Executive Medical Director for Behavioral Health

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Exhibit 42

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF KIMBERLY SWARTZ

1. I, Kimberly Swartz, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I am the Director of Preventive Reproductive Health, in the Maternal and Child Health Division at the Vermont Department of Health (VDH) and have served in this position since 2014. I oversee Vermont's family planning services grants. I am responsible for preparing subrecipient agreements, monitoring grant activities, and for all federal reporting requirements. In addition, I oversee the Center for Disease Control-funded Rape Prevention and Education Program. I also supervise the program manager for adolescent sexual and reproductive health. I have a Master's degree in health sciences from the University of Toronto. I have worked at VDH for more than seven years, with five in the Maternal and Child Health Division. Previously, I served as a program manager in the chronic disease division of VDH as part of the women's health preventive screening program.

3. I submit this Declaration in support of the State of Oregon's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule").

4. I make the statements set forth below based on my personal knowledge, through information obtained from other VDH personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me.

5. Title X of the Public Health Service Act authorizes the Title X Family Planning program, which is administered by HHS. The Title X Family Planning program distributes funding to grantees to provide individuals with comprehensive family planning and preventive health services.

6. VDH is the sole Title X grantee for the State of Vermont and the funds are administered by the Division of Maternal and Child Health. VDH has overseen administration of Vermont's Title X funds since Congress passed Title X in 1970.

7. In fiscal year 2017-2018, Vermont's Title X grant award was $781,000. This is consistent with the level of funding Vermont has received over the last ten years, with minor fluctuations.

8. Some of the critical services funded with Title X dollars include:

- Contraceptive management of FDA-approved contraceptive methods and client counseling on contraception use;
- Pap tests;
- Screening tests for sexually transmitted infections (STI), including Human Immunodeficiency Virus (HIV); and
- Pregnancy tests as indicated and according to nationally-recognized standards of care.

9. VDH releases a Request for Proposals from potential Title X sub-grantees at the beginning of every three-year project period. Since the program's inception, Planned Parenthood of Northern New England (PPNNE) has been the sole bidder and has been awarded the funds to distribute among ten of the twelve PPNNE Health Centers in Vermont. Although VDH releases its Request for Proposals broadly, to my knowledge PPNNE is the only provider in Vermont currently willing and able to implement the Title X program statewide.

10. Vermont's Title X Health Centers are geographically spread out across the state's fourteen counties. These Health Centers serve largely rural and vulnerable populations.

11. Approximately 10,000 Vermonters currently access Title X services annually, 46% of whom are under the age of 25 and 47% of whom are between the ages of 25-44. Twelve percent of individuals accessing Title X services are male. In addition, 77% of individuals accessing Title X services are at or below 250% federal poverty level (FPL), with 41% at or below 100% FPL. Approximately 7% Title X patients identify as people of color, compared with less than 5% of Vermont's population as a whole.

12. In 2017, Title X funding provided 1449 Pap tests and 1907 clinical breast exams. In addition, 4908 females and 1067 males received chlamydia testing.

13. One estimate shows that approximately 1,900 unintended pregnancies were averted by Title-X funded clinics in Vermont in 2014. Of those, 400 would have been teen pregnancies.

14. Title X programs have provided high-quality standard of care services. For example, non-directive options pregnancy counseling that includes all options is consistent with medical and ethical standards and the advice of medical professional organizations. VDH has worked with partners like the Blueprint Women's Health Initiative to ensure that medical providers are trained in best practice approaches to contraceptive counseling, which is grounded in medical accuracy and a comprehensive understanding of the full range of contraceptive methods.

15. PPNNE offers education and counseling on reproductive health for both men and women; the provision of birth control, including emergency contraception; testing and treatment of HIV, gonorrhea, chlamydia and the HPV virus; pregnancy testing and services; breast and cervical cancer screenings; and safe and legal abortion. In addition, all PPNNE health centers in Vermont offer PEP and PReP for HIV prevention; trans-health services for transgender patients; primary care; prenatal screenings and referrals; and referrals for female and male sterilizations (Essure and vasectomies).

16. PPNNE is monitored by VDH to ensure compliance with all Title X program polices, statutes and regulations, legislative mandates and program priorities. VDH enforces strict accounting protocols and audit procedures to ensure that Title X funds are used for Title X services only. The Office of Population Affairs monitors VDH through a comprehensive Program Review approximately every 3 years. VDH and PPNNE have a demonstrated history of full compliance with Title X policies.

17. Because the Final Rule threatens cuts in funding to grantees for the non-compliance of their subgrantees, VDH understands that it would be expected to ensure that its subgrantees are in compliance. This would add to the administrative costs of the Title X program. In addition, under the Final Rule, a staff member or practitioner's decisions with respect to "assist[ing] in the performance" of care will not only disrupt the care of individual patients dependent on that provider, but also undermine the efficacy of the Title X program.

18. The Final Rule's broad requirements to allow religious objection without notice are unnecessary, will increase the overall cost of medical care, and ultimately hinder access to reproductive services. Vermont's Title X provider network has spent the past several years improving existing facilities and opening new facilities to better reach underserved areas of the state. Vermont, similar to much of the United States, has a shortage of qualified medical providers to meet current patient care needs. Requiring, for instance, that facilities maintain additional staff to cover patient needs in the event of any sudden religious objection puts further strain on the network of providers. This will lead to delays in access to care, which could have significant impacts on unintended pregnancy rates, STI treatment, and early cancer detection and intervention. These unprevented and untreated diseases and pregnancies will result in increased costs to the State.

19. PPNNE has historically been the only Title X applicant within the State, and there are no known other organizations able to provide the same services statewide.

20. If Vermont becomes ineligible for Title X funds, Vermont has no known, sustainable source of funds available to replace the Title X funding.

I hereby declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

Executed on this 7th day of June, 2019.

Kimberly Swartz
Director, Preventive Reproductive Health
Maternal and Child Health Division
Vermont Department of Health

Exhibit 43

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE DECLARATION OF CRAIG S. THOMAS, M.D.

DECLARATION OF CRAIG S. THOMAS, M.D.

Pursuant to 28 U.S.C. § 1746, I, Craig S. Thomas, M.D., hereby declare as follows:

1. I am the President of Hawaii Emergency Physicians Associated, Inc., a Hawai'i professional corporation and the largest emergency department physician group in the State of Hawai'i ("HEPA").

2. I am aware that from or around October 12, 2011, HEPA and Hawaii Health Systems Corporation, a body corporate and politic and an instrumentality and agency of the State of Hawai'i ("HHSC"), pursuant to Chapter 323F, Hawaii Revised Statutes, entered into a professional services agreement, in which HEPA agreed to provide emergency department physician services to certain HHSC facilities.

3. I submit this Declaration in support of the State of Hawai'i's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through HHSC personnel who have assisted me in gathering this information from its facilities, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon HHSC.

4. HHSC is a public hospital system comprised of a network of hospitals and clinics within its regional health care systems on the islands of Oahu, Kauai, and Hawaii (which is divided into two regions, East Hawai'i, and West Hawai'i due to the size of the island). HHSC is dedicated to providing high quality health care services to residents and visitors in the State of Hawaii regardless of the ability to pay. In this regard, HHSC serves as a vital component of the State of Hawai'i health care safety net. HHSC facilities include Hilo Medical Center, Yukio Okutsu State

Veterans Home, Hale Ho'ola Hamakua, Ka'u Hospital, Kona Community Hospital, Kohala Hospital, Leahi Hospital, Maluhia, Kauai Veterans Memorial Hospital, Samuel Mahelona Memorial Hospital, and all related outpatient and ancillary facilities.

5. I am aware that in fiscal year 2018, HHSC facilities provided a total of 13,016 acute care admissions, 575 long-term care admissions, delivered 1,872 babies, handled 75,456 emergency department visits, and employed a total of 2,526 full time equivalent personnel. In fiscal year 2018, HHSC facilities provided approximately 12% of all acute care discharges and 16% of all emergency department visits statewide, approximately 69% of all acute care discharges and 84% of all emergency department visits in Hawai'i County (of which HHSC operates four of the five hospitals, and approximately 19% of acute care discharges and 37% of all emergency department visits in Kauai County (of which HHSC operates two of the three hospitals).

6. HEPA contracts with HHSC to provide emergency department physician services at Hilo Medical Center ("HMC") and Hale Ho'ola Hamakua ("HHH"), a critical access hospital, ("CAH") on the island of Hawai'i, Kauai Veteran's Memorial Hospital ("KVMH") and Samuel Mahelona Memorial Hospital ("SMMH") both of which are on the island of Kauai and both of which are CAHs.

7. In fiscal year 2018, the HMC and HHH emergency departments experienced 48,715 and 2,022 visits respectively, KVMH and SMMH experienced 6,820 and 6,259 visits respectively.

8. HHSC facilities protect an employee's right to not participate in the treatment of a patient where that treatment presents a conflict with the sincerely held religious belief of the employee, provided that the employee submits a request not to participate in treatment prior to

the need for the employee to participate in any such treatment and the employee is willing to be reassigned to another department. Reassignment is commonly referred to as "floating".

9. The absence of advance notice of a conflict or ambiguity about whether a particular treatment causes a conflict may have an immediate and damaging impact on HHSC and the rural communities that it serves. The requirement of prior notice is essential in the HHSC emergency departments for which HEPA provides services because HEPA's ability to effectively provide the necessary services in these rural areas is incumbent upon the hospitals being able to provide the necessary staff with needed skills and expertise.

10. Some of the HHSC rural hospitals, for example HHH, may only have one nurse on shift with the necessary competencies to work in the emergency department. Without advance notice, if this employee refuses to provide care and the hospital cannot get another employee in place, which is likely due to the long distances that employees residing in these rural areas must commute, patient care and in turn the public health of the communities that HHSC serves will suffer severe impacts.

11. HEPA doctors staffing HHSC emergency departments work on three different electronic health record ("EHR") systems. "Floating" one employee to another area or department of the hospital may not be reasonable because the objecting employee may not have access rights to the EHR in the department that the employee is "floating" to. Similarly, an employee who works in the intensive care unit may not have access rights to the emergency department. Security of personal health information ("PHI") of patients is of great importance. As a result, facilities take great care in determining the extent of the access rights of all of its employees.

12. The Final Rule presents unworkable situations for our HHSC in the following ways:

A. While accommodating employees' personal beliefs and objections is desirable, the ability of the hospital and HEPA to always deliver the community standard of care is the most important factor to be considered. We can make reasonable accommodations, but "reasonable" must be understood to allow for care to be delivered according to community standards which in many cases includes the timeliness or rapidity with which such care is provided.

B. Hospitals are under strict regulation and must deliver care that meets accepted professional and community standards for each condition or face lawsuits for malpractice, loss of the right to provide care from regulatory agencies, and loss of reimbursements from third party payors. HEPA, as the sole provider of emergency services at the HHSC facilities identified above, is similarly obligated to provide timely care that complies with local and national standards. The standard of care for many conditions is time sensitive. Care delivered incompletely, or too late, may result in death or adverse outcomes that would not have occurred had the standard been met.

C. For example, when a patient injured in a car crash arrives in shock at the emergency department blood products must be rapidly administered or the patient will die. When a woman presents with lower abdominal pain due to an ectopic pregnancy the failure to quickly operate can result in rupture, hemorrhage, and death. Even in end-of-life situations, if a patient and family expect advance directives eschewing advanced life support to be followed and they are not, this can inflict pain and suffering on the patient and family. These outcomes are not hypothetical; they may and frequently are the result when care is untimely or inappropriate.

D. The unforeseen refusal of an employee, whether HHSC's or HEPA's, to participate in care will likely result in failure to meet the standard of care in situations where staffing limitations do not allow for the rapid substitution of another properly trained employee.

13. Rural hospitals provide the only emergency and hospital care available to a large geographic area while having a limited pool of employees. The one physician on duty must provide a full complement of services to meet appropriate standards. It is difficult to see how HEPA can make reasonable accommodation for emergency physicians unable to provide necessary care. Hospitals have similar restrictions, if they are unable to ascertain in advance whether an employee will perform the necessary duties of their position, and determine whether they can make reasonable accommodations, the health of all individuals in that community is potentially affected and the health of some will be compromised.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 10th day of June 2019

Craig S. Thomas M.D.
President
Hawaii Emergency Physicians Associated, Inc

Exhibit 44

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF WAYNE TURNAGE

1. I, Wayne Turnage, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the District of Columbia's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and the United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). The statements below are based on my personal knowledge of information and data produced by the Department of Health Care Finance ("DHCF"), the Department of Health ("DC Health"), and the Department of Behavioral Health ("DBH"). In addition, I have familiarized myself with the District's obligations under the Final Rule in order to assess its immediate impact on the Health Cluster.

3. I am the Deputy Mayor for Health and Human Services for the District of Columbia and the Executive Director of the District of Columbia Department of Health Care Finance. I have been the Deputy Mayor for Health and Human Services since March 2019, and the Director of the District of Columbia Department of Health Care Finance since 2011. Prior to 2011, I served as the Deputy Secretary of Health and Human Resources from 2002 to 2004 under Governor Mark Warner in the State of Virginia, and as a researcher for both public and private organizations from 1985 to 2002. I received my Master of Public Administration degree from the Ohio State University in 1982, and my Bachelor of Science degree from North Carolina A & T University in 1980. The Deputy Mayor for Health and Human Services supports the Mayor of the District of Columbia in coordinating a comprehensive system of benefits, goods and services across multiple agencies to ensure that children, youth, and adults, with and without disabilities, can lead healthy, meaningful and productive lives. The District of Columbia Department of Health Care Finance, Department of Behavioral Health, and DC Health, all contribute to the local Health and Human Services that fall under the purview of the Deputy Mayor for Health and Human Services.

4. The District of Columbia Department of Health Care Finance (DHCF) is the single state agency for the administration of Medicaid in the District of Columbia (the "District"). DHCF is accountable to the United States Centers for Medicare and Medicaid Services ("CMS"), the federal agency responsible for administration and oversight of the Medicaid program under Titles IXX and XXI of the Social Security Act, as amended by the Patient Protection and Affordable Care Act (the "ACA") and accompanying regulations. The mission of the Department of Health Care Finance is to improve health outcomes by providing access to comprehensive, cost-effective and quality healthcare services for residents of the District of Columbia. These programs fund health care to over 250,000 residents who meet income thresholds established by the District in accordance with federal guidelines.

5. DC Health promotes health, wellness, and equity across the District, and protects the safety of residents, visitors and those doing business in our nation's Capital. DC Health is responsible for identifying health risks; educating the public; preventing and controlling diseases, injuries and exposure to environmental hazards; promoting effective community collaborations; and optimizing equitable access to community resources.

6. The District of Columbia Department of Behavioral Health (DBH) provides prevention, intervention and treatment services and supports for children, youth and adults with mental and/or substance use disorders including emergency psychiatric care and community-based outpatient and residential services. DBH serves eligible adults, children and youth and their families through a network of community-based providers and unique government-delivered services. It operates Saint Elizabeths Hospital—the District's inpatient psychiatric facility.

7. DHCF received more than $2.2 billion from HHS/CMS in Fiscal Year 2019 for provider payments and the administrative costs of the District's Medicaid and CHIP programs.

8. In addition to this essential funding that HHS provides to ensure that all District residents have adequate healthcare coverage, several divisions and programs in DC Health and DBH receive grants from HHS agencies to address specific public health problems in the District. Among these grants are:

- An approximate $1.8 million grant from the Centers for Disease Control and Prevention ("CDC") to DC Health's Community Health Administration ("CHA") to support programs to prevent and manage diabetes, heart disease, and stroke;
- An approximate $1.9 million grant from the Health Resources and Services Administration ("HRSA") to the CHA to support the District's Maternal, Infant and Early Childhood Home Visiting Program;
- Grants for more than $45.5 million from the HRSA to DC Health's HIV/AIDS, Hepatitis, STD, and TB Administration ("HAHSTA") under Parts A and B of the Ryan White Comprehensive AIDS Resources Emergency ("CARE") Act to address the unmet health needs of persons living with HIV disease by funding primary health care and support services that enhance access to and retention in care, and to improve access to primary medical care and medication for the treatment of HIV;
- A grant for more than $6.3 million from the CDC to HAHSTA to reduce transmission and prevent new infections of HIV and STDs and enhance interventional surveillance; and
- Several grants totaling more than $38 million from HHS's Substance Abuse and Mental Health Services Administration ("SAMHSA") to DBH to help provide mental health services; substance abuse prevention, treatment, and recovery services; treatment for substance use disorders and/or co-occurring mental disorders for youth

and their families and caregivers; and prevention, treatment, and recovery support services to individuals with opioid use disorder.

9. HHS funding is essential to the functioning of DHCF, DC Health, and DBH to accomplish their respective missions, which include critical efforts to maintain essential health care coverage for the more than 250,000 District residents enrolled in the Medicaid and CHIP programs, to address serious public health concerns, including the opioid epidemic and maternal mortality, and to provide care to eligible adults with mental health and substance use disorders in the District.

10. Should HHS's Office of Civil Rights ("OCR") find that the District does not comply with the Final Rule, this crucial funding for healthcare and public health projects could be terminated.

11. It is my understanding that the Final Rule expands definitions of terms like "assist in the performance," "discrimination," and "health care entity" in ways that affect how DHCF, DC Health, and DBH function, yet there is a lack of clarity as to who and what falls under these terms. Even so, DHCF, DC Health, and DBH must prepare for compliance with Final Rule.

12. The Final Rule could have an immediate impact upon DBH and the persons served at St. Elizabeths and the other locations DBH serves. My understanding is that under the Final Rule, any employee may object on religious, moral or other grounds to providing any of the innumerable mental health services that DBH provides to the persons with mental health disorders in the District. For example, as worded, under the Final Rule, an employee could refuse to counsel or even to provide janitorial services to an LGBTQIA+ person if the employee has a religious, moral, or other objection to that person's sexual orientation or gender expression. As worded, under the Final Rule, DBH would not be able to discipline, terminate, or take any adverse action against an employee who refused to provide services to a person based on a religious, moral, or other objection—even if the employee

provided no advance notice. This could wreak havoc upon DBH's ability to plan and staff to provide patient care – which in turn could harm the mental health of the people we serve.

13. In addition, DBH must review all agreements of any kind with more than 50 subrecipients of HHS funding for the provision of mental health services to ensure that the other parties to the agreements are aware of the Final Rule and their obligations under it. It is my understanding that the Final Rule threatens the District's HHS funding if third parties that receive HHS funds through DBH are found to be out of compliance with the Final Rule.

14. It is my understanding that the Final Rule threatens to terminate all HHS funding to States, including the District, that violate the Final Rule through subrecipients of HHS funds. Consequently, although DHCF and DC Health do not operate any healthcare facilities in the District, DHCF and DC Health must review and assess agreements with all affected subcontractors or subgrantees of any kind to enforce the Final Rule and the District's obligations under it. This includes approximately 12,000 Medicaid providers that deliver health and other services to District residents.

15. In addition to the increased burdens imposed on the District to ensure that subrecipients of HHS funding comply with the Final Rule, its subcontractors or subgrantees may still fail to comply, and jeopardize billions in critical funding from HHS.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 13th day of June, 2019

Wayne Turnage, M.P.A.
Deputy Mayor for Health and Human Services

Exhibit 45

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

JOINT DECLARATION OF DR. TERRY VANDEN HOEK AND RHONDA PERNA

1. I, Terry Vanden Hoek, and I, Rhonda Perna, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. We submit this Declaration in support of the State of Illinois's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). We have compiled the information in the statements set forth below either through personal knowledge, through University of Illinois Hospital & Health Sciences System personnel who have assisted us in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by us. We have also familiarized ourselves with the Final Rule in order to understand its immediate impact upon the University of Illinois Hospital & Health Sciences System.

3. I, Dr. Terry Vanden Hoek, am the Head of Emergency Medicine and Chief Medical Officer at the University of Illinois Hospital & Health Sciences System located in Chicago, IL. I have been employed as the Head of Emergency Medicine at the University of Illinois Hospital & Health Sciences System for 8 years, and I have been the Chief Medical Officer at the University of Illinois Hospital & Health Sciences System for over 1 year. I received my Bachelor of Science degree from Calvin College, I received my M.D. at the University of Chicago, and I did my Emergency Medical training at the University of Cincinnati.

4. I, Rhonda Perna, am the Senior Director, Risk Management, Patient Safety, and Physician Excellence at the University of Illinois Hospital & Health Sciences System located in Chicago, IL. I have been employed as Senior Director, Risk Management, Patient Safety, and Physician Excellence at the University of Illinois Hospital & Health Sciences System since December 2014. My educational background includes the following degrees: a B.S. in Biology from St. Mary's College, 1980, a B.S.N. from Creighton University, 1981, an M.B.A. from University of Dallas, 1988,

and a J.D. from Seattle University, 2004. I am also licensed to practice law in the state of Washington and I have a nursing license in the state of Illinois.

5. The University of Illinois Hospital & Health Sciences System provides comprehensive care, education, and research to the people of Illinois. The University of Illinois Hospital & Health Sciences System comprises a clinical enterprise that includes a 465-bed tertiary care hospital, 21 outpatient clinics, and 11 Mile Square Health Center facilities which are Federal Qualified Health Centers.

6. The hospital cares for more than 135,000 unique patients every year. The hospital consists of numerous departments, including emergency medicine, surgery, infectious diseases, nephrology, radiology, ophthalmology, pediatrics, and organ transplants. Among the many medical treatments provided to the public, the hospital offers abortions and vaccinations, including pediatric vaccinations.

7. The University of Illinois Hospital & Health Sciences System also includes the seven University of Illinois at Chicago health science colleges: the College of Applied Health Sciences, the College of Dentistry, the School of Public Health, the Jane Addams College of Social Work, and the Colleges of Medicine, Pharmacy, and Nursing, including regional campuses in Peoria, Quad Cities, Rockford, Springfield, and Urbana. The University of Illinois College of Medicine is the largest medical school in the country.

8. The University of Illinois Hospital & Health Sciences System employs over 4,000 individuals, including over 1,100 physicians and advanced practice providers.

9. The University of Illinois Hospital & Health Sciences System received in excess of $765,000 in federal funds during fiscal year 2018 alone.

10. These funds are essential to the functioning of the University of Illinois Hospital & Health Sciences System and maintaining public health within the state of Illinois.

Existing University of Illinois Hospital & Health Sciences System policy to address religious objections

11. The University of Illinois Hospital and Clinics within the University of Illinois Hospital & Health Sciences System are committed to protecting the rights of credentialed providers and healthcare personnel to opt out of providing healthcare services due to their religious beliefs or a conflicting moral conviction while ensuring that all patients receive appropriate care without an unreasonable delay that causes impairment of the patient's health.

12. The University of Illinois Hospital and Clinics within the University of Illinois Hospital & Health Sciences System maintain a policy expressly stating that conscience protections apply to credentialed providers and healthcare personnel who refuse to perform, accommodate, or assist with certain healthcare services (such as abortions, sterilizations, and do-not-resuscitate orders) on religious and moral grounds. This policy is consistent with, and seeks to comply with, the Illinois Health Care Right of Conscience Act, 745 ILCS 70/.

13. Pursuant to the policy, credentialed providers and healthcare personnel desiring exclusion from patient care must: (1) notify his/her supervisor or designee immediately of his/her concern and verbally request that he/she be excused from active participation in a particular procedure or aspect of a procedure; (2) provide appropriate care to the patient until alternative arrangements for patient care is obtained; and (3) document verbal requests for exclusion from patient care.

14. Requiring individuals who desire to be excluded from providing certain healthcare services on religious or moral grounds to take the steps set forth above allows our institution to meaningfully accommodate an individual's beliefs while also avoiding disruptions in patient care.

Immediate impact of the Final Rule upon University of Illinois Hospital & Health Sciences System

15. The Final Rule has an immediate and damaging impact upon the University of Illinois Hospital & Health Sciences System and the communities it serves in Illinois.

16. It is our understanding that the Final Rule expands definitions of terms, such as "assist in the performance," "discrimination," "health care entity," in ways that affect how the University of Illinois Hospital & Health Sciences System functions.

17. It is unclear from the Final Rule who/what falls under these terms, yet the University of Illinois Hospital & Health Sciences System must prepare for compliance with the Rule.

18. It is also our understanding that the Final Rule prohibits any restrictions upon the ability of individuals to object to assisting in the performance of any procedure they find objectionable on religious or moral grounds.

19. As a result of the Rule and the risk that any individual may now refuse to provide patient care at any time, the University of Illinois Hospital & Health Sciences System must create contingency staffing plans to ensure that more than one of each necessary professional is available at all times. As a result of the Rule, we have begun to have conversations about the creation of these contingency staffing plans.

20. In most cases, because of union contracts, preparing for contingency staffing requires hiring additional staff rather than "substituting" existing staff into other roles. For

example, certain collective bargaining agreements do not allow staff to work across units. Thus, for example, a nurse in the obstetrics department who raised a conscience objection to a procedure could not be substituted with another qualified nurse with the emergency department.

21. The costs and difficulty of establishing contingency staffing plans for every staff member a patient may encounter in a hospital visit are illustrated below in the context of an emergency room visit.

22. The hospital in the University of Illinois Hospital & Health Sciences System has a standard emergency room and a specialized obstetrics emergency room. Any pregnant woman who presents to the standard emergency room with an obstetrics problem is transferred to the obstetrics emergency room. A woman who arrives at the standard emergency room with an obstetrics problem, such as an ectopic pregnancy, and who is transferred to the obstetrics emergency room will encounter a large number of staff members in her course of treatment.

23. These staff members include: (i) a clerk in the emergency department; (ii) a transporter to take the patient to the obstetrics emergency room; (iii) a triage nurse; (iv) a physician, who may be accompanied by residents, to perform a medical screening exam; (v) an ultrasound technician specially trained in prenatal ultrasound; (vi) a maternal fetal medicine physician to interpret the ultrasound; (vii) a lab technician; and a (viii) respiratory therapist.

24. If the woman is transferred from the obstetrics emergency room to the obstetrics operating room, as would likely be the case for a woman with an ectopic pregnancy, she will there encounter an (ix) operating room technician; (x) a circulating nurse; (xi) an anesthesiologist; (xii) a surgeon; (xiii) a scrub technician; (xiv) a surgical technician; (xv) medical residents; and (xvi) a supervising charge nurse.

25. Each of these staff members plays a critical role in an emergency situation, and as we understand the Final Rule's definitions, would have "assisted in the performance" of the emergency medical treatment to address the ectopic pregnancy. In light of the Final Rule, the University of Illinois Hospital & Health Sciences System must prepare for the possibility that any one of these critical staff members could object on religious or moral grounds at any time to assisting in the provision of care to a woman with an emergency situation such as an ectopic pregnancy. In essence, the requirements of the Final Rule force the hospital at the University of Illinois Hospital & Health Sciences System to double-staff each essential role to avoid any staff member abruptly objecting, refusing to provide care, and harming a patient. Such additional staffing is costly and virtually unfeasible in every situation.

26. The Final Rule also has grave implications in non-emergency care situations.

27. Staff at the hospital and clinics of the University of Illinois Hospital & Health Sciences System administer multiple vaccinations, including pediatric vaccinations, on a daily basis. In light of the number of vaccines hospital and clinic staff administer, accommodating an individual's refusal to provide vaccinations on religious or moral grounds would in nearly every case significantly burden the University of Illinois Hospital & Health Sciences System.

28. It is our understanding however, that the inability to accommodate such a refusal could expose the University of Illinois Hospital & Health Sciences System to devastating consequences. These consequences, as we understand them, include the loss of federal health-related funds, including the hundreds of thousands of dollars the University of Illinois Hospital & Health Sciences System receives from the federal government.

