Exhibit 12

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

March 20, 2018

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

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

Dear Secretary Azar:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the proposed rule titled, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" as published by the Office for Civil Rights (OCR) in the January 26, 2018 *Federal Register*.

In this regulation, OCR proposes to revise regulations to ensure that health care professionals have the right to decline to participate in medical procedures to which they are opposed on moral or religious grounds. HHS also announced the creation of the Conscience and Religious Freedom Division.

While these actions by HHS do not appear to suggest the creation of new rights or obligations under federal law, they do signal an intent to broaden the scope of existing conscience objection regulations and promote stricter enforcement of those laws. The AAFP is concerned that these actions could restrict access to care for vulnerable patients seeking the aid of their family physician or other health care professionals.

The AAFP recognizes and respect the rights of health care professionals to decline to participate in care that violates their personal code of ethics. However, our policies call for ensuring that all patients have access to health care, regardless of actual or perceived race, color, religion, gender, sexual orientation, gender identity, ethnic affiliation, health, age, disability, economic status, body habitus or national origin. Denying access to care to a patient on religious, ethical or moral grounds is in direct conflict with AAFP policy. There is a distinct difference between declining to participate in a procedure versus denying access to care to an individual patient. The former is a protected right, the latter is an unacceptable shirking of our basic responsibility to care for our patients and contrary to the key underpinnings of the Code of Medical Ethics.

It is the AAFP's policy on professional responsibility in physician and patient relationships that good medical care requires a mutually trusting and satisfactory relationship between physician and patient.

No physician shall be compelled to prescribe any treatment or perform any act which violates his/her good judgment or personally held moral principles. In these circumstances, the physician may withdraw from the case so long as adequate notice is given to enable the patient to engage the services of another physician.

The AAFP will continue to monitor the actions of HHS and its Conscience and Religious Freedom Division. We caution the administration to abide by its insistence that the division's focus would be on "actions" and not on denying care to specific groups of people.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

John Meigs, Jr., MD, FAAFP
Board Chair

About Family Medicine
Family physicians conduct approximately one in five of the total medical office visits in the United States per year – more than any other specialty. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families and communities. Family medicine's cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient's integrated care team. More Americans depend on family physicians than on any other medical specialty.

Exhibit 13

March 26, 2018

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

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

Dear Secretary Azar:

On behalf of the more than 123,000 PAs (physician assistants) throughout the United States, the American Academy of PAs (AAPA) welcomes the opportunity to submit comments to the Department of Health and Human Services (HHS) regarding the recent creation of the Conscience and Religious Freedom Division, along with the release of a rule to impose additional enforcement mechanisms with regard to federal laws that grant healthcare professionals the right to decline to participate in medical procedures to which they are opposed on moral or religious grounds.

In the proposed rule, the Office for Civil Rights (OCR) seeks to strengthen enforcement of existing statutory conscience protections for healthcare providers to protect them from being coerced into participating in activities that may violate their beliefs. The proposed rule also creates a new Conscience and Religious Freedom Division within OCR.

AAPA's policy, which is contained in its Guidelines for Ethical Conduct for the PA Profession, provides guidance on how PAs should act in situations where they believe their beliefs may be compromised, and how best to manage these beliefs in relation to a PA's obligation to provide the best possible care to their patients.

AAPA is concerned that the proposal's effort to broaden the scope of conscience objection regulations and to increase related enforcement efforts could have a negative impact on access to healthcare for patients, especially those who are most vulnerable and those who may live in rural or underserved areas. AAPA is also concerned new paperwork requirements related to "Assurance and Certification of Compliance" could be excessively burdensome to healthcare providers.

PA Practice

PAs are medical professionals who manage the full scope of patient care, often serving patients with multiple comorbidities. They conduct physical exams, order and interpret tests, diagnose and treat illnesses, develop and manage treatment plans, prescribe medications, assist in surgery, and counsel

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patients on preventative healthcare, and often serve as a patient's principal healthcare professional. PAs are one of three categories of healthcare professionals, including physicians and nurse practitioners, who are authorized by law to provide primary care in the United States. In addition to primary care, PAs practice in a wide range of settings and medical specialties, improving healthcare access and quality.

AAPA Policy on Personal Beliefs and Patient Access to Care

The foremost value of the PA profession is respect for the health, safety, welfare, and dignity of all human beings, which requires PAs to always act in the best interest of their patients. This concept is the foundation of the patient–PA relationship, and underpins PAs' ethical obligation to see that each of their patients receives appropriate care.

The PA profession's policy on nondiscrimination is as follows: "PAs should not discriminate against classes or categories of patients in the delivery of needed healthcare. Such classes and categories include gender, color, creed, race, religion, age, ethnic or national origin, political beliefs, nature of illness, disability, socioeconomic status, physical stature, body size, gender identity, marital status, or sexual orientation."

Importantly, our policy also holds that, "While PAs are not expected to ignore their own personal values, scientific or ethical standards, or the law, they should not allow their personal beliefs to restrict patient access to care. A PA has an ethical duty to offer each patient the full range of information on relevant options for their healthcare. *If personal moral, religious, or ethical beliefs prevent a PA from offering the full range of treatments available or care the patient desires, the PA has an ethical duty to refer a patient to another qualified provider.*" [Emphasis added.]

AAPA View and Recommendations

AAPA has significant concerns about the proposed regulatory changes because they put the personal beliefs of healthcare providers above each provider's paramount responsibility to ensure that every patient has access to care. We urge the administration to be cognizant of creating new barriers for healthcare for our most vulnerable populations, which would undermine the progress made in addressing medical disparities among these groups. Doing what is best for the patient must continue to be of utmost concern.

In promulgating the final rule and undertaking new initiatives, AAPA urges the department to work with all relevant healthcare provider groups to ensure that any actions are supported by and consistent with best healthcare practices, and that every patient has access to appropriate care.

AAPA looks forward to working with Secretary Azar, HHS and all relevant parties moving forward. Please do not hesitate to contact Tate Heuer, AAPA Vice President, Federal Advocacy, at 571-319-4338 or theuer@aapa.org, with any questions.

Sincerely,

L. Gail Curtis, MPAS, PA-C, DFAAPA
President and Chair of the Board

Exhibit 14

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.[1] 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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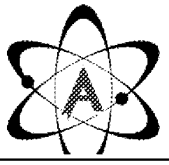
Exhibit 15



AMERICAN ATHEISTS

March 26, 2018

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

Re: Public Comments Regarding Proposed Rules on "Protecting Statutory Conscience Rights in Health Care" (RIN 0945-ZA03, Docket HHS-OCR-2018-0002)

Dear Madam or Sir:

American Atheists writes in response to the request for public comments regarding the proposed rules entitled "Protecting Statutory Conscience Rights in Health Care," published January 26, 2018.[1] We are strongly opposed to the proposed rules because they go far beyond the statutory religious exceptions created by federal law, because they provide protection only for religious conduct based only a specific set of beliefs and undermine the religious liberty of others, and because they threaten the safety, health and well-being of millions of Americans. These proposed rules will undoubtedly lead to increased discrimination and denials of care for vulnerable people across our nation, and so we emphatically urge you to withdraw them.

American Atheists is a national civil rights organization that works to achieve religious equality for all Americans by protecting what Thomas Jefferson called the "wall of separation" between government and religion created by the First Amendment. We strive to create an environment where atheism and atheists are accepted as members of our nation's communities and where casual bigotry against our community is seen as abhorrent and unacceptable. We promote understanding of atheists through education, outreach, and community-building and work to end the stigma associated with being an atheist in America. As advocates for the health, safety, and well-being of all Americans, American Atheists objects to efforts to subordinate medical care to the religious beliefs of providers and institutions.

1. **The proposed rules misapply nondiscrimination principles and constitute a constitutionally impermissible establishment of religion.**

As a foundational matter, the First Amendment to the US Constitution provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof." This Establishment Clause is a critical element protecting religious freedom in the United States, because, as

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

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the Founders recognized, there can be no religious freedom when the government imposes religion on its citizens. However, in the name of protecting freedom of conscience, these proposed rules do just that.

Congress had previously passed a few narrow statutory provisions allowing for specific, limited circumstances in which health care providers may not be required to participate in abortion and sterilization procedures.[2] These proposed rules now seek to build those narrow exceptions into an ambiguous framework that "prohibits discrimination" against only those health care providers who refuse to engage in health care practices which offend specific religious viewpoints - those most often held by conservative Christians. Although the proposed rules repeatedly compare this Procrustean amalgamation of provisions to various civil rights laws, it requires a fundamentally different analysis than those well-established protections which prohibit discrimination based on neutral concepts like religion, race, or sex. Unlike those protections, the one-sided religious conduct-based "nondiscrimination protections" established by these proposed rules are not viewpoint neutral. Instead they enshrine a particular religious viewpoint into law and thereby unconstitutionally favor a particular religion.

These proposed rules are clearly not intended to protect religious liberty in a broader sense. They do nothing, for example, to protect the health care provider or patient whose beliefs dictate that abortion services should be widely accessible, that contraception should be freely available to everyone, that discrimination is immoral and must be prevented, that terminally ill individuals should be able to receive medical aid-in-dying, or that only the individuals involved should be able to determine if sterilization is the best option for them. Why is the religious liberty of health care providers who share religious viewpoints with conservative Christians worth more than other health care providers' or patients' religious liberty? By seeking to impose these values as universal justifications for religious refusals for all health care providers, the Department undermines the separation of religion and government.

Moreover, it is irrelevant that these proposed rules are cloaked in the language of nondiscrimination; it is nonsensical to apply to these ill-defined protections the well-developed legal doctrines that apply to nondiscrimination laws. For example, the preamble to the proposed rules seeks to bootstrap the doctrine of disparate impact, normally applicable in contexts like systemic employment discrimination, to give the Department wide-ranging power to investigate even when there is no valid complaint.[3] This would allow the Department to investigate and bring claims against facially neutral policies by grantees, such as hospitals, insurance companies, and states, which may impact this ill-defined group of health care providers (who share beliefs approved of by conservative Christians).

For example, the Department could challenge states that have freedom of conscience laws that require basic referral by the health care provider. Or the Department could challenge the laws in ten states that require emergency care facilities to offer emergency contraception to rape victims they treat. Or the Department might challenge the 15 states with policies requiring coverage for medically necessary health care for transgender people, based on the erroneous belief that they require participation in

[2] The Church Amendments, 42 U.S.C. § 300a-7 (2018); The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[3] *See supra* note 1, at 3892-3.

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sterilization.[4] Or the Department might investigate laws which require fake clinics masquerading as abortion providers to provide a disclaimer to patients. Since these so-called "nondiscrimination protections" refers to an array of conduct, rather than a particular protected characteristic, there really is no end to how the Department might use this new investigatory power to attack any laws or policies that promote contraception, provide access for abortion, prohibit discrimination, or protect patients. In this circumstance, the vagueness of this protected category is a feature, not an error, as it allows for unhindered discretion in review.

Finally, the Establishment Clause of the First Amendment and federal law require the Department to consider the impact any accommodation or religious exemption for religious health care providers would have on third parties. Specifically, the Constitution bars the federal government from crafting "affirmative" accommodations within its programs if the accommodations would harm any program beneficiaries.[5] The Constitution commands that "an accommodation must be measured so that it does not override other significant interests";[6] "impose unjustified burdens on other[s]";[7] or have a "detrimental effect on any third party."[8]

However, these proposed rules unjustifiably expand the limited religious exceptions created by Congress. Additional religious exemptions that enable entities receiving taxpayer funding to refuse to provide critical health care services on the basis of religious objections would undoubtedly harm third parties, in violation of the Establishment Clause.[9]

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[4] We are concerned that the proposed rules' sweeping terms and HHS's troubling discussions of a case involving a transgender patient will encourage the mistaken belief that treatments that have an incidental impact on fertility, such as some procedures used to treat gender dysphoria, are sterilization procedures. Treatments for many serious medical conditions may have the incidental effect of causing or contributing to infertility, however the primary purpose of such procedures is not to sterilize but to treat an unrelated medical condition. If religious exemptions related to sterilization are misinterpreted to include treatments that have simply an incidental effect on fertility—as the vague and sweeping language of these proposed rules encourage—it will lead to health care refusals that go far beyond what federal law allows and unlawfully encourage individuals and institutions to refuse a dangerously broad range of medically necessary treatments.