We declare under penalty of perjury that, to the best of our knowledge, the foregoing is true and correct.

Executed on this 5 day of June, 2019

Terry Vanden Hoek, MD, FACEP

Chief Medical Officer and Head of Emergency Medicine
University of Illinois Hospital & Health Sciences System

Rhonda Perna, RN, JD, CPHRM

Senior Director, Risk Management, Patient Safety, and Physician Excellence
University of Illinois Hospital & Health Sciences System

Exhibit 46

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA, Defendants.	CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF FIKIRTE WAGAW

1. I, Fikirte Wagaw, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the City of Chicago's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through the City of Chicago's Department of Public Health ("CDPH") personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and reviewed by me. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon CDPH.

3. I am the First Deputy Commissioner of CDPH located in Chicago, Illinois. My educational background includes a BA in Psychology and a Masters of Public Health with a focus on health policy and administration. I have worked in the field of Public Health for 23 years. I have been employed as First Deputy Commissioner since June 2016. I previously worked at CDPH in many other capacities over 14 years, mostly in the HIV/STI Bureau where I oversaw HIV prevention and care programs funded by and provided by CDPH with a focus on populations and communities disproportionately impacted by HIV and sexually transmitted infections.

CDPH Relies Heavily on Federal Funding to Serve Chicago's Public Health Needs

4. CDPH operates the City's public health system, whose work focuses on assuring that the City's policies, systems, and environments support the health and well-being of its 2.7 million residents and more than 50 million visitors each year. CDPH provides or directly funds a wide array of health services and programs in areas like communicable diseases, mental health, inspection of food establishments, and paint-based lead inspections in homes. CDPH's work is

guided by Healthy Chicago 2.0, the citywide plan to improve health equity by focusing on neighborhoods and communities that face the greatest health disparities, and allocating its limited resources to these areas where they are needed most.

5. CDPH has approximately 600 employees who work out of more than 20 locations, and is organized into 8 Bureaus: Health Protection; Behavioral Health; HIV/STI; Maternal, Infant, Child and Adolescent Health; External Affairs; Strategy and Development; Finance and Contracts; and Administration and Operations.

6. CDPH's 2019 annual budget is $177 million. Approximately 50% of this total budget—over $89 million—comes from federal health care grants from HHS. These grants include approximately $6.5 million for HPV and other vaccine coverage; $9.25 million for maternal and child health; $40 million for HIV prevention and treatment; $3.4 million for sexually transmitted disease and teen pregnancy prevention; and over $19 million for bioterrorism and Ebola preparedness and response.

7. Some of the federal funds CDPH receives are passed through by the State of Illinois and its Department of Public Health. For example, the Illinois Department of Public Health provided CDPH with a $9.02 million, two-year grant in 2017 that funds programs for maternal and child health services, including an at-home visitation program for at-risk pregnant mothers and their infants. This state grant originated with funds from HHS.

8. CDPH operates 13 clinics located throughout the City that provide health care services to its residents without charge to the individual, including pediatric vaccinations, mental health services, and testing and treatment for sexually transmitted diseases ("STIs"). Some clinics offer multiple services in one location. Specifically, CDPH operates 5 clinics that provide immunizations, 5 mental health clinics, 3 clinics for STI screening and treatment, and 7 clinics for

the Supplemental Nutrition Program for Women, Infants, and Children ("WIC"). CDPH also provides in-home nurse case management for children with high lead blood levels and mothers of high risk infants.

9. In addition to operating its own clinics, CDPH uses many of the health care grants it receives from HHS to partner with approximately 89 community-based providers through approximately 150 contracts who offer services to some of the City's most vulnerable and marginalized populations. Indeed, the majority of health services CDPH provides are through delegate agency agreements with these community-based providers. In 2018, CDPH awarded $57.8 million in delegate agency contracts, of which approximately $30 million were sourced from HHS funding.

10. For example, CDPH partners with Planned Parenthood to provide teen pregnancy prevention, STI/HIV health education and STI screening to youth and young adults in Chicago, providing almost $420,000 in 2018-2019. It also partners with an array of community organizations that serve Chicago's LGBTQ communities, which are disproportionately impacted by discrimination and certain diseases such as HIV. Some of these community-based organizations receiving HHS grants include:

a. Access Community Health, which was awarded $101,663.00 for Integrated HIV Surveillance and Prevention in 2018;

b. Center on Halsted, which was awarded $113,769.00 for Integrated HIV Surveillance and Prevention in 2018;

c. Heartland Human Care Services, which was awarded $177,692.00 for a Reduce HIV & Improve Care for MSM & Transgender Persons Grant in 2018;

d. Howard Brown Health, which was awarded $129,276.00 for STD Assessment, Assurance, Policy Development and Prevention Strategies, and $177,692.00 Reduce HIV & Improve Care for MSM & Transgender Persons Grant, in 2018;

e. Chicago Black Gay Men's Caucus, which was awarded $255,959.00 for Integrated HIV Surveillance and Prevention in 2019;

f. AIDS Foundation of Chicago, which was awarded $5,878,915.70 for an HIV Emergency Relief Project in 2018; and

g. Hektoen Institute for Medical Research, which was awarded $260,500.30 for an HIV Emergency Relief Project Grant in 2018, $247,942.00 for Reduce HIV & Improve Care for MSM & Transgender Persons Grant in 2018, and $31,459 for Integrated HIV Surveillance and Prevention in 2019.

11. Accordingly, the funds CDPH receives from HHS are essential to the functioning of our public health system and for maintaining the health and well-being of our residents.

Compliance With the Final Rule Will Be Difficult and Damaging to Public Health

12. The Final Rule could have far-reaching and devastating effects on CDPH's ability to protect and improve Chicago's public health. Foregoing federal health care funds or choosing to not comply with the Final Rule is simply not an option: HHS grants comprise 50% of CDPH's annual budget, and CDPH would be unable to operate in a meaningful way without this funding source.

13. Compliance with the Final Rule, however, will be burdensome, and difficult to implement and enforce, putting Chicago's citywide public health plan (Healthy Chicago 2.0), and CDPH's mission and very existence at risk. This is due to the Final Rule's broad definitions expanding the scope of such terms as "assist in the performance," "discrimination," and "health care entity," its lack of objective procedural standards for reviewing compliance complaints, its conflict with other federal and state law requirements, and its harsh penalties.

14. For example, due to its limited resources, CDPH relies greatly on a referral system: its staff frequently and regularly provides patients with information about, descriptions

of, and directions to other private or county-or-state-run health facilities in order to arrange for health services CDPH does not provide.

15. If an employee at one of CDPH's clinics refuses to provide referrals, or even directions, to Planned Parenthood for family planning services or emergency contraception based upon a religious objection, any number of patients could be left without receiving critical health care services. And in the case of communicable diseases, all it takes is one untreated case to spread through the population to create a health crisis, as has been recently seen in the outbreak of measles cases. Furthermore, such action would be at odds with state law, which requires Illinois health care providers to give patients information concerning their condition and proposed treatment. *See* 410 ILCS 50/3.

16. Likewise, there is no reasonable way for CDPH to monitor, review, or enforce the provisions of the new rule with its delegate agencies. The Final Rule appears to extend to non-compliance by any and all subcontractors receiving HHS funds through the City, and their employees. The City of Chicago requires its delegate agencies to comply with all applicable federal, state, and local laws. CDPH monitors its' agencies through regular reports submitted to CDPH, as well as supplemental site visits. It is not feasible, however, to ensure that every one of the third party employees working on over 150 contracts at 89 delegate agencies would be adequately aware of the Final Rule's provisions, nor trained to appropriately respond to and accommodate a refusal to provide services based on religious or moral objections, especially given the lack of specific procedures or protocols in the rule itself. Indeed, while CDPH tracks services provided by its delegates, it does not currently track or receive reports about refusals to provide services.

17. Thus, the act of a single third party over whom the City lacks sufficient knowledge or control could jeopardize all of CDPH's federal health care funding.

18. Due to the Final Rule, CDPH is in the process of developing and implementing a new complaint policy and procedure to receive, investigate, and respond to religious objections and moral conscience complaints. Development, socialization and implementation of this procedure among our workforce will expend vital resources. That procedure will require full investigation and resolution of all such complaint—activities which will also use valuable resources. These new procedures, however, only apply to CDPH's workforce, and thus will not cover CDPH's delegate agencies and their employees.

19. CDPH serves underserved and disproportionately impacted communities, including at-risk pregnant women and infants, and the LGBTQ community, from whom it has gained trust over the years. CDPH prioritizes access to care for all, and the Final Rule has the potential to disrupt this work, damaging the trust we have built in the LGBTQ and other marginalized communities and creating barriers to care, both real and perceived.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 12th day of June, 2019

Fikirte Wagaw, MPH
First Deputy Commissioner, Chicago Department of Public Health

Exhibit 47

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services*; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF MARIE ZIMMERMAN

1. I, Marie Zimmerman, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I submit this Declaration in support of the State of Minnesota, related to litigation involving the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through Minnesota Department of Human Services ("MDHS") personnel who have assisted me in gathering this information from our agency, or on the basis of documents that I reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon MDHS.

3. I am employed by MDHS as the Assistant Commissioner for Health Care and Minnesota's Medicaid Director. In this position, I oversee and lead Minnesota's Medicaid program, Medical Assistance, and its Basic Health Program (MinnesotaCare).

4. MDHS receives funding from HHS that it passes through to subcontractors to deliver health services. For example, MDHS reimburses fee-for-service Medical Assistance providers for Medicaid services they provide. It also contracts with managed care organizations ("MCOs" or "Plans") to provide managed care to Medicaid and MinnesotaCare recipients.

5. MDHS anticipates that individuals or entities may assert religious or moral objections to certain services covered by MinnesotaCare or Medicaid. For example, Medical Assistance services reimbursed by MDHS on a fee-for-service basis include abortions, prescription contraceptives, STD prevention services, and vaccinations. Medical Assistance services reimbursed by MDHS through MCOs include contraceptives, STD prevention services, and vaccinations.

6. In contracting with MCOs for Medicaid and MinnesotaCare, MDHS uses a model contract, which includes a requirement that the MCOs comply with federal law. The model contract permits annual adjustments to the agreed-upon rates MCOs are paid in order to account for legislative changes. This language is part of all current contracts between MDHS and the MCOs. Given the breadth of the Final Rule, MCOs may seek higher capitation rates to account for increased costs, which could increase costs to the State.

7. In state fiscal year 2018, MDHS received approximately $7.1 billion in federal matching funds for the State's Medicaid program, and $369 million in federal funds for MinnesotaCare. MDHS also received approximately $491 million from HHS for Medicaid administrative costs. MDHS projects it will receive $7.8 billion in state fiscal year 2020 for Medicaid, and $444.2 million for MinnesotaCare. These HHS funds would be at risk if CMS withheld funds for alleged noncompliance with the Final Rule.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 6 day of June, 2019

MARIE ZIMMERMAN

Assistant Commissioner for Health Care and Minnesota's Medicaid Director

|#4499766-v1

Exhibit 48

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, *in his official capacity as Secretary of the United States Department of Health and Human Services,* and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 19-cv-04676

DECLARATION OF HOWARD A. ZUCKER, M.D., J.D.

I, HOWARD A. ZUCKER, M.D., J.D., pursuant to 28 U.S.C. Section 1746 declare under penalty of perjury as follows:

1. I am the Commissioner of the New York State Department of Health ("Department"). I make this declaration in my capacity as the Commissioner after consultation with Department program staff directing the initiatives detailed below. I respectfully submit this Declaration in order to place before the Court certain testimony and documents relevant to the

relief requested. I am familiar with the matters set forth herein, either from professional knowledge, conversations with Department staff, or on the basis of documents that have been provided to and reviewed by me.

2. I have extensive knowledge of pediatric medicine and care and am aware of many family health issues. I am board-certified in six specialties/subspecialties and trained in pediatrics at Johns Hopkins Hospital, anesthesiology at the Hospital of the University of Pennsylvania, pediatric critical care medicine/pediatric anesthesiology at The Children's Hospital of Philadelphia, and pediatric cardiology at Children's Hospital Boston/Harvard Medical School. I was a professor of clinical anesthesiology at Albert Einstein College of Medicine of Yeshiva University and pediatric cardiac anesthesiologist at Montefiore Medical Center in the Bronx. I also served as associate professor of clinical pediatrics and anesthesiology at Columbia University College of Physicians & Surgeons and pediatric director of the ICU at New York Presbyterian Hospital. I am a former Columbia University Pediatrics Teacher of the Year.

3. As Commissioner of the Department, I must "take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law." Public Health Law ("PHL") §206(1)(a).

4. I preside over the state's Medicaid program, the New York State Public Health and Health Planning Council, and the Wadsworth Center, New York's premier public health lab, as well as the entire health care workforce, and health care facilities, including hospitals, long-term care and nursing homes. The Department also owns and operates four New York State veterans' homes and Helen Hayes Hospital.

5. The U.S. Department of Health and Human Services regulation at issue here ("Final Rule") will cause irreparable harm to the Department and the people of the State of New York, will force the Department to expend costs and take on other burdens that cannot be recouped, and will severely inhibit the Department's regulatory role.

6. By granting individual health care providers the absolute right to deny lawful and medically necessary treatment, services (including emergency treatment or services), and information to patients based on the provider's own personal views, the Final Rule is forcing the Department to choose between keeping federal funds necessary to implement and administer many valuable life-saving health programs and the lives of the people it is meant to serve and protect.

Current Conscience Protection Statutes in New York State

7. The New York Civil Rights Law ("CRL") prohibits discrimination against a person who refuses to perform or assist in the performance of a certain act. It requires someone with an objection to file a prior written refusal with the reasons for the refusal with the appropriate and responsible facility or individual. *See* CRL § 79-I(1). The facility or individual is prohibited from discriminating against the individual who files such refusal to act. Id.

8. Furthermore, a civil action for negligence or malpractice cannot be brought against the individual refusing to act based on the refusal. CRL § 79-I(2).

9. Requiring an individual to provide notice of an objection to perform or assist in a particular service allows a facility or practice to prepare in advance how such a refusal would be accommodated. It would ensure that the appropriate health care treatment or service is provided to the patient, who may be experiencing a medical crisis where time is of the essence for providing treatment.

10. The Family Health Care Decision Act, Article 29-CC of the PHL, addresses issues related to the decision to withdraw or withhold life-sustaining treatment. *See* PHL § 2994-f(1). An attending physician or nurse who receives such a decision must record it in the patient's medical record and review the medical basis for the decision. Id. If the attending physician or nurse has an objection, he or she must make it known promptly and provide the reason(s). PHL § 2994-f (1)(b). Additionally, the objector must make "all reasonable efforts to arrange for the transfer of the patient to another physician or nurse practitioner, if necessary, or promptly refer the matter to the ethics review committee." Id.

11. A private hospital is not required to honor a patient's health care decision if the decision is contrary to a formal policy of the hospital that is "expressly based on sincerely held religious beliefs or sincerely held moral convictions central to the facility's operating principles". PHL § 2994-n(1)(a). Also, the hospital must inform the patient, family or surrogate of any such policy prior to or at admission, if reasonably possible. PHL § 2994-n(1)(b).

12. Finally, the patient must be transferred promptly to another hospital that is reasonably accessible under the circumstances and will honor the decision. PHL § 2994-n(1)(c).

13. This same requirement applies to individual health care providers. *See* PHL § 2994-n(2).

14. Again, the decision must be contrary to the individual health care provider's "sincerely held religious beliefs or sincerely held moral convictions". PHL § 2994-n(2)(a).

15. The individual health care provider must promptly inform the individual making the decision and the hospital of his or her refusal to honor the decision based on the objection. PHL § 2994-n(2)(b). The hospital, at its own expense, must promptly transfer the care of that patient to a health care provider willing to honor the decision and the objecting individual provider must cooperate in facilitating the transfer.

16. Nothing in the Family Health Care Decision Act "creates, expands, diminishes, impairs, or supersedes any authority that an individual may have under law to make or express decisions, wishes, or instructions regarding health care on his or her own behalf, including decisions about life-sustaining treatment." PHL § 2994-q(1).

17. Additionally, the Act does not "affect existing law concerning implied consent to health care in an emergency", "intend[] to permit or promote suicide, assisted suicide, or euthanasia", "affect existing law with respect to sterilization", nor "diminishes the duty of parents and legal guardians under existing law to consent to treatment for minors". PHL § 2994-q(2) – (5).

18. The New York statutes contain certain elements that are strikingly absent from the Final Rule. For example, the Final Rule has no similar provision requiring an objector to give

advance notice of issues, procedures, or situations to which he or she would object to providing or assisting in the provision of. Also, the forms of employer inquiry permitted under the Final Rule do not provide an employer – like a hospital, nursing home, or research laboratory – sufficient advance notice that an employee has an objection. As the Department understands the Final Rule, an employer is only permitted to inquire once per calendar year about an employee's objections. Furthermore, any types of alternative staffing arrangements made by a health provider may not exclude an objecting employee from a "field of practice," and any accommodation offered by an employer must be voluntarily accepted by the employee. As the Department understands the Final Rule, if an employee rejects a proposed accommodation, no matter how reasonable, the employer may not move the employee or otherwise take any adverse action against him/her. These aspects of the Final Rule seriously hinders the ability of employers to create advance staffing plans that allow them both to deliver uninterrupted patient care and to provide accommodations to objectors.

19. The New York State requirements for advance notification and for religious beliefs or moral convictions to be sincerely held impose a level of responsibility on the objector to validate the reason for objecting to providing or assisting in providing potentially life-saving care.

20. Furthermore, the New York State conscience protections narrowly define the population the statutes apply to, e.g., health care providers and not individuals receiving state funds or employees of state or local governments/agencies.

The Final Rule Prevents Enforcement of Patients' Rights and Protections

21. The Patient's Bill of Rights found in Sections 405.7 and 751.9 of Title 10 of the Official Compilation of Codes Rules and Regulations of the State of New York ("NYCRR") contain, prohibits discrimination based on "race, color, religion, sex, gender identity[1], national origin, disability, sexual orientation, age, or source of payment".

[1] Pursuant to the authority vested in the Commissioner of Health by PHL § 2803, 10 NYCRR §§ 405.7 and 751.9 were amended, and were effective on January 9, 2019, upon publication of a Notice of Adoption in the New York State Register, adding gender identity.

22. The statement of rights of patients under PHL §2803(1)(g) has always included the right to receive treatment without discrimination based on characteristics defined by the Human Rights Law and the regulations of the New York State Division of Human Rights.

23. There are various provisions in the PHL that require medical professionals and health care entities to take specific actions and/or provide specific information to patients related to their health care, including supporting the patient's ability to make appropriate health care decisions.

24. Pursuant to PHL § 2805-b, hospitals and medical practitioners must admit and treat persons in need of emergency care and treatment. An individual needing emergency care must be admitted quickly without being questioned about how the patient or his or her family will pay for the services. PHL § 2805-b(1). Denial of such treatment and care by a licensed practitioner or general hospital is considered a misdemeanor and any person

> who in any manner excludes, obstructs or interferes with the ingress of another person into a general hospital who appears there for the purpose of being examined or diagnosed or treated; or any person who obstructs or prevents such other person from being examined or diagnosed or treated by an attending physician thereat shall be guilty of a misdemeanor and subject to a term of imprisonment not to exceed one year and a fine not to exceed one thousand dollars.

PHL § 2805-b(2)(a) and (b).

25. The Patient's Bill of Rights also states patients have the right to receive emergency care if it is needed. 10 NYCRR § 405.7(c)(4).

26. As Commissioner, I am required to establish "minimum standards in accordance with established and accepted medical principles for local maternal and child health services." PHL § 2500(1).

27. The Final Rule puts the health and welfare of newborns at jeopardy since the Department requires health care practitioners to take certain preventive measures to reduce particular health risks.

28. PHL requires all newborns to be screened for phenylketonuria and other diseases and conditions, including hearing impairments. PHL § 2500-a(1)(a); *see also*, part 69 of 10 NYCRR.

29. There is an exception to the hearing test requirement when an infant or child's parent or guardian is a member of a recognized religious organization whose teachings and tenets are contrary to the required testing and provides notice of the objection to the person charged with administering the testing, but this does not cover a licensed healthcare professional from objecting to participating in or performing a test, as well as advising against testing.

30. Part 69 of Title 10 of the NYCRR also covers umbilical blood testing for syphilis; early intervention for identification, tracking, and screening of children at risk of developmental delay; rape crisis program counselor certification; and testing newborns for human immunodeficiency virus ("HIV").

31. "In order to improve the health outcomes of newborns, and to improve access to care and treatment for newborns infected with [HIV] or exposed to and their mothers," the Department is required to "establish a comprehensive program for the testing of newborns for the presence of human immunodeficiency virus and/or the presence of antibodies to such virus" and promulgate regulations implementing such a program. PHL § 2500-f(1) and (2), see also 10 NYCRR § 69.

32. The Final Rule would protect a licensed practitioner from declining to perform the testing or not providing a parent or guardian with appropriate information about testing and possibly recommending against it, contrary to the PHL and regulations. The Department previously received a complaint that a nurse practitioner/midwife, based on her own personal opinion and belief, told a patient that she did not need newborn screening. The mother called the Department to complain because newborn screening had identified congenital hypothyroidism in one of her other children.

33. Section 12.3 of 10 NYCRR requires an attending physician, licensed midwife, registered professional nurse or other licensed medical professional to ensure a dose of vitamin k

is administered all newborns and infants to prevent hemorrhagic diseases and coagulation disorders related to vitamin K deficiency within 6 hours of birth.

34. Additionally, 10 NYCRR § 12.2 is intended to prevent purulent conjunctivitis of the newborn. "It shall be the duty of the attending physician, licensed midwife, licensed nurse or other authorized provider in attendance at a delivery to place into the eyes of the infant, on delivery, an agent effective for preventing purulent conjunctivitis of the newborn, such as tetracycline or erythromycin eye preparation or a one percent solution of nitrate of silver." Id.

35. The Department also has special programs relating to identifying individuals exposed to diethylstilbestrol ("DES") and educating the public on symptoms and malignancies associated with exposure. DES is a man-made form of the hormone estrogen. From the late 1940s to around 1970 DES was given to some pregnant women to prevent miscarriages. In 1971 the federal Food and Drug Administration ("FDA") advised doctors to stop prescribing DES for pregnant women because it could potentially cause problems with the reproductive organs of their children. It is critical for women exposed to DES to know of the hazards and afflictions associated with DES exposure to be able to make the appropriate health care decisions for treatment.

36. Lack of informed consent is defined in the PHL as the "failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical, dental or podiatric practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation." PHL § 2805-d(1); *see also*, 10 NYCRR § 405.7(c)(8) and (9).

37. A patient has the right to receive treatment without discrimination and needs to be able to make health care decisions based on knowledge of all treatment and care options, not just the ones a health care professional personally believes are appropriate.

38. Additionally, PHL § 2500-e requires testing and follow-up care for hepatitis B for pregnant women. *See also*, 10 NYCRR § 69-3. Pursuant to the Final Rule, a health care professional could refuse to test or treat based on a personal bias and judgment call against a

pregnant mother. Hepatitis is caused by viruses (A, B, and C) as well as liver damage from alcohol use, and certain medications. Hepatitis B is the most common serious liver infection in the world. It is caused by the hepatitis B virus ("HBV") which is 100 times more infectious than the AIDS virus. HBV is most efficiently transmitted through contact with blood and body fluids of an infected person. This can occur through direct blood-to-blood contact, sex, illicit drug use, and from an infected mother to her newborn during delivery. HBV spreads because many people are unaware they are infected with the virus and unknowingly pass it on to those who are in close contact with them. Testing, providing the appropriate information, and treating for HBV is crucial for the health and welfare of the mother and the child.

39. Hospitals are required to provide emergency treatment to a rape survivor which includes written and oral information relating to emergency contraception and shall provide emergency contraception if requested. PHL § 2805-p(2).

40. The statute defines emergency contraception as "one or more prescription drugs used separately or in combination to be administered or self-administered by a patient to prevent pregnancy within a medically recommended amount of time after sexual intercourse and dispensed for that purpose" according to professional standards of practice and determined by the FDA to be safe. PHL § 2805-p(1)(a).

41. Emergency treatment is defined as "any medical examination or treatment provided by a hospital to a rape survivor following an alleged rape". PHL § 2805-p(1)(b).

42. Patients in New York have the right to receive statutorily required care and services as well as be made aware of the appropriate care and treatment to make fully informed decisions about their health care.

43. A violation of any of these statutes by a health care professional or health care entity based on an objection covered by the Final Rule would result in serious harm and possibly death to persons seeking care. The Department would be placed in the untenable position of being unable to take enforcement actions against objectors or risk losing all federal funds by violating the Final Rule's prohibitions against retaliation and discrimination against objectors.

The Final Rule Disregards Department's Oversight Role

44. The Department is tasked with ensuring the health, safety, and welfare of the public and accomplishes this goal through various oversight roles, duties, and services it performs.

45. The Department receives and investigates complaints of misconduct in a multitude of areas related to health care facilities, health care providers, physicians, labs, Medicaid benefits, and Medicaid-related services, just to name a few.

46. Many of the complaints involve allegations of poor performance, low quality of care, or failure to perform.

47. Pursuant to PHL § 12, any person who "violates, disobeys or disregards" the PHL shall be subject to a civil penalty of up to $2,000 for each violation, or up to $5,000 if the same violation is subsequently committed, or as high as $10,000 if the "violation directly results in serious physical harm to any patient or patients." PHL § 12(1)(a)-(c)[2].

48. Section 88.6(e) of the Final Rule prohibits intimidating or retaliatory acts, *i.e.*, acts that

> intimidate, threaten, coerce, or discriminate against any person, entity, or health care entity for the purpose of interfering with any right or privilege under the Federal health care conscience and associated anti-discrimination laws or this part, or because such person, entity, or health care entity has made a complaint or participated in any manner in an investigation or review under the Federal health care conscience and associated anti-discrimination laws or this part.

49. Discriminate (or discrimination) is defined in Section 88.2 and prevents the Department from "utilize[ing] any criterion, method of administration, or site selection, the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that tends to subject individuals or entities protected under this part to any adverse effect described in this definition, or have the effect of defeating or

[2] On April 1, 2020, PHL § 12(1) will no longer contain the penalties up to $5,000 and $10,000 currently contained in (b) and (c).

substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected under this part."

50. As explained further through the examples provided below, the Department's ability to cite and take enforcement action for violations of the PHL is severely undermined if a person or entity can simply assert a conscience objection with no notice, and thus shield their unlawful actions from the Department's enforcement oversight.

The Final Rule Impacts the Department's Oversight of Health Care Facilities

51. The Department licenses and regulates health care facilities under Article 28 of the PHL.

52. The powers and duties of the Commissioner as related to the operation of health care facilities are set forth in PHL § 2803. "The commissioner shall have the power to inquire into the operation of hospitals and to conduct periodic inspections of facilities with respect to the fitness and adequacy of the premises, equipment, personnel, rules and by-laws, standards of medical care, hospital service, including health-related service, system of accounts, records, and the adequacy of financial resources and sources of future revenues." PHL § 2803(1)(a).

53. The Commissioner, or designees, are required to survey a facility and conduct "unannounced comprehensive inspection[s]" to assess the adequacy of care given to patients. Id.

54. "The purpose of such inspection shall be to determine compliance by residential health care facilities with statutes, and with regulations promulgated under the provisions of those statutes, governing minimum standards of construction, quality and adequacy of care, rights of patients, rates of payment and reimbursement." PHL § 2803(1)(b).