[5] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

[6] *Cutter v. Wilkinson*, 544 U.S. at 722.

[7] *Id.* at 726.

[8] *Id.* at 720, 722; *See also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. at 2781; *Estate of Thornton v. Caldor*, 472 U.S. at 710 ("unyielding weighting" of religious exercise "over all other interests…contravenes a fundamental principle" by having "a primary effect that impermissibly advances a particular religious practice."); *Texas Monthly, Inc. v. Bullock*, 480 U.S. 1, 18 n.8 (1989) (religious accommodations may not impose "substantial burdens on nonbeneficiaries").

[9] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in *Hobby Lobby*, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious

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2. The proposed rules unlawfully exceed the Department's authority by impermissibly expanding religious refusals to provide care.

The proposed rules exceed OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[10] Instead, the proposed rules appropriate language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the proposed rules creates a regulatory scheme that is not only nonsensical but is affirmatively harmful.

Already existing refusal of care laws are used across the country to deny patients the care they need.[11] The proposed rules attempt to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.[12] But the proposed rules attempt 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.[13] Such an attempted expansion goes beyond what the statute enacted by Congress allows. Furthermore, the proposed rules would expansively apply other provisions of the Church Amendments to, among other things, individuals working under global health programs funded by the Department thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the proposed rules define common phrases and words used throughout existing refusal-of-care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be

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objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

[10] *OCR's Mission and Vision*, Dep't of Health and Human Servs. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[11] *See, e.g.*, *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, Nat'l Women's L. Ctr. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., *Health Care Denied*, Am. Civil Liberties Union (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, Pub. Rights Private Conscience Project (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[12] The Church Amendments, 42 U.S.C. § 300a-7 (2018).

[13] *See supra* note 1, at 185.

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refused to include merely "making arrangements for the procedure" no matter how tangential.[14] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The proposed rules' definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.[15]

Furthermore, the proposed rules' new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the proposed rules seek to enforce. Specifically, under the Coats and Weldon Amendments "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[16] The proposed rules instead combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[17] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert.[18]

In addition, the proposed rules attempt to create new rights to refuse care out of existing law in spite of congressional intent. For example, 42 U.S.C. § 1395cc(f) requires that covered entities maintain written policies and procedures to inform patients of, among other things, their "individual rights under State law to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advanced directives."[19] However, the proposed rules attempt to rewrite this provision by prohibiting this statute from being construed to require covered entities to provide full information to patients about services to which they may object.[20] Such an attempt to subvert the plain language of the statute flies in the face of clear congressional intent and exceeds the Department's authority.

The Department claims that its unwarranted new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. The preamble of the proposed rules discuss at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[21] By claiming to allow individuals and institutions to

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[14] *Id.* at 180.
[15] *Id.* at 183.
[16] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[17] *See supra* note 1, at 182.
[18] The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[19] Agreements with Providers of Services; Enrollment Processes, 42 U.S.C. § 1395cc (2016).
[20] *See supra* note 1, at 194.
[21] *See, e.g., supra* note 1, at 3888-89.

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refuse care to patients based on the providers' religious or moral beliefs in such sweeping ways, the proposed rules create conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. Moreover, the proposed rules invite states to further expand refusals of care by making clear that these expansive rules are a floor, and not a ceiling, for religious exemption laws.[22] It is therefore plainly incorrect for the Department to claim that the proposed rules "do[] not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns, as required by Executive Order 13132.[23]

3. **Expanding religious refusals will create barriers to medically necessary health care, exacerbate health disparities, and encourage discrimination.**

Religion has been invoked in countless ways to deny individuals access to needed health care, including birth control, sterilization, certain infertility treatments, abortion,[24] transition-related medical care for transgender patients,[25] reproductive health care for trafficking victims,[26] and end of life care.[27]

In just a few specific examples: LGBTQ individuals have been denied appropriate mental health services and counseling,[28] a newborn was denied care because her parents were lesbians,[29] a woman suffering a miscarriage was denied prescription medication,[30] and an individual was denied his HIV medication,[31] all because of someone else's religious beliefs. One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the

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[22] *See id.*

[23] Federalism, Executive Order 13132 (Aug. 4, 1999), https://www.gpo.gov/fdsys/pkg/FR-1999-08-10/pdf/99-20729.pdf.

[24] Nat'l Women's Law Ctr., *Health Care Refusals Harm Patients: The Threat to Reproductive Health Care* (May 2014), http://www.nwlc.org/sites/default/files/pdfs/refusals_harm_patients_repro_factsheet_5-30-14.pdf. *See also* American Civil Liberties Union, *Health Care Denied* (May 2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[25] Nat'l Women's Law Ctr., *Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS* (May 2014), http://www.nwlc.org/sites/default/files/pdfs/lgbt_refusals_factsheet_05-09-14.pdf.

[26] *ACLU of Mass. v. Sebelius*, 821 F. Supp. 2d 474 (D. Mass. 2012), *vacated as moot sub nom., ACLU of Mass. v. U.S. Conference of Catholic Bishops*, 705 F.3d 44 (1st Cir. 2013).

[27] Directive 24 denies respect for advance medical directives. U.S. Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services (5th ed. 2009), http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf.

[28] *Ward v. Wilbanks*, 09-CV-11237, 2010 WL 3026428 (E.D. Mich. July 26, 2010), *rev'd and remanded sub nom. Ward v. Polite*, 667 F.3d 727 (6th Cir. 2012), *dismissed with prej.* by *Ward v. Wilbanks*, 09-CV-11237 (E.D. Mich. Dec. 12, 2012) (case settled).

[29] Abby Phillip, *Pediatrician Refuses to Treat Baby with Lesbian Parents and There's Nothing Illegal About It*, Wash. Post., Feb. 19, 2015, https://www.washingtonpost.com/news/morning-mix/wp/2015/02/19/pediatrician-refuses-to-treat-baby-with-lesbian-parents-and-theres-nothing-illegal-about-it/.

[30] *Denied Care When Losing a Pregnancy: Pharmacies Refuse to Fill Needed Prescriptions*, Nat'l Women's Law Ctr. (Apr. 16, 2015), http://www.nwlc.org/our-blog/denied-care-when-losing-pregnancy-pharmacies-refuse-fill-needed-prescriptions.

[31] Complaint, *Simoes v. Trinitas Reg'l Med. Ctr.*, No. UNNL-1868-12 (N.J. Super. Ct. Law Div. May 23, 2012).

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miscarriage management she needed because the hospital objected to this care.[32] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[33] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[34] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic health care provider refused to give her the procedure.[35] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[36] Such occurrences are all too common, and every day they put the lives of Americans at risk for the sake of others' religious beliefs.

These refusals of care have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[37] In rural areas there may be no other sources of health and life preserving medical care.[38] When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen

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[32] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, Pub. Rights Private Conscience Project at 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[33] *See* Julia Kaye, et al., *Health Care Denied*, American Civil Liberties Union at 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[34] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, Pub. Rights Private Conscience Project at 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[35] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, Nat'l Women's Law Ctr. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, Wash. Post (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.

[36] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, Pub. Rights Private Conscience Project at 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[37] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, Kaiser Family Found. 1at 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[38] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, The Cecil G. Sheps Ctr. for Health Servs. Res. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

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states, women of color are more likely than white women to give birth in Catholic hospitals.[39] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs), which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering professional standards of care. Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[40] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[41]

By expanding refusals of care the proposed rules will exacerbate the barriers to health care services patients need. It is evident that the harm caused by these proposed rules will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[42] The proposed rules plainly fail on both counts. Although the proposed rules attempt to quantify the costs of compliance, they completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[43]

If finalized, the proposed rules will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[44]

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[39] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, Pub. Rights Private Conscience Project at 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

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

[41] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, Am. Civil Liberties Union & Merger Watch (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

[42] Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

[43] *See supra* note 1, at 94-177.

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

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OCR must work to address these disparities, yet the proposed rules seek to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed, rather than using already limited resources to protect patient access to health care. The proposed rules will harm patient care and are antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[45]

4. The proposed rules conflict with other existing federal laws.

The proposed rules would generate chaos through their failure to account for existing federal laws that conflict with the new health care refusals it would create.

For example, the proposed rules make no mention of Title VII,[46] the leading federal law barring employment discrimination, nor to current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[47] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[48] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect the potential accommodation would have on patients, coworkers, public safety, and other legal obligations. The proposed rules, however, set out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[49]

Furthermore, the language in the proposed rules would seem to put health care entities in the untenable position of being forced to hire people who intend to refuse to perform essential elements of a position, even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling, even though the employer would not be required to do so under Title VII.[50] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

Dep't of Health and Human Servs. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[45] *See supra* note 9.

[46] 42 U.S.C. § 2000e-2 (1964).

[47] *Title VII of the Civil Rights Act of 1964*, U.S. Equal Emp't. Opportunity Comm'n (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[48] *See id.*

[49] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.

[50] *See supra* note 1, at 180-181.

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In addition, the proposed rules fail to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or, if medically warranted, to transfer the person to another facility.[51] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[52] Because the proposed rules do not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

Conclusion

The proposed rules are unnecessary and dangerous - we strongly urge you to withdraw them. The rules would undermine the ability of patients to receive medically necessary health care and to receive complete and medically accurate information about their treatment options. In defiance of statutory authority and the US Constitution, these rules put religion above the safety, well-being, and very lives of patients. If you should have any questions regarding American Atheists' opposition to these proposed rules, please contact me at 908.276.7300 x9 or by email at agill@atheists.org.

Sincerely,

Alison Gill, Esq.
Legal and Policy Director
American Atheists

[51] 42 U.S.C. § 1295dd(a)-(c) (2003).

[52] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

American Atheists
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Exhibit 16

American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

March 27, 2018

Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW.
Washington, DC 20201

Re: RIN 0945-ZA03

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

WASHINGTON, DC OFFICE
2121 K Street NW, Suite 325
Washington, DC 20037-1886

202-728-0610
800-320-0610
www.acep.org

On behalf of more than 37,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the draft rule relating to protecting conscience rights in health care, as it affects our practice of emergency medicine and the patients we serve.

While we believe that enforcement of existing federal conscience protections for health care providers is important, we strongly object to this proposed rule and do not believe it should be finalized. As written, it does not reflect nor allow for our moral and legal duty as emergency physicians to treat everyone who comes through our doors. Both by law[1] and by oath, emergency physicians care for all patients seeking emergency medical treatment. Denial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical[2].

ACEP has specific comments on multiple sections of the proposed rule, which are found below.

Application of Proposals in Emergency Situations

As emergency physicians, we are surprised and concerned that the proposed rule does not in any way address how conscience rights of individuals and institutions interact

[1] 42 U.S. Code § 1395dd - Examination and treatment for emergency medical conditions and women in labor
[2] ACEP Code of Ethics for Emergency Physicians; Approved Jan 2017; https://www.acep.org/clinical---practice-management/code-of-ethics-for-emergency-physicians

with the mandated provision of emergency services. The Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and stabilize patients who come to the emergency department. Such patients have every right to expect the best possible care and to receive the most appropriate treatment and information about their condition.

Patients with life-threatening injuries or illnesses may not have time to wait to be referred to another physician or other healthcare professional to treat them if the present provider has a moral or religious objection. Likewise, emergency departments operate on tight budgets and do not have the staffing capacity to be able to have additional personnel on hand 24 hours a day, 7 days a week to respond to different types of emergency situations that might arise involving patients with different backgrounds, sexual orientations, gender identities, or religious or cultural beliefs. The proposed rule seems to demand that, in order to meet EMTALA requirements, an emergency department anticipate every possible basis for a religious or moral objection, survey its employees to ascertain on which basis they might object, and staff accordingly. This is an impossible task that jeopardizes the ability to provide care, both for standard emergency room readiness and for emergency preparedness. Emergency departments serve as the safety-net in many communities, providing a place where those who are most vulnerable and those in need of the most immediate attention can receive care. By not addressing the rights and needs of patients undergoing an emergency, the legal obligations of emergency physicians, and the budget and staffing constraints that emergency departments face, this rule has the potential of undermining the critical role that emergency departments play across the country.

Definition of Referrals

Under the proposed rule, health care providers could refuse not only to perform any given health care service, but also to provide patients access to information about or referrals for such services. The Department of Health and Human Services (HHS) defines a referral broadly in the rule as "the provision of any information… by any method… pertaining to a service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or direction that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."

Such a broad definition of referral as referenced under the proposed rule's prohibition could create unintended consequences, such as preventing patients from getting appropriate care now or even in the future. For example, this definition would allow a primary care physician with a moral or religious objection to abortion to deny referring a pregnant woman (who may not have any immediate intentions or desire for an abortion) to a particular obstetrician-gynecologist out of fear that the woman could eventually receive an abortion from that obstetrician-gynecologist, whether at some point in the future of this pregnancy or even for a future pregnancy.

Another situation where this definition could lead to an undesirable outcome for a patient is when a provider has an objection to a patient's end-of-life wishes expressed in an advance directive. Emergency physicians often treat patients with advanced illness, and ACEP strongly believes that providers should respect the wishes of dying patients including those expressed in advance directives. Most States today allow for a conscience objection and the right to refuse to comply with a patient's advance directive, but they all impose

an obligation to inform such patients and, more importantly, to make some level of effort to transfer the patient to another provider or facility that will comply with the patient's wishes. However, under this proposed rule, providers with a religious or moral objection to their patients' end-of-life or advanced care wishes would have no obligation to either treat these patients in accordance with their wishes or refer them to another provider who would. Unfortunately, it is unclear how such State laws would interact with or be impacted by the federal enforcement aspects of this proposed rule, were it to be finalized. What is clear however, is that if this proposed rule is finalized, the patient's wishes could be ignored and the patient ultimately loses.

In all, the proposed rule's far-reaching definition of referral will likely cause confusion about when a referral may or may not be appropriate, thereby increasing the chances that patients do not receive accurate or timely information that may be critical to their overall health and wellbeing. The proposed rule therefore threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied, or potentially whether they were even denied medically appropriate and necessary services to begin with. Additionally, given that many insurance plans such as HMOs require referrals before coverage of specialty services, the proposed rule could place patients at financial risk based on the refusal of their primary care physician to provide a referral.

The definition of referral is representative of one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them. The rule does not mention the rights of patients even once or seek comment on how patients can still be treated if providers have a moral and religious objection to their treatment. It seems to imply that these providers have no responsibility to their patients to make sure they receive the best possible care when they are unable to provide it themselves, and there is no process or guidance in place for these providers to still try to serve their patients. The lack of attention to protecting and serving patients is one of the major reasons we believe that the rule should be withdrawn.

Requirement to Submit Written Assurances and Certifications of Compliance

HHS would require certain recipients of federal funding (including hospitals that provide care to patients under Medicare Part A) to submit annual written assurances and certifications of compliance with the federal health care conscience and associated anti-discrimination laws as a condition of the terms of acceptance of the federal financial assistance or other federal funding from HHS. There are several exceptions from the proposed requirements for written assurance and certification of compliance, including physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program. However, "excepted" providers could become subject to the written certification requirement if they receive HHS funds under a separate agency or program, such as a clinical trial.

ACEP finds the lack of clarity around this requirement extremely concerning, as we believe that it will pose a significant burden on health care professionals including emergency physicians.

First, the rule does not account for all the possible circumstances or arrangements that would potentially force "excepted" physicians to file certifications. For example, some emergency physicians who are participating in Medicare Part B also have joined an accountable care organization (ACO) led by a hospital where they see patients. In many cases, the ACO has entered into a contract with the Centers for Medicare

& Medicaid Services (CMS) to be part of the Medicare Shared Savings Program or a Center for Medicare & Medicaid Innovation (CMMI) ACO model. Since the ACO includes both physicians and a hospital and therefore receives payments from both Parts A and B of Medicare, it is unclear whether emergency physicians who are part of the ACO would lose their exemption status. Numerous other alternative payment models besides ACO models are operated by CMS and involve participation from both hospitals and physicians. HHS should clarify whether physicians who are part of these models would still be exempted from the certification requirement.

Second, it is unclear whether clinicians who treat Medicaid patients are exempt from the requirement. In the rule, HHS includes Medicaid in the list of examples for why some exemptions may be appropriate[3], but does not actually list reimbursement from the program as one of the exceptions. Some of our members may see only patients with Medicaid, so this lack of clarity is of great concern to them.

Third, ACEP is concerned about the cost-burden that this proposal will have on the hospitals, free-standing emergency departments, and emergency physicians who are subject to the requirement. CMS estimates that the assurance and certification requirement alone could cost health care entities nearly $1,000 initially and $900 annually thereafter to sign documents, review policies and procedures, and update policies and procedures and conduct training. This substantial cost is on top of the cost of posting a notice, which is estimated to be $140 per entity. Since emergency physicians by law must provide services to patients regardless of their insurance status, their total reimbursement, if any, rarely covers the full cost of providing the services. By adding more burdensome government mandates that emergency departments must cover out of their own constrained budgets, the proposed rule could potentially jeopardize the financial viability of the emergency care safety net. While we believe the proposed rule should be withdrawn because it is so problematic, in the event the rule is finalized, ACEP requests that at minimum emergency departments, and the physicians and other health care providers that furnish care within them, be exempt from the written assurances and certifications of compliance requirement.

Notice Requirement

The proposed rule requires all health entities to post a notice on their websites and in locations in their organizations where public notices are typically posted. This notice advises people about their rights and the entity's obligation to abide by federal health care conscience and associated anti-discrimination laws. The notice also provides information about how to file a complaint with the Office of Civil Rights within HHS. The rule requires entities to use a prescribed notice, found in "Appendix A" of the rule, but seeks comment on whether to permit entities to draft their own notices.

ACEP objects to this posting requirement. Beyond our concerns with the burden of having to adhere to another government-imposed mandate as discussed above, we also are troubled by the fact that the notice in no way addresses the needs of patients or our responsibilities as providers to treat them. It does not provide any information about the fundamental rights of patients to receive the most accurate information and best available treatment options for their conditions. We therefore have grave concerns about posting the notice as currently drafted.

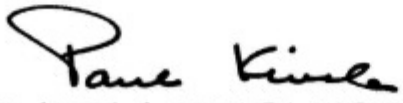
[3] On pages 73- 74 of the proposed rule, HHS states "Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions."

It is also unclear whose exact responsibility it is to post the notice(s). Most emergency physicians are employed by a group independent from the hospital that houses the emergency department where they see patients. Therefore, would the hospital's posted notice be sufficient, or would the group that the hospital's emergency physicians are employed by need to also take on this responsibility as a separate entity, with a separate, additional posting in the emergency department?

If so, posting this notice in the emergency department could potentially be considered a violation of EMTALA. EMTALA requires providers to screen and stabilize patients who come to the emergency department. Therefore, notices that could potentially dissuade patients from receiving care that is mandated by Federal law cannot be posted publicly in the emergency department. Since the notice proposed in this rule explicitly states that providers have the right to decline treatment for patients based on their conscience, religious beliefs, or moral convictions, some patients may become concerned that they would not be treated appropriately and decide to leave before they treated— a violation of EMTALA.

In light of the above concerns, ACEP urges the Department to withdraw the proposed rule. We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,



Paul D. Kivela, MD, MBA, FACEP
ACEP President

Exhibit 17

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.[1]

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

409 12th Street, S.W. • Washington, DC 20024-2188 • Tel: 202.638.5577 • www.acog.org

[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 18

ADEA | THE VOICE OF DENTAL EDUCATION

AMERICAN DENTAL EDUCATION ASSOCIATION

The mission of ADEA is to lead institutions and individuals in the dental education community to address contemporary issues influencing education, research and the delivery of oral health care for the overall health and safety of the public.

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adea.org

March 27, 2018

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

Submitted electronically via regulations.gov

Re: Proposed Rule, Protecting Statutory Conscience Rights in Health Care: Delegations of Authority (HHS-OCR-2018-0002).

On behalf of the American Dental Education Associations (ADEA) and our more than 20,000 members, we submit the following comments in response to the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) Notice of Proposed Rulemaking published in the Federal Register on Jan. 26, 2018 entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Proposed Rule)."

The Proposed Rule states that HHS is considering creating a new division to review complaints from physicians, nurses and others under existing statutes, most of which allow health care providers to opt out of certain medical procedures that they believe violate their religious beliefs and moral convictions.

Additionally, the Proposed Rule states that this new division within OCR, the Conscience and Religious Freedom Division, would have the authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by the department and its components, and use enforcement tools otherwise available in civil rights law to address violations and resolve complaints. As part of that authority, the division may require that certain recipients of federal funding keep more robust records, provide assurances and certifications of compliance, issue notices to their employees regarding their conscience and anti-discrimination rights, and cooperate with investigations, reviews and other enforcement actions.

Consistent with the mission of OCR, "…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," ADEA believes the role of dental care providers is to improve the oral health of all Americans and ensure they have equal access to care.

This Proposed Rule seems contrary to the HHS OCR mission. Allowing taxpayer-funded health care providers to use their personal religious litmus test to determine whom they serve and which services they will provide is contrary to the core mission of HHS and would cause harm to the very Americans that HHS and all health care providers seek to protect and serve. Additionally, the Proposed Rule will unconstitutionally entrench discrimination in health care.

Current Conscience and Religious Freedom Protections

We believe the Proposed Rule creates an additional regulatory burden where extensive regulations already exist. Currently, HHS enforces existing federal laws that protect the free exercise of religion and conscience and prohibit discrimination and coercion in health and human services for HHS-funded or conducted programs.

According to HHS, 25 statutory conscience provisions[1] currently exist to protect U.S. health care workers. These existing federal laws prohibit religious discrimination in employment for recipients of HHS federal financial assistance, including provisions in the Social Security Act, the Public Health Service Act, the Family Violence Prevention and Service Act, the Maternal and Child Health Services Block Grant, Projects for Assistance in Transition from Homelessness, Community Mental Health Services Block Grant, and Substance Abuse Prevention and Treatment Block Grants.

There are currently conscience protections regarding:

1. The Church Amendments—abortion, sterilization and certain other health services to participants in programs, and their personnel, funded by HHS;
2. Coats-Snowe Amendments—conscience protections for health care entities related to abortion provision or training, referral for such abortion or training, or accreditation standards related to abortion health care entities as it concerns abortion training, referral for such abortion or training, or accreditation standards related to abortion;
3. Weldon Amendment—protections from discrimination for health care entities and individuals who object to furthering or participating in abortion under programs funded by the department's yearly appropriations;
4. Patient Protection and Affordable Care Act (ACA)—under the ACA there are protections related to assisted suicide, the individual mandate and other matters of conscience;
5. Advanced Directives—advanced directive options; and
6. Medicaid or Medicare Advantage—for objections to counseling and referral for certain services in Medicaid or Medicare Advantage.

Principles of Ethics and Codes of Conduct

Principles and laws on religious freedom currently protect physicians, nurses and other health care providers who refuse participation in medical procedures to which they hold conscientious objections. As such, each health profession and its related training institutions have a code of ethics to which they universally subscribe.

The dental profession has an over 150-year-old history of committing to a set of ethical declarations developed primarily for the benefit of the patient. As educators and members of the

[1] Protecting Statutory Conscience Rights in Health Care: Delegations of Authority, 83 Fed. Reg. 3880 (January 26, 2018), p. 3881 (to be codified at 45 CFR Part 88).

profession, dental faculty teach their students to recognize their responsibility not only to patients but also to society, to other health professionals and to themselves.

Most dental educators are also members of the American Dental Association (ADA) and subscribe to the ADA Principles of Ethics, Code of Professional Conduct, and the related Advisory Opinions provided on various ethical conundrums. They provide guidance and offer justification for the Code of Professional Conduct and the Advisory Opinions.

The Code of Professional Conduct is an expression of specific types of conduct that are either required or prohibited. The Code of Professional Conduct is binding on members of the ADA, and violations may result in disciplinary action; whereas the Advisory Opinions are interpretations that apply the Code of Professional Conduct to specific situations.

We believe that the five fundamental principles that form the foundation of the existing ADA Code, enunciated below, would make compliance with the Proposed Rule difficult to uphold for students, faculty members, and private practitioners, as they already primarily place the needs of the patient above that of the dental practitioner.