55. The Department's surveillance teams issue Statements of Deficiency ("SOD") to any facility that is found to be violating a statute or regulation in its provision of care. The facility is obligated to provide the Department with a Plan of Corrections ("POC") to address how the violations will be remedied.

56. The Commissioner has the power to "institute or cause to be instituted in a court of competent jurisdiction proceedings to compel compliance with the provisions of this article or the determinations, rules, regulations and orders of the commissioner or the council." PHL § 2803(5).

57. "The commissioner shall have the power to assess penalties in accordance with the system of penalties adopted pursuant to subdivision six of this section and pursuant to a hearing conducted" pursuant to PHL § 12-A. PHL § 2803(7).

58. Following a hearing held pursuant to PHL § 12-A, "the commissioner may make appropriate determinations and issue an order in accordance therewith." PHL § 12-A(7).

59. In order to comply with the Final Rule, the surveyors will not be able to cite a violation if the person, or entity, who committed the violation claims it was based on a conscience objection. If the individual or entity challenges the issuance of a SOD as retaliatory or discriminatory for asserting a conscience objection, all those involved in the administrative hearing process will be unable to assess penalties.

60. The Department also receives and investigates complaints about quality of care. The Department recently received a complaint from a gay man who claimed he was refused treatment at an Article 28 facility because a facility employee objected to the patient's sexual orientation on religious grounds.

61. According to the complainant, when the patient's sexual orientation was revealed, the hospital representative working with the patient began "demonstrative praying and self-blessing with the sign of the cross". The complainant alleges that the hospital representative used her personal beliefs to make evident to the patient and his husband that something she witnessed prompted her to ask for helps from higher powers.

62. According to the complainant, the hospital representative "has every right to exercise [ ] First Amendment rights. However, whether or not [the hospital representative] can use them to denigrate [ ] patients and their family members on the basis of something that [his or her] religion does not approve of is a different question. [He or she] knew or should have known that [ ] demonstrative and rather aggressive expression of [his or her] religion—right after the

patient and his husband revealed their sexual orientation—is a form of harassment, humiliation, and/or discrimination."

63. The Department will conduct a full investigation on quality of care to see if this patient received the appropriate level of care. Under the Final Rule, however, the Department would appear to be unable to take enforcement action against the individual or facility that asserted the objection for violating PHL and regulations.

64. The Department will need to immediately begin retraining staff to ensure that Department surveyors, investigators, and other staff understand the impact of the Final Rule and how it affects their regular duties. In order to complete the training modules on the implementation of the Final Rule, the Department will need to pull surveyors and investigators from the field and bring them to Albany from around the state for training. This will cause the Department to fall behind in its survey schedule. *See infra*, ¶¶ 167-174.

65. The Department also expects to receive increased complaints, which will need to be investigated. This will place a burden on Department investigators and surveyors. The Department will also need to expend resources and lose employee productivity to conduct training with the complaint intake staff.

66. The Department sends surveyors out in teams to conduct recertification surveys. The surveyors often bring complaints the Department has received related to that facility or entity for investigation while conducting the survey. With an increased volume of complaints, the survey and investigation will take longer due to the need to interview additional facility staff and to assess whether the Final Rule is applicable.

The Final Rule Impacts Oversight Duties of the Office of Professional Medical Conduct

67. The Department must investigate "each complaint [of professional misconduct] received regardless of the source" and may initiate its own investigation if there is a suspicion of professional misconduct. PHL § 230(10)(a)(i)(A).

68. The Director of the Office of Professional Medical Conduct ("OPMC"), in consultation with an investigation committee, can conduct a comprehensive review of patient

records of a licensee and office records of the licensee. *See generally*, PHL § 230(10)(a). The licensee must cooperate with any OPMC investigation.

69. The definitions of professional misconduct are found in State Education Law ("EL") § 6530. This section provides an extensive list of what would be defined as professional misconduct, including but not limited to Sections:

> (10) Refusing to provide professional service to a person because of such person's race, creed, color or national origin; (16) A willful or grossly negligent failure to comply with substantial provisions of federal, state, or local laws, rules, or regulations governing the practice of medicine; and (30) Abandoning or neglecting a patient under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care, or abandoning a professional employment by a group practice, hospital, clinic or other health care facility, without reasonable notice and under circumstances which seriously impair the delivery of professional care to patients or clients.

70. Allowing individuals to refuse to provide health care services, or information about available health care services, to which they object ignores the health needs of the patient who is denied services. Legal and ethical principles of informed consent require health care providers to inform their patients about all their treatment options, which are supported by respected medical opinion, including those the provider does not offer or favor. As such, health care professionals must endeavor to give their patients complete and accurate information about the services available to them.

71. The Department has serious concerns that OPMC will not be able to perform its legally required functions, consistent with the Final Rule. If a doctor objects to performing emergency surgery on a woman bleeding out after an abortion, sterilization, or some other procedure or post-partum event, it is unclear whether the Final Rule permits OPMC to conduct any review of the doctor's decision and actions with respect to that patient. The Final Rule defines discrimination as using "any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that tends to subject individuals or entities protected

under this part to any adverse effect described in this definition, or to have the effect of defeating or substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected under this part," which includes withholding or denying a license. As a result, OPMC will be challenged to meet its statutory obligation to investigate and possibly discipline a physician for the harm caused by a licensed health care provider's refusal to act or seek an alternative.

72. Similarly, the Final Rule also appears to be in direct conflict with the Emergency Medical Treatment and Labor Act ("EMTALA"), which ensures public access to emergency services for treatment of an emergency medical condition.

73. OPMC has not had to investigate or prosecute violations of the current statutes that require emergency care/treatment since they require notice based on a sincerely held belief and, therefore, advanced notice of an objection allows for accommodations to be made prior to an objectionable situation arising.

The Final Rule Impacts Women's Reproductive Health Services

74. The most detrimental impact of the Final Rule's apparent overbreadth is on the provision of women's reproductive health services. The absence of a medically acceptable definition for abortion and sterilization services creates ambiguity as to which additional family planning or reproductive health care services are covered.

75. For example, a pharmacist or health care provider could refuse to provide a woman with contraception of any kind based on moral beliefs, even including emergency contraception if the woman were raped or sexually assaulted. *See supra*, ¶¶ 39-41. A health care provider could also deny a woman who wishes to achieve pregnancy from accessing basic infertility services, based on personal beliefs about that individual's right and ability to parent. Furthermore, a provider of in vitro fertilization treatment exercising their religious belief or moral conviction could refuse to provide services to a woman based on marital status or sexual orientation, for example.

76. Refusals to provide reproductive health services or coverage increases the difficulty for women to access and afford needed and available services and can lead to adverse health, economic and social outcomes for women and their families.

77. Furthermore, refusals to provide the necessary information on all care and treatment options deprives a woman of making a fully informed decision about her health care. *See supra*, ¶¶ 36, 37.

78. The Department is particularly concerned that the Final Rule does not include exceptions for emergencies for the health and safety of the patient such as is recognized by the federal Medicaid program that allows for coverage of abortion services when in the professional judgement of the health care provider, the life of the mother would be endangered if the fetus were carried to term.

79. These rules have the consequence of potentially urgent and life-saving care being delayed to a woman on an emergency basis due to a religious belief or an undefined amorphous "other" objection. A woman with an ectopic pregnancy needs immediate care and is placed at great risk if the treating physician suddenly decides, with no prior notice, that he or she has some sort of objection to treating her condition.

80. In a separate rule, HHS's new gag rule related to receipt of Title X awards would impose new requirements on all of the Department's subrecipients of funds and prohibit counseling and referrals for abortion services. Title X funding provides affordable and critically-needed family planning services and supports outreach to communities traditionally lacking access to such services.

81. The rule's restrictions on counseling and referrals for abortion services do not merely impose technical changes in how the program is administered, but rather impose a substantial and dramatic change in how Title X clinics provide medical care to their patients. Indeed, the rule would prohibit the very type of care Title X clinics were *required* to provide when existing grantees, such as, the Department competed for, and were awarded, the current cycle of Title X funding.

82. The New York State Comprehensive Family Planning & Reproductive Health Program ("NYS FPP") receives and administers Title X funds along with state funds to ensure that low-income families, women, and communities of color across the State have access to affordable, high-quality and comprehensive family planning care, improving health outcomes and the quality of life of millions of New Yorkers. The Department is responsible for ensuring access to adequate family planning services throughout New York State through the NYS FPP.

83. Implementation of this new gag rule is currently stayed pending the outcome of litigation, but the Final Rule does an end-run around the delay or denial of implementation and would allow for refusal to provide counseling and referrals for abortion services. Thus, some of the projected impacts related to the gag rule would still come to fruition and the Department would experience immediate and irreparable financial harm because of the effects that refusals would have outside of the Title X program.

84. Through its Medicaid and other public programs, the Department would have to absorb the myriad costs of increased rates of unplanned pregnancies, sexually-transmitted infections, and advanced cancer diagnoses that will inevitably result from the Final Rule due to refusals to appropriately counsel and refer patients, as well as objections by private employers to provide insurance coverage for contraception or abortion. These costs will likely be significant and are not recoverable.

The Final Rule will Immediately Impact Programs Receiving HHS Funds

85. Programs within the Department receive HHS funds or administer funds to outside contractors and subcontractors, and many of these programs cover services or populations that are highly susceptible to immediate religious or moral objections.

86. The Department risks losing all the federal funds it receives based on a violation by any of its employees, contractors, and even subcontractors of the programs that use these federal funds, if an objection is not dealt with in a manner that complies with the Final Rule, or if HHS believes that the Department's policies or practices do not on their face comply with the Rule's requirements.

87. The largest portion of HHS funds comes through Centers for Medicare & Medicaid Services ("CMS") for the Medicaid program. CMS is part of HHS and is responsible for implementing laws passed by Congress related to Medicaid and issues various forms of guidance to explain how laws will be implemented and what states and others need to do to comply.

88. The Medicaid program was established pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396, *et seq*. It was designed as a joint state and federal program to provide medical care to those who would be otherwise unable to afford such care. Under the terms of the Medicaid program the federal government contributes a percentage of the funding. In New York, responsibility for the remaining monies is divided between the State and local government.

89. The Department is the single State agency responsible for the administration of the New York Medicaid Program. The purpose of the Medicaid Program is to make medically necessary covered health and medical services available to eligible individuals.

90. Not only is the Department a State agency under the Final Rule's definition, many of the Department's programs are affected by Medicaid and/or receive some form of federal funding from HHS, thus subjecting them to the Final Rule.

91. The Office for Civil Rights ("OCR") within HHS will be the enforcement arm for the Final Rule and has authority to conduct investigations whenever it receives or discovers information that "indicates a threatened, potential, or actual failure to comply" with the Final Rule. *See* § 88.7 *Enforcement authority* of the Final Rule.

92. If OCR determines a recipient or subrecipient of HHS funds has not complied with the Final Rule all federal funding can be temporarily suspended or terminated in whole or in part. *See* § 88.7(i)(3) of the Final Rule.

93. Current gross Medicaid spending in New York is $74,500,000,000 (billion) with $42,500,000,000 (billion) of that as federal share. It is not quite a 50-50 split due to enhanced federal matching percentages for certain programs and populations.

94. For any determined violation of the Final Rule by an employee, contractor, or subcontractor, the Department would be at risk of losing more than $42,000,000,000 (billion) from the federal match it receives for administering the Medicaid program alone.

95. The Department receives funds from HHS for many different programs, but some programs will be more likely to receive conscience objections and thus be at immediate risk of jeopardizing all federal funds received by the Department. Several examples are set forth below.

96. The Department receives block grant funds for prevention purposes to assist the *Support and Technical Assistance to Rape Crisis Centers*, which provide training and technical assistance ("TTA") to 53 Rape Crisis Programs with a focus on the work being done to implement the *Enough is Enough Campus Sexual Assault Prevention* program in partnership with colleges and universities across the state. These funds also support a child abuse provider training program designed to improve New York State's medical response to child abuse by providing education to healthcare professionals in the identification and management of child sexual abuse cases.

97. The Department receives Title V Maternal and Child Health Services Block Grant ("MCHBG") funds that are used to support numerous programs. These funds support *Migrant Health Services*, which gives grants to health clinics to serve migrants; provide grants to licensed Article 28 facilities that sponsor health clinics located in schools; support *Comprehensive Adolescent Pregnancy Prevention*, which implements comprehensive sexual health evidence-based programs ("EBPs") that have been proven based on scientific research to change behavior, such as delaying sexual activity, increasing condom or contraceptive use, or reducing pregnancy among youth through 48 community based organizations; support counties to care for families with children with special health care needs connect to services and supports; supports University Centers of Excellence in Disabilities to support counties and families; provides grants to schools to provide dental sealants for school-age children; supports seventeen regional perinatal centers provide or coordinate statewide maternal-fetal and newborn transfers of high-risk patients from their affiliate hospitals, and are responsible for support, education, consultation, and improvements

in the quality of care in the affiliate hospitals within their regions; and supports lead poisoning prevention through the Centers for Environmental Health.

98. The Department receives Title X funds, which are used to support Comprehensive Family Planning and Reproductive Health Care Services Program to provide comprehensive, confidential reproductive health services for low-income, uninsured and underinsured women and men of reproductive age, including adolescents, through a statewide network of 48 grant-funded health care facilities that operate 160 service sites. *See also, supra*, ¶¶ 77-80.

99. HHS funds that go to the *Maternal, Infant and Early Childhood Home Visiting* ("MIECHV") program serve communities with concentrations of premature birth, low-birth weight infants and infant mortality, and supports those evidenced-based home visiting programs that have demonstrated improvements in maternal and child health outcomes, e.g., Nurse-Family Partnership ("NFP"), and Healthy Families New York ("HFNY"). Nineteen projects (8 NFP, 11 HFNY) are being implemented in nine counties across the state: Bronx, Duchess, Erie, Kings, Monroe, Nassau, Onondaga, Queens, and Schenectady.

100. The Department receives funds to administer the Personal Responsibility Education Program Competitive Grants ("Competitive PREP"), which awards grants for educating youth on both abstinence and contraception. Competitive PREP implements comprehensive sexual health EBPs that have been proven based on scientific research to change behavior, such as delaying sexual activity, increasing condom or contraceptive use, or reducing pregnancy among youth and promotes healthy life skills in preparation for adulthood. Services are provided by seven community-based organizations. Competitive PREP targets young people who are homeless, in foster care, live in rural areas or areas with high teen birth rates, and are from minority groups, which include sexual minorities. *See generally*, HHS website https://www.acf.hhs.gov/fysb/prep-competitive. These "grants also support pregnant youth and mothers under the age of 21." Id.

101. The Sexual Risk Avoidance Education ("SRAE") grants focus on medically accurate and complete evidence-based sexuality education, and adult supervision programs as an innovative strategy to promote abstinence from sexual activity and support a healthy transition to

adolescence among early adolescent youth between the ages of 10-13 through 12 community-based organizations.

102. Health Research, Inc. ("HRI") administers numerous federal grants the Department receives through a contractual relationship. HRI subcontracts with various funded agencies to administer the programs.

103. The CDC provides funding to HRI for several initiatives, including the following: the New York State Perinatal Quality Collaborative ("NYSPQC"); New York Rape Prevention and Education Program supports six Regional Centers of Sexual Violence Prevention (Regional Centers) that are implementing evidence-based/informed primary prevention strategies in 17 counties in New York State that had the highest average number of reported forcible rapes over a five-year period; and for sexual violence prevention through the *Strengths-Based Curriculum to Reduce Risk for Future Sexual Violence Perpetration Among Middle School Boys*, which is a research project regarding the implementation of the Council for Boys and Young Men Curriculum with males aged 12-14 to reduce risk for future sexual violence perpetration.

104. HHS's Office of the Assistant Secretary for Health ("OASH") provides funding to HRI for Pathways to Success: New York State Building Supportive Communities for Young Families in New York City, which improves the educational, health and social outcomes for expectant and parenting teens, women, fathers, and their families. It focuses on the three boroughs of New York City (Kings, Bronx, and Queens) having the highest teen birth rates among 15 to 24-year-old females.

105. HHS's CMS provides a Medicaid match for Maternal and Infant Community Health Collaboratives ("MICHC") seek to improve maternal and infant health outcomes for high need, low-income or Medicaid-eligible women and their families by supporting the development of multi-dimensional community systems of integrated and coordinated community health programs and services. Twenty-three MICHC projects serve 32 high-risk communities and include the services of Community Health Workers.

106. HHS's Office of Refugee resettlement ("ORR") funds programs to assist with the United States' humanitarian efforts regarding refugee populations. The Department receives funds for Refugee and Entrant Assistance.

107. Each of these programs serves an already vulnerable or marginalized population and is likely to see immediate objections based on the overbroad protections the Final Rule provides to those who would decline to provide or assist in treatment—or even to discuss certain types of treatment or other health options.

The Final Rule Impacts Services Provided by the AIDS Institute

108. The AIDS Institute funds several programs through contracts that will likely be immediately susceptible to objections, based on the services provided and the vulnerable populations served.

109. The AIDS Institute funds STD disease intervention services through five County Health Department contracts, to improve the provision of STD partner services within the county, and to ensure persons who are reactive for an STD/HIV and their partners are promptly linked to medical care, HIV testing, additional STD screening, and other essential prevention and support services.

110. The AIDS Institute provides funding for Safety Net for targeted populations in three county health departments to provide screening of chlamydia and gonorrhea in high-risk populations, specifically through the purchase of nucleic acid amplification test kits, which is the test technology that is recommended by the CDC and the Association of Public Health Laboratories.

111. The AIDS Institute awards federal funds from HHS to service providers to support a variety of services for persons at risk for and living with HIV, hepatitis C, and STDs; lesbian, gay, bisexual, and transgender ("LGBT") populations; and drug users. The Final Rule's broad definitions raise concerns about the potential for individuals serving these populations to use them to object and, effectively, to discriminate against persons for whom services are intended.

112. The AIDS Institute funds testing and awareness among young gay men and men who have sex with men of color, through nine different community-based organizations (for an annual amount of $10,000 each), to provide a community-based approach to implement a variety of community-based projects. These projects are aimed at increasing STD awareness and access to available, age appropriate and culturally competent (race/ethnicity, gender identity and sexual orientation) services among the populations that they serve.

113. The AIDS Institute funds laboratory testing services through one contract to provide laboratory testing services to selected health care providers that provide STD testing for high priority populations. Selected providers include local health department STD clinics, family planning clinics, juvenile detention centers, adolescent health centers and community-based organizations. Laboratory testing will be provided for chlamydia, gonorrhea, and syphilis and will include test kits, supplies, courier service, results reporting, and test requisition software, maintenance, and training.

114. A primary goal of AIDS Institute programs is to reach underserved populations and to address the individual, group, and community-level barriers that prevent linkage to and retention in care and services. The implementation of the Final Rule raises concerns about increased stigma, discrimination, and health disparities to those with HIV/AIDS and those struggling with substance use disorder.

115. For example, the AIDS Institute has previously received complaints from individuals who have gone to an emergency room for a post-exposure prophylactic and been denied because a health care worker has made a personal judgment against the perceived life-style of the individual seeking care. Under the Final Rule, this refusal based on a personal objection would be protected and prevent an individual from receiving appropriate and legal care and treatment. After the Final Rule, the Department has serious concerns that it would not be able to address these types of complaints as violations of state law.

116. Pursuant to PHL § 2781-a(1), anyone 13 years or older receiving treatment as an inpatient in hospitals, in emergency rooms, or receiving primary care services must be offered

HIV-related testing. "Primary care" is defined to include "the medical fields of family medicine, general pediatrics, primary care, internal medicine, primary care obstetrics, or primary care gynecology, without regard to board certification". PHL § 2781-a(2).

117. The testing must be offered in a way that is "culturally and linguistically appropriate" to the individual seeking health care services. PHL § 2781-a(3).

118. Under the Final Rule, the Department would be unable to enforce this provision of law if someone asserts a conscience objection to offering HIV testing or does not offer it in the appropriate language for the individual.

The Final Rule Impacts New York State Early Intervention Program

119. The Department's Center for Community Health oversees/administers the State's various supplemental programs, such as the Early Intervention Program ("EIP").

120. The EIP serves infants and toddlers with developmental delays. The Part C EIP was created by Congress in 1986 as part of the Individuals with Disabilities Education Act ("IDEA"). IDEA authorizes EIP for infants and toddlers with disabilities and requires states to provide a free appropriate education for all students with disabilities, ages 3-21.

121. New York joined the federal EIP in 1987 with the New York State Department of Health appointed as the lead agency. State law was enacted in 1992 establishing an entitlement to EIP services for eligible children effective July 1, 1993. In New York, early intervention services are provided to eligible children and their families at no cost, or minimal cost, to families, and the program is delivered in partnership with local governments. If a child is uninsured, the initial service coordinator ("ISC") is responsible for assisting in identifying and applying for benefit programs for which the child or family may be eligible, including Medicaid, the Children's Health Insurance Program known as Child Health Plus in New York, and Social Security Disability Income, however, the children are not required to enroll in order for EIP services to be provided.

122. Each year, New York's EIP serves more than 68,000 children ages 0-3 who have moderate to severe developmental delays.

123. It is important for the Department to ensure that those providing care to displaced young children and local health departments/Early Intervention Officials take the appropriate action to assist these children so that children who have developmental delays or special health needs, or who are experiencing difficulty or showing signs of distress, can be connected to services as early as possible.

124. The EIP includes 1,312 providers that contract with New York State to bill for EIP services. Total annual expenditures for New York's EIP total more than $650 million across all payers (Medicaid, commercial insurance, and state and local funding).

125. The EIP spending breakdown for the 2018-18 program year is as follows:

a.	Commercial Insurance	$12.3 million	1.80%
b.	Medicaid	$293.7 million	44.1%
c.	State Funds	$177 million	26.5%
d.	County Funds	$184 million	27.6%

126. While EIP costs and services vary based on the child's needs and intensity of services offered, for the 2017 program year the average cost of services delivered ranged from $5,860 to $24,744 per child.

127. For the 2017-18 program year, total EIP spending for services was $666.5 million.

128. The majority of funds for the EIP are from Medicaid and the Final Rule would allow an employee of a state agency, contractor, or subcontractor or a person, entity or health care entity to refuse to authorize, provide, or participate in providing EIP services if that individual or entity raises a conscience objection to doing so. For example, an individual can refuse to authorize or provide EIP services to the child of a same-sex couple or transgender parent based on that individual's objection (moral, ethical, religious, or other) to same-sex marriage or transgender individuals.

129. The Department would be unable to take any action against such an objector under the Final Rule.

New York State Child Health Plus Expenses

130. New York State has long been committed to ensuring that all children in the state have access to comprehensive health care services. All children under age 19, regardless of immigration status, are eligible for the child health insurance program, Child Health Plus ("CHP"), in New York State.

131. CHP covers nearly 400,000 children. Children with household incomes at or below 160% of the federal poverty level ($19,416 for household of one, $40,152 for a household of four) are eligible for CHP coverage with no monthly premium contribution. Children in households with income up to 400% of the federal poverty level are eligible on a sliding scale with monthly premium contributions of $9 to $60 per month. Available at (https://www.health.ny.gov/health_care/child_health_plus/eligibility_and_cost.htm).

132. CHP provides children with comprehensive health insurance coverage. The benefits package includes well-child care; physical exams; immunizations; diagnosis and treatment of illness or injury; X-rays and lab tests; outpatient surgery; emergency care; prescription and non-prescription drugs, if ordered by a physician; inpatient hospital medical and surgical care; short-term therapeutic outpatient services (chemotherapy, hemodialysis); inpatient and outpatient treatment for alcoholism, substance abuse, and mental health; dental care; vision care; speech and hearing services; durable medical equipment; emergency ground ambulance transportation to a hospital; and hospice.

133. Generally, the CHP program is jointly funded by the federal and the state governments.

134. Studies of the CHP program in New York and nationally have found that children enrolled in the program have greater access to care than uninsured children, better health outcomes, and fewer absences from school.

135. The Final Rule would allow an employee of a state agency, contractor, or subcontractor or a person, or health care entity to refuse to authorize, provide, or participate in providing CHP services if that individual or entity raises a conscience objection to doing so. For

example, an individual can refuse to authorize or provide CHP services to the child of a gay or lesbian couple or transgender parent based on that individual's objection (moral, ethical, religious, or other) to same-sex marriage or transgender individuals.

136. The Department would be unable to take any action against such an objector under the Final Rule.

Communities of Color and Minority Populations are Disproportionately Harmed

137. As part of the prior Regulatory Impact Analysis of the Rules, the commentary from HHS related to Patient Benefits from Conscience Protections on page 3917 in the Federal Register (Vol. 83, No. 18, January 26, 2018) is extremely dismissive of the harmful impact the Final Rule will have on ethnic minorities and instead glosses over it with a cavalier statement about how "facilitating open communication between providers and their patients also helps to eliminate barriers to care, particularly for people of faith, and especially in migrant communities where culturally competent care matters greatly". *See* 84 Fed. Reg. at 23249.

138. The Final Rule further states that "[i]t is important for patients seeking care to feel assured that their religious beliefs and their moral convictions will be honored. This will ensure that they feel they are being treated fairly. And for some, being able to find health care providers that share the same moral convictions can be a source of personal healing." Id.

139. This is an absolute fallacy. Ethnic minority patients will be faced with many barriers when trying to receive health services under the Final Rule.

140. Literature indicates that communities with a high concentration of minority populations, such as Minority Areas, are poorer, rely on government assistance, and have a higher incidence of sexually transmitted diseases ("STD"s), chronic diseases, and injuries. *See* CDC Health Disparities and Inequalities Report-United States, Vol. 60, 2011 (and Supp.).

141. The increasing diversity of New York State's population brings opportunities and challenges for public health and health care providers, government agencies, and policy makers. The U.S. Census Bureau reports in 2017 that approximately 36 percent of New York State's population were non-Whites. Hispanics represented 18.8 percent of the population followed by

Black non-Hispanics with 15.7 percent, and Asians with 8.3 percent. Approximately 3 percent were of two or more races, while American Indians, Native Hawaiians and other races represented less than 1 percent. Available at the American Community Survey on the U.S. Census Bureau (https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk). The New York State population is projected to become increasingly diverse; by 2025, Asians will see the largest growth rate with a 208.2 percent increase, followed by Hispanics with a 150.1 percent growth rate, and the Black population with a 53.3 percent growth rate. Available at (https://www.health.ny.gov/statistics/community/minority/docs/mcd_reports/albany_county_city_of_albany.pdf), page 3.

142. There is a lack of transparency on how a provider or entity that exerts its rights under the Final Rule will meet the notice requirements and ensure that the message is received by all employees. The Final Rule does not address how language barriers will be addressed. Furthermore, it is also unclear how recipients of services will be made aware of an entity's or provider's objection to perform or assist in a procedure or service.

143. The Department requires appropriate language access for patients at health care facilities and hospitals.

144. Language access is a problem not only for employees knowing their rights as well as recipients understanding why they are being denied a service or delayed in receiving a service and in being able to make an informed decision about health care services.

145. Hospitals are required to "develop a language assistance program to ensure meaningful access to the hospital's services and reasonable accommodation for all patients who require language assistance." 10 NYCRR 405.7(a)(7).

146. Clear and effective communication should not be a barrier to anyone receiving appropriate care and services. Patients in New York have the right to understand their rights and utilize them. "If for any reason [they] do not understand or [they] need help, the hospital must provide assistance, including an interpreter." 10 NYCRR 405.7(c), Patients' Bill of Rights. Agencies in New York are required to provide interpretation services and translation on documents

and forms to any non-English speakers, regardless of immigration status. Pursuant to 10 NYCRR § 405.7, all hospitals in New York State are required "to develop a language access plan, appoint a Language Access Coordinator, provide interpreters within 10 minutes in the emergency room and 20 minutes elsewhere in the hospital, and notify patients about their rights to language services, among other things. The regulations also prohibit the use of family members, strangers and minor children as interpreters except in emergencies."