1. Patient Autonomy—duty to respect the patient's rights to self-determination and confidentiality within the bounds of accepted treatment;
2. Nonmaleficence—not harming or inflicting the least harm possible to reach a beneficial outcome, including once a dentist has undertaken a course of treatment, the dentist should not discontinue that treatment without giving the patient adequate notice and the opportunity to obtain the services of another dentist;
3. Beneficence—the dentist has a duty to promote the patient's welfare—under this principle, the dentist's primary obligation is service to the patient and the public at large;
4. Justice—dental professionals have a duty to be fair in their dealings with patients, colleagues and society; the dentist's primary obligations include dealing with people justly and delivering dental care without prejudice;
5. Veracity—dental professionals have a duty to be honest and trustworthy in their dealings with people—the dentist's primary obligations include respecting the position of trust inherent in the dentist-patient relationship, communicating truthfully and without deception, and maintaining intellectual integrity.

Courts Have Previously Applied a Balancing Test

The use of religion to discriminate has been rejected in other contexts and should not be expanded in health care. The courts have long used a balancing test to determine the constitutionality of law and regulations touching on religious rights. For example, shortly after the enactment of the Civil Rights Act of 1964, prohibiting discrimination based on race in public accommodations, the owner of a restaurant chain argued that the Act violated his religious beliefs opposing integration and that he should therefore be allowed to exclude African Americans from his restaurant.[2]

Bob Jones University used the same argument twenty years later. The university wanted to maintain its policy denying admission to "applicants engaged in an interracial marriage or known

[2] *See* Newman v. Piggie Park Enters, Inc., 256 F. Supp. 941, 944 (D. S.C. 1966), aff'd in part and rev'd in part on other grounds, 377 F.2d 433 (4th Cir. 1967), aff'd and modified on other grounds, 390 U.S. 400 (1968).

to advocate interracial marriage or dating" but still get special tax status reserved for institutions that do not discriminate. This was based, according to Bob Jones University, on their religious beliefs.[3]

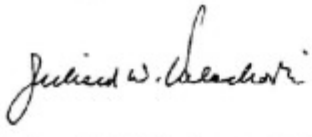
Some faith-based organizations have argued that they should be allowed to pay women less than their male counterparts based on religious beliefs that "the husband is the head of the household." When faced with equal pay and employment discrimination laws that required employers to treat women and men equally, these organizations argued those laws were an infringement of their religious liberty.

Just as the judicial precedent established in these court cases rejected attempts to discriminate in the name of religious beliefs, HHS should not infringe on patients' rights by expanding discrimination in health care in the name of protecting providers.

Conclusion

ADEA fully appreciates and respects health care providers' rights to their religious beliefs. However, these beliefs should not supersede patients' rights to treatment nor create unnecessary barriers to care. These barriers, in turn, can result in poorer health outcomes and often have serious or even deadly consequences. Therefore, we believe that existing religious/conscious-based provider statutes and regulations are sufficient and do not support this Proposed Rule.

Sincerely.



Richard. W. Valachovic, D.M.D., M.P.H.
President and CEO

[3] *See* Bob Jones Univ. v. United States, 461 U.S. 574, 581 (1983).

Exhibit 19

AHCA AMERICAN HEALTH CARE ASSOCIATION
NCAL NATIONAL CENTER FOR ASSISTED LIVING

1201 L Street, NW, Washington, DC 20005
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www.ahcancal.org

Roger Severino
Director
Office for Civil Rights, Department for Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W. Room 509-F
Washington, DC 20201

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

Dear Mr. Severino:

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) is the nation's largest association of long term and post-acute care providers, with more than 13,000 member facilities who provide care to approximately 1.7 million residents and patients every year. Thank you for the opportunity to comment on the Office for Civil Rights' proposed rule intended to protect statutory conscience rights in health care.

AHCA/NCAL has concerns about the increased regulatory burden of this proposed rule for long term and post-acute care providers. Staff, residents, and residents' families from nursing centers, centers providing care for individuals with intellectual or developmental disabilities, and assisted living communities that accept Medicaid already have multiple outlets for reporting complaints or concerns. Furthermore, these are highly regulated sectors. In particular, nursing centers are in the process of implementing myriad new requirements through 2019 and are one of the most highly regulated sectors in the country. These requirements add another regulatory burden that reduces time for providing high quality patient-centered care.

We respectfully request that the Department of Health and Human Services do not apply the proposed regulations to these long term and post-acute care providers. For questions or to discuss these comments further, please contact Lillian Hummel at 202-898-2845

Sincerely,

Lillian Hummel

Senior Director, Policy and Program Integrity

Exhibit 20

American Hospital Association

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

March 26, 2018

Roger Severino
Director, Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 515F
Washington, DC 20201

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

Dear Mr. Severino:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) proposed rule regarding certain statutory conscience protections.

Hospitals and health systems are committed to respecting the conscience objections of hospital employees and medical staff. Conscience protections for health care professionals are long-standing and deeply rooted in our health care delivery system. For decades, the AHA and its members have supported policies to accommodate the differing convictions of our employees and medical staff by making provisions for them to decline to participate in delivering services they say they cannot perform in good conscience. Existing federal and state laws protect health care workers who express religious objections related to performing certain procedures.

At the same time, hospitals and health systems have obligations to their patients and are committed to providing the care they need. Existing laws create protections for patients and impose certain obligations on providers to ensure that patients have access to necessary care. Hospitals and health systems value every individual they have the opportunity to serve, and oppose discrimination against patients based on characteristics such as race, religion, national origin, sexual orientation or gender identity.

The intersection of these equally important obligations can present unique challenges. Neither obligation can or should be addressed in a vacuum. OCR's framework for enforcing the conscience protections at issue should account for this intersection of hospitals' obligation to ensure needed care for patients and the obligation to honor conscience objections of employees.

With this as a backdrop, we make the following recommendations.

THE POLICIES, PRACTICES, AND COURT PRECEDENT GOVERNING ENFORCEMENT OF OTHER CIVIL RIGHTS PROTECTIONS SHOULD BE THE MODEL FOR ENFORCEMENT OF THE CONSCIENCE PROTECTIONS AT ISSUE.

OCR observes that the conscience protections at issue are civil rights to be enforced no less than other civil rights protections. The AHA agrees that the conscience protections are among the civil rights of hospital employees and medical staff. They should, therefore, be duly protected.

In keeping with the principle that the conscience protections should be treated akin to other civil rights, the AHA urges OCR to ensure that the enforcement policies and practices applicable to the conscience protections are comparable to the long-standing policies and practices applicable when guaranteeing other civil rights protections for employees and staff. OCR should not invent new, distinct, or additional policies and practices that add unnecessary complexity and burden or prefer conscience protections over other civil rights. Rather, OCR should use existing civil rights frameworks as the model for the conscience protections at issue. This not only would place the conscience protections on a level playing field with other civil rights, but would ensure that the conscience protections are guaranteed through an enforcement framework that already has proven effective in analogous civil rights contexts.

To this end, **OCR should explicitly adopt a reasonable accommodation framework that provides the flexibility for HHS to take into account particular facts and circumstances to determine that a hospital has done all it reasonably could under the circumstances to accommodate conscience objections of employees or medical staff** (*Bruff v. North Miss. Health Servs.*, 244 F.3d 495 (5th Cir. 2001)).

Employment discrimination on the basis of religion is prohibited and employers are required to reasonably accommodate the sincerely held religious beliefs of employees, absent a showing of undue hardship on the employer (*See* 29 C.F.R. § 1605.2). This has been true for over a half century, and this framework has successfully protected employees, including those of hospitals and health systems, from religious discrimination. Analogous reasonable accommodation frameworks also have been successfully employed in other civil rights contexts, such as the Rehabilitation Act of 1973.

This framework has proven successful in the hospital context, in part, because it allows for an assessment of the reasonableness of a requested accommodation in context. The requirement of reasonably accommodating the sincerely held religious beliefs of employees and medical staff, absent a showing of undue hardship, guarantees robust protections for the religious beliefs of hospital employees and medical staff.

Consistent with this framework, a hospital should be responsible for providing *reasonable* conscience-based accommodations and an employee is responsible for providing fair notice of a specific and sincerely held religious or moral objection. A hospital should not be sanctioned for failing to accommodate the moral or religious beliefs of an employee or medical staff where, despite being on notice of his or her right to do so, the individual did not give the hospital advance notice of his or her objection (*Wessling v. Kroger Co.*, 554 F. Supp. 548 (E.D. Mich. 1982) (no Title VII violation when the employee did not give the employer notice of a desire for a religious accommodation)).

Adoption of this framework in the conscience rule would assure hospitals that they may continue with a time-tested way of honoring their responsibilities to ensure access to necessary care for all patients, while effectively protecting the religious and other conscience rights of employees and medical staff. It also would avoid the unnecessary and duplicative administrative burdens for hospitals that imposing an additional and different framework would create.

Hospitals have existing policies, procedures, and best practices. They also have decades of experience with how to meet their responsibility to provide reasonable accommodations. Adopting a parallel framework for the conscience protections would enable hospitals to seamlessly incorporate the conscience rights of employees and medical staff into the existing compliance frameworks. The religious and moral beliefs of hospital employees and medical staff would be protected, while reducing the complexity and burden for hospitals. **OCR should expressly affirm these guiding principles.**

DUE PROCESS PROTECTIONS SHOULD BE EXPLICITLY INCLUDED IN THE REGULATIONS.

The proposed regulations are silent on procedural protections for a recipient of funding before the Department may take an adverse action. OCR should affirmatively recognize the due process rights of recipients of federal funds. The regulations should reinforce those rights with a clear acknowledgement of the procedural protections applicable to any action by the Department that would adversely affect a recipient's continued receipt of, or future eligibility for, federal funding. For example, the Social Security Act controls whether participation in, or receipt of funding from, the Medicare program may be limited or terminated; the Medicare law and regulations control the procedural protections for providers.

As discussed above, there are existing and proven civil rights policies and practices that should apply equally here. In particular, the conscience regulations should expressly adopt the longstanding due process protections for Title VI enforcement. The same protections should apply for challenges to any finding of noncompliance with the conscience protections that OCR may make or any penalty or other adverse action for noncompliance with the conscience protections that OCR may seek to impose.

Additionally, the regulations should be explicit about the grounds for imposing any contemplated sanction and the procedural protections. The proposed regulation lists numerous potential adverse actions available to OCR or the Department without delineating the specific circumstances that must occur before taking any such action. The implication is that they are

available at OCR's or the Department's discretion, without reference to any reasonable standards. The regulation should expressly identify which sanction is applicable under which circumstances. It also should identify the related procedural protections, including notice and hearing rights. This would further the government's interests in not only ensuring fundamental fairness but also avoiding inappropriate disruption of health services that are federally funded.

REGULATORY BURDEN SHOULD BE EASED WHEREVER POSSIBLE.

The proposed requirement that a recipient report reviews, investigations, and complaints to any component of the Department from which it receives funding is burdensome and unnecessary. So, too, is the proposed requirement that a recipient seeking new or renewed funding report reviews, investigations, and complaints from the prior five years. No such requirements apply in other civil rights contexts. Because OCR will know of all such reviews, investigations, and complaints, OCR should instead be the source of this information within the Department. OCR will be the central repository of all such data and can make it readily available to other Departmental components, greatly reducing unnecessary burden on regulated parties.

Additionally, the sweep of these proposed disclosures is problematic. There is no distinction in the proposed treatment of, for example, general compliance reviews (unprompted by any particular concern), rejections of frivolous complaints, findings of compliance, or cases where a sanction is ultimately overturned. With new, renewed, or continuing funding at stake, the proposed reporting requirement risks inappropriately suggesting to the decision-maker that there is a cause for concern when there is in fact none, improperly biasing the decision-making against the recipient. The regulation should not effectively create a presumption of noncompliance. **The proposed reporting requirement should not be finalized.**

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Maureen Mudron, AHA deputy general counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

Exhibit 21

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 in any way 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 22

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

[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

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

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

Policy Recommendations and Conclusion

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

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

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

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

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

Sincerely,

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

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

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

Exhibit 23

March 27, 2018

[Submitted electronically to www.regulations.gov]

Mr. Roger Severino
Director, Office of Civil Rights (OCR)
U.S. Department of Health and Human Services (HHS)
Attention: Conscience NPRM, RIN 0945–ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Proposed Rule (Docket ID number HHS–OCR–2018–0002)

Dear Mr. Severino:

The American Pharmacists Association (APhA) appreciates the opportunity to submit our comments on HHS's "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Proposed Rule" (the "Proposed Rule"). Founded in 1852 as the American Pharmaceutical Association, APhA represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA supports HHS's efforts to clarify OCR authority for federal enforcement of the established laws protecting the freedoms of conscience and religious exercise protected by the First Amendment to the U.S. Constitution and Federal statutes (collectively referred to in the Proposed Rule as ''Federal health care conscience and associated anti–discrimination laws").[1]

APhA appreciates HHS's concern that the public and many health care providers and entities are largely uninformed of conscience protections afforded to individuals and institutions.