147. The commentary related to providing notice of a physician or entity's right to object alludes to a premise that this ensures that ethnic minority patients can find a health care provider that shares similar beliefs and moral convictions, which can be healing, if they are able to determine that their health care provider has to right to object and refuse to provide or assist in the provision of certain services. Furthermore, the section addressing estimated benefits of the Final Rule focus on keeping health professionals from leaving the field and encouraging those who would question entering the field based on their personal moral convictions and decreasing the harms "providers suffer when forced to violate their consciences....". *See* 84 Fed. Reg 23246. The Final Rule assumes a trickle-down effect on patients who will theoretically receive better care if doctors aren't prohibited from exercising their rights and are allowed to refuse to provide the care that the patients may actually be seeking. Id. This is a clear indication that the Final Rule is neither directed at nor intended to benefit individual patients and the public; rather, the Final Rule allows someone to say, "I refuse to treat/serve you or assist in your treatment/service because of my own personal beliefs."

148. It takes time to develop and build a good rapport with a health care provider, even if the health service recipient is not an ethnic minority. It is impossible for a patient to maintain that important level of trust with his or her provider if at any moment, with no notice required to a facility or recipient, a provider can refuse to perform or assist in performing a procedure or health care service that a recipient has requested or is medically beneficial and/or necessary.

149. The Final Rule's impact on the refugee community will be deleterious. A research article on NIH's website indicates that refugees will face a more significant impact of disease (due

to a higher exposure to physical and psychological trauma while fleeing from their country of origin) and have more healthcare challenges due to many barriers, including language. Available at (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5681803/). Many of the refugees come to the United States need a procedure or service banned or unavailable in their country of origin. The article provides examples of individuals seeking care or who had a family member being treated and could not make informed decisions about health care and treatment due to language barriers. Id. The individuals' needs, and the needs of the family, will not be met and they will experience retraumatization with having their ability to make health care decisions compromised and/or denied by a government that asserts its authority.

150. The Department would be unable to take any action against such an objector under the Final Rule for violation of patient's rights, including language requirements.

The Final Rule Harms Rural and Underserved Communities

151. New York is a geographically diverse state with very rural areas. It may not be feasible or even possible to find another health service provider or facility that will meet the needs of the individual who is denied services due to provider conscience objections.

152. The Final Rule will further limit access to critical health care services for patients residing in underserved, rural areas where extensive provider shortages exist and where there are limited to no referral options available.

153. Current medical practice standards strive to balance the rights of the provider with the rights of the patient. The ambiguity and broadening of this rule will tip this balance away for the needs of the patient. While professional standards of practice support a provider's right to refuse to provide abortion or sterilization services when those services violate moral or religious beliefs, they also require that a provider assume the responsibility to assure patients access to information and services for the patient to make an informed decision on their health and well-being.

154. In rural areas of New York State, the only choice that an individual has in obtaining health care services may be a facility with a known religious affiliation or contract. This individual

may want or require services to which the provider may have a religious, moral, ethical, or other objection. In these instances, individuals may be denied health care services that meet their needs based on religious preferences or whim, since the fervor of the belief would not have to be substantiated or "sincerely held".

155. The Department is aware of currently underserved areas of the state as well as areas with a high concentration of religious-affiliated facilities and providers through the Health Resources & Services Administration ("HRSA"). HRSA defines Health Care Provider Shortage Areas ("HPSA") and Medically Underserved Areas ("MUA"). *See* (https://data.hrsa.gov/tools/shortage-area/hpsa-find) and (https://data.hrsa.gov/tools/shortage-area/mua-find). The Final Rule would further empower objections to provide or assist in providing care to individuals who may not easily have access to services anywhere else.

Additional Health Risks

156. The Department is responsible for investigations of and control of all communicable disease in New York State, outside of New York City.

157. The Department also operates the Vaccines for Children Program, which supplies vaccines for children who are uninsured and who receive Medicaid.

158. Children must be vaccinated against poliomyelitis, mumps, measles, diphtheria, rubella, varicella, Haemophilus influenzae type b (Hib), pertussis, tetanus, pneumococcal disease, and hepatitis B; receive a booster immunization before entering sixth grade against diphtheria and tetanus toxoids, and an acellular pertussis vaccine; and between seventh and twelfth grade receive an immunization against meningococcal disease. PHL § 2164(2)(a), (b), and (c).

159. A child is not permitted to attend school without a certification of immunizations from a health practitioner. PHL § 2164(5) and (7)(a); *see also*, 10 NYCRR 66-1.3(a)-(c).

160. There is an exception to the applicability of Section 2164 for "children whose parent, parents, or guardian hold genuine and sincere religious beliefs which are contrary to the practices required herein and no certification shall be required as a prerequisite to such child being

admitted or received into school or attending school." PHL § 2164(9); *see also*, 10 NYCRR 66-1.3(d).

161. The "principal or person in charge of the school" determines whether to grant the requested religious exemption. 10 NYCRR §66-1.3(d); *see also*, §§ 66-1.4, 66-1.5, and 66-1.9. The principal or person in charge of the school "may require supporting documents", such as a note from the student's clergy stating that immunization violates the student's "sincere and genuine religious beliefs". PHL § 2164(9); 10 NYCRR § 66-1.3(d).

162. Some religious-affiliated schools don't allow a religious exemption at all, which is possible since as a private religious school, the principal or person in charge of the school can make the determination that the particular religion does not have a religious belief contrary to the practice of immunization as set out in PHL § 2164. In practice, many parochial schools do allow for the exception, and some non-religious school principals or persons in charge of the school grant religious exemption whenever there is an assertion of religious belief without requiring supporting documents.

163. The Department's role is to audit the vaccination records of schools to ensure that the school has documented that every student is either immune or has a religious or medical exemption. If a school is delinquent in this regard, the Department may require the school to carry out a plan of correction. It is possible under the Final Rule that the Department could be accused of retaliating or discriminating against those who are opposed to vaccinations.

164. The New York State immunization requirements are integral to the control of acute communicable diseases under Article 21 of the Public Health Law. Children who are not immune, do not have medical exemptions, and whose parent or legal guardian do not hold "genuine and sincere religious beliefs", which are contrary to the practice of immunization, must be vaccinated in order to prevent outbreaks of communicable diseases that cause preventable hospitalizations and deaths.

165. The Final Rule could undermine the ability of a religious school to determine that the students' religion contains no beliefs contrary to immunization, and the Final Rule could

undermine the prerogative of the principal or person in charge of any school to require supporting documents that evidence a religious belief. New York already faces a measles outbreak, and this Final Rule could aggravate this growing threat to public health by decreasing vaccination rates.

166. Currently, some areas of New York State are experiencing a measles outbreak, including the lower Hudson Valley and parts of New York City. Measles can be dangerous and spreads easily whenever vaccination rates fall below 95% and "herd immunity" is lost. As of June 12, 2019, there are more than 336 confirmed cases of measles in New York State outside of New York City (266 in Rockland County, 43 in Orange County, 18 in Westchester County, 7 in Sullivan County, 1 in Suffolk County, and 1 in Greene County). These statistics are updated regularly on the Department's website. *See* (https://www.health.ny.gov/publications/2170/).

167. Health care workers can be exposed to serious and even deadly diseases, such as those currently dealing with the measles outbreak, and they work directly with patients who can be very vulnerable and immunocompromised. Choosing not to give or receive a vaccine creates a serious risk for the health care worker and the patients for whom they are providing care.

168. Achieving and sustaining high vaccination coverage among health care personnel will protect staff and their patients reduce disease burden and health-care costs. The Department recommends the following vaccines for health care workers: Hepatitis B; Influenza; measles, mumps, rubella ("MMR"); varicella (chickenpox); meningococcal; and tetanus, diphtheria, pertussis ("TdaP").

169. In Sections 405.3, 415.26, 751.6, 763.13, 766.11, 793.5 of 10 NYCRR, all persons who work at hospitals, nursing homes, diagnostic and treatment centers, home health agencies and programs and hospices are required to be immune to measles and rubella. There is no religious exception for this vaccination requirement.

170. The Final Rule is susceptible to abuse by those opposed to vaccines since someone (parent or guardian or a health care worker) can assert an objection to either giving or receiving a vaccination without providing any evidence of "genuine and sincere religious beliefs" as required by current New York State law. Even with this requirement in statute, the Department is dealing

with a health crisis with the current measles outbreak due to noncompliance with the appropriate checks for religious beliefs, which could indicate the threat of an even greater crisis if there are no limitations placed on asserting an objection.

171. Some of my duties as Commissioner include maintaining awareness of the "interests of health and life of the people of the state", "investigate the causes of disease, epidemics and the sources of mortality", and "establish and operate such adult and child immunization programs as are necessary to prevent or minimize the spread of disease and to protect the public health". *See* PHL §206(a), (d) and (l).

172. I am also charged with the critical duty to "make such rules and regulations which may be necessary to require pre-employment physical examination and thereafter require such annual examinations of all hospital employees for discovery of tuberculosis and other communicable diseases as he deems necessary for the safety and well-being of the people of the state." PHL §206(m).

The Final Rule Is Unduly Burdensome

173. The Final Rule will result in an administrative burden for private and public institutions, providers, grant awardees, and other sub-recipients that are impacted by the Final Rule. In a time where resources are limited, the costs of implementing this rule is an unnecessary waste and burden.

174. As a regulator, the Department conducts surveys of all facilities licensed under Article 28 of the PHL to enforce the provisions of the PHL and regulations. The Department also licenses health care practitioners and will investigate and penalize those that violate the law.

175. The Department will need to expend time and money to identify the appropriate staff that will need to be retrained to understand the implications of the Final Rule and its effects on the Department's programs and functions. The Department will need to provide an initial training to all staff prior to the Final Rule's effective date of July 22, 2019, to ensure that staff are aware of it and how it will affect their duties. The Department would need to bring in hundreds of employees from across the state to Albany for training. This will be expensive since each time the

Department will need to cover transportation, hotel rooms, car rentals, etc. Additionally, there is lost work time as the staff are being trained, which will set back the Department's statutory survey requirements.

176. Based on our actual costs per day we estimate we would be losing the following: $53,333 per day lost work hours on day one, in addition to the costs associated with the actual training amounting to $75,000 (hosting and facilitating training) which equals $75,000, plus the loss of 12.5 federally mandated surveys equal to $29,653. The Department will immediately lose $157,986 to implement the Final Rule.

177. The Final Rule estimates that institutions will incur only a one-time "familiarization" cost of two hours (measured in two hours of time for one lawyer earning $134.50/hour). *See* page 299 of the Final Rule. This estimate is preposterous. The Department anticipates that any training on a rule of such magnitude would be measured in days or weeks, not hours.

178. CMS outlines the responsibilities and methods for each state oversight agency to administer surveillance activities. This is memorialized in an agreement between the Secretary of Health and Human Services and the Commissioner of the New York State Department of Health, and specifically noted in Section 1864 and related provisions of the Social Security Act. Within the agreement, the responsibilities delegated to the State are outlined, including identifying whether or not providers receiving Medicare and Medicaid funds comply with the federal Conditions of Participation through prescribed inspection processes and procedure.

179. In addition, the primary mission of CMS is to administer the Medicare program and certain related provisions of the Social Security Act in a manner that promotes the timely and economic delivery of appropriate quality of care to eligible individuals, promotes awareness for beneficiaries of the services for which they are eligible, and promotes efficiency and quality within the health care delivery system.

180. To guide the state, CMS has the overall policy making responsibility for monitoring, surveillance, and overall administrative control of the certification process, including

its financial and surveyor training aspects. CMS establishes operational policy for the certification process and conveying operational instructions (training) and official interpretations of policy to the State agencies performing these functions. CMS is required to provide timely updates to the State Operations Manual and provide states with the resources necessary to carry out the responsibilities outlined above

181. Since the Department relies on this guidance from CMS, the Department will need to conduct another training once CMS issues its policies, guidance, and interpretation of the Final Rule. Surveyors and investigators will need to be retrained to know that certain violations of the PHL and the regulations will no longer be enforceable against an individual or entity that asserts the violation occurred based on a conscience objection since any administrative action taken against that entity or individual would fall under the broad definition of retaliation and discrimination in the Final Rule.

182. Until that happens, the Department, in addition to immediately conducting retraining and familiarization sessions, will also need to pull staff from other duties to assess whether internal guidance and policies in all program areas need to be amended to address the impact of the Final Rule and ensure compliance. To give just a few examples, Department surveyors, investigators, and other staff rely upon Department internal manuals to conduct their job functions, like a Nursing Home Incident Reporting Manual authored in August 2016 by the Department's Division of Nursing Homes and ICF/IID Surveillance Center for Health Care Provider Services and Oversight. That manual sets out the elements of an incident of neglect that would trigger a Departmental investigation. One element includes a health worker's "[f]ailure to carry out physician orders, medication omission, treatment omission or failure to follow the care plan or provide emergency services." The Department must now review whether such a statement – without being modified to exclude a failure to follow orders because of an employee's religious objection – is out of compliance with the Final Rule.

183. In another example, the Department also issues guidance to nursing homes and hospitals concerning the PHL's requirement of providing informed consent to patients, as well as

other provisions of the PHL, like the Palliative Care Information Act ("PCIA"). The PCIA requires physicians and nurse practitioners to offer to provide terminally ill patients with information and counseling concerning palliative care and end-of-life options. *See* PHL 2997-d. In light of the Final Rule's purported implementation of federal statutes concerning assisted suicide, euthanasia, or mercy killing, the Department must now review whether its guidance documents to nursing homes and hospitals – concerning compliance with New York's PCIA – are out of compliance with the Final Rule.

184. The Department will also need to take additional time and expense to ensure that all employees who deal with complaints from individuals and patients for violations of the PHL or regulations by health care entities, health care workers, other employees, or licensed health care practitioners whether as a surveyor, investigator, administrative hearings officer or administrative law judge knows the provisions of the Final Rule and its impact on the Department.

185. The Final Rule also holds the Department responsible for any action by one of its subcontractors that is found to be out of compliance. This aspect of the Final Rule also requires substantial immediate work by the Department, to make sure that all of our contractual relationships with subcontractors comply with the Final Rule when it goes into effect. The Department provides funds from HHS to nearly 1,000 different subcontractors, based on a model contract that it then it modifies for specific contractors. Prior to the Final Rule's effective date, the Department must review the model contract to determine whether any of its provisions conflict with the Final Rule. For example, the model contract incorporates New York State's non-discrimination laws, which prohibit discrimination based on sexual orientation and gender identity. It is not clear to the Department yet whether this incorporation of state law conflicts with the Final Rule's definition of "discrimination".

186. The Department must also triage among the nearly one thousand contracts it has with specific contractors to try and identify contractors, and the services they provide, that may be areas of likely objection from their employees – e.g., HIV and STD screening, testing, and prevention; contraception, family planning, and abortion; or counseling and health care for LGBT

individuals – and determine if those contracts contain unique provisions that conflict with the Final Rule. Finally, to the extent that the Department determines that its master contract or some of its specific contracts with subcontractors are in conflict with the Final Rule, it must alter those contracts to bring them into compliance with the Final Rule.

Conclusion

187. The Department would be detrimentally affected by the Final Rule through its ability to enforce laws and general oversight responsibilities. The Department will experience it from the administrative side as an owner and operator of four veterans' homes and one hospital, Helen Hayes Hospital.

188. The Final Rule will increase risks for patients and residents because there is no requirement that an employee of a facility or entity that is subject to the Final Rule provide advance notice of situations where that employee would "refuse to perform, assist in the performance of, or undergo certain health care services or research activities to which they may object for religious, moral, ethical, or other reasons". *See* Section 88.1 of the Final Rule. While the facility must provide all employees of their right to refuse, not allowing for a reciprocal notification prevents the employer from planning in advance how a refusal situation would be handled. This is especially important in emergency situations where immediate care is crucial to the recovery and survival of a patient or resident.

189. The expectation is that this Rule will create more conscience objections by employees. The HHS commentary addressing Societal Benefits from Conscience Protection on page 23,250 of the Federal Register "[HHS] expects that, as a result of this proposed rule, more individuals, having been apprised of those rights, will assert them," and that this "will contribute to the general public's knowledge and appreciation of . . . the protections afforded by Federal law."

190. This Rule is open to abuse due to the broad and ambiguous definitions as well as a lack of requirements for prior notice of an objection or that the belief the objection is based on be sincerely held. This opens up facilities to dealing with the abuse of the Final Rule by individuals

refusing to perform or assist in the performance of providing a health care procedure, health research, or administering or receiving a vaccine.

191. All health care facilities are required to ensure that they are properly staffed and able to address immediate health care needs and remain fully staffed at times of crisis. To do this, a facility must be able to have an advance plan. Facilities are unable to plan for situations where employees would object since the Final Rule does not require any notice of an objection.

192. It will also create an undue burden on marginalized patients (*i.e.*, ethnic minorities, those in extremely rural areas, especially patients with HIV/AIDS and those struggling with substance use disorder) who already confront discrimination in obtaining health care. It would do so needlessly because existing federal and state laws already provide a time-tested, established framework that balances respect for religious freedom with the rights and needs of patients, employers, and states.

193. I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

EXECUTED this 13th day of June, 2019 at New York, New York.

Howard Alan Zucker MD, JD

HOWARD A. ZUCKER, M.D., J.D.
Commissioner, New York State
Department of Health

Exhibit 49

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

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March 27, 2018

Roger Severino, Director
Office of Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201

Department of Health and Human Services, Office for Civil Rights
RIN 0945-ZA03
Docket ID No. HHS-OCR-2018-0002

Dear Director Severino:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 66,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, I write to provide input for the Notice of Proposed Rulemaking (NPRM) regarding Protecting Statutory Conscience Rights in Health Care.

America's pediatricians represent all faiths and serve children and families of all faiths. The free exercise of religion is an important societal value, which must be balanced against other important societal values, such as protecting children from serious harm and ensuring child health and well-being.

All children need access to appropriate, evidence-based health services to ensure they can grow, develop, and thrive. The inability to receive needed health care services can have a profound impact on the health of children. The AAP publishes policies and reports based on the best available scientific evidence that are designed to ensure children receive the health and social services they need. The AAP urges the U.S. Department of Health and Human Services (HHS) to ensure that health providers follow evidence-based or evidence-informed practices such as those published by professional medical organizations like the AAP. As HHS considers expanding conscience protections and the enforcement thereof, we respectfully offer these suggestions to ensure that HHS policy facilitates optimal access to services that support healthy children and families.

Introduction

Some health care professionals and health care organizations do morally object to particular services or treatments and refuse to provide them. Possible examples of such conscientious objection in pediatric practice include refusals to prescribe contraception, specifically emergency contraception[i]; perform routine neonatal male circumcision[ii]; or administer vaccines developed with virus strains or cell lines derived from voluntarily aborted human fetuses.[iii] Such objections may limit patients' access to information or treatment, and given this, the implementation of such objections is an important issue.

There are morally important reasons to protect the individual's exercise of conscience. Conscience is closely related to integrity. Performing an action that violates one's conscience undermines one's sense of integrity and self-respect and produces guilt, remorse, or shame.[iv,v] Integrity is valuable, and harms associated with the loss of self-respect should be avoided. This view of conscience provides a justification for respecting conscience independent of particular religious beliefs about conscience or morality. Claims of conscience are generally negative (the right to not perform an action) rather than positive (the right to perform an action).[vi]

Nevertheless, constraints on claims of conscience can be justified on the basis of health care professionals' role responsibilities and the power differential created by licensure. Health care professionals – and other health care entities – fulfill a particular societal role with associated expectations and responsibilities. For example, health care professionals' primary focus should be on their patients' rather than their own benefit. These role expectations are based in part on the power differential between health care professionals' and patients, which is the result of the providers' knowledge and patients' conditions. Role obligations are generally voluntarily accepted; therefore, health care professionals' claims of conscientious objection may justifiably be limited.

The AAP supports a balance between the individual physician's moral integrity and his or her fiduciary obligations to patients. **A physician's duty to perform a procedure within the scope of his or her training increases as the availability of alternative providers decreases and the risk to the patient increases.** Physicians should work to ensure that health care-delivery systems enable physicians to act according to their consciences and patients to obtain desired and appropriate health care. When an entire health care organization—and not just one provider—objects to providing a specific service, the availability of alternative providers naturally decreases even further.

However, physicians have a duty to disclose to patients and prospective patients standard treatments and procedures that they refuse to provide but are normally provided by other health care professionals. Physicians have a moral obligation to inform their patients of relevant alternatives as part of the informed-consent process. Physicians should convey information relevant to the patient's decision-making in a timely manner, using widely accepted and easily understood medical terminology, and should document this process in the patient's medical record. Physicians who consider certain treatments immoral or who claim a conscience or religious objection have a duty to refer patients who desire these treatments in a timely manner when failing to do so would harm the patients. Such physicians must also provide appropriate

ongoing care in the interim. These same obligations should be applicable to all recipients of federal funds for the provision of health care.

HHS's NPRM must not induce any health care entity, as defined in the NPRM, to abrogate its moral responsibilities of serving patients. The AAP strongly warns of harms to children's health should HHS not require providers, grantees, or any other entities subject to the NPRM to fulfill the moral obligation to:

- Ensure that patients obtain desired and appropriate health care;
- Disclose to patients and prospective patients standard treatments and procedures that they refuse to provide which are normally provided by other health care professionals;
- Inform patients of alternative providers as part of the informed-consent process;
- Provide information relevant to the patient's decision-making in a timely manner, using widely-accepted and easily-understood medical terminology, and document this process in the patient's medical record; and
- Refer patients who desire these treatments in a timely manner when failing to do so would harm the patients. Such entities must also provide appropriate ongoing care in the interim.

Specific Concerns Regarding the NPRM's Potential Impact on Child Health and Wellbeing

Institutional discrimination/HHS grantees/Medicaid and CHIP coverage/access

The Academy believes that the United States can and should ensure that all children, adolescents, and young adults from birth through the age of 26 years who reside within its borders have affordable access to high-quality and comprehensive health care, regardless of their or their families' incomes. Public and private health insurance should safeguard existing benefits for children and take further steps to cover the full array of essential health care services recommended by the AAP, including reproductive health and pregnancy-related services. CMS funds critical programs to support adolescent health, reduce unintended pregnancy, and provide reproductive health care, and these programs and services are critical to the health of adolescents and adults. The AAP urges HHS to ensure that no individual accessing services through a public health insurance is denied access to essential care.

As HHS considers potential changes to regulations and policy guidance to encourage the provision of grants and contracts to faith-based organizations, we urge you to ensure that federal policy does not undermine children's access to needed care and services. This includes a focus on upholding federal statutory safeguards for Medicaid beneficiaries that ensure access to qualified providers and appropriate and meaningful services. The AAP believes it essential that all states should uphold this fundamental protection affording access to any qualified, willing provider from which a beneficiary wishes to seek care. This essential protection is critical to the health of adolescents and young adults.

Vaccines

The Academy strongly supports all children and their families following the recommended childhood vaccination schedule.[vii] Routine childhood immunizations against infectious diseases are an integral part of our public health infrastructure and childhood immunization is one of the greatest accomplishments of modern medicine. In the United States 2009 birth cohort, routine childhood immunization will prevent approximately 42,000 early deaths and 20 million cases of disease, saving $13.5 billion in direct costs and $68.8 billion in societal costs.[viii] For children born in the United States between 1994 and 2013, "vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the course of their lifetimes."[ix]

However, vaccines are not 100% effective in all individuals receiving them. Certain infants, children, and adolescents cannot safely receive specific vaccines because of age or specific health conditions. These individuals benefit from the effectiveness of immunizations through a mechanism known as community immunity (also known as "herd" immunity). Community immunity occurs when nearly all individuals for whom a vaccine is not contraindicated have been appropriately immunized, minimizing the risk of illness or spread of a vaccine-preventable infectious agent to those who do not have the direct benefit of immunization. Although there is variance for levels of immunization required to generate community immunity specific to each disease and vaccine, it is generally understood that population immunization rates of at least 90% are required, as reflected in the Healthy People 2020 goals.[x] Certain highly contagious diseases, such as pertussis and measles, require a population immunization rate of ≥95% to achieve community immunity. But despite the importance of vaccines to children's health—and public health overall—some religious adherents object to their use.[xi]

For example, some religious adherents object to vaccines for chicken pox, hepatitis A, hepatitis B, polio, and measles, mumps and rubella (MMR) because they all have an attenuated connection to fetal-tissue research conducted in the 1960's.[xii] While the individual doses of these vaccines are not produced using fetal tissue, nor do they contain fetal tissue, the listed vaccines are grown in human cell cultures developed from two cell lines that trace back to two fetuses, both of which were legally aborted for unrelated medical reasons in the early 1960s. In addition, some object to the vaccine against the human papillomavirus (HPV). Certain strains of HPV can cause a variety of cancers, most notably cervical cancer.[xiii] Each year, approximately 11,000 women in the United States are diagnosed with cervical cancer – and almost half that number die from it.[xiv] Because HPV is often transmitted through sexual contact, and because the HPV vaccine is most effective when administered before the patient comes in contact with the virus, medical experts and organizations – including the AAP – recommend that the HPV vaccine be administered at 11 or 12 years of age.[xv] But because HPV can be transmitted sexually, some religious objectors oppose the vaccine on the basis that it allegedly encourages teens to engage in premarital sex, and that the correct way to limit transmission is through abstinence.[xvi]

In addition, all 50 states, the District of Columbia, and Puerto Rico have regulations requiring proof of immunization for child care and school attendance as a public health strategy to protect children in these settings, and to secondarily serve as a mechanism to promote timely immunization of children by their caregivers. Although all states and the District of Columbia

have mechanisms to exempt school attendees from specific immunization requirements for medical reasons, the majority also have a heterogeneous collection of regulations and laws that allow nonmedical exemptions, including those based on one's religious beliefs, from childhood immunizations otherwise required for child care and school attendance.

The AAP supports regulations and laws requiring certification of immunization to attend child care and school as a sound means of providing a safe environment for attendees and employees of these settings. The AAP also supports medically indicated exemptions to specific immunizations as determined for each individual child. The AAP views nonmedical exemptions to school-required immunizations as inappropriate for individual, public health, and ethical reasons and advocates for their elimination.[xvii] HHS policy should support organizations focused on advancing public health, a critical component of which is vaccination. We urge HHS not to make any policy changes that would provide grants or contracts to organizations that advocate for or adhere to vaccine policies not based on the best available evidence and science.

Unfortunately, we have seen the impact when immunization rates decline. In 2015, the United States experienced a large, multi-state outbreak of measles linked in part to exposures at Disneyland in California. The outbreak likely started from a traveler who became infected with measles and then visited the amusement park while infectious. Most of those infected were intentionally unvaccinated, some of them did not know their vaccination status, and a minority of them were vaccinated. Once outbreaks get started even vaccinated people can be affected because no vaccine is 100 percent effective. Analysis by CDC scientists showed that the measles virus type in this outbreak (B3) was identical to the virus type that caused the large measles outbreak in the Philippines in 2014.