[1] Church Amendments (42 U.S.C. 300a–7), Coats-Snowe Amendment (42 U.S.C. 238n), Consolidated Appropriations Act, 2017 (Pub. L. 115–31, Div. H, Tit. V, sec. 507(d) (the Weldon Amendment) and at Div. H, Tit. II, sec. 209), (ACA) related to assisted suicide (42 U.S.C. 18113), the ACA individual mandate (26 U.S.C. 5000A(d)(2)), and other matters of conscience (42 U.S.C. 18023(c)(2)(A)(i)–(iii), (b)(1)(A) and (b)(4)), Counseling and referral for certain services in Medicaid or Medicare Advantage (42 U.S.C. 1395w– 22(j)(3)(B) and 1396u–2(b)(3)(B)), Advanced directives (42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406), Helms Amendment ((22 U.S.C. 7631(d), Consolidated Appropriations Act, 2017, Pub. L. 115–31, Div. J, Title VII, sec. 7018), hearing screening (42 U.S.C. 280g–1(d)), occupational illness testing (29 U.S.C. 669(a)(5)), vaccination (42 U.S.C. 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. 290bb–36(f)), and religious nonmedical health care (e.g., 42 U.S.C. 1320a–1, 1320c–11, 1395i–5 and 1397j–1(b)).

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www.pharmacist.com

We agree that these protections extend the conscience rights and self-determination to all, including health care providers. APhA's support of conscience rights protections is reflected in our House of Delegates (HOD) policy, which states:

> "APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient's access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal."[2]

Due to their application to pharmacists and pharmacies that receive reimbursement directly or indirectly from HHS for the provision of pharmacy services, our comments focus on the conscience provision of the Church Amendments (42 US.S.C 300a–7(d)).[3]

I. Balancing Patient & Provider Rights

APhA's policy recognizes the need to establish systems to ensure patient access to necessary medications while supporting the ability of pharmacists to refuse to participate in procedures to which they have moral or religious objections. The Department states the Proposed Rule will not limit patient access to health care and is merely designed to protect the conscience rights of health care providers and entities. To ensure HHS achieves its goal, APhA recommends HHS revise the Proposed Rule to acknowledge that health care providers and entities may establish systems to help meet patients' health care needs. APhA has long recommended that prior to serving any patient, pharmacists discuss objections they may have with their supervisor and develop ways to honor these personal convictions while also meeting the needs of patients.

II. Assurance and Certification of Compliance

APhA appreciates HHS trying to find the appropriate balance in the Proposed Rule between protecting the health care workforce and avoiding undue administrative burden on providers and health care entities. While HHS proposes to lessen the assurance and certification reporting requirements for sub-recipients by making them exempt, the Department notes that Section 88.4(c) also contains several important exceptions from the proposed requirements for written assurance and certification of compliance. One of these exceptions is for "[p]hysicians, physician offices, and other health care practitioners participating in Part B of the Medicare program." It is important to note that while pharmacies and pharmacists participate in the Medicare program, primarily in Part D, but also in Part B (e.g., certain immunizations). However, many of the Part B statutory provisions and regulations do not include pharmacists or pharmacies as health care providers, eligible clinicians or other similar terms,[4] and therefore,

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[2] JAPhA 38(4):417 July/August 1998) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2010) (Reviewed 2015). Pg. 48. Available at: http://www.pharmacist.com/sites/default/files/files/16898%20CURRENT%20ADOPTED%20POLICY%20MANUAL%20-%20FINAL.pdf

[3] "No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions." *See*, 42 U.S.C. § 300a–7(d). Available at: https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapVIII-sec300a-7.pdf

[4] HHS does include pharmacists in other terms used in the Proposed Rule. *See*, pg. 3893 "Thus, the Department's proposed inclusion of the terms "health care professional" and "health care personnel" is intended, for example, to cover pharmacists,

pharmacists may not be covered by this exception. Accordingly, APhA requests HHS clarify that pharmacists and pharmacies are included in provisions applicable to other recipient or sub-recipient providers, entities or practitioners, when applicable.

Thank you for the opportunity to provide comments on the Proposed Rule. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs
The Honorable Alex Azar, Secretary, HHS
Conscience and Religious Freedom Division, OCR, HHS

nurses, occupational therapists, public-health workers, and technicians, as well as psychiatrists, psychologists, counselors, and other mental health providers, but the definition does not enumerate these health care job categories because they are reasonably included in such terms."

Exhibit 24

APTA
American Physical Therapy Association

1111 North Fairfax Street
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March 15, 2018

Alexander M. Azar II
Secretary
US Department of Health and Human Services
Attn: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Ave, SW
Washington, DC 20201

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

Dear Secretary Azar:

On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) appreciates the opportunity to comment on the Office for Civil Rights of the US Department of Health and Human Services' (HHS) Protecting Statutory Conscience Rights in Health Care; Delegations of Authority proposed rule (Proposed Rule). We understand that the purpose of the Proposed Rule is to protect the rights of individuals and entities to refuse to perform, assist in performance, or undergo health care or research activities to which they may object for religious, moral, ethical, or other reasons. APTA has concerns that the rule, if implemented as proposed, could undermine the ability of patients to receive the health care they need, particularly those most vulnerable.

The mission of APTA is to build a community to advance the physical therapy profession to improve the health of society. Physical therapists play a unique role in society in prevention, wellness, fitness, health promotion, and management of disease and disability by serving as a dynamic bridge between health and health services delivery for individuals across the age span. While physical therapists are experts in rehabilitation and habilitation, they also have the expertise and the opportunity to help individuals improve overall health and prevent the need for otherwise avoidable health care services. Physical therapists' roles may include education, direct intervention, research, advocacy, and collaborative consultation. These roles are essential to the profession's vision of transforming society by optimizing movement to improve the human experience.

Conflict with APTA Code of Ethics

Health care providers' responsibilities are enshrined in professional codes of ethics that define what it means to be a health care professional. Values generally agreed upon across health care professions include the obligation to do no harm; work for the public good; and demonstrate respect for others. Physical therapists operate under the Code of Ethics for the Physical Therapist, which delineates the ethical obligations of all physical therapists, as determined by the House of Delegates, APTA's policymaking body.

The purposes of the Code of Ethics for the Physical Therapist (Code of Ethics) are to define the ethical principles that form the foundation of physical therapist practice; provide standards of behavior and performance that form the basis of professional accountability to the public; provide guidance for physical therapists facing ethical challenges; educate physical therapists, students, other health care professionals, regulators, and the public regarding the core values, ethical principles, and standards that guide the professional conduct of the physical therapist; and establish the standards by which the APTA can determine if a physical therapist has engaged in unethical conduct.

The Code of Ethics represents the fundamental tenets of APTA and is an indispensable document with which all APTA documents must comply. Therefore, federal, state, and local legislation, regulations, or policies that enable the physical therapist to put their moral and religious objections ahead of the needs of the patient are unnecessary and counter to the conduct described in the Code of Ethics, as well as the Guide for Professional Conduct. Physical therapists have a duty to protect the intent of the Code of Ethics; practice in a manner that is consistent with the Code of Ethics; and ensure the best interests of the patient are at the core of all decisions and interactions.

The 8 principles that physical therapists must follow are:

1. Physical therapists shall respect the inherent dignity and rights of all individuals.
2. Physical therapists shall be trustworthy and compassionate in addressing the rights and needs of patients/clients.
3. Physical therapists shall be accountable for making sound professional judgments.
4. Physical therapists shall demonstrate integrity in their relationships with patients/clients, families, colleagues, students, research participants, other health care providers, employers, payers, and the public.
5. Physical therapists shall fulfill their legal and professional obligations.
6. Physical therapists shall enhance their expertise through the lifelong acquisition and refinement of knowledge, skills, abilities, and professional behaviors.
7. Physical therapists shall promote organizational behaviors and business practices that benefit patients/clients and society.
8. Physical therapists shall participate in efforts to meet the health needs of people locally, nationally, or globally.[1]

[1] APTA Code of Ethics for the Physical Therapist. https://www.apta.org/uploadedFiles/APTAorg/About_Us/Policies/Ethics/CodeofEthics.pdf (Accessed January 23, 2018).

The APTA House of Delegates also has issued a non-discrimination policy, which states:

"Physical therapy practitioners shall provide quality, nonjudgmental care in accordance with their knowledge and expertise to all persons who need it, regardless of the nature of the health problem. When providing care to individuals with infectious disease, the American Physical Therapy Association advocates that members be guided in their actions by guidelines developed by the Centers for Disease Control and Prevention (CDC) and regulations set by the Occupational Safety and Health Administration (OSHA)."[2]

APTA Urges HHS Not to Finalize the Proposed Rule

The Proposed Rule promotes the freedom to discriminate against others under the guise of religion or morality, which challenges the Code of Ethics and the principle of patient-centered care, both of which are foundational to the physical therapy profession. The Proposed Rule also would severely compromise patient access to medically necessary health care services. Therefore, APTA strongly opposes the Proposed Rule and urges HHS not to move forward with implementation.

Conclusion

APTA appreciates the opportunity to provide comments on the Proposed Rule. Should you have any questions or need additional information, please contact Kara Gainer, Director of Regulatory Affairs, at karagainer@apta.org or 703/706-8547. Thank you for your consideration.

Sincerely,

Sharon L. Dunn, PT, PhD
Board-Certified Orthopaedic Clinical Specialist
President

SLD: krg

[2] House of Delegates. Non-Discrimination in the Provision of Physical Therapy Services http://www.apta.org/uploadedFiles/APTAorg/About_Us/Policies/Health_Social_Environment/NonDiscriminationProvisionPTServices.pdf#search=%22non-discrimination%22 (Accessed January 23, 2018).

Exhibit 25

AMERICAN PSYCHIATRIC ASSOCIATION

800 Maine Avenue, S.W.
Suite 900
Washington, D.C. 20024

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

RE: Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03; (Docket HHS-OCR-2018-0002)

Dear Mr. Severino:

On behalf of the American Psychiatric Association (APA), a national medical specialty society representing more than 37,800 physicians specializing in psychiatry, we are writing in response to the Department of Health and Human Services' (HHS) proposed rule, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, as published in the Federal Register on January 26, 2018. We appreciate the opportunity to comment on this important proposal and focus our comments on certain negative impacts it may have on health outcomes and patients' mental health, if not amended to clearly express its limitations.

As the frontline physicians providing treatment for mental illness and substance use disorders, our goal is to ensure all patients have access to effective treatment and receive care that is compassionate to their individual needs. According to the most recent National Survey on Drug Use and Health, 89.4 percent of people aged 12 or older who needed substance use treatment at a specialty facility did not receive it. In addition, 56.9 percent of adults with any mental illness did not receive mental health care.[1] An untreated mental illness leads to increased incarceration rates (jails are the single largest mental health facilities in the United States), homelessness, and medical services.[2,3,4] The indirect cost of untreated mental illness to employers is estimated to be as high as $100 billion a year in the U.S. alone.[5] Lack of coverage, limited access to providers, and stigma are among the main barriers to accessing care. It is important for us to work together to

[1] Center for Behavioral Health Statistics and Quality. (2017). 2016 National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD.
[2] Steadman, Henry, et al., "Prevalence of Serious Mental Illness among Jail Inmates." Psychiatric Services 60, no. 6 (2009): 761–765.
[3] Swanson, Jeffery, et al., Costs of Criminal Justice Involvement in Connecticut: Final Report (Durham: Duke University School of Medicine, 2011).
[4] Angela A. Aidala and William McIlster, "Frequent Users Service Enhancement 'FUSE' Initiative," New York City FUSE II (2014).
[5] Finch, R. A. & Phillips, K. (2005). An employer's guide to behavioral health services. Washington, DC: National Business Group on Health/Center for Prevention and Health Services. Available from: www.businessgrouphealth.org/publications/index.cfm

address these challenges to reduce the burden of mental health and substance use issues on patients, their families, and the government. We must also ensure that we do not exacerbate the need for services by adding barriers, such as discrimination or fear of discrimination against people in need of treatment.