Another measles outbreak occurred in Minnesota in the spring and summer of 2017, primarily concentrated within the Somali-American community. At the start of the outbreak, only about 42 percent of Somali-Minnesota 2-year-olds were vaccinated, largely due to many parents in the Somali-American community holding unfounded fears that the measles-mumps-rubella (MMR) vaccine causes autism. In a community with previously high vaccination coverage, the sudden drop in MMR vaccination rates resulted in a coverage level low enough to sustain widespread measles transmission in the community following introduction of the virus. Over the course of the outbreak, more than 8,000 people in Minnesota were exposed to measles, 500 were asked to stay home from work or school, 79 people were confirmed with measles, 73 of which were children under 10 years old, and 71 of the cases were in people who were unvaccinated for measles.[xviii]

In addition, each year, more than 200,000 individuals are hospitalized and 3,000-49,000 deaths occur from influenza-related complications.[xix] Serious morbidity and mortality can result from influenza infection in any person of any age. Rates of serious influenza-related illness and death are highest among children younger than 2 years old, seniors 65 years and older, and people of any age with medical conditions that place them at increased risk of having complications from influenza, such as pregnant women and people with underlying chronic cardiopulmonary, neuromuscular, and immunodeficient conditions. Hospital-acquired influenza has been shown to have a particularly high mortality rate, with a median of 16% among all patients and a range of 33% to 60% in high-risk groups such as transplant recipients and patients in the ICU.[xx]

Transmission from an infected, previously healthy child or adult begins as early as 1 day before the onset of symptoms and persists for up to 7 days; infants and immunocompromised people may shed virus even longer. Some infected people remain asymptomatic yet contagious.[xxi]

Because of the numbers cited above, the AAP also supports mandatory influenza immunization for all health care personnel as a matter of patient safety. Voluntary programs have failed to increase immunization rates to acceptable levels. Large health care organizations have implemented highly successful mandatory annual influenza immunization programs without significant problems. Mandating influenza vaccine for all health care personnel nationwide is ethical, just, and necessary. As such, we urge HHS not to make any policy changes that would weaken existing measures to immunize health care personnel and protect patients from vaccine-preventable infectious diseases.

Mental Health Services

Suicide affects young people from all races and socioeconomic groups, although some groups have higher rates than others. American Indian/Alaska Native males have the highest suicide rate, and black females have the lowest rate of suicide. Sexual minority youth (ie, lesbian, gay, bisexual, transgender, or questioning) have more than twice the rate of suicidal ideation compared to the average of all other children in the same age range.[xxii] The 2013 Youth Risk Behavior Survey of students in grades 9 through 12 in the United States indicated that during the 12 months before the survey, 39.1% of girls and 20.8% of boys felt sad or hopeless almost every day for at least 2 weeks in a row, 16.9% of girls and 10.3% of boys had planned a suicide attempt, 10.6% of girls and 5.4% of boys had attempted suicide, and 3.6% of girls and 1.8% of boys had made a suicide attempt that required medical attention.[xxiii]

The leading methods of suicide for the 15- to 19-year age group in 2013 were suffocation (43%), discharge of firearms (42%), poisoning (6%), and falling (3%).[xxiv] Particular attention should be given to access to firearms, because reducing firearm access may prevent suicides. Firearms in the home, regardless of whether they are kept unloaded or stored locked, are associated with a higher risk of completed adolescent suicide.[xxv,xxvi] However, in another study examining firearm security, each of the practices of securing the firearm (keeping it locked and unloaded) and securing the ammunition (keeping it locked and stored away from the firearm) were associated with reduced risk of youth shootings that resulted in unintentional or self-inflicted injury or death.[xxvii]

Youth seem to be at much greater risk from media exposure than adults and may imitate suicidal behavior seen on television.[xxviii] Media coverage of an adolescent's suicide may lead to cluster suicides, with the magnitude of additional deaths proportional to the amount, duration, and prominence of the media coverage.[xxix] A prospective study found increased suicidality with exposure to the suicide of a schoolmate.[xxx] Newspaper reports about suicide were associated with an increase in adolescent suicide clustering, with greater clustering associated with article front-page placement, mention of suicide or the method of suicide in the article title, and detailed description in the article text about the individual or the suicide act.[xxxi] More research is needed to determine the psychological mechanisms behind suicide clustering.[xxxii,xxxiii] The National

Institute of Mental Health suggests best practices for media and online reporting of deaths by suicide.[xxxiv]

Families and children, from infancy through adolescence, need access to mental health screening and assessment and a full array of evidence-based therapeutic services to appropriately address their mental and behavioral needs. In particular, adolescents, including LGBTQ youth, need non-judgmental treatment for mental health disorders. The AAP strongly urges HHS not to permit entities to infringe upon such treatment including through the use of "conversion" or "reparative therapy" which is never indicated for LGBTQ youth (add endnote from the LGBTQ section).

Sexual Assault

Sexual assault includes any situation in which there is nonvoluntary sexual contact, with or without penetration and/or touching of the anogenital area or breasts, that occurs because of physical force, psychological coercion, or incapacitation or impairment (e.g., secondary to alcohol or drug use). Sexual assault also occurs when victims cannot consent or understand the consequences of their choice because of their age or because of developmental challenges.[xxxv] National data show that teenagers and young adults ages 12 to 34 years have the highest rates of being sexually assaulted of any age group.[xxxvi] Annual rates of sexual assault were reported in 2012 (for 2011) by the U.S. Department of Justice to be 0.9 per 1000 persons 12 years and older (male and female).[xxxvii]

When an adolescent discloses that an acute sexual assault has occurred, it is incumbent on the health care provider to provide a nonjudgmental response. A supportive environment may encourage the adolescent to provide a clear history of what happened, agree to a timely medical and/or forensic evaluation, and engage in counseling and education to address the sequelae of the event and to help prevent future sexual violence. It is important to obtain the history of what happened from the adolescent, when possible. As in any other medical encounters, the physician should learn about relevant past medical and social history. Physicians should consider the possibility that the adolescent could be a victim of human trafficking and commercial sexual exploitation and ask appropriate questions, such as "Has anyone ever asked you to have sex in exchange for something you wanted?"[xxxviii] In addition, the physician should address the physical, psychological, and safety needs of the adolescent victim of sexual violence and be aware that responses to sexual assault can vary. The health care provider should address the adolescent's immediate health concerns, including any acute injuries, the likelihood of exposure to sexually transmitted infection (STIs), the possibility of pregnancy, and other physical or mental health concerns. Treatment guidelines for STIs from the CDC[xxxix] include recommendations for comprehensive clinical treatment of victims of sexual assault, including emergency contraception and HIV prophylaxis. Sexual assault is associated with a risk of pregnancy; 1 study reported a national pregnancy rate of 5% per rape among females 12 to 45 years of age.[xl,xli,xlii,xliii,xliv] Pregnancy prevention and emergency contraception should be addressed with every adolescent female, including rape and sexual assault victims. The discussion can include the risks of failure of the preventive measures and options for pregnancy management. It is critical that no entities, whether individual health care providers or organizations, be sanctioned by HHS in limiting the range of options that a pediatrician may discuss with sexual assault victims.

Global Health

The President's Emergency Plan for AIDS Relief (PEPFAR), the U.S. government's effort to prevent and treat HIV and AIDS worldwide, already includes a broad conscience clause (Leadership Act Section 301(d)) that allows participating organizations to deny patients information or care. This includes barrier means of contraception (e.g., condoms), which are one of the mainstays of HIV prevention. The NPRM would apply provisions of the Church Amendments to other global health programs funded by the Department, thereby allowing global health providers and entities to refuse individuals the care in contexts where suitable alternatives may be hard to find or nonexistent.

Sexuality Education and Reproductive Health

Pediatricians are an important source of health care for adolescents and young adults, especially younger adolescents, and can play a significant role in continuously addressing sexual and reproductive health needs during adolescence and young adulthood. Office visits present opportunities to educate adolescents on sexual health and development; to promote healthy relationships and to discuss prevention of sexually transmitted infections (STIs) including HIV, unintended pregnancies, and reproductive health-related cancers; to discuss planning for the timing and spacing of children, planning for pregnancy, and delivering preconception health care, as appropriate; and to address issues or concerns related to sexual function and fertility.[xlv] Pediatricians can help adolescents sort out whether they feel safe in their relationships as well as how to avoid risky sexual situations. Pediatricians also can facilitate discussion between the parent and adolescent on sexual and reproductive health.[xlvi] Pediatricians are in an important position to identify patients who are at risk for immediate harm (e.g., abuse, sex trafficking) and work collaboratively as part of a team of professionals from a number of disciplines to address these needs.

Sixty-five percent of reported *Chlamydia* and 50% of reported gonorrhea cases occur among 15- to 24-year-olds.[xlvii] Teen-aged birth rates in the United States have declined to the lowest rates seen in 7 decades yet still rank highest among industrialized countries. Pregnancy and birth are significant contributors to high school dropout rates among female youth; only approximately 50% of teen-aged mothers earn a high school diploma by 22 years of age versus approximately 90% of females who did not give birth during adolescence.[xlviii] Child sex trafficking and commercial sexual exploitation of children (CSEC) is increasingly being identified as a public health problem in the United States, and victims of sex trafficking and CSEC may present for medical care for a variety of reasons related to infections, reproductive issues, and trauma and mental health.[xlix]

The AAP believes that all children and adolescents should have access to developmentally appropriate, evidence-based, comprehensive, and medically accurate human sexuality education that empowers them to make informed, positive, and safe choices about healthy relationships, responsible sexual activity, and their reproductive health. This includes information about methods of contraception and sexual consent, as well as information that affirms gender identity and sexual orientation. The Academy supports approaches to sexual and reproductive health that are based on evidence and medical consensus. As such, the AAP recommends that pediatricians counsel their patients to use the most effective methods of contraception, starting with long-

acting reversible contraception such as implants and intrauterine devices. The AAP also strongly encourages the delivery of sexuality education that is based on modern conceptions of human sexuality. Access to accurate reproductive health care and sexual health information is critical to the overall development and well-being of children and adolescents.

The Academy's policy statement on Sexuality Education for Children and Adolescents recognizes that the development of healthy sexuality depends on forming attitudes and beliefs about sexual behavior, which can be influenced by religious concerns in addition to ethnic, racial, cultural, and moral ones. It is imperative that the administration of programs that pertain to reproductive health and education be done with respect for a multiplicity of religious values and belief systems, while prioritizing adolescents' right to accurate sexual health information.

The federal government oversees several programs that fund the delivery of evidence-based sexuality education. These programs help states implement innovative approaches to preventing unintended teen pregnancy, HIV, and other sexually transmitted infections, as well as youth development and adulthood preparation. The AAP urges HHS to continue to prioritize the funding of evidence-based or evidence-informed models in the administration of these programs, and to ensure that federal dollars for these programs are granted to organizations that meet the criteria laid out in these federal programs. The AAP also urges HHS to ensure that all programs that provide access to reproductive health care services prioritize access to the most effective methods of contraception.

Contraception

Pediatricians play an important role in adolescent pregnancy prevention and contraception. Nearly half of US high school students report ever having had sexual intercourse.[l] Each year, approximately 750 000 adolescents become pregnant, with more than 80% of these pregnancies unplanned, indicating an unmet need for effective contraception in this population.[li,lii]

Although condoms are the most frequently used form of contraception (52% of females reported condom use at last sex), use of more effective hormonal methods, including combined oral contraceptives (COCs) and other hormonal methods, was lower, at 31% and 12%, respectively, in 2011.[liii] Use of highly effective long-acting reversible contraceptives, such as implants or intrauterine devices (IUDs), was much lower.[liv] Adolescents consider pediatricians and other health care providers a highly trusted source of sexual health information.[lv,lvi] Pediatricians' long-term relationships with adolescents and families allow them to ask about sensitive topics, such as sexuality and relationships, and to promote healthy sexual decision-making, including abstinence and contraceptive use for teenagers who are sexually active. Additionally, medical indications for hormonal contraception, such as dysmenorrhea, heavy menstrual bleeding or other abnormal uterine bleeding, acne, and polycystic ovary syndrome, are often uncovered during adolescent visits. A working knowledge of contraception will assist the pediatrician in both sexual health promotion and treatment of common adolescent gynecologic problems. Contraception has been inconsistently covered as part of insurance plans. However, the Institute of Medicine has recommended contraception as an essential component of adolescent preventive care,[lvii] and the Patient Protection and Affordable Care Act of 2010 (Pub L No. 111–148) requires coverage of preventive services for women, which includes contraception, without a copay.[lviii,lix]

Abortion

Ensuring that adolescents have access to health care, including reproductive health care, has been a long-standing objective of the AAP.[lx] Timely access to medical care is especially important for pregnant teenagers because of the significant medical, personal, and social consequences of adolescent childbearing. The AAP strongly advocates for the prevention of unintended adolescent pregnancy by supporting comprehensive health and sexuality education, abstinence, and the use of effective contraception by sexually active youths. For 2 decades, the AAP has been on record as supporting the access of minors to all options regarding undesired pregnancy, including the right to obtain an abortion. Membership surveys of pediatricians, adolescent medicine specialists, and obstetricians confirm this support.[lxi,lxii,lxiii]

In the United States, minors have the right to obtain an abortion without parental consent unless otherwise specified by state law. State legislation that mandates parental involvement (parental consent or notification) as a condition of service when a minor seeks an abortion has generated considerable controversy. U.S. Supreme Court rulings, although upholding the constitutional rights of minors to choose abortion, have held that it is not unconstitutional for states to impose requirements for parental involvement as long as "adequate provision for judicial bypass" is available for minors who believe that parental involvement would not be in their best interest.[lxiv, lxv] Subsequently, there has been renewed activity to include mandatory parental consent or notification requirements in state and federal abortion-related legislation.

The American Medical Association, the Society for Adolescent Health and Medicine, the American Public Health Association, the American College of Obstetricians and Gynecologists, the AAP, and other health professional organizations have reached a consensus that a minor should not be compelled or required to involve her parents in her decision to obtain an abortion, although she should be encouraged to discuss the pregnancy with her parents and/or other responsible adults.[lxvi,lxvii,lxviii,lxix,lxx,lxxi,lxxii] These conclusions result from objective analyses of current data, which indicate that legislation mandating parental involvement does not achieve the intended benefit of promoting family communication but does increase the risk of harm to the adolescent by delaying access to appropriate medical care or increasing the rate of unwanted births.

Beliefs about abortion are deeply personal and are shaped by class, culture, religion, and personal history, as well as the current social and political climate. The AAP acknowledges and respects the diversity of beliefs about abortion. The AAP affirms the value of parental involvement in decision-making by adolescents and the importance of productive family communication in general. The AAP is foremost an advocate of strong family relationships, and holds that parents are generally supportive and act in the best interests of their children. We strongly urge HHS policy not to enable entities to infringe on the ability of parents and children to act in their best interests.

Medical Neglect

The AAP asserts that every child should have the opportunity to grow and develop free from preventable illness or injury. Children also have the right to appropriate medical evaluation when it is likely that a serious illness, injury, or other medical condition endangers their lives or threatens substantial harm or suffering. Under such circumstances, parents and other guardians have a responsibility to seek medical treatment, regardless of their religious beliefs and preferences. The AAP emphasizes that all children who need medical care that is likely to prevent substantial harm or suffering or death should receive that treatment.[lxxiii]

The U.S. Constitution requires that government not interfere with religious practices or endorse particular religions. However, these constitutional principles do not stand alone and may, at times, conflict with the independent government interest in protecting children. Government obligation arises from that interest when parental religious practices subject minor children to possible loss of life or to substantial risk of harm. Constitutional guarantees of freedom of religion do not permit children to be harmed through religious practices, nor do they allow religion to be a valid legal defense when an individual harms or neglects a child. As HHS considers the implementation, expansion, and enforcement of religious objections to medical care, we urge you to avoid policy changes that would result in financial support for organizations that encourage or engage in faith-based medical neglect.

Religious Nonmedical Health Care Institutions

Medicare and Medicaid cover care provided at religious nonmedical health care institutions (RNHCIs) and exempt these institutions from medical oversight requirements.[lxxiv] RNHCIs provide custodial rather than skilled nursing care. Given patients' exemptions from undergoing medical examinations, it is not possible to determine whether patients of RNHCIs would otherwise qualify for benefits.[lxxv,lxxvi] Because providing public funding for unproven alternative spiritual healing practices may be perceived as legitimating these services, parents may not believe that they have an obligation to seek medical treatment. Although the AAP recognizes the importance of addressing children's spiritual needs as part of the comprehensive care of children, it opposes public funding of religious or spiritual healing practices.[lxxvii]

Newborn Hearing Screening

Although most infants can hear normally, 1 to 3 of every 1,000 children are born with some degree of hearing loss.[lxxviii] Without newborn hearing screening, it is difficult to detect hearing loss in the first months and years of an infant's life. About half of the children with hearing loss have no risk factors for it. Newborn hearing screening can detect possible hearing loss in the first days of a child's life. If a possible hearing loss is found, further tests will be done to confirm the results. When hearing loss is confirmed, treatment and early intervention should start as soon as possible. Studies show that children with hearing loss who receive appropriate early intervention services by age 6 months usually develop good language and learning skills. That is why the AAP recommends that all babies receive newborn hearing screening before they go home from the hospital. We would thus strongly urge HHS to support hearing screenings for all newborns, without exception.

Unaccompanied Children

Children, unaccompanied and in family units, seeking safe haven in the United States often experience traumatic events in their countries of origin, during their journeys to the United States, and throughout the difficult process of resettlement. Upon arriving in the U.S., unaccompanied immigrant children are transferred to the custody of HHS's Office of Refugee Resettlement (ORR) and placed in shelters, many of which are run by faith-based organizations. Children, especially those who have been exposed to trauma and violence, should not be placed in settings that do not meet basic standards for children's physical and mental health and that expose children to additional risk, fear, and trauma. Children in federal custody and in the custody of sponsors, whether unaccompanied or accompanied, should receive timely, comprehensive medical care, including reproductive services and abortion care, that is culturally and linguistically sensitive by medical providers trained to care for children.[lxxix] This care should be consistent throughout all stages of the immigration processing pathway.

Recent actions by the Office of Refugee Resettlement in the case of "Jane Doe" are quite troubling. No woman or girl should face political interference in their health care decisions, including while she is in an ORR shelter, or held in any federally-funded detention facility. Safe, legal abortion is a necessary component of women's health care. When abortion care is illegal or highly restricted, women resort to unsafe means to end an unwanted pregnancy, including self-inflicted abdominal and bodily trauma, ingestion of dangerous chemicals, self-medication with a variety of drugs, and reliance on unqualified abortion providers. By obstructing basic access to safe and legal abortion, ORR is risking the health and lives of women and adolescents in its custody. ORR's action also appears to be a violation of the terms of the *Flores v. Reno* Settlement Agreement.

We urge HHS to ensure that no grantee of the federal government be permitted to deny any child, especially a child who has been exposed to trauma and violence, access to timely, comprehensive medical care, including reproductive services and abortion care.

Adoption and Foster Care

The AAP supports families in all their diversity, because the family has always been the basic social unit in which children develop the supporting and nurturing relationships with adults that they need to thrive. Children may be born to, adopted by, or cared for temporarily by married couples, nonmarried couples, single parents, grandparents, or legal guardians, and any of these may be heterosexual, gay or lesbian, or of another orientation. Children need secure and enduring relationships with committed and nurturing adults to enhance their life experiences for optimal social-emotional and cognitive development. Scientific evidence affirms that children have similar developmental and emotional needs and receive similar parenting whether they are raised by parents of the same or different genders.[lxxx] If two parents are not available to the child, adoption or foster parenting remain acceptable options to provide a loving home for a child and should be available without regard to the sexual orientation of the parent(s).[lxxxi] We urge HHS not to permit entities to discriminate against prospective or current adoptive or foster parents on the basis of sexual orientation of the parents.

LGBTQ Children

All children and adolescents deserve the opportunity to learn and develop in a safe and supportive environment. Lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth face high rates of bullying and other factors that contribute to health disparities such as higher rates of depression and suicidal ideation, higher rates of substance use, and more sexually transmitted and HIV infections.[lxxxii] Supportive and affirming communities, schools, friends and families can buffer all young people – especially LGBTQ youth – from negative experiences and outcomes while simultaneously promoting positive health and well-being.[lxxxiii] Policies that single-out or discriminate against LGBTQ youth are harmful to social-emotional health and may have lifelong consequences.[lxxxiv] All health care entities receiving federal funding, including those that are faith-based, should be welcoming to children who are members of the LGBTQ community.

The AAP advocates for policies that are gender-affirming for children – an approach that is supported by other medical professional organizations. In 2016, the AAP joined with other organizations to produce the document, "Supporting & Caring for Transgender Children," a guide for community members and allies to ensure that transgender young people are affirmed, respected, and able to thrive.[lxxxv] Section 1557 of the ACA contains essential nondiscrimination provisions for LGBTQ youth including prohibitions for discrimination on the basis of gender identity. These protections should be maintained and all covered entities, including faith-based organizations, should be required to comply.

All children and adolescents deserve the opportunity to learn and develop in a safe and supportive environment. “Conversion” or “reparative therapy” is never indicated for LGBTQ youth.[lxxxvi] This type of therapy is not effective and may be harmful to LGBTQ individuals by increasing internalized stigma, distress, and depression.[lxxxvii] We urge HHS to refrain from supporting entities who do not treat LGBTQ youth as they do all others, who discriminate or condone discrimination against them, their families, or LGBTQ parents, or who support, condone, or provide “conversion” or “reparative therapy”.

Child Welfare Services

Children in foster care have such unique vulnerabilities and health disparities that the AAP classifies them as a population of children with special health care needs. Children in foster care face greater health needs because of their experiences of complex trauma, including abuse, neglect, witnessed violence, and parental substance use disorders (SUD). Children in foster care have typically experienced multiple caregivers, impacting their ability to form a safe, stable, and nurturing attachment relationship with a caregiver. One third of children in foster care have a chronic medical condition, and 60 percent of those under age 5 have developmental health issues.[lxxxviii , lxxxix] Up to 80 percent of children entering foster care have a significant mental health need.[xc] Ensuring access to appropriate and trauma-informed services is critical to meeting the needs of this vulnerable population.

In FY 2016, the number of children entering foster care increased to over 270,000, up from 251,352 in FY 2012. This is the fourth year in a row that removals have increased after declining over the past decade. Parental substance use was a factor for the removal in over a third of those

cases, second only to neglect as a factor for placement in foster care. Of note, infants represented nearly a fifth of all removals from families to foster care, totaling 49,234 in FY 2016. A total of 437,465 children were in foster care on the last day of FY 2016.[xci] As the opioid epidemic continues to contribute to rising foster care placements, we need federal policies that support child and family healing and that provide a sufficient number of nurturing, high-quality foster and adoptive families.

Children fare best when they are raised in families equipped to meet their needs. Child welfare services can support the intensive family preservation services and parental SUD treatment needed to help families heal when it is possible to keep children together with their parents. When out-of-home placements are necessary for a child's health and safety, access to quality parenting from foster or kinship care providers can support a child's healing. High-quality foster parent training and recruitment is essential to ensure sufficient access to families with the necessary background and training in trauma, child development, and parenting skills. In light of the ongoing opioid epidemic and its impact on rising foster care placements, there is a significant need to expand recruitment broadly to meet growing need and to also better support and retain foster families and kinship caregivers.

Given the uniquely vulnerable health needs of children in foster care, and the need for expanded capacity for foster and adoptive homes, the AAP recommends that HHS not make any changes in federal child welfare policy that would result in discrimination against LGBTQ children and youth in foster care, or LGBTQ families seeking to serve as foster or adoptive parents. Faith-based organizations play an important role in providing child welfare services and families to provide nurturing homes for children. However, no federal policy changes should allow for discrimination against children or families in child welfare services on the basis of religion, sexual orientation, or gender identity. All children who enter the child welfare system should receive compassionate, high-quality, and trauma-informed care and support services.

HHS should not support entities involved in child welfare services that engage in discrimination against children or families based on sexual orientation, gender identity, marital status, or faith.

Conclusion

The AAP wishes to underscore its recognition of the important role of religion in the personal, spiritual, and social lives of many individuals, including health providers. Balancing that role with efforts to ensure children have appropriate access to needed health and social services is critical to meeting their health needs and supporting their health and wellbeing. As HHS considers potential changes to regulations and policy guidance to encourage the provision of grants and contracts to faith-based organizations, we urge you to ensure that federal policy does not undermine children's access to needed care and services.

Thank you again for the opportunity to provide feedback on this important issue. If you have any questions, please reach out to Ami Gadhia in our Washington, D.C. office at 202/347-8600 or agadhia@aap.org.

Sincerely,

Colleen A. Kraft MD, FAAP
President
CAK/avg

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[lxxvii]AAP Committee on Bioethics, "Conflicts Between Religious or Spiritual Beliefs and Pediatric Care: Informed Refusal, Exemptions, and Public Funding," Pediatrics October 2013, 2013;132;962; DOI: 10.1542/peds.2013-2716. Retried from http://pediatrics.aappublications.org/content/pediatrics/132/5/962.full.pdf.
[lxxviii] https://www.healthychildren.org/English/ages-stages/baby/Pages/Purpose-of-Newborn-Hearing-Screening.aspx.
[lxxix] Council on Community Pediatrics. Detention of Immigrant Children. Pediatrics. 2017; 139(5). Available at: http://pediatrics.aappublications.org/content/139/5/e20170483.
[lxxx] AAP Committee on Psychosocial Aspects of Child and Family Health, "Promoting the Well-Being of Children Whose Parents Are Gay or Lesbian—Policy Statement," Pediatrics Apr 2013, 131 (4) 827-830; DOI: 10.1542/peds.2013-0376.
[lxxxi] ibid

[lxxxviii] Szilagyi, M. et al. (2015). Policy Statement: Health Care Issues for Children and Adolescents in Foster Care and Kinship Care. *Pediatrics*. 2015; 136; e1131. Retrieved from http://pediatrics.aappublications.org/content/pediatrics/136/4/e1131.full.pdf.
[lxxxix]

[xc] *Ibid.*
[xci] U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Children, Youth, and Families, Children's Bureau (2017). The AFCARS Report FY 2016. Retrieved from https://www.acf.hhs.gov/sites/default/files/cb/afcarsreport24.pdf.

Exhibit 50

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Office of the President
Haywood Brown, MD, FACOG

March 27, 2018

VIA ELECTRONIC SUBMISSION

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

Re: RIN 0945-A03; Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

The American College of Obstetricians and Gynecologists (ACOG) writes in response to the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (Proposed Rule), published in the Federal Register on January 26, 2018 by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).

The creation of the Proposed Rule, coupled with the creation of a new division within OCR – the "Conscience and Religious Freedom Division" – suggests a concerning expansion of OCR's authority in a way that threatens to restrict access for patients seeking medical care and support. We are concerned that the Proposed Rule and new office will encourage some providers and institutions to place their personal beliefs over their patients' medical needs, a move that can have real-world, potentially life-and-death consequences for patients. ACOG opposes this expansion and calls on HHS and OCR to immediately withdraw the Proposed Rule.

ACOG believes that respect for an individual's conscience is important in the practice of medicine, and recognizes that physicians may find that providing indicated care could present a conflict of conscience. ACOG is committed to ensuring all women have unhindered access to health care and opposes all forms of discrimination.[i]

As outlined in the American Medical Association's Code of Medical Ethics, responsibility to the patient is paramount for all physicians. ACOG holds that providers with moral or religious objections should ensure that processes are in place to protect access to and maintain a continuity of care for all patients. If health care providers feel that they cannot provide the standard services that patients request or require, they should refer patients in a timely

manner to other providers. In an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care. Conscientious refusals should be limited if they constitute an imposition of religious or moral beliefs on patients, negatively affect a patient's health, are based on scientific misinformation, or create or reinforce racial or socioeconomic inequalities. The Proposed Rule disregards these rigorous standards of care established by the medical community.

The Proposed Rule demonstrates political interference in the patient-physician relationship. Institutions, facilities, and providers must give patients the full range of appropriate medical care to meet each patient's needs as well as relevant information regarding evidence-based options for care, outcomes associated with different interventions, and, in some cases, transfer to a full-service facility. Communication is the foundation of a positive patient-physician relationship and the informed consent process.[ii,iii] By allowing providers to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to make the health care decision that is right for them. All patients should be fully informed of their options.[iv]

ACOG evaluates policies based on the standard of "first, do no harm" to patients, and the result of the Proposed Rule could be just the opposite. Across the country, refusals of care based on personal beliefs have kept women from needed medical care.[v]

The Proposed Rule expands existing conscientious refusal laws by allowing any entity involved in a patient's care to claim a conflict of conscience, from a hospital board of directors to an individual who schedules procedures, and by allowing the refusal of "any lawful health service or activity."[vi] This threatens patients' access to all health care services, including vaccinations and blood transfusions.

ACOG believes that the top priority in any federal rulemaking must be ensuring access to comprehensive, evidence-based health care services. Access to comprehensive reproductive health care services is essential to women's health and well-being.[vii] ACOG urges HHS and OCR to put patients first and withdraw the Proposed Rule.

Sincerely,

Haywood L. Brown, MD, FACOG
President
American College of Obstetricians and Gynecologists

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[i] American College of Obstetricians and Gynecologists. Statement of Policy: Racial Bias. Feb 2017. *Accessed online:* https://www.acog.org/-/media/Statements-of-Policy/Public/StatementofPolicy93RacialBias2017-2.pdf?dmc=1&ts=20180326T1531018088

[ii] Informed consent. ACOG Committee Opinion No. 439. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009; 114:401–8.

[iii] Partnering with patients to improve safety. Committee Opinion No. 490. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;117:1247–9.

[iv] Effective patient–physician communication. Committee Opinion No. 587. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:389–93.

[v] American College of Obstetricians and Gynecologists. Position Statement: Restrictions to Comprehensive Reproductive Health Care. April 2016. *Accessed online:* https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Restrictions-to-Comprehensive-Reproductive-Health-Care

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

[vii] Increasing access to abortion. Committee Opinion No. 613. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;124:1060–5.

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Exhibit 51

AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

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

March 27, 2018

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

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

Dear Secretary Azar:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

James L. Madara, MD

Exhibit 52

ANA
AMERICAN NURSES ASSOCIATION

AMERICAN ACADEMY OF NURSING
transforming health policy and practice through nursing knowledge

March 23, 2018

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

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

Submitted electronically to www.regulations.gov

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

Dear Sir/Madam:

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

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

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

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

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

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

Code of Ethics for Nurses and Moral and Ethical Obligations

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

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

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

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

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

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

Considerations for Access to Reproductive Health Care Services

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

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

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

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

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

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

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

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[6]National Women's Law Center. *Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care.* February 16, 2018. Web: https://nwlc.org/resources/trump-administration-proposes-sweeping-rule-to-permit-personal-beliefs-to-dictate-health-care/

[7]Ibid.

[8]Biggs, M. Antonia and John M. Neuhaus and Diana G. Foster. *Mental Health Diagnoses 3 Years After Receiving or Being Denied an Abortion in the United States.* The American Journal of Public Health: 2015 December; 105(12): 2557-2563.

[9]National Women's Law Center. *Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care.*

[10]Harris, LH et al. *Obstetrician-gynecologists' objections to and willingness to help patients obtain an abortion.* Obstetrics and Gynecology: 2011 October; 118(4): 905-912.

[11]Chavkin, W. et al. *Conscientious objection and refusal to provide reproductive healthcare: a White Paper examining prevalence, health consequences, and policy responses.* The International Journal of Gynaecology and Obstetrics: 2013 December; 123 Supplement 3: S41-56.

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

Considerations for the Protection of LGBTQ Access to Health Care Services

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

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

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

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

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

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

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

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

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

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

Policy Recommendations and Conclusion

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

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

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

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

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

Sincerely,

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

Exhibit 53

ATTORNEYS GENERAL OF NEW YORK, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, NEW JERSEY, NEW MEXICO, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, VIRGINIA, WASHINGTON

March 27, 2018

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

Re: Proposed Rule: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority [Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03]

The undersigned State Attorneys General submit these comments to urge the Department of Health and Human Services ("HHS") to withdraw the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the "Proposed Rule").[1] HHS has proposed to codify a sweeping and overbroad right that would allow individuals and entire institutions to deny lawful and medically necessary care to patients for "religious, moral, ethical, or other reasons." This Proposed Rule is unsupported by the federal health care conscience laws it purports to implement; conflicts with federal statutes regarding emergency health care, religious accommodations, and comprehensive family planning services; undermines the States' health care policies and laws; would lead to status-based discrimination against patients; and would violate both the Spending Clause and the Establishment Clause of the United States Constitution. The Proposed Rule impermissibly seeks to coerce state compliance with its unlawful requirements by threatening to terminate billions of dollars in federal health care funding if at any point HHS determines that a state has failed—or even "threatened" to fail—to comply with the Proposed Rule's extensive mandates.

If adopted, the Proposed Rule would effectuate a substantial change in the delivery of health care, and it would do so at the expense of not only employers and states, but also of patients whose access to medically necessary care would be seriously threatened by the Proposed Rule. At a time when many Americans are struggling to obtain affordable health care, the Proposed Rule would reduce access to health care by allowing a vast new set of individuals and institutions to opt out of providing that care. It would also unnecessarily decrease the information patients receive about their health care options, undermining their ability to choose the best options for their own health care. It would impose particularly onerous burdens on marginalized patients who already

[1] 83 Fed. Reg. 3880 (Jan. 26, 2018).

confront discrimination in obtaining health care. It would do so needlessly because existing federal and state laws already provide a time-tested, established framework that balances respect for religious freedom with the rights and needs of patients, employers, and states.

The Proposed Rule prioritizes providers over patients. If implemented, the Proposed Rule will enable health care workers to refuse to provide life-saving care without notice to their employers—and to the detriment of patients—and impose massive burdens on both private and public institutions. As officials of States entrusted with the power to protect the health, safety, and welfare of the public, we urge that the Proposed Rule be withdrawn.

I. Background

The Proposed Rule purports to implement a litany of federal statutes concerning conscience objections in health care.[2] Several of these statutes concern behavior by state governments. Generally speaking, the statutes concerning state behavior relate to the procedures of: abortion and sterilization; assisted suicide, euthanasia, and mercy killing; and counseling and referral. [3]

(A) Three Long-standing Statutes Concern Objections to Abortion and Sterilization.

The Church Amendments, originally passed in the 1970s and now codified at 42 U.S.C. § 300a-7, provide in relevant part that:

1. the receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act does not obligate any individual "to perform or assist in the performance of any sterilization procedure or abortion" if doing so would be contrary to the individual's religious beliefs or moral convictions;
2. entities that receive a grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act cannot discriminate against physicians or health personnel because they assisted in a sterilization procedure or abortion, because they refused to participate in a sterilization procedure or abortion on the grounds of religious beliefs or moral

[2] 83 Fed. Reg. at 3881-86.

[3] Additional statutes that may apply to states that are not discussed in this section include: 29 U.S.C. § 669(a)(5)-1 (concerning occupational illness examinations and tests); 42 U.S.C. §§ 290bb-36(f), 5106i (concerning medical service or treatment, including suicide assessment, early intervention, and treatment services, for youth whose parents or guardians object based on religious beliefs or, in certain cases, moral objections); 42 U.S.C. §§ 1320a-1, 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), 1397j-1(b), 5106ia(2)-1 (concerning certain exemptions from law and standards for religious nonmedical health care institutions and "an elder's right to practice his or her religion through reliance on prayer alone for healing" in certain cases); and 42 U.S.C. § 1396s(c)(2)(B)(ii) (concerning pediatric vaccination).

convictions, or because of their religious beliefs or moral convictions regarding sterilization or abortion;

3. entities that receive a grant or contract for biomedical or behavioral research cannot discriminate against physicians or health personnel because they assisted in any lawful health service or research activity, because they refused to do so on the grounds of religious beliefs or moral convictions, or because of their religious beliefs or moral convictions regarding the service or activity;
4. HHS's funding of a health service program or research activity does not obligate any individual to "perform or assist in the performance of" any part of that health service program or research activity if contrary to the individual's religious beliefs or convictions; and
5. entities that receive a grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 cannot discriminate against applicants for training or study based on "the applicant's reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions."

The Coats-Snowe Amendment, passed in 1996 and codified at 42 U.S.C. § 238n, prohibits state governments that receive federal funds, among others, from discriminating against:

1. any health care entity that refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions;
2. any health care entity that refuses to make arrangements for any of the activities specified in paragraph (1); or
3. any health care entity that attends (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

The Weldon Amendment, an appropriations rider first passed in 2004 and that has been attached to the Labor, Health and Human Services, Education, and Related Agencies Appropriations Act every year since, states in relevant part that none of the funds appropriated in the Act may be made available to any state government if it discriminates against any "institutional or individual health care entity" because it "does not provide, pay for, provide coverage of, or refer for abortions."[4]

[4] The citation for the 2017 appropriations bill's Weldon Amendment is Consolidated Appropriations Act of 2017, Public Law 115-31, 131 Stat. 135, 562.

(B) Two Statutes Concern Objections to Assisted Suicide, Euthanasia, and Mercy Killing.

Section 1553 of the Affordable Care Act, codified at 42 U.S.C. § 18113, proscribes state governments that receive federal funding under the Affordable Care Act from discriminating against an "individual or institutional health care entity on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing."[5]

A statutory provision applying to state-administered Medicaid programs, 42 U.S.C. § 14406, clarifies that the advanced directives requirements applicable to those programs, codified at 42 U.S.C. § 1396a(w), do not require a provider, organization, or employee of a provider or organization "to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing or to apply to or to affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing."

(C) A Medicaid Managed Care Organization Statute Concerns Objections to Counseling or Referral.

A statutory provision related to state-administered Medicaid programs, 42 U.S.C. § 1396u-2(b)(3)(B), explains that a Medicaid managed care organization is not required "to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds" and "makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service."

II. The Proposed Rule Exceeds HHS's Authority under the Referenced Statutes by Adopting Excessively Broad Definitions of Statutory Text.

The Proposed Rule states that "the statutory provisions and the regulatory provisions contained in [the Proposed Rule] are to be interpreted and implemented broadly to effectuate their protective purposes."[6] In HHS's attempt to broaden what it views as the referenced statutes' purposes, however, it has ventured far beyond the text of those statutes and the bounds of the statutory authority Congress delegated to it. HHS has done this by proposing excessively broad definitions of statutory terms, at least one of which is already more narrowly defined by the statutes themselves.

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[5] 42 U.S.C. § 18113(a).

[6] 83 Fed. Reg. at 3923.

(A) The Proposed Rule's Definition of "Assist in the Performance" Is Excessively Broad.

The Proposed Rule aims to enforce "[f]ederal health care conscience and associated anti-discrimination laws," which allow certain individuals and entities to "refuse to perform, assist in the performance of, or undergo" health care services or research "to which they may object for religious, moral, ethical, or other reasons."[7] In implementing this aim, the Proposed Rule adopts a definition of **"assist in the performance"** that is untethered from and unsupported by the statutory text. HHS proposes that this common-sense phrase actually "means to participate in any program or activity with an *articulable connection* to a procedure, health service, health program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes but is not limited to counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity."[8]

The Proposed Rule's overly broad definition of "assist in the performance"—which requires only an "articulable connection" to a procedure, health service, health program, or research activity—is intended to capture acts with only a remote connection to a given medical procedure. Indeed, it expressly includes "counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity." This strained definition is much broader than that contemplated by Congress, as evidenced by the text of the statutes the Proposed Rule purports to implement. Indeed, the statutory text when read as a whole demonstrates that Congress made clear textual distinctions when discussing the performance of a medical procedure and other services, such as counseling. This Proposed Rule blurs that Congressionally-adopted distinction. For example, the first four subsections of the Church Amendments refer to the performance or assistance in the performance of a particular activity or activities.[9] The fifth and last, however, applies to "reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations…."[10] When Congress intended to include activities such as counseling in its mandates, it did so. Likewise, the Coats-Snowe Amendment extends to those who refuse "to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions," among others, indicating that Congress again knew how to—and did—include training and referrals in its mandates when it desired to do so.[11] The Weldon Amendment is yet another example of how Congress's drafting decisions reflect its intent, as the Amendment reaches entities that do not "provide, pay for, provide coverage of, or refer for abortions."[12] Congress mentions "referral" separate and apart from "assistance in the

[7] 83 Fed. Reg. at 3923.

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

[9] 42 U.S.C. §§ 300a-7(b)-(d).

[10] 42 U.S.C. § 300a-7(e).

[11] 42 U.S.C. § 238n(a)(1); *see also* 42 U.S.C. § 238n.

[12] Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 562.

performance" in at least five other statutory provisions that the Proposed Rule claims to implement and to which HHS seeks to apply this definition.[13] Such an application to these statutes would make the statutory text superfluous and flout the authority delegated to HHS by Congress.

(B) The Proposed Rule's Definition of "Health Care Entity" Is Excessively Broad.

The Proposed Rule would apply the protections of the referenced statutes not only to individual health care professionals, but also to other "health care entities" on the basis of their "religious, moral, ethical, or other" objections.[14] The Proposed Rule's definition of **"health care entity"** extends far broader than the statutory text it professes to interpret, including "health care personnel" beyond health care professionals like doctors and nurses, laboratories, and health plan sponsors, issuers, and third-party administrators. The Coats-Snowe Amendment, the Weldon Amendment, and the Affordable Care Act each define "health care entity," and none of the statutory definitions is as broad as the one contemplated by the Proposed Rule.[15]

None of the statutory definitions, for example, include "health care personnel" as a category distinct from "an individual physician or other health care professional." Including "health care personnel" in conjunction with the broad definition of "assist in the performance" could force an employer to plan its employee schedules around not only doctors and nurses who may be asked to perform or assist in the performance of a procedure, but also around a receptionist who may otherwise have to schedule an appointment for that procedure. This would not only impose significant burdens on employers, but it would also write out of the statutory texts altogether those specific activities and procedures to which the statutes apply. The definition of "health care professional," on the other hand, is already appropriately defined under at least two of the statutes referenced by the Proposed Rule.[16]

Moreover, none of the statutory definitions include "a laboratory" or "a plan sponsor, issuer, or third-party administrator." The addition of laboratories is unrelated to the procedures targeted by any of the referenced statutes, and their inclusion could lead to the refusal of all manner of routine testing, including pregnancy testing, because of an "articulable connection" to an objected-to procedure. Most importantly, the addition of plan sponsors (typically employers), plan issuers (such as insurance companies), and third-party administrators (which perform claims processing and administrative tasks as opposed to actual health care services), enlarges the number of entities affected by the Proposed Rule in ways that are unnecessary, not contemplated by the

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[13] 22 U.S.C. § 7631(d)(1)(B) (President's Emergency Program for AIDS Relief); 42 U.S.C. § 1395w-22(j)(3)(B) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization); 42 U.S.C. § 18023(b)(4) (Affordable Care Act); 42 U.S.C. § 18023(c)(2)(A)(i)-(iii) (Affordable Care Act); Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 539 (Medicare Advantage).

[14] 83 Fed. Reg. at 3923.

[15] 42 U.S.C. § 238n(c)(2) (Coats-Snowe); 42 U.S.C. § 18113(b) (Affordable Care Act); Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 562 (Weldon Amendment).

[16] 42 U.S.C. § 1395w-22(j)(3)(D) (Medicare+Choice) (including physicians, specialists, physician assistants, nurses, and social workers, among others); 42 U.S.C. § 1396u-2(b)(3)(C) (Medicaid managed care organization) (same).

statutes, and not sensible. These new categories of "health care entit[ies]," particularly when combined with the excessively broad definition of "assist in the performance," could lead to objections by human resources analysts, customer service representatives, data entry clerks, and numerous others who believe that analyzing benefits, answering a benefits-related question, or entering a pre-authorization for an objected-to procedure, for example, is assisting in the performance of that procedure. It is difficult to estimate the immense scope of administrative difficulty that this definition could cause at facilities nationwide, and the Proposed Rule offers no reasonable explanation for these new categories of "health care entit[ies]." In fact, there is no judicious interpretation of "health care entity" that includes every employer who offers a health care plan because 49% of Americans have employer-provided health insurance.[17] This definition applied to the Weldon Amendment could also prohibit a state government from requiring an employer to provide insurance coverage for lawful abortions.

(C) The Proposed Rule's Definition of "Referral or Refer For" Is Excessively Broad.

Finally, several of the federal health care conscience statutes prohibit discrimination against health care providers who elect not to provide "referrals" or "refer for" objected-to procedures. The Proposed Rule defines **"referral or refer for"** in an unjustified and unreasonable manner, allowing a health care provider to refuse to provide "any information" by "any method" that could provide "any assistance" to an individual when obtaining an objected-to procedure is a "possible outcome" of the information.[18] Based on this definition, a health care professional would not be required to refer a woman to Planned Parenthood for prenatal care—even if it were the only option she could afford—because abortion is a "possible outcome of the referral." Likewise, a health care professional would not be required to refer a woman for the treatment of an extensive ovarian or other reproductive system cancer because sterilization is a "possible outcome of the referral." The Proposed Rule's expansive definition would serve to drastically decrease access to information about health care services and access to those services themselves and to undermine the States' interest in ensuring access to health care to their citizens.

III. The Proposed Rule is Contrary to Federal Law—Resulting in Harm to Patients.

(A) The Proposed Rule Conflicts with the Emergency Medical Treatment and Labor Act (EMTALA).

While the Proposed Rule asserts the primacy of provider conscience, it contains no protections to ensure that patients have adequate access to necessary health care in emergencies. In fact, the Proposed Rule does not reference the treatment of patients in emergency situations at all. This places the Proposed Rule in direct conflict with the Emergency Medical Treatment and

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[17] *Health Insurance Coverage of the Total Population (2016)*, Kaiser Family Foundation, https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Mar. 12, 2018).

[18] 83 Fed. Reg. at 3924.

Labor Act ("EMTALA"),[19] a federal law requiring hospitals to provide for emergency care. The absence of an explicit recognition of the EMTALA requirements in the Proposed Rule could jeopardize patient lives. EMTALA defines the term "emergency medical condition" to include:

> a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy….[20]

Yet, under the Proposed Rule, a woman suffering an ectopic pregnancy, for example, could be turned away from her nearest provider and forced to locate a doctor willing and available to provide her with an appropriate treatment before it is too late. The Proposed Rule's impact on access to emergency care would likely be particularly dangerous in the rural areas of the States where an alternative provider may be difficult—or even impossible—to find in the necessary timeframe.

This reduction in access to emergency care is not supported by the statutes upon which the Proposed Rule purports to be based. Indeed, Representative Weldon stated shortly after his Amendment's passage that the law was not intended to reach emergency abortions and that EMTALA requires critical-care health facilities to provide appropriate treatment to women in need of emergency abortions, the Weldon Amendment notwithstanding. Representative Weldon explained:

> 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. …It simply prohibits coercion *in nonlife-threatening situations*. …It ensures that in situations where a mother's life is in danger a health care provider must act to protect the mother's life. In fact, Congress passed the Federal Emergency Medical Treatment and Active Labor Act (EMTALA) forbidding critical-care health facilities to abandon patients in medical emergencies, and requires them to provide treatment to stabilize the medical condition of such patients—particularly pregnant women.[21]

Moreover, at least one of the statutes referenced in the Proposed Rule is clear that it shall not be "construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1395dd of this title (popularly known as "EMTALA")."[22]

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[19] 42 U.S.C. § 1395dd.

[20] 42 U.S.C. § 1395dd(e)(1)(A).

[21] 151 Cong. Rec. H176-77 (Jan. 25, 2005) (statement of Rep. Weldon) (emphases added).

[22] 42 U.S.C. § 18023(d).

Any proper rule implementing this statute, as well as the others referenced, must explicitly ensure that patients receive emergency medical treatment.

(B) The Proposed Rule Conflicts with the Affordable Care Act.

The Affordable Care Act prohibits the Secretary of Health and Human Services from promulgating any regulation that:

1. creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
2. impedes timely access to health care services;
3. interferes with communications regarding a full range of treatment options between the patient and the provider;
4. restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
5. violates the principles of informed consent and the ethical standards of health care professionals; or
6. limits the availability of health care treatment for the full duration of a patient's medical needs.[23]

The Proposed Rule violates nearly every one of these proscriptions. First, by not clarifying that emergency medical care is mandatory under federal law, the Proposed Rule creates unreasonable barriers to timely access to appropriate medical care. Second, by disavowing principles of informed consent in its broad definitions of "assist in the performance" and "referral or refer for," the Proposed Rule interferes with "communications regarding a full range of treatment options between the patient and the provider," "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," and "violates the principles of informed consent and the ethical standards of health care professionals."[24] The Proposed Rule's violation of these federal protections is unlawful. It is also unnecessary given that the States already have systems in place to protect religious freedom while ensuring access to health care and compliance with federal law.[25]

(C) The Proposed Rule Does Not Properly Account for the Costs It Seeks to Impose on Patients.

The Proposed Rule also fails to comply with the requirement that federal agencies accurately assess the costs and benefits of their proposed regulations whenever possible.[26] HHS

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[23] 42 U.S.C. § 18114.

[24] *Id.*

[25] *See infra* Section V.

[26] The Proposed Rule states that "The Department has examined the impacts of the proposed rule as required under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 13771 on Reducing Regulation

estimates that the first year of this rule would cost the economy, mostly in the already highly-regulated health care industry, $312.3 million, and years two through five would cost the economy $125.5 million annually. This estimate fails to include or account for, in any measure, the potentially substantial monetary costs of the health consequences resulting from the denials of care that would inevitably follow the Proposed Rule's unlawful expansion of the referenced statutes. At least some of these costs would likely be borne by states. For example, for each pregnant teen who is not referred to affordable prenatal care for fear that abortion is a "possible outcome of the referral," the subsequent health care for that teen and her child (if carried to term) could cost a state Medicaid program $2,369 to $3,242, depending on when the care was ultimately initiated.[27]

Moreover, as "Non-quantified Costs" of the Proposed Rule, HHS lists only vaguely and briefly: "Any ancillary costs resulting from a protection of conscience rights,"[28] while ignoring the impact on patient care. It does not list the loss of health or human dignity caused when a health care professional denies care to someone facing an emergency medical issue or with some other medical need. It does not list the emotional and other harm inherent in going forward with a medical procedure and later discovering that a better option was available—an option that a health care professional decided not to disclose at the time of treatment. It does not list the loss of the Constitutional right to abortion that will occur when women are denied information about termination of pregnancy before the procedure can no longer be lawfully performed.[29]

IV. The Proposed Rule is Contrary to Federal Law and Unconstitutional—Resulting in Harm to Employers.

(A) The Proposed Rule Conflicts with Title VII of the Civil Rights Act of 1964.

The Proposed Rule defines "discriminate or discrimination" without explaining how it interacts with existing laws protecting employees from discrimination on the basis of religion. For example, Title VII of the Civil Rights Act of 1964 ("Title VII") prohibits discrimination in employment on the basis of religious beliefs.[30] Its protection also extends to "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional

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and Controlling Regulatory Costs (January 30, 2017), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354, 5 U.S.C. 601-612), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-04), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), the Assessment of Federal Regulation and Policies on Families (Pub. L. 105-277, section 654, 5 U.S.C. 601 (note)), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520)." 83 Fed. Reg. at 3901-02.

[27] William J. Hueston, et al., *How Much Money Can Early Prenatal Care for Teen Pregnancies Save?: A Cost-Benefit Analysis*, 21 J. Am. Bd. Family Med. 184 (2008). Women who are denied abortions based on existing legal restrictions are also more likely to receive public assistance than women who obtain abortions—both shortly after the denial and for years afterward. *See* Diana Greene Foster, et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407 (2018).

[28] Table 1—Accounting Table of Benefits and Costs of All Proposed Changes, 83 Fed. Reg. at 3902.

[29] *See An Overview of Abortion Laws*, Guttmacher Inst. (last updated Mar. 20, 2018), https://www.guttmacher.org/state-policy/explore/overview-abortion-laws (last visited Mar. 26 2018).

[30] 42 U.S.C. § 2000e-2(a).

religious views."[31] Title VII, unlike the Proposed Rule, states that employers are not obligated to accommodate employees' religious beliefs to the extent that such an accommodation would cause "undue hardship" on the employer.[32] This carefully constructed balancing test, which is conducted on a case by case basis, recognizes that employers should not be forced to sacrifice their principal obligations—to their business, their patients, and their other employees—in order to accommodate the religious beliefs of one employee. Moreover, at least one of the statutes referenced in the Proposed Rule is clear that it shall not "alter the rights and obligations of employees and employers under [T]itle VII of the Civil Rights Act of 1964."[33] Any proper rule implementing this statute, as well as the others referenced, must ensure that employers are not faced with undue hardships in accommodating employee beliefs.

By contrast, the Proposed Rule ignores the "undue hardship" test and instead contains a blanket prohibition on "discrimination." This blanket prohibition could be interpreted to prevent the transfer of an employee to another area of a health care entity or a different shift even if the employee's beliefs prevent the employee from performing the essential functions of the initial position. When applied without any reference to employer or patient needs, this broad definition of discrimination could be interpreted to require a health care entity to hire someone who cannot deliver health care services that are critical to the health care entity's mission or risk sanction. For example, even a small women's health clinic could be in violation of the Proposed Rule for refusing to hire a doctor who would not perform, or a receptionist who would not schedule, a tubal ligation. Congress did not intend to so constrain health care providers as to force them to abandon patient care—or their missions and businesses altogether.[34]

(B) The Proposed Rule Conflicts with Title X of the Public Health Service Act of 1970.

Family planning projects funded through Title X are required to counsel pregnant patients about all health care options, including abortion, and provide referrals for those options if requested.[35] The Proposed Rule ignores Title X and, in fact, conflicts with its requirements. Specifically, the Proposed Rule defines discrimination to include the utilization of:

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[31] 29 C.F.R. § 1605.1.

[32] 42 U.S.C. § 2000e(j). The New York State Human Rights Law also requires the accommodation of religious beliefs "unless, after engaging in a bona fide effort, the employer demonstrates that it is unable to reasonably accommodate the employee's or prospective employee's sincerely held religious observance or practice without undue hardship on the conduct of the employer's business." N.Y. Human Rights L. § 296(10).

[33] 42 U.S.C. § 18023(c)(3).

[34] *See* 151 Cong. Rec. H176-77 (Jan. 25, 2005) (statement of Rep. Weldon) ("The amendment does not apply to willing abortion providers. Hyde-Weldon allows any health care entity to participate in abortions in any way they choose.").

[35] *See* Title X, Public Health Service Act of 1970 § 1001, 42 U.S.C. § 300; Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135, 521 (2017) ("all pregnancy counseling shall be nondirective"); 42 C.F.R. § 59.5(a)(5) (requiring that a family planning project offer pregnant women the opportunity to be provided information and counseling regarding prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination). *Id.* (dictating that a family planning project, "[i]f requested to provide such information and counseling, provide

> any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that tends to subject individuals or entities protected under this part to any adverse effect described in this definition….[36]

An "adverse effect" as referenced in this definition includes the denial of grants or contracts or any other benefits or privileges.[37] Thus, a state could be unable to select Title X sub-recipients on the basis of their willingness to counsel about and refer for abortions. Application of the definition of "discriminate or discrimination" without any reference to states' Title X obligations leaves states with a Hobbesian choice: they can either withhold federal family planning dollars from organizations unwilling to provide "non-directive" pregnancy counseling about (and potential referral to) all of the health care options—in direct contravention of the Proposed Rule—or provide such funding—in direct contravention of Title X. Like the Weldon Amendment, Congress passes the non-directive pregnancy counseling requirement applicable to Title X in appropriations measures each year and did so as recently as last year.[38] Congress surely did not intend in 2017 that the non-directive pregnancy counseling requirement be nullified by a new agency interpretation of statutes predating this Congressional action.