The APA's chief concern is that the proposed rule, if not clarified, may be inappropriately misinterpreted or misapplied by health care professionals to condone or permit discrimination against entire classes of vulnerable patient populations resulting in reduced access to health services. The regulation purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three federal statutes. Each of these statutes refers to specific, limited circumstances in which health care providers or health care entities may not be required to participate in abortion and sterilization *procedures*. They do not permit discrimination against patients for their individual characteristics. In other words, the amendments allow a physician to refuse to perform an abortion, but the same physician cannot refuse other treatment because the woman had an abortion.

The wording of the regulation is not clear on these limited circumstances and creates the possibility of an overly broad misinterpretation that goes far beyond what the statutes permit. For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity could encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason.

Previous regulations and court cases dictate that the rule may not be used in such a discriminatory manner and the rule should clearly state and convey to health providers the established limitations of the regulation. Specifically:

- HHS explicitly recognized in 2008 a concern "that the proposed regulation could serve as a pretext for health care workers to claim religious beliefs or moral objections….in order to discriminate against certain classes of patients, including illegal immigrants, drug and alcohol users, patients with disabilities or patients with HIV, or on the basis of race or sexual preference." 73 Fed. Reg. at 78,079 -80. It clarified that the regulation was not intended to permit unlawful discrimination on any basis, for "the health care provider conscience protection provisions have existed in law for many years, and this regulation only implements these existing requirements. As a result, there is nothing in this regulation that newly permits" discrimination against categories of individuals based on their individual characteristics for any reason (including, e.g., on the basis of race, color, national origin, disability, age, sex, religion, or sexual preference). 73 Fed. Reg. at 78,080.
- In 2011, an HHS action rescinded much of the 2008 Federal Health Care Conscience Rule, at least in part, as a response to litigation that was filed contesting it. The 2011 issuance made clear that the "conscience statutes were intended to protect health care providers from being forced to participate in medical procedures that violated their moral and religious beliefs. They 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." 76 Fed. Reg. at 9,973-74.

- Discriminating against an individual in the provision of health care services in general is an action that would be "outside the scope of the health care provider conscience protections. Those laws protect health care workers' conscience rights with respect to particular actions or activities, not with respect to an individual's characteristics that are protected by federal law." 73 Fed. Reg. at 78,080. If a decision to deny health care "is being made based on an individual's characteristics that are federally protected, that is impermissible." Fed. Reg. at 78,084.
- The authority of administrative agencies is constrained by the language of the statutes they administer. When it engages in rule making, an agency's interpretation of the statutory provision it administers must be reasonable and consider all important aspects of the issue. *See Chevron v. Natural Resources Defense Council*, 467 US 837 (1984). The agency must always stay within the bounds of its statutory authority. *City of Arlington, Tex. V. F.C.C.,* 569 US 290, 297 (2013).
- Protections for religious conscience in the realm of health care do not provide a shield for persons or entities who might cloak illegal discrimination as a religious practice and the government has compelling interest to prohibit any such discrimination. *Burwell v. Hobby Lobby Stores, Inc.*, 134 S.Ct. 2751, 2783 (June 30, 2014).

Accordingly, the regulation should make it clear that religious conscience objections are limited to procedures that are contrary to the health care workers established religious doctrines, and do not allow discrimination against entire classes of individuals whose actions the religious doctrine may not condone. Accommodations should also be made for patients in emergency situations and those living in rural areas. For example, a woman with a complicated pregnancy or in areas where access to health care is limited. Likewise, any notice displayed in healthcare facilities should be required to inform patients and the workforce that **healthcare providers and facilities can refuse to perform procedures for any patient on the basis that the procedure violates the religious or conscious beliefs of the provider, but health care providers may not otherwise discriminate or refuse to provide health care to any individual based on sex, race, color, age, national origin, religion, disability, sexual orientation, gender identity, citizenship, pregnancy or maternity, veteran status, or any other status protected by applicable national, federal, state or local law. Information should also be made available to patients about where they may receive health procedures being refused and the location of such services.**

Without such clear limitations, notices may be broadly interpreted by patients and health care providers alike to permit discrimination against people based upon their protected class, which will interfere with the physician-patient relationship, foster distrust, and negatively impact patient outcomes. There is ample evidence that patients in protected classes are already hesitant to seek medical and mental health care, e.g. LGBTQ patients, and that discriminatory policies have detrimental mental health and medical

impacts on the population subject to discrimination.[6] The literature on the "minority stress model" highlights the impact of social prejudice, isolation and invisibility as the primary factors leading to an increased health burden and greater risk of mental health issues, homelessness and unemployment.[7] Research shows that LGBTQ patients have many of the same health concerns as the general population, but they experience some health challenges at higher rates, and face several unique health challenges shaped by a host of social, economic, and structural factors. LGBTQ individuals are two and a half times more likely to experience depression, anxiety, and substance misuse. Additionally, these patients experience higher rates of sexual and physical violence against them as compared to their heterosexual counterparts.[8] Among transgender patients, the risk of physical conditions is also exacerbated with increased rates of tobacco use, HIV and AIDS, and weight problems. Despite the need for health services, half of gender minorities educate their own providers about necessary care and 20 percent report being denied care.[9,10,11] Such discrimination and discouraging use of the health care systems by entire categories of individuals cannot be condoned by the federal government under the guise of a conscience statute and regulations need to clearly preclude such unlawful discrimination.

All patients should be treated with dignity and respect and have access to care without fear of discrimination. **Accordingly, we urge you to clarify that nothing in the law or the rule, which permits conscience and religious objection to performing abortion and sterilization procedures inimical to a health care provider's established religious beliefs, should be construed to permit discrimination in the provision of health care services based on sex, race, color, age, national origin, religion, disability, sexual orientation, gender identity, citizenship, pregnancy or maternity, veteran status, or any other status protected by applicable national, federal, state or local law.**

Thank you again for the opportunity to respond to the proposed rule. If you have questions, please contact Kristin Kroeger, APA's Chief of Policy, Programs, and Partnerships, at kkroeger@psych.org.

Sincerely,

Saul Levin, MD, MPA

Saul Levin, MD, MPA, FRCP-E
CEO and Medical Director

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[6] Hatzenbuehler ML, McLaughlin KA, Keyes KM, Hasin DS. 2010. The impact of institutional discrimination on psychiatric disorders in lesbian, gay, and bisexual populations: a prospective study. *Am J Public Health*. 100(3): 452-459.
[7] Ilan Meyer. "Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence" *Psychological Bulletin*. 2003 Sep; 129(5): 674–697.
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Exhibit 26

March 26, 2018

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

Attention: Conscience NPRM, RIN 0945-ZA03

Dear Sir/Madam:

The American Psychological Association (APA) appreciates this opportunity to respond to a request for information published in the *Federal Register* on January 26, 2018 (Docket No. HHS-OCR-2018-0002): *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*. This proposed rule is intended to implement and enforce federal health care conscience and associated anti-discrimination laws that, for example, protect the rights of persons, entities, and health care entities to refuse to perform, assist in the performance of, or undergo health care services or research activities to which they may object for religious, moral, ethical, or other reasons.

APA is the largest scientific and professional organization representing psychology in the United States. APA's membership includes nearly 115,700 researchers, educators, clinicians, consultants and students. APA works to advance the creation, communication and application of psychological knowledge to benefit society and improve people's lives. We place a strong emphasis on, and are committed to, promoting and advocating for patient well-being.

APA is responding to the specific request for "information, data, studies, reports, or other documentation that support what costs, if any, result from ancillary effects of this proposed rule." Based on available data, we do not agree with the assertion that "the proposed rule would generate benefits by securing a public good -- a society free from discrimination." APA is concerned that the proposed rule would in fact increase discrimination against several groups, limiting or even eliminating access to necessary health care. This is particularly problematic for health care organizations whose codes of ethics mandate helping all those in need. In this comment, we will explain how enhancing conscience-based exemptions will harm psychology training programs, sexual and gender minorities, women, and efforts to combat HIV/AIDS.

APA strongly believes that people should not be discriminated against because of their religious beliefs or moral convictions. For example, a psychologist should never be denied employment

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Arthur C. Evans, Jr., PhD
Chief Executive Officer and
Executive Vice President

because of religious beliefs; a psychologist's conscience-based practices must be accommodated within reason; and a psychologist should never be harassed due to ethical principles. We acknowledge that religious organizations play a central role in HHS' mission to deliver services and provide access to programs that will improve the health and well-being of Americans. We also affirm health providers' legally protected rights to express and maintain religious- or conscience-based views that are central to their values and mission. However, we recognize that prejudice based on religion can in some instances result in discrimination against religious individuals or organizations.[i] Accordingly, we support efforts to ensure that faith-based groups whose religion supports a particular system of conscience-based convictions are able to provide services and supports.

However, the framework protecting religious- and conscience-based exemptions is already enshrined in law and need not be further expanded or enforced. Rather, we argue that the rights of patients must be paramount. Our guidelines for serving a diverse public assert that "psychologists need to interact beneficially and non-injuriously with all clients/patients who seek care. When such conflicts occur, the overriding consideration must always be the welfare the client/patient."[ii] Our Ethics Code reiterates that psychologists may not practice "unfair discrimination based on age, gender, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, disability, socioeconomic status, or any basis proscribed by law."[iii] We firmly believe that these principles – placing patient welfare front and center – should hold true across health care settings.

Psychology licensure requires that students are trained to serve broad populations within their competence; training programs and trainees cannot be selective about the core competencies needed for the practice of psychology because these competencies are determined by the profession for the benefit of the public. The proposed rule would limit the freedom of professional education and training programs in psychology to determine the training our students should acquire to meet the responsibilities of a practicing psychologist. Our Standards of Accreditation require psychology training programs to ensure that all students attain an understanding of cultural and individual diversity as related to both the science and practice of psychology, along with the relevant skills and competencies to provide services to all segments of the public. Programs may not restrict or otherwise "constrain" academic freedom in accord with these procedures, and programs must prepare their graduates "to navigate cultural and individual differences in research and practice," including those that "may produce value conflicts or other tensions arising from the intersection of different areas of diversity."[iv] We oppose efforts to limit our disciplinary and institutional freedom to train our students to best serve diverse populations, as demanded by our profession's requirements for licensure.

Were this proposed rule to be finalized in its current form, it would harm sexual and gender minorities, especially those in more rural areas with fewer available health care providers. Sexual minorities already have poorer access to health services than heterosexual people[v]. They are more likely to be uninsured,[vi] and to have delayed medical care or unmet medical needs.[vii] While a variety of economic and social factors contribute to these disparities, provider insensitivity or discrimination is also influential. A recent survey found that 18% of sexual and gender minorities have avoided medical care due to fear of discrimination, and the same proportion reported being personally discriminated against when going to a doctor or health clinic. The

survey revealed even starker statistics for transgender people: 31% said they have no regular doctor or form of health care, and 22% said they have avoided doctors or health care out of concern they would be discriminated against.[viii] Particularly troublesome is the situation where the disclosure by the patient that may trigger the provider's conflict of conscience does not occur until the patient has already established the therapeutic alliance and is thus especially vulnerable to harm from interruption of that relationship. People can be prejudiced against sexual and gender minorities for many reasons, but many claim conscience-based convictions as the source of their actions. Thus, permitting conscience-based discrimination can be expected to increase experiences of patient discrimination and lead to reduced access to health care.

This proposed rule would limit women's access to reproductive health care, which would have harmful consequences to their physical and mental health. Autonomy and confidentiality in one's reproductive health decisions is both a human right and public health concern.[ix] Research has shown that women with an unplanned pregnancy are at higher risk for depression, anxiety, and lower reported levels of happiness.[x] In turn, these mental health effects will have other negative impacts on parental and family health. APA supports the right to reproductive choice and freedom from discrimination in that choice.[xi]

The proposed rule would also limit the availability of effective public health strategies to prevent and treat HIV/AIDS in populations severely impacted by the epidemic. Thirty-six million persons are living with HIV infection around the world, and 1.8 million are newly infected each year.[xii] Yet tremendous progress in the prevention and treatment of HIV/AIDS has inspired governments and multilateral organizations to set a goal of ending the epidemic by 2030.[xiii] The President's Emergency Plan for AIDS Relief (PEPFAR) relies on life-saving antiretroviral treatment for all of the people in high-burden countries, coupled with comprehensive services for preventing and treating HIV, to reach global AIDS eradication goals.[xiv] We are concerned that the rule may permit entities receiving PEPFAR funds to deny sex workers, men who have sex with men, people who inject drugs, and transgender persons access to tailored evidence-based combinations of HIV prevention interventions. Federal resources are best spent advancing the implementation of scientifically sound comprehensive strategies in the most impacted areas in the U.S. and abroad, coupled with partnerships with health care providers and communities on the ground. Allowing groups to claim a conscience-based exemption to the provision of what we know are the most effective programs could jeopardize the continued success of U.S. global efforts to eradicate HIV.

Finally, one of the most troubling provisions in this rule focuses on referrals; this was not included in the 2008 rule, *Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law*. As explained above, it is problematic that providers may refuse to provide services to some individuals. It is more so that they may even refuse to provide referrals, including the provision of any form of information, by any method, pertaining to any aspect of a service that may be objected to on conscience-based grounds. This additional provision increases the likelihood that some people (e.g., sexual and gender minorities or women seeking reproductive health care) will not be able to receive the care that they need.

APA urges HHS to seriously consider the likely adverse health effects of condoning discrimination through expanding conscience-based exemptions. While we recognize the important role and rights of faith-based health care providers, we are concerned that further codifying their ability to limit service provision to women, sexual and gender minorities, and other vulnerable people will harm the mental and physical health of those in need of support. Please contact Gabriel Twose, Ph.D. (202-336-5931; gtwose@apa.org) in our Public Interest Government Relations Office if we can provide any further information.

Sincerely,

Arthur C. Evans, Jr., Ph.D.
Chief Executive Officer

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[i] American Psychological Association. (2007). Resolution on religious, religion-based and/or religion-derived prejudice. Retrieved from http://www.apa.org/about/policy/religious-discrimination.pdf

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Exhibit 27

AMERICAN SPEECH-LANGUAGE-HEARING ASSOCIATION

Submitted to https://www.regulations.gov/

March 23, 2018

Roger Severino
Director, Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Protecting Statutory Conscience Rights in Health Care Proposed Rule (RIN 0945-ZA03)

Dear Director Severino:

On behalf of the American Speech-Language-Hearing Association, I write to offer comments on the proposed rule, Protecting Statutory Conscience Rights in Health Care.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 198,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students.

ASHA supports the work of the Office for Civil Rights (OCR) to promote and protect the health care rights of all Americans by ensuring people have needed access and opportunity to participate in and receive health care services without discrimination. There is a need to ensure knowledge, compliance, and enforcement so that this promotion and protection extends to both service providers and recipients of services.

ASHA requests that OCR provide clarification on the circumstances under which services may be denied, and on the documentation required for denial, objection, and termination of services. To ensure patient safety and a continuum of care, there should be clear guidelines for avoiding client/patient abandonment. As such guidance is established, care should be taken to mitigate the risk of making determinations based on stereotyping and visual assessment. Patient privacy, as well as that of the service provider, must be held paramount.

Upon review of the proposed rule, it is unclear if the protection extends beyond the recipient of the services to include the procedure/service provided. ASHA recommends that OCR clarify that the protections espoused in the proposed rule extend only to procedures that infringe on the religious beliefs of the health care provider and not provide a blanket refusal to treat a category of individuals.

ASHA urges OCR to provide clarification on the application of the legislation that requires providing referrals and resources for the patient to locate reasonable alternatives to services. This is especially significant in areas with personnel shortages and where pre-existing health care disparities will negatively impact access to care including rural and remote areas, urban centers, and areas with large racial/ethnic minority populations.

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Finally, ASHA recommends that employers receive clarification on the application of conscience rights and how they impact factors such as health care providers' productivity and performance.

Thank you for the opportunity to provide comments on the Protecting Statutory Conscience Rights in Health Care proposed rule. If you or your staff have any questions, please contact Daneen G. Sekoni, MHSA, ASHA's director of health care policy, health care reform, at dsekoni@asha.org.

Sincerely,

Elise Davis-McFarland

Elise Davis-McFarland, PhD, CCC-SLP
2018 ASHA President

Exhibit 28

AMERICANS UNITED
FOR SEPARATION OF CHURCH AND STATE

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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, S.W.
Washington, D.C. 20201
Submitted via Regulations.gov

RE: Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom It May Concern:

Americans United for Separation of Church and State submits the following comments to the Notice of Proposed Rulemaking by the Department of Health and Human Services, "Protecting Statutory Conscience Rights in Health Care," which was published on January 26, 2018.

Americans United is a nonpartisan advocacy organization dedicated to preserving and advancing the constitutional principle of church-state separation, which is the foundation of religious freedom for everyone. The U.S. Constitution grants all Americans the right to believe—or not believe—without government interference or coercion. But it also ensures that no one can use religion as a justification for ignoring the laws that protect the rights of others.

The Proposed Rule attempts to expand existing refusal-of-care laws and would allow hospitals, insurance companies, and almost anyone involved in the provision of healthcare to use religious beliefs to deny patients care.

Religious freedom is fundamental, but so is the right to get the healthcare you need. The government should never allow the religious beliefs of a healthcare provider to come before what is best for the patient. A patient's healthcare should always come first.

The Proposed Rule would exceed the Department's authority, threaten the health and well-being of patients, violate the Constitution, conflict with existing laws, and undermine healthcare providers' ability to deliver care. Accordingly, we urge the Department to withdraw the Proposed Rule.

The Proposed Rule Exceeds the Department's Authority by Impermissibly Expanding Refusal-of-Care Laws

With this Proposed Rule, the Department is attempting to allow any individual or entity that is tangentially involved—even a hospital board of directors or a receptionist who schedules

procedures—to use religious beliefs to determine a patient's access to care. This sweeping religious exemption extends far beyond any statutory authority.

The Proposed Rule claims to clarify three existing refusal-of-care laws—the Weldon, Church, and Coats-Snowe Amendments—related to abortion and sterilization. Each of these statutes refers to specific, limited circumstances in which healthcare providers or healthcare entities may not be required to participate in abortion and sterilization procedures. The Proposed Rule, however, attempts to expand the reach of these refusal-of- care laws to healthcare services beyond abortion and sterilization. In fact, it seeks to allow individuals to refuse to provide "*any* lawful health service . . . based on religious beliefs or moral convictions."[1]

In addition, the Proposed Rule violates statutory authority by attempting to expand the refusal-of-care laws to allow an overly broad range of individuals to refuse to provide services. It does so by stretching and misconstruing several definitions that exist in current law, including "health care entity," "assist in the performance," and "referral."

Under the Coats-Snowe and Weldon Amendments, "health care entity" is defined to encompass a limited and specific range of individuals and entities. The Proposed Rule, however, includes a far broader definition. It even includes a plan sponsor "not primarily engaged in the business of health care." This definition could allow an employer acting as a third-party administrator or insurance plan sponsor to qualify as a "health care entity" and deny insurance coverage to its employees.

The definition of "assist in the performance" includes "making arrangements for the procedure" and participation "in activity with an articulable connection" to the service. This twists the meaning of "assist in the performance" to include anyone with even a tenuous connection to the procedure and expands the types of services that can be refused. For example, a receptionist in a physician's office could refuse to schedule appointments, the hospital room scheduler could refuse to schedule procedures, the technician charged with cleaning surgical instruments could refuse to do so, or an ambulance driver could refuse to transport a woman who needs care for a miscarriage. The Proposed Rule creates the potential for a wide range of workers to interfere with and interrupt the delivery of healthcare.

The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term. The Proposed Rule would allow a provider to refuse to provide any information to a patient seeking care, including where that patient could go to get the care they need.

Finally, it should be noted that under the Proposed Rule, the Department is attempting to use the Office for Civil Rights to affirmatively allow a host of institutions and individuals to use religion to deny patients healthcare and to disregard the nondiscrimination laws that OCR is charged with enforcing. The Department has appropriated language from civil rights statutes and regulations that were intended to improve access to healthcare and is using it to create a regulatory scheme that is harmful and would instead protect those who seek to discriminate.

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[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3882 (proposed Jan. 26, 2018).

The Proposed Rule's Attempt to Allow Broad Refusals of Care Threatens the Health and Well-Being of Patients

The Proposed Rule would allow institutions and individuals—ranging from hospitals and insurance companies to providers and support staff—to refuse to provide care to patients in need. At the same time, it fails to account for the increased discrimination and flat-out denials of care that some of the most vulnerable members of our communities could face if it were implemented. The Proposed Rule's broad scope could potentially affect patients who need services and information in a wide range of areas. Most clearly, it would exacerbate barriers to care that already exist for women, people of color, LGBTQ people, people with disabilities, immigrants, and people who live in rural areas. It could also make getting care for HIV/AIDS, drug addiction, infertility, vaccinations, mental illness, sexually transmitted infections, and end-of-life care, for example, difficult for patients.

Women

The Proposed Rule seeks to allow providers and healthcare entities to discriminate against women and deny them the care and information they need. Religious beliefs have already been used to deny access to services most often needed by women, such as abortion, sterilization, certain infertility treatments, and miscarriage management. The Proposed Rule, however, would go even further, seeking to allow a broader range of providers to deny women a broader range of services.

Existing refusals already have serious health consequences for women and can result in infertility, infection, and even death. This discrimination disproportionately affects women of color who already face additional barriers to accessing reproductive healthcare. For example:

> When she was 18 weeks pregnant and her water broke, Tamesha Means rushed to her local hospital (which was religiously affiliated and the only one in her county). The hospital did not tell Tamesha that her pregnancy was not viable and that the safest course of action for her would be to end it. Instead, the hospital gave her two Tylenol and sent her home. Tamesha returned to the hospital the next day because she was severely bleeding. Despite showing signs of infection, the hospital sent her home again. Returning a third time in excruciating pain, the hospital was about to send Tamesha home when she began to deliver. The baby died within hours.[2]

Unfortunately, Tamesha is not the only woman who has been refused full information about her condition and treatment options. Other women experiencing miscarriages have also been refused treatment and left in the dark about their options, sometimes for several weeks. As a result, women have experienced grave medical problems such as sepsis, even resulting in stays in the ICU and acute kidney injury, and hemorrhaging requiring blood transfusions.[3]

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[2] American Civil Liberties Union, *Health Care Denied: Patients & Physicians Speak Out About Catholic Hospitals & the Threat to Women's Health & Lives* (2016); Public Rights/Private Conscience Project, Columbia Law School, *Bearing Faith: The Limits of Catholic Health Care for Women of Color* (2018).

[3] *Health Care Denied.*

The Proposed Rule's expansion of these refusals will put women at even greater risk for harm. Information, counseling, referral and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Medical guidelines state that survivors of sexual assault should be provided emergency contraception subject to informed consent and that it should be immediately available where survivors are treated. For individuals with cancer, the standard of care includes education and informed consent around fertility preservation. Yet, the Proposed Rule seeks to allow even more institutions and individuals to deny women this vital information and services.

LGBTQ People

The Proposed Rule also seeks to allow providers and healthcare institutions to refuse care, including transition-related care, to LGBTQ patients. This ignores both the well-established consensus in the medical community that transition-related care is medically necessary and the reality that this care is often life-saving. The Proposed Rule's vague and sweeping language could encourage providers to refuse other care to LGBTQ patients as well. A provider could argue that it can refuse to administer an HIV test, prescribe PrEP, or screen a transgender man for a urinary tract infection. Moreover, the Proposed Rule could also encourage providers to deny any care to an LGBTQ patient simply because of the provider's personal disapproval of the patient's sexuality or gender identity.

People with Disabilities

Many people with disabilities rely on a case manager to coordinate necessary services, a transportation provider to drive them to appointments, or a personal care attendant to administer their medications and manage their daily activities. Under this Proposed Rule, any of these providers could believe they are entitled to object to providing any of these service covered. And if they did, they would not even have to tell the individual where they could obtain the service, how to find an alternative provider, or even whether the service is available to them. For example, a case manager might refuse to set up a routine gynecological appointment because contraception might be discussed, or a personal home health aide could refuse to administer a contraceptive drug. For people who require such assistance, a denial based on a case manager, driver, or attendant's religious beliefs could mean they lose access to vital healthcare altogether.