(C) The Proposed Rule Violates the Establishment Clause.

The Proposed Rule's failure to consider the needs of patients or employers, including those governed by Title X, in its mandates implies that health care professionals have an unprecedented absolute right to religious accommodation, which is incompatible with the United States Constitution. Indeed, the Proposed Rule does not include any provision for balancing or accounting for a patient's right to care or an employer's commitment to deliver that care. Laws that compel employers to "conform their business practices to the particular religious practices of . . . employees" violate the Establishment Clause.[39] In *Estate of Thornton v. Caldor*, the Supreme Court invalidated a law providing employees with the absolute right not to work on their chosen Sabbath in part because the law unfairly and significantly burdened the employers and fellow employees who did not share the employee's Sabbath. "The First Amendment ... gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities."[40] The Court found the law "unyielding[ly] weight[ed]" the interests of Sabbatarians "over all other interests" and was invalid under the Establishment Clause.[41] To the extent that the Proposed Rule requires businesses to accommodate their employees' religious

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neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.").

[36] 83 Fed. Reg. at 3923-24.

[37] *Id.*

[38] Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135, 521 (2017).

[39] *Estate of Thornton v. Caldor*, 472 U.S. 703, 709 (1995).

[40] *Id.* at 710 (quoting *Otten v. Baltimore & Ohio R.R. Co.*, 205 F.2d 58, 61 (1953)).

[41] *Id.*

beliefs at all costs, it is directly analogous to the law successfully challenged in *Caldor* and thus contravenes the First Amendment.

V. The Proposed Rule Undermines State Policies Regarding Health Care and Would Require States to Violate Their Own Laws.

HHS states that while the Proposed Rule "is expected to affect State and local governments, the anticipated effect is not substantial."[42] The States disagree. In order to ensure access to care for their citizens, the States have enacted laws to guarantee emergency and medically necessary care as well as informed consent. State laws also protect the religious freedom of employees while respecting the business necessities of their employers. These important, sometimes competing needs have been carefully balanced in various ways in each of the States. The Proposed Rule upsets these delicate and long-standing balances and ignores the needs of patients and employers.

First, as noted above, the Proposed Rule does not so much as mention the provision of emergency health care, which can require abortions or other procedures to which a health care professional may object. In addition to conflicting with federal law requiring emergency medical care,[43] the Proposed Rule is at odds with state law that requires the provision of emergency medical care.[44] In many states, mandatory emergency care includes the provision of emergency contraception to survivors of sexual assault.[45] In addition to mandating emergency care, several state regulations also prohibit health care professionals from abandoning a patient in medical need without first arranging for the patient's care.[46] The Proposed Rule ignores the requirement of emergency or medically necessary care under federal or state law,[47] seemingly leaving the provision of this care solely to chance.

Second, the Proposed Rule does not allow for state laws that already facilitate the accommodation of religious or moral objections, balancing conscience protection with patients' rights to access care. For example, several states have laws allowing an individual to refuse to

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[42] 83 Fed. Reg. at 3918.

[43] *See supra* Section III.

[44] *E.g.*, N.Y. Pub. Health Law § 2805-b.

[45] *See, e.g.*, MGL c. 111, s. 70E (requiring the provision of information about emergency contraction and emergency contraception to survivors of sexual assault); N.J.S.A. 26:2H-12.6c (same); N.Y. Pub. Health Law § 2805-p (same); Wash. Rev. Code § 70.41.350 (same). *See also* 410 ILCS 70/2.2(b) (similar).

[46] Conn. Gen. Stat. § 19a-580a ("An attending physician or health care provider who is unwilling to comply with the wishes of the patient …, shall, as promptly as practicable, take all reasonable steps to transfer care of the patient to a physician or health care provider who is willing to comply with the wishes of the patient…."); 8 NYCRR § 29.2 (noting unprofessional conduct includes "abandoning or neglecting a patient or client under and in need of immediate professional care, without making arrangements for the continuation of such care…"); Wash. Admin. Code § 246-840-700; Wash. Admin. Code § 246-817-380; Wash. Admin. Code § 246-808-330. *See also* N.J.S.A. 45:14-67.1 (requiring a pharmacy to fill lawful prescriptions without undue delays despite employee objections); Wash. Admin. Code § 246-869-010 (same).

[47] States are required to define medically necessary care for their Medicaid plans. 42 C.F.R. § 438.210(a)(5). The Proposed Rule, however, would undermine the ability of states to use these federally-mandated definitions of medically necessary care to select Medicaid providers.

assist in a non-emergency abortion as long as the individual notifies the employer in advance.[48] This type of state law facilitates accommodations such as "staffing or scheduling practices that respect an exercise of conscience rights under Federal law."[49] The Proposed Rule, however, states that "OCR will regard as presumptively discriminatory any law, regulation, policy, or other such exercise of authority that has as its purpose, or explicit or otherwise clear application, the targeting of religious or conscience-motivated conduct." Thus, HHS would regard these laws, which are targeted at religious or conscience-motivated conduct—but only to accommodate it—as presumptively discriminatory. Given that all federal health care funding could be terminated for any "threatened failure to comply" with the Proposed Rule, states are faced with either having no such laws (or even policies for their own hospital systems), which would threaten efficient health care administration and the provision of care, or losing all federal funding to provide that care.

Third, the Proposed Rule does not acknowledge or recognize the import of patient informed consent, which is protected by the Affordable Care Act and state law. The Proposed Rule does not require that a patient be informed that a health care provider is refusing to counsel them about, or refer them to, certain health care services. States such as New York and Massachusetts mandate informed consent for patients to ensure that patients can make their own informed medical decisions.[50] In other states, the failure to inform patients of possible alternative treatments increases the risk of malpractice liability for the health care providers involved in the patients' care and the health care facility at which the care is performed.[51] The complexity of identifying which members of a large health care team have objections to providing full informed consent—and about which topics—not only risks delay in necessary care, but increases the risk of liability for health care providers and facilities. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which consisted of leading experts in research, law, medicine, and medical ethics, issued a seminal 1982 report on the ethical and legal implications of informed consent that concluded that patients must be provided with "all relevant information regarding their condition and alternative treatments."[52] Other federal laws recognize the importance of informed consent, including two of the statutes that the Proposed Rule professes to implement. These statutes require plans that refuse "to provide, reimburse for, or provide coverage of a counseling or referral service" on the basis of a moral or religious objection to "make[] available information on its policies regarding such service to prospective enrollees before

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[48] *See, e.g.*, Conn. Regs. § 19–13–D54(f); 720 ILCS 510/13; MGL c. 112 s. 12I; N.Y. Civ. Rights L. § 79-1. *See also* Wash. Rev. Code § 48.43.065 (protecting right of provider, carrier, or facility to refrain from participating in provision or payment for specific service they find objectionable, but requiring advanced notice); Wash. Rev. Code § 70.47.160 (same); Wash. Admin. Code § 284-43-5020 (requiring carriers to file plan ensuring timely access to services).

[49] 83 Fed. Reg. at 3913.

[50] MGL c. 111, s. 70E; N.Y. Pub. Health L. § 2805-d. *See also* 720 ILCS 510/13 ("If any request for an abortion is denied [because of a conscience objection], the patient shall be promptly notified.")

[51] *See, e.g.*, Wash. Rev. Code § 7.70.050.

[52] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship, Washington, DC: U.S. Government Printing Office, 1982, https://repository.library.georgetown.edu/handle/10822/559354.

or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service."[53] Both laws also provide that they shall not "be construed to affect disclosure requirements under State law."[54] The Proposed Rule seeks not only to write the disclosure requirement out of these two statutes but also to take power from the states that Congress has expressly reserved to them. An agency action that seeks to preempt state laws without the proper Congressionally delegated authority is unlawful.[55]

VI. The Proposed Rule's Funding Termination Scheme Exceeds HHS's Statutory Authority and Is Unconstitutional.

(A) The Proposed Rule Exceeds HHS's Statutory Authority by Threatening to Terminate All Federal Health Care Funding to Recipients for Any "Failure or Threatened Failure" to Comply.

The Proposed Rule seeks to impose new and unnecessary conditions on billions of federal health care dollars that states rely on to ensure access to care for patients. The Proposed Rule emphasizes its intention to terminate a "variety of financing streams" for *any* failure—or *threatened* failure—to comply with any of the statutes referenced, and it does so without so much as defining the term "threatened failure."[56] HHS does provide a non-exclusive list of "examples" of financing streams that it proposes should be dependent on the states' ability to avoid a vague and non-defined "threatened failure" to comply with the Proposed Rule. This list expressly includes reimbursement for health-related activities provided by programs including: Medicaid and the Children's Health Insurance Program; public health and prevention programs; HIV/AIDS and STD prevention and education; substance abuse screening; biomedical and behavioral research at state institutions of higher education; services for older Americans; medical assistance to refugees; and adult protection services to combat elder justice abuse.[57]

HHS states that "Congress has exercised the broad authority afforded to it under the Spending Clause to attach conditions on Federal funds for respect of conscience…."[58] Indeed, the relevant statutes condition funding from specific sources to specific requirements and prohibitions. For example, the first two of the five requirements of the Church Amendments condition only grants, contracts, loans, or loan guarantees under the Public Health Service Act, the Community

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[53] 42 U.S.C. § 1395w-22(j)(3)(B) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization).

[54] 42 U.S.C. § 1395w-22(j)(3)(C) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization).

[55] *See Texas v. United States*, 95 F. Supp. 3d 965, 980-81 (N.D. Tex. 2015) (enjoining a U.S. Department of Labor rule implementing the Family and Medical Leave Act on the ground that compliance with the rule would require the plaintiff states to violate their own state laws and that the rule exceeded the agency's congressionally delegated authority).

[56] 83 Fed. Reg. at 3905, 3931.

[57] 83 Fed. Reg. at 3905.

[58] 83 Fed. Reg. at 3889.

Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act.[59] The third Church Amendment requirement conditions only grants or contracts "for biomedical or behavioral research," the fourth applies to HHS's funding of a particular health service program or research activity, and the fifth conditions funds similar to those conditioned by the first two.[60] Many of the referenced statutes have a similar framework.[61] The Proposed Rule ignores the sources of funds Congress has conditioned upon obedience to each statute, instead threatening to terminate *all* federal health care funding to recipients for *any* failure—or *threatened* failure—to comply with any of the statutes referenced.[62] These sanctions far exceed HHS's statutory authority,[63] and if acted upon, would unjustifiably terminate sources of funding that states rely on to provide critical, and sometimes life-saving, health services to their citizens.

Moreover, the Proposed Rule's funding termination provisions require no administrative process before HHS terminates all federal health care funding for a state or other entity. Under the Proposed Rule, HHS can terminate all federal health care funding solely upon its determination that "there appears to be a failure or threatened failure to comply" with either the referenced statutes or the Proposed Rule itself.[64] It can do so even if only a state's sub-recipient—not the state itself—is accused of wrongdoing.[65] It can also do so while a state or other entity is attempting to resolve the matter informally.[66]

(B) The Proposed Rule Violates the Spending Clause.

As noted in Section VI(A), *supra*, there is no statutory authority for HHS's assertion of a vast new power to terminate broad swaths of federal health care funding that are unrelated to the program funds that Congress has expressly conditioned. If, however, Congress did delegate to HHS the authority to terminate *all* federal health care funding to the states on the basis of a failure or threatened failure to comply with any of the referenced statutes, such an action would violate the Spending Clause.

Congress may use the Spending Clause power to condition grants of federal funds upon the states taking certain actions that Congress could not otherwise require them to take, but this

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[59] 42 U.S.C. §§ 300a-7(b)-(c)(1).

[60] 42 U.S.C. §§ 300a-7(c)(2)-(e).

[61] *E.g.*, 22 U.S.C. § 7631(d) (President's Emergency Program for AIDS Relief); 42 U.S.C. §§ 1395w-22(j)(3)(A)-(B) (Medicare+Choice); 42 U.S.C. §§ 1396u-2(b)(3)(A)-(B) (Medicaid managed care organization); 42 U.S.C. § 18113 (Affordable Care Act).

[62] 83 Fed. Reg. at 3931.

[63] *See County of Santa Clara v. Trump*, 250 F. Supp.3d 497, 530-532 (N.D. Cal. 2017) (enjoining executive order regarding sanctuary cities in part because order violated separation of powers by attempting to exercise Congress's spending power in its enforcement).

[64] *Id.*

[65] 83 Fed. Reg. at 3929.

[66] 83 Fed. Reg. at 3931.

power is not without limit.[67] Importantly, if Congress seeks to condition the states' receipt of federal funds, it "must do so unambiguously."[68] Conditions on federal grants can also be barred if they are unrelated "to the federal interest in particular national projects or programs."[69] Additionally, "the financial inducement offered by Congress" cannot be "so coercive as to pass the point at which pressure turns into compulsion."[70] The Proposed Rule would violate each of these limits on Congress's exercise of the Spending Clause power.

In the first instance, the vague notion of a "threatened failure to comply" offends the requirement that Congress must unambiguously state the prohibited conduct that will trigger the loss of funding under its Spending Clause power.[71] Additionally, because the Proposed Rule conflicts with other federal laws, the states risk all of their federal health care funding by merely complying with (other) federal law—leaving them no unambiguously compliant course of action. For example, if a pregnancy counselor at a public health department that receives Title X funds objects to providing counseling about or referral to abortion services, the facility will have to decide whether to 1) transfer that employee in violation of the Proposed Rule or 2) allow that employee not to counsel about or refer to these services in violation of Title X. Should it choose the first option, it could lose all of its federal health care funding; should it choose the second option, it could lose all of its federal Title X funding.

Next, the funding that HHS proposes it should be allowed to terminate, on the basis of a "threatened failure to comply" with the Proposed Rule, includes programs, like the Children's Health Insurance Plan, that are entirely unrelated to the federal interest in protecting conscience objections to a narrow category of procedures, such as abortion and sterilization.[72]

Last, the Supreme Court has already held that Congress's imposition of new, unrelated conditions on an amount *less* than the amount of funding at stake under the Proposed Rule was so coercive as to be likened to a "gun to the head."[73] In *National Federation of Independent Business v. Sebelius*, the Supreme Court reasoned that a Congressional threat to a state's Medicaid funding was unconstitutional because it was so coercive as to deprive states of any meaningful choice whether to accept the condition attached to receipt of federal funds.[74] The Proposed Rule would eliminate not only states' Medicaid funding, but a host of other federal health care funding as well.

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[67] *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 578 (2012).

[68] *Id.* at 576.

[69] *South Dakota v. Dole*, 483 U.S. 203, 207 (1987) (internal citation omitted).

[70] *Sebelius*, 567 U.S. at 580 (internal citation and quotation marks omitted).

[71] *Dole*, 483 U.S. at 207.

[72] 83 Fed. Reg. at 3905.

[73] *Sebelius*, 567 U.S. at 581.

[74] *Id.* at 579-585.

VII. The Proposed Rule Will Increase Discrimination, Limit Health Care Providers, and Harm Patients.

The States maintain a quintessential interest in the civil rights and health of their residents, an interest alternately described as quasi-sovereign and within those police powers reserved to them.[75] The States have considered the Proposed Rule in light of their twin duties to protect civil rights and the public health, and believe that it harms both patients and health care providers. Despite HHS's stated interest in "a society free from discrimination,"[76] the Proposed Rule substantially increases the risk of discrimination against patients on the basis of, *inter alia*, sex, sexual orientation, or gender identity. The Proposed Rule also risks having a chilling effect upon health care providers in a manner that will likely harm patients and vulnerable populations. Both of these anticipated harms arise from the unnecessary and unsupported breadth and scope of the Proposed Rule.

(A) The Proposed Rule Will Increase Status-Based Discrimination Against Patients.

The statutes referenced in the Proposed Rule in no way permit entities or health care personnel to deny care to a patient based on his or her status, *e.g.*, a patient's status as lesbian, gay, bisexual, or transgender. Rather, those statutes set forth narrowly tailored exemptions to the provision of specific procedures, irrespective of a patient's status.[77] Against this backdrop of narrow statutory protections allowing health care workers to opt out of certain procedures and services, HHS seeks to expand the scope of the referenced statutes, its regulatory footprint, and its own power. As set forth in Section II, *supra*, the Proposed Rule defines the terms "assist in the performance" and "health care entity" in ways that broaden the scope of the referenced statutes, vastly expand the number of individuals potentially eligible to assert a "religious, moral, ethical, or other" objection, and dramatically increase the types of services to which they may object. This expanded universe of individuals who can refuse to provide patient care or perform activities with an "articulable connection" to patient care, combined with the enormous sanctions faced by states and other entities if they do not allow for these exemptions, raises the specter of heightening status-based discrimination against existing patient populations.

The States have serious concerns, for example, that an expanded universe of potential conscience objectors may seek to use the statutory tether of a "sterilization procedure" to deny care to transgender patients. Transgender people regularly experience discrimination within the health care industry, resulting in substantial health disparities with the non-transgender

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[75] *See, e.g.*, *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 488 (1987) (acknowledging state police power and interest in public health); *Snapp v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 609 (1982) (acknowledging state interest in eradicating the "political social, and moral damage" resulting from "invidious discrimination"); *Mackey v. Montrym*, 443 U.S. 1, 17 (1979) (acknowledging state interest in public health and safety).

[76] 83 Fed. Reg. at 3903.

[77] *See, e.g.*, 42 U.S.C. § 300a-7(b)(1) (Church Amendment) (referring to "performance of any sterilization *procedure or abortion*" (emphasis added)).

population.[78] This discrimination includes both denials of care related to gender transition as well as denials of care for routine medical issues—*e.g.*, physicals, treatment for the flu, or care for diabetes—completely unrelated to their transgender status.[79] In some instances, this discrimination has occurred in emergency medical settings in which prompt and effective care for patients is urgent and its absence could be life-threatening.[80] Similarly, the States also have concerns that an expanded universe of conscience objectors could seek to use the Proposed Rule to deny medical care to male patients who seek pre- or post-exposure prophylactic medications to prevent HIV infection based upon those men's actual or perceived sexual orientation.[81] Any regulatory expansion of statutory conscience exceptions that results in status-based discrimination would fundamentally undermine patient health and the interest of the States in preserving that health within their borders.

(B) The Proposed Rule Will Have a Chilling Effect Upon Health Care Providers, Further Harming Patients.

The Proposed Rule would also inhibit the provision of health care in a manner that harms public health and likely falls more heavily on the shoulders of vulnerable populations. Not only does the Proposed Rule vastly expand the scope of individuals who may lodge conscience-based objections to the provision of medical procedures and other services with an "articulable connection" to those procedures,[82] it also exceeds its statutory authority in intending to cut off all federal health care funding for any failure or threatened failure to comply with the Proposed Rule.[83] This regulatory combination is an especially dangerous one that is likely to have a chilling effect upon health care providers. Health care providers faced with a potentially limitless universe of conscience objections from any employee, including members of the janitorial or secretarial staff, have strong incentives to cease offering procedures like abortion or gender transition-related

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[78] *See, e.g.*, Grant, Jaime M., et al., *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey*, (Nat'l Ctr. Transgender Equal./Nat'l Gay & Lesbian Task Force, Washington, D.C.), 2011 ("2011 Report"), at 6; James, Sandy E., et al., *The Report of the 2015 U.S. Transgender Survey*, (Nat'l Ctr. Transgender Equal., Washington D.C.), 2016 ("2016 Report"), at 103-07.

[79] *See* 2011 Report, at 6 (noting that 19% of survey respondents reported being refused medical care due to their transgender or gender non-conforming status); 2016 Report, at 96-97 (noting that 15% of survey respondents reported a health care provider asking unnecessary or invasive questions about their transgender status unrelated to the reason for their visit; 8% of respondents reported a provider's denial of transition-related care; and 3% of respondents reported a denial of care unrelated to gender transition).

[80] *See, e.g.*, *Rumble v. Fairview Health Servs.*, 2015 U.S. Dist. LEXIS 31591 (D. Minn. Mar. 16, 2015) (detailing emergency room physician's actions toward transgender man in suit brought under Affordable Care Act and Minnesota Human Rights Law).

[81] *See, e.g.*, Donald G. McNeil, Jr., *He Took a Drug to Prevent AIDS. Then He Couldn't Get Disability Insurance*, N.Y. Times (Feb. 12, 2018), *available at*: https://www.nytimes.com/2018/02/12/health/truvada-hiv-insurance.html (last visited Mar. 26, 2018).

[82] *See supra* Section II.

[83] *See supra* Section VI(A).

therapies or surgeries in order to avoid any possibility of the loss of all federal health care funding, including Medicaid funding, which could literally close a health care provider's doors.

Such a net reduction in the medical care offered by health care providers would harm the public health in each of the States. Additionally, because the Proposed Rule generally targets health care services supported by federal funds, its impact would be felt most by low-income patients who are far less likely to have alternative health care services available after a provider ceases to provide certain medical care or procedures. Further, patients reliant upon federal funding for the provision of health care are disproportionately non-white: 21% black and 25% Hispanic, as compared to those communities' respective proportions of 13.3% and 17.8% in the United States population. Consequently, any chilling effect the Proposed Rule has upon health care providers' decisions to offer abortion or other procedures will be borne disproportionately by minority populations.[84]

VIII. Conclusion

If adopted, the Proposed Rule will harm patients by increasing discrimination and decreasing the provision of health care and information about health care. It will harm the Constitutional rights of the States and their residents. It will needlessly and carelessly upset the balance that has long been struck in federal and state law to protect the religious freedom of providers, the business needs of employers, and the health care needs of patients. Accordingly, we urge HHS to withdraw the Proposed Rule.

Respectfully submitted,

ERIC T. SCHNEIDERMAN
New York Attorney General

George Jepsen
Connecticut Attorney General

Matthew P. Denn
Delaware Attorney General

[84] *Compare Medicaid Enrollment by Race/Ethnicity*, Kaiser Family Foundation, https://www.kff.org/medicaid/state-indicator/medicaid-enrollment-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Mar. 23, 2018), *and Quick Facts: United States*, United States Census Bureau, https://www.census.gov/quickfacts/fact/table/US/PST045216 (last visited Mar. 23, 2018).

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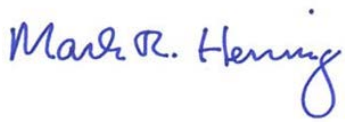

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Exhibit 54

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

March 27, 2018

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

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

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

Dear Director Severino:

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

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

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

Recommendations

Our recommendations are as follows:

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

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

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

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

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

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

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

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

Sincerely,

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

* * *

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

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

Issue:

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

Recommendation:

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

Rationale:

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

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

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

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

Issue:

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

Recommendation:

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

Rationale:

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

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

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

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

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

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

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

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

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

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

Issue:

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

Recommendation:

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

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

Rationale:

The Preamble to the Proposed Rule states:

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

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

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

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

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

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

The Department further explained:

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

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

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

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

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

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

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

83 Fed. Reg. 3880, 3892.

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

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

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

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

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

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

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

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

Issue:

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

Recommendation:

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

Rationale:

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

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

83 Fed. Reg. 3880, 3924.

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

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

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

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

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

V. Written Assurance and Certification (Proposed § 88.4)

Issue:

The requirements for written assurances and certification are unnecessarily duplicative.

Recommendation:

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

Rationale:

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

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

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

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

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

VI. Notice (Proposed § 88.5)

Issue # 1:

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

Recommendation:

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

Rationale:

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

Issue # 2:

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

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

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

Recommendation:

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

Rationale:

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

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

VII. Effective Date

Issue:

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

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

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

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

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

Recommendation:

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

Rationale:

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

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

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

Other areas of communication that require review and revision include:

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

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

Exhibit 55

STATE OF CALIFORNIA
Dave Jones, Insurance Commissioner

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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.

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[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
Insurance Commissioner

[5] 72 Fed. Reg. at 9971

Exhibit 56

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Attorney General

State of California
DEPARTMENT OF JUSTICE

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March 27, 2018

Via Federal eRulemaking Portal
Secretary Alex Azar
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

RE: Comments on Proposed Rule: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (Jan. 26, 2018), RIN 0945-ZA03

Dear Secretary Azar:

I write today to urge the U.S. Department of Health and Human Services (HHS) to withdraw the Proposed Rule: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 Fed. Reg. 3,880 (Jan. 26, 2018), RIN 0945-ZA03 ("Proposed Rule" or "Rule"). This Proposed Rule would impede access to care and create barriers to patients' exercise of their rights. Further, it undermines HHS's mission to "enhance the health and well-being of all Americans, by providing for effective health and human services."

As California's Attorney General, I have a constitutional duty to protect Californians, by safeguarding their health and safety, and defending the State's laws. Cal. Const., art. V, § 13. This Rule is an unlawful attempt by the Administration to proceed without congressional authority and is in conflict with the Constitution and multiple existing laws. If implemented, it will have significant negative impacts on States; their residents, including women, LGBTQ individuals, and other marginalized populations; and numerous entities in the State that receive federal healthcare funding. Thus, I urge that the Rule be withdrawn.

Among its many problems, the Proposed Rule threatens the removal of *all* federal healthcare funds from recipients, including the State, deemed not in compliance with the Rule. Jeopardizing this funding would have significant effects on California families as these funds support public healthcare programs and public health initiatives.

The Rule would also create rampant confusion about basic patient rights and federally entitled healthcare services, while discouraging providers from providing safe, legal care. The Rule not only permits any individual, entity, or provider to deny basic healthcare services—

including emergency care—but also discharges a provider from the duties to cite evidence to support the denial of services, to notify a supervisor of the denial of services, and to provide notice or alternative options to patients that may want to seek services from another provider. There is little evidence that in drafting the Rule, HHS considered the impact to patients. 83 Fed. Reg. at 3,902; *Id*. at 3,902-3,918 (failing to mention, let alone quantify the impact of this Rule on patients). Moreover, the effects of the Proposed Rule would be widespread as it implicates "*any* program or activity with an *articulable connection* to a procedure, health service, health program, or research activity," 83 Fed. Reg. at 3,923. The consequences of this overbroad Rule will disproportionately affect the most vulnerable populations, and in particular, could have a chilling effect on those seeking to exercise their constitutionally protected healthcare rights.

a. The Proposed Rule Targets the State of California and its Interests in Protecting its Residents, Healthcare Industry, and Consumer Protections

The Proposed Rule particularly aims to upend and target California's concerted efforts to balance the rights of patients and providers. The Rule suggests that further federal guidance is needed because of an increase in lawsuits against state and local laws; however, HHS puts forth little actual evidence. In targeting California's carefully crafted laws, the Rule tramples on the rights of patients and takes aim at California specifically.

First, the Rule references two pending federal lawsuits stemming from the California Department of Managed Health Care's (DMHC) August 22, 2014 letters issued to health plans regarding abortion coverage. 83 Fed. Reg. at 3,889 (citing *Foothill Church v. Rouillard*, No. 2:15-cv-02165-KJM-EFB, 2016 WL 3688422 (E.D. Cal. July 11, 2016); *Skyline Wesleyan Church v. Cal. Dep't of Managed Health Care*, No. 3:16-cv-00501 (S.D. Cal. 2016)). Then, noting that HHS's Office of Civil Rights (OCR) previously closed three complaints against DMHC, the Rule states that OCR's finding that the Weldon Amendment had not been violated by California law requiring that health plans include coverage for abortion "no longer reflects the current position of HHS, OCR, or the HHS office of the General Counsel." 83 Fed. Reg. at 3,890. This reversal in the agency's interpretation of the Weldon Amendment is apparently based on a misreading of the law, and is arbitrary and capricious. 5 U.S.C. § 706; *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974); *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010). Moreover, HHS cites no authority that permits it to reverse its position in this manner. Later, the Proposed Rule—apparently referencing California's Reproductive Freedom, Accountability, Comprehensive Care, and Transparency (FACT) Act—announces that even requiring a clinic to post notices mentioning the existence of government programs that include abortion services would be considered a referral for abortion under the Weldon Amendment and Section 1303 of the Affordable Care Act.[1] 83 Fed. Reg. at 3,895. Such a broad definition of "refer for" is

[1] Section 1303 prohibits the use of certain Federal funds to pay for abortion coverage by qualified health plans. 42 U.S.C. § 18023(b)(2)(A). However, Section 1303 permits an issuer to charge and collect $1 per enrollee per month for coverage of abortion services so long as the

unsupported by the plain language of these statutes, and is thus outside of HHS's delegated authority. *See infra* at 3-4.

HHS's attempt to redefine the law threatens California's sovereign and quasi-sovereign interests in regulating healthcare, criminal acts, and California-licensed entities and professionals. *See also New York v. United States*, 505 U.S. 144, 155-56 (1992); Cal. Bus. & Prof. Code §§ 101, 101.6, 125.6 (providing that a California licensee is subject to disciplinary action if he or she refuses to perform the licensed activity or aids or incites the refusal to perform the licensed activity by another licensee because of another person's sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status); 733 (a California licensee "shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient"); 2761; Cal. Penal Code § 13823.11(e) and (g)(4); Cal. Health & Saf. Code §§ 10123.196, 1367.25, 123420(d); Cal. Civ. Code § 51; *No. Coast Women's Care Med. Group, Inc. v. San Diego County Superior Court*, 44 Cal.4th 1145 (2008). "[T]he structure and limitations of federalism . . . allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (internal quotation marks and citation omitted).

Furthermore, the estimated costs and benefits of the Rule do not justify it, but rather reveal it to be greatly wasteful of public funds. HHS admits that OCR has received only 44 complaints over the last 10 years of alleged instances of violations of conscience rights. 83 Fed. Reg. at 3,886. Yet, as HHS further admits, it will cost nearly $1.4 billion over the first years to implement the Rule, and for the affected entities to comply with the new assurance and certification requirements. *Id.* at 3,902, 3,912-13. Meanwhile, HHS disclaims any ability to quantify the benefits. *Id.* at 3,902, 3,916-17.

In undercutting important patient protections and creating barriers to care, the Proposed Rule not only oversteps on policy grounds, but also has numerous legal deficiencies. Below I address many, but by no means all, of these deficiencies.

b. The Proposed Rule Exceeds Congressional Authority

As a threshold matter, the Proposed Rule exceeds the authority of the statutes it cites, and therefore violates the Administrative Procedure Act. 5 U.S.C. § 706. Nothing in the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, or other statutes permits HHS to redefine the terms used in these underlying statutory schemes. Yet the Proposed Rule has characterized numerous terms, including "assist in the performance," "health care entity," and "referral or refer for," so broadly as to materially alter well-established statutory language.

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funds are deposited in a separate account, maintained separately, and used only for abortion services.

For example, contrary to the implementing statutes, the Proposed Rule suggests that "assist in the performance" encompasses participating in "any" program or activity with an "articulable connection" to a procedure, health service, health program, or research activity, including "counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity." 42 Fed. Reg. at 3,923. Only the Church Amendments refer to "assist in the performance" of an activity, and nothing in that statutory scheme envisions the broad definition in the Proposed Rule. 42 U.S.C. § 300a-7. That Congress specifically references "to counsel" in a separate Church Amendment provision, "training" in the Coats-Snowe Amendment, and "refer for" in the Weldon Amendment confirms that the Proposed Rule's definition of "assist in the performance" should not include these additional activities. Reading and interpreting the statutes in these ways will allow for unlawful refusals of care.

Similarly, "health care entity" is defined in the Coats-Snowe Amendment, the Weldon Amendment, and the Affordable Care Act, yet the Proposed Rule goes beyond these definitions to include "health care personnel," as distinct from a "health care professional," such as a doctor or nurse. 42 Fed. Reg. at 3,924. Therefore, it appears that, under the Proposed Rule, even someone like a receptionist at a doctor's office could refuse to provide services, including making an appointment for a patient, based on his or her moral objections. By expanding "health care entity" to cover personnel, "health care professional" is rendered superfluous, contrary to the rules of statutory interpretation. Additionally, the Proposed Rule's definition of "health care entity" is overbroad, given that it includes "a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan." 42 Fed. Reg. at 3,924. In short, the Rule's redefinition of "health care entity" is arbitrary and capricious, as it runs counter to OCRs' previous, well-reasoned interpretation of the term.

The Proposed Rule's definition of "referral or refer for" is particularly broad, suggesting that "any method," even posting of notices, would be considered a "referral." 42 Fed. Reg. at 3,924. These new exceptions created by the Rule are not envisioned by any federal statute, and would permit healthcare professionals to elude the scope of state laws protecting a patient's rights to healthcare services.

c. The Proposed Rule is Contrary to Law

The Rule also violates the U.S. Constitution in several respects, including conflicting with the Spending Clause, the Due Process Clause, the Establishment Clause, and Separation of Powers. Furthermore, the Rule conflicts with several federal statutes. 5 U.S.C. § 706.

The Proposed Rule violates the Spending Clause because it (a) coerces states and their entities to follow the Proposed Rule or lose billions of dollars in federal funds; (b) is vague and does not provide adequate notice of what specific action or conduct, if engaged in, will result in the withholding of federal funds; (c) constitutes post-acceptance conditions on federal funds; and (d) is not rationally related to the federal interest in the particular program that receives federal funds. *See NFIB v. Sebelius*, 567 U.S. 519, 582-83 (2012); *Pennhurst State Sch. and Hospital v.*

Halderman, 451 U.S. 1, 17 (1981) (If Congress desires to condition the States' receipt of federal funds, it "must do so unambiguously . . . enabl[ing] the States to exercise their choice knowingly, cognizant of the consequences of their participation"); *South Dakota v. Dole*, 483 U.S. 203 (1987); *Massachusetts v. United States*, 435 U.S. 444, 461 (1978) (plurality op.) (conditioning federal grants illegitimate if unrelated "to the federal interest in particular national projects or programs"). The Rule is tantamount to "a gun to the head." *NFIB*, 567 U.S. at 581. If California opts out of complying with the Rule (or even "[i]f there appears to be a failure or threatened failure to comply"), it "would stand to lose not a relatively small percentage" of its existing federal healthcare funding, but all of it. *Id*.; 83 Fed. Reg. at 3,931.

It violates the Due Process Clause, as well, because it is unconstitutionally vague and permits OCR to immediately withhold billions of federal funding, if there "appears to be a failure" to comply, or just an apparent "threatened" failure to comply, and there is no review process. 83 Fed. Reg. at 3,931; *see Mathews v. Eldridge*, 424 U.S. 319, 349 (1976) ("The essence of due process is the requirement that a person in jeopardy of serious loss be given notice of the case against him and opportunity to meet it.") (internal alterations and quotations omitted); *Goldberg v. Kelly*, 397 U.S. 254 (1970). To satisfy due process, the law must (1) "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly," and (2) "provide explicit standards for those who apply them." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). This Proposed Rule does not meet either of these requirements.

The Rule also constitutes an undue burden on a woman's decision to terminate her pregnancy before viability. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016); *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992) (plurality op.). The net effect of this rule will result in women being denied access to crucial information and even necessary treatment, including lawful abortions.

The Proposed Rule violates the Establishment Clause by accommodating religious beliefs to such an extent that it places an undue burden on third parties—patients. *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985); *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005) ("[A]n accommodation must be measured so that it does not override other significant interests"); *Santa Fe Indep. Sch. Dist. v. Doe*, 530 U.S. 290 (2000); *Lee v. Weisman*, 505 U.S. 557 (1992). Furthermore, the Proposed Rule constitutes excessive government entanglement with religion. *Larkin v. Grendel's Den*, 459 U.S. 116, 122-27 (1982); *Williams v. California*, 764 F.3d 1002, 1015 (9th Cir. 2014); *see also Larson v. Valente*, 456 U.S. 228, 244 (1982); *Kiryas Joel Village Sch. Dist. v. Grument*, 512 U.S. 687, 703 (1994) ("[G]overnment should not prefer . . . religion to irreligion").

Last, the Proposed Rule violates the Separation of Powers. U.S. Const. art. I, § 8, cl. 1; *Dole*, 483 U.S. at 206; *Clinton v. City of New York*, 524 U.S. 417, 438 (1998). Although *Congress* may attach conditions to receipt of federal funds, the executive branch cannot "amend[] parts of duly enacted statutes" after they become law, including to place conditions on

receipt of federal funds. *Clinton*, 524 U.S. at 439. HHS's attempt to broaden those statutes is thus a violation of the Separation of Powers.

In addition to these Constitutional violations, the Proposed Rule conflicts with several federal statutes and is written so broadly it could implicate others. First, the Proposed Rule clashes with several provisions of the Affordable Care Act, most notably section 1554, which prohibits the Secretary of HHS from creating barriers to healthcare, and section 1557, which prohibits discrimination in health programs or activities. 42 U.S.C. §§ 18114, 18116 (2015). Second, the Proposed Rule fails to reconcile its provisions with Title VII and the body of case law that has developed with regard to balancing religious freedoms and consumer rights. 42 U.S.C. § 2000e-2(e); *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 830 (9th Cir. 1999); *Peterson v. Hewlett Packard Co.*, 358 F.3d 599, 606-607 (9th Cir. 2004); *Opuku-Boateng v. State of California*, 95 F.3d 1461 (9th Cir. 1996). Third, the Proposed Rule contravenes Title X of the Public Health Services Act, 42 U.S.C. §§ 300-300a-6, which provides federal funding for family-planning services. Lastly, the Proposed Rule disregards the Emergency Medical Treatment & Labor Act (EMTALA), commonly known as the Patient Anti-Dumping Act, enacted by Congress in response to growing concern about the provision of adequate medical services to individuals, particularly the indigent and the uninsured, who sought care from hospital emergency rooms. 42 U.S.C. § 1395dd(a) (1986); *Jackson v. East Bay Hosp.*, 246 F.3d 1248, 1254 (9th Cir. 2001) (citation omitted).

To reiterate, the Proposed Rule fails to account for its potential impact on States and their citizens. The Rule will have damaging, irreparable repercussions for certain patient populations including women, LGBTQ individuals, and others. Even if OCR concludes, after an investigation, that a provider should have provided certain services that were denied for claimed religious or moral reasons, it will be too late for the patient who was wrongly deprived of that necessary care. As California knows from experience, OCR could take years to conduct an investigation; however, any correction at the end of that process would be inadequate for the patient whose healthcare has been compromised. This will be made worse by providers who are fearful of the federal government's enforcement of the Rule and threatened loss of funds, and who instead of treating a patient or providing a referral, will simply chose not to provide particular services, reducing access to care.

For the reasons set forth above, California strongly opposes the Proposed Rule and urges that it be withdrawn.

Sincerely,

XAVIER BECERRA
Attorney General of California

Exhibit 57

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

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

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

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

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

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

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

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

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

39% Democrat • 33% Republican • 22% Independent

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

Highlights of Online Survey of Faith-Based Professionals

2,865 faith-based healthcare professionals

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

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

April 2009 Phone Survey of the American Public

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

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

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

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

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

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

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

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

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

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

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

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

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

Online Survey of Faith-Based Medical Professionals

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

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

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

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

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

Discrimination is widespread in education and professional practice.

Asked to assess their educational experiences:

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

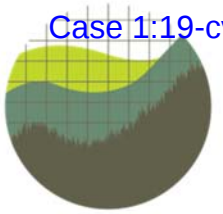
Asked to assess their professional experiences:

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

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

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

Exhibit 58



Institute for Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

March 27, 2018

VIA ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services

Attn: Office for Civil Rights

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

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law[1] respectfully submits the following comments to the Department of Health and Human Services ("HHS" or "the Department") regarding its proposed rule on statutory conscience protections in health care ("Proposed Rule").[2] Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

Our comments focus, first, on HHS's failure to provide a reasoned explanation for disregarding relevant prior findings and, second, on serious errors and oversights in the Department's Regulatory Impact Analysis for the Proposed Rule. Specifically, we note the following:

- HHS disregards, without explanation, concerns that it raised in its 2011 rulemaking on conscience protections ("2011 Rule"), such as the possibility that an overly broad conscience protections rule would interfere with patients' ability to offer informed consent and the possibility that an overly broad rule would lead providers to believe—mistakenly—that statutory conscience protections allow them to discriminate against certain types of patients.
- HHS's Regulatory Impact Analysis ignores the Proposed Rule's potentially substantial indirect costs, such as reduced access to health care for patients and increased personnel expenses for providers.
- The Regulatory Impact Analysis fails to assess the distributional impacts of the Proposed Rule.
- The Regulatory Impact Analysis underestimates the number of entities covered by the Proposed Rule's assurance and certification requirement and, as a result, understates the Proposed Rule's direct compliance costs.

[1] This document does not purport to present New York University School of Law's views, if any.

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

I. HHS Fails to Provide a Reasoned Explanation for Disregarding Findings It Made in the 2011 Rule.

This is not HHS's first rulemaking on conscience protections. In 2008, the Department finalized a regulation ("2008 Rule") that, among other things, purported to clarify the scope of conscience protections under the Church Amendments, Section 245 of the Public Health Service Act, and the Weldon Amendment by expansively defining certain statutory terms.[3] HHS subsequently rescinded all of the 2008 Rule's definitions in the 2011 Rule, citing concerns about their potential to (1) compromise patients' ability to offer informed consent, (2) cause confusion about the scope of statutory protections, and (3) inadvertently encourage providers to discriminate against certain categories of patients.[4]

When an agency amends, suspends, or repeals a rule, the agency must provide "a reasoned explanation . . . for disregarding facts or circumstances that underlay or were engendered by the prior policy."[5] Underlying the 2011 Rule was a conclusion by HHS that expansive definitions of statutory terms would compromise patients' ability to offer informed consent and foster confusion and discrimination. Accordingly, before it can adopt the Proposed Rule, which defines statutory terms even more broadly than the 2008 Rule did, the Department must acknowledge its prior concerns about expansive definitions and explain either why those concerns are not implicated by the definitions proposed here or why the Proposed Rule is justified despite those concerns. In the absence of such an explanation, the Proposed Rule is arbitrary and capricious.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Compromise Patients' Ability to Provide Informed Consent

When it rescinded the majority of the 2008 Rule in 2011, HHS did so, in part, to "clarify any mistaken belief that [the 2008 Rule] altered the scope of information that must be provided to a patient by their provider in order to fulfill informed consent requirements."[6] The 2011

[3] Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072, 78,073 (Dec. 19, 2008) (hereinafter "2008 Rule").

[4] Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9973-74 (Feb. 23, 2011) (hereinafter "2011 Rule").

[5] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).

[6] 2011 Rule, 76 Fed. Reg. at 9973.

Rule emphasized that making a patient aware of all available health care options is "crucial to the provision of quality health care services."[7]

The Proposed Rule is likely to limit patients' awareness of their health care options to an even greater extent than the 2008 Rule would have.[8] For example, the Proposed Rule suggests that a provider has no obligation to offer patients a disclaimer regarding health care procedures to which the provider has a religious or moral objection.[9] In other words, providers need not warn patients that they are not being informed of all available treatment options. And yet HHS fails even to acknowledge its 2011 finding that a conscience protections rule could not properly "alter[ ] the scope of information that must be provided to a patient,"[10] much less explain why the Department no longer holds that view.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Cause Confusion About the Scope of Statutory Protections

The 2011 Rule highlighted commenters' concern that the definitions in the 2008 Rule "were far broader than scope of the federal provider conscience statutes."[11] In rescinding those definitions, the Department noted its agreement that the definitions "may have caused confusion regarding the scope" of statutory protections.[12]

Definitions included in the Proposed Rule are even broader than those adopted in 2008. For example, whereas the 2008 Rule interpreted statutory protections against "assist[ing] in in the performance" of an objectionable procedure to encompass any action with a "reasonable" connection to that procedure,[13] the Proposed Rule requires only an "articulable" connection to the procedure.[14] But the Proposed Rule nevertheless fails to acknowledge HHS's prior finding as to the potential for broad definitions to cause confusion. Nor does the Department explain why the Proposed Rule is justified in spite of this potential for confusion.

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[7] *Id.*

[8] Proposed Rule, 83 Fed. Reg. at 3924.

[9] *See id.* at 3894-95 (defining "referral or refer for" to include "disclaimers," and noting that referral was not defined in the 2008 Rule).

[10] 2011 Rule, 76 Fed. Reg. at 9973.

[11] *Id.*

[12] *Id.*

[13] 2008 Rule, 73 Fed. Reg. at 78,097.

[14] Proposed Rule, 83 Fed. Reg. at 78,090-91.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Encourage Discrimination Against Categories of Patients

HHS's 2011 decision to rescind the definitions in the 2008 Rule was also motivated by concern that the definitions would lead providers to believe, incorrectly, that statutory protections extended not just to refusals to perform particular procedures, but also to refusals to care for particular types of patients. As the Department explained in the 2011 Rule, statutory conscience protections "were never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable."[15] But the Department agreed with commenters that the 2008 Rule could nevertheless give the impression that "Federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs."[16] As a result, HHS feared that the 2008 Rule could reduce access to "a wide range of medical services, including care for sexual assault victims, provision of HIV/AIDS treatment, and emergency services."[17]

Again, the definitions in the Proposed Rule are even broader than those that caused the Department concern in 2011 and are thus likely to give rise to the same harmful misimpressions about the scope of statutory conscience protections. But the Department neither acknowledges its prior concerns regarding the inadvertent encouragement of discrimination nor explains why proceeding with the Proposed Rule is reasonable despite those concerns.

II. HHS Fails to Consider the Proposed Rule's Indirect Costs

A rational cost-benefit analysis considers both the direct *and* indirect effects of a proposed rule. To that end, Executive Order 12,866 requires agencies to consider not just "direct cost . . . to businesses and others in complying with the regulation," but also "any adverse effects" the rule might have on "the efficient functioning of the economy, private markets . . . health, safety, and the natural environment."[18] Longstanding guidance on regulatory impact analysis from the White House Office of Management and Budget similarly instructs agencies to "look beyond the direct benefits and direct costs of [their] rulemaking and consider any important

[15] 2011 Rule, 76 Fed. Reg. at 9973-74.

[16] *Id.* at 9973.

[17] *Id.* at 9974.

[18] E.O. 12,866 § 6(a)(3)(C)(ii).

ancillary benefits and countervailing risks."[19] The Supreme Court, too, has made clear that "'cost' includes more than the expense of complying with regulations" and that "any disadvantage could be termed a cost."[20]

Despite HHS's clear obligation to consider indirect consequences, the Regulatory Impact Analysis for the Proposed Rule assesses only direct compliance costs and ignores the ways in which the Proposed Rule is likely to reduce patients' access to health care and increase providers' personnel expenses.

HHS Fails to Consider Costs to Patients from the Express Denial of Medical Services

For a variety of reasons, the Proposed Rule is likely to reduce the availability and consumption of medical services, negatively affecting patient health and wellbeing. As discussed in Section I of these comments, the Proposed Rule's expansive definitions of statutory terms are likely to lead some providers to adopt a much broader interpretation of statutory conscience protections than Congress intended. This, in turn, will increase the frequency with which patients are denied care due to a provider's religious or moral objections. Such denials can impose a variety of costs—financial, physical, and psychological—on patients.

At minimum, a patient denied care must incur the cost of seeking out an alternative provider. Assuming patients typically choose the most convenient healthcare provider available, a second-choice provider may be farther away than the first. Traveling farther away, the patient loses time and money spent on transportation, and may be required to request time off from work or pay for childcare services. For some patients, these costs may be insurmountable.

Furthermore, some patients who are denied care may be too discouraged to seek out alternative sources of healthcare services. These patients may eschew treatment altogether, leading to negative health consequences.

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[19] Office of Mgmt. & Budget, Circular A-4 (2003), https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.

[20] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015); *see also Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin.,* 956 F.2d 321, 326-27 (D.C. Cir. 1992) (striking down fuel-efficiency rule for failure to consider indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (holding that EPA was required to consider the indirect safety effects of substitute options for car brakes when banning asbestos-based brakes under the Toxic Substances Control Act).

Finally, the Proposed Rule may discourage some patients from seeking medical services in the first place, simply because they *fear* being rejected by a provider. This assumption is reciprocal to the Department's assumption that some potential healthcare providers are currently (absent the Proposed Rule) discouraged from entering the profession because they fear they will be discriminated against for their religious and moral convictions.[21]

HHS Fails to Consider Costs to Patients from the Undisclosed Denial of Medical Services

The Proposed Rule's likely health costs extend beyond patients who are (or who fear that they will be) expressly denied care. As explained in Section I of these comments, the Proposed Rule encourages providers not merely to refuse to provide referrals for procedures or services to which they object, but also to refuse to warn patients that the provider is declining to recommend such treatments. A patient who does not realize she is being denied information about a particular health care option might choose an alternative that is less beneficial to her health or wellbeing.[22]

HHS Fails to Consider Indirect Personnel Costs for Providers

In addition to imposing health costs on patients, the Proposed Rule may indirectly increase personnel costs for some health care entities. For example, if the Proposed Rule causes support staff at a given health care facility to decline to perform services that they previously performed (or to decline to treat patients whom they previously treated), the facility will need to pay for additional labor to meet the same level of demand.

[21] Proposed Rule, 83 Fed. Reg. at 3916.

[22] The Department solicits comment on methodologies that can be used to quantify ancillary health costs. There are a number of ways to assess such impacts, including: retrospective cohort studies (e.g., studying the conditions of women's health in the 1960's and 1970's when information on abortion was limited); cohort studies in other countries or states where abortion counseling and referral is restricted; prospective cohort studies (i.e., a pilot program testing the regulation on a subset of the population); self-report surveys administered to a sample population of women (assessing, for example, their awareness of the existence of and details of abortions procedures); estimations of the potential effects by using statistics in the current environment as indicators; or any other of a number of epidemiological and other studies that are routinely performed by public health professionals when evaluating policies that affect public health.

III. HHS Fails to Consider the Proposed Rule's Distributional Impacts

Executive Order 12,866 requires agencies to "consider . . . distributive impacts" that will result from a proposed regulatory action.[23] In addition to failing to take the aforementioned ancillary costs into consideration, the Department has failed to consider how these costs will burden certain groups disproportionately. The Department's failure to consider such distributional impacts is particularly egregious given that it lists the promotion of "a society free from discrimination" as one of the chief benefits of the Proposed Rule.[24] HHS cannot rationally tout the Proposed Rule's potential to reduce discrimination against religious health care providers while ignoring its potential to increase discrimination against other groups.[25]

Specifically, the Department should consider whether and to what extent the Proposed Rule will disproportionately burden the following subpopulations:

- Immigrant Women: Recent immigrants may be less well informed on the availability of reproductive health care in the U.S., and therefore in greater need of the counselling and referral services that the Proposed Rule covers.

- Rural Women: Increasing the incidence of health care providers refusing to provide counseling or referrals may create a greater problem for women who live in rural areas than for women at large, due to the increased search and travel costs associated with finding an alternative provider in rural areas.

- Low-Income Women: Women with lower incomes have fewer resources available to allocate to transportation and child care. If refused counseling or referral services, these women may suffer greater costs when seeking alternative health care providers. The refusal may even result in an insurmountable obstacle to obtaining the health service sought.

- Women of Color: Women of color disproportionately earn lower incomes and live in underserved areas. If refused counseling or referrals, these women may experience greater burdens to seek alternative health care providers.

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[23] E.O. 12,866 § 6(b)(5).

[24] Proposed Rule, 83 Fed. Reg. at 3903.

[25] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (noting that "reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions"); *Sierra Club v. Sigler*, 695 F.2d 957, 979 (5th Cir. 1983) (an agency "cannot tip the scales . . . by promoting [an action's] possible benefits while ignoring [its] costs.").

- LGBTQ Individuals: As discussed in Section I, the Proposed Rule, like the 2008 Rule, may lead health care workers to believe they can permissibly refuse to provide any type of medical service to gay or transgender individuals (or their families) based on moral or religious objections. Such refusals would decrease the quantity and quality of health care available to that population.

- Individuals with HIV/AIDS: Similarly, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical service to individuals with HIV/AIDS. Again, such refusals would decrease the quantity and quality of health care available to that population.

- Interracial/Interfaith Families: Finally, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical services to interracial or interfaith families because they morally object to such relationships. As with LGBTQ patients and HIV-positive patients, this misimpression could result in reduced access to health care for interracial and interfaith families.

IV. HHS Underestimates the Number of Entities Affected by the Proposed Rule and, as a Result, Underestimates the Proposed Rule's Compliance Costs

In addition to overlooking the Proposed Rule's indirect costs, HHS also underestimates the Proposed Rule's *direct* costs. Section 88.4 of the Proposed Rule requires certain recipients of HHS funding "to submit written assurances and certifications of compliance" with statutory conscience protections.[26] In calculating compliance costs for this assurance and certification requirement, the Department estimates that the requirement would apply to between 94,279 and 152,519 individuals and entities.[27] But that estimate excludes a large number of individuals and entities that, under a plain reading of the Proposed Rule, would in fact be required to submit assurances and certifications.[28]

HHS assumes that "all physicians" will be exempt from complying with the assurance and certification requirement, either because they do not accept HHS funds or because they "meet the proposed criteria for exemption . . . in proposed § 88.4(c)(1)."[29] But § 88.4(c)(1) exempts physicians and physician offices only if they (1) participate in Medicare Part B and

[26] Proposed Rule, 83 Fed. Reg. at 3896.

[27] *Id.* at 3910.

[28] *Id*. at 3910, 3915.

[29] *Id.* at 3909-10.

(2) "are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism."[30] It is patently unreasonable for the Department to assume that this exemption encompasses every physician who receives HHS funds. Some physicians, for example, accept both Medicare *and* Medicaid funding.

HHS makes a similar error in estimating the number of individuals and entities that would be exempt from the assurance and certification requirement due to § 88.4(c)(2), which exempts recipients of funding under certain grant programs administered by the Administration for Children and Families that have a purpose unrelated to health care provision or medical research. The Department assumes that "all persons and entities that provide child and youth services . . . [and] all entities providing services for the elderly and persons with disabilities . . . would fall within this exemption."[31] As with the exemption for physicians, however, the § 88.4(c)(2) exemption is unavailable if HHS money is accepted from any other source. It seems unlikely that *no* entities that provide services for children, the elderly, or the disabled receive HHS funding from *any* source other than non-healthcare-related grant programs administered by the Administration for Children and Families.

Because it underestimates the number of entities that will be obligated to comply with the Proposed Rule's assurance and certification requirement, HHS also underestimates the Proposed Rule's total compliance costs.

Respectfully,

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Theodore Gifford
Jack Lienke
Jason A. Schwartz

[30] *Id.* at 3929.

[31] *Id.* at 3910.