Patients in Immigrant and Rural Communities

The sheer distance to a healthcare facility can be a significant barrier to getting care. Immigrant patients often lack access to transportation or may need translation services and may have to travel great distances to get the care they need. Patients living in rural communities also face many barriers to care including cost of transportation, taking time from work, and other incidentals. For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely because there may be no other sources of health and life-preserving medical care.

The Proposed Rules Violates the Establishment Clause of the First Amendment

Religious freedom is a fundamental right, protected by our Constitution and federal law. It guarantees us all the right to believe (or not) as we see fit. But it doesn't give anyone the right to use religion to harm others.

The Proposed Rule seeks to allow a wide range of institutions and individuals to cite religious or moral objections to deny patients the care they need. As explained above, countless patients could face harm. This is not just bad policy—it also violates the Establishment Clause of the First Amendment of the U.S. Constitution.

The Establishment Clause requires the Department to "take adequate account of the burdens" that an exemption "may impose on nonbeneficiaries" and must ensure that any exemption is "measured so that it does not override other significant interests."[4] It prohibits the Department from granting religious and moral exemptions that would detrimentally affect any third party.[5]

For example, in *Estate of Thornton v. Caldor, Inc.*, the Supreme Court invalidated a statute that gave employees an unqualified right to take time off on the Sabbath day of their choosing.[6] The statute violated the Establishment Clause because it "would require the imposition of significant burdens on other employees required to work in place of the Sabbath observers."[7]

The Court acknowledged the limitations imposed by the Establishment Clause most recently in *Burwell v. Hobby Lobby Stores, Inc.*[8] In holding that the Religious Freedom Restoration Act (RFRA)[9] afforded certain employers an accommodation from the Affordable Care Act's contraceptive coverage requirement, the Court concluded that the accommodation's effect on women who work at those companies "would be precisely zero."[10] And in his concurrence, Justice Kennedy emphasized that a religious accommodations must not "unduly restrict other persons, such as employees, in protecting their own interests."[11]

The exemption in the Proposed Rule would clearly impose burdens on others: it seeks to allow providers to refuse care to patients and lacks any safeguards to ensure patients are able to obtain the care they need. Thus, the Proposed Rule runs afoul of the clear mandates of the Establishment Clause.

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[4] *Cutter v. Wilkinson*, 544 U.S. 544, 720, 722 (2005); *see also Estate of Thornton v. Caldor, Inc.* 472 U.S. 703, 709-10 (1985).
[5] *E.g.*, *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014) (citing *Cutter*, 544 U.S. at 720); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring); *Cutter*, 544 U.S. at 726 (may not "impose unjustified burdens on other[s]"); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (may not "impose substantial burdens on nonbeneficiaries").
[6] *Caldor*, 472 U.S. at 705–08.
[7] *Id.* at 710.
[8] 134 S. Ct. 2751 (2014).
[9] 42 U.S.C. §§ 2000bb–2000bb-4.
[10] *Hobby Lobby*, 134 S. Ct. at 2760. Indeed, every member of the Court reaffirmed that the burdens on third parties must be considered. *See id.*; *id.* at 2786-87 (Kennedy, J., concurring); *id.* at 2790 & n.8 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting).
[11] *Id.* at 2786-87 (Kennedy, J., concurring).

There Are No Exceptions to this Rule that Are Relevant to the Proposed Rule

There have been only two situations in which the Supreme Court has upheld religious exemptions that had the effect of burdening third parties in any meaningful way. In both, the Court has held that the Free Exercise Clause warranted the exemptions in order to protect the autonomy and ecclesiastical authority of religious institutions, such as a church's selection of clergy.[12]

The Supreme Court has also occasionally permitted accommodations when the potential consequences for third parties would be so diffuse and amorphous as to have no meaningful effect on any particular individual.[13]

Neither exception is applicable here. Allowing institutions and individuals throughout the healthcare system to deny care to patients has nothing to do with how a church selects its minister, for example. Moreover, these refusals of care will meaningfully and concretely harm countless patients who seek care with hospitals, insurance companies, providers, and support staff that may use the exemption.

The Proposed Rule Conflicts with Federal, State, and Local Laws

The Propose Rule conflict with several important federal, state, and local laws, including those that govern informed consent requirements, establish emergency care safeguards, and protect against discrimination.

First, the Proposed Rule conflicts with informed consent requirements. Federal and state laws require providers to inform patients of medically accurate information about treatment choices and alternatives. This allows patients to competently and voluntarily make decisions about their medical treatment or refuse treatment altogether. Existing refusal-of-care laws already interfere with this ethical and legal principle. And under the Proposed Rule, the problem will only grow worse—more healthcare entities will limit the type of care they are willing to provide or discuss with patients. A patient may never know about the range of treatment options, including what may be the standard of care for the particular circumstance the patient is facing. This will deter open conversations between providers and patients and take away patients' ability to make decisions about their care.

Second, the Proposed Rule fails to address potential conflicts with emergency care requirements. Under the Emergency Medical Treatment and Active Labor Act (EMTALA), a hospital receiving government funds and providing emergency services is required also to provide medical screening and stabilizing treatment to a patient who has an emergency

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[12] In *Hosanna-Tabor Evangelical Lutheran Church & School v. EEOC*, 565 U.S. 171, 196 (2012), the Court held that the Americans with Disabilities Act could not be enforced against a church in a way that would interfere with the church's selection of its ministers. And in *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 337-39 (1987), the Court upheld, under Title VII's limited religious exemption, a church's firing of an employee who was not in religious good standing.

[13] In *Walz v. Tax Commission*, 397 U.S. 664, 673 (1970), the Court held that the government may exempt houses of worship from property taxes as part of a broad exemption for nonprofit entities, because the public as a whole bore the incidence of the forgone tax revenues—and did so only in the most abstract way—while also sharing in the social benefits of a system that encouraged all nonprofits to flourish.

medical condition (including severe pain or labor).[14] All hospitals, even religiously affiliated ones, have to comply with EMTALA.[15] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not bound by EMTALA's requirements. This could result in patients not receiving necessary, life-saving care—care to which they are entitled by law—when facing a medical emergency.

Third, the proposed regulation conflicts with Title VII of the Civil Rights Act.[16] Title VII is the preeminent federal law that addresses employment discrimination. It requires employers to reasonably accommodate employees' religion unless doing so would impose an undue hardship on employers.[17] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When healthcare workers request an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on coworkers, customers, and patients, as well as factors like public safety, patient health, and other legal obligations. Introducing another standard under the proposed regulation would clearly create confusion for healthcare employers that would still be subject to Title VII. When similar regulations were proposed in the past, the U.S. Equal Employment Opportunity Commission, the agency responsible for enforcing Title VII, raised concerns and stated that Title VII should remain the relevant legal standard.[18]

Finally, the Proposed Rule claims to supersede laws passed by state and local governments to ensure patients' access to healthcare and prevent discrimination against individuals seeking care. Thus, the Proposed Rule would have a substantial and direct effect on states, clearly implicating federalism concerns.[19] Moreover, the Proposed Rule invites states to expand refusals of care by making clear that this expansive rule is a floor, not a ceiling.

The Proposed Rule Will Undermine Healthcare Providers' Ability to Serve Patients

The Proposed Rule ignores the many providers with deeply held professional, ethical, religious, or moral convictions that affirmatively motivate them to provide patients with a full-range of healthcare options, including abortion, transition-related care, and end-of-life care.

Existing refusals of care based on religious beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to offer their patients comprehensive care.[20] Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of what the providers believe they are ethically and morally obligated to do. The Proposed Rule would exacerbate these problems

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[14] 42 U.S.C. § 1295dd(a)-(c).
[15] *See, e.g.*, *Shelton v. Univ. of Med. & Dentistry*, 223 F.3d 220 (3d Cir. 2000); *In re Baby K*, 16 F.3d 590 (4th Cir. 1994); *Nonsen v. Med. Staffing Network, Inc.*, 2006 WL 1529664 (W.D. Wis.).
[16] 42 U.S.C. §2000e *et seq.*
[17] 42 U.S.C. § 2000e(j).
[18] Letter from Reed L. Russell, Legal Counsel, EEOC to Dep't of Health & Human Servs., regarding "Provider Conscience Regulation (Sept. 24, 2008).
[19] *See* Exec. Order 13132, 64 Fed. Reg. 43255 (Aug. 10, 1999).
[20] Providers have disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health. Lori R. Freedman, Uta Landy, & Jodi Steinauer, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, Am. J. Pub. Health (2008).

by emboldening healthcare entities and institutions to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule does not provide any protections for healthcare professionals who want to provide, counsel, or refer for healthcare services that the rule implicates.

Here are just two examples of what providers told us. An emergency physician who provided care 24/7 to all comers for 30 years said: "I feel that any rule that would allow providers to pick and choose what care to provide and to whom to provide it based on their personal religious beliefs is morally and ethically reprehensible and bad medicine." Another person who worked in medicine for 20 years told us: "We didn't judge patients on any criteria other than what help they needed. That is all that a patient should ever be judged by."

Conclusion

Religious freedom should be a shield that protects people from discrimination—never a tool to cause harm or deny basic medical care to any American. The Proposed Rule violates this fundamental principle. Because patients' health needs must come first and no one should lose access to critical healthcare because of a doctor's or a hospital's religious beliefs, we urge the Department to withdraw the Proposed Rule.

Thank you for the opportunity to provide comments. If you should have further questions, please contact Dena Sher, (202) 466-3234 or sher@au.org.

Sincerely,

Dena Sher
Assistant Legislative Director

Maggie Garrett
Legislative Director

Exhibit 29

Anne Arundel Medical Center
2001 Medical Parkway
Annapolis, Md. 21401
443-481-1000
askAAMC.org

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, S.W.
Washington, D.C. 20201

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

To whom it may concern:

I am writing on behalf of Anne Arundel Medical Center (AAMC) in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. AAMC is a health system based in Annapolis, Maryland. Our health system includes Maryland's third busiest hospital, five outpatient pavilions, a 40-bed substance use and mental health treatment facility, and a medical group with more than 55 locations throughout our service area. Last fiscal year (FY 2017), AAMC saw 26,300 inpatient admissions and did more than 920,000 office visits. We have more than 4,700 employees and 1,100 members of Medical Staff.

Notably, AAMC was recently recognized by the Human Rights Campaign's Healthcare Equality Index as a "2018 LGBTQ Healthcare Equality Top Performer." We are proud that AAMC fosters a culture and environment that is welcoming, fair, and open to all patients, regardless of sexual orientation or gender identity.

Providing quality, consistent patient care is a priority for AAMC. Both federal and state laws already protect individual health care employees from discrimination on the basis of their religious beliefs. These protections are meaningful and familiar to health care providers that have navigated these personnel obligations alongside our commitment to providing seamless, respectful healthcare to patients. The proposed regulation creates a complex, burdensome notice and reporting process for organizations and hospitals that is not only unnecessary, but also threatens to undermine the continuity of patient care at our facility.

These are our concerns:

1. **The proposed regulation attempts to inappropriately broaden religious exemptions in a way that would deny patients medically necessary or lifesaving care.**

Hospitals and healthcare organizations are in the business of providing healthcare services and information to our patients and communities. The broad and undefined nature of the proposed regulation prioritizes individual providers' beliefs over life-saving patient care and threatens to prevent the provision of services to patients in need. The lack of definition, structure, and guidelines will leave healthcare providers without standards and structures to guide the provision of necessary care to the most vulnerable populations, especially lesbian, gay, bisexual, and transgender (LGBT) people and women.

The scope of the regulation and the health care workers it applies to may make it impossible for some providers to offer certain treatments or to see certain patients. The proposed regulation purports to extend the interpretation of existing statutory exemptions far beyond the current standards. Under the proposed regulation a provider could be seen as empowered to refuse to provide any health care service or information for a religious or moral reason – capturing Pre-Exposure Prophylaxis (PrEP), infertility care, hormone therapy and other non-surgical gender transition-related services, and possibly even HIV treatment under the auspices of "any" service.

2. **The proposed regulation conflicts with Title VII and fails to inform hospitals of the boundaries of the regulation when the exemption may cause an undue hardship on the hospital.**

Title VII requires employers to reasonably accommodate the sincerely-held religious beliefs, observances, and practices of its applicants and employees, when requested, unless the accommodation would impose an undue hardship on business operations. This is defined as more than a de minimis cost. The proposed regulation fails to mention Title VII and the balancing of employee rights and provider hardships. Hospitals and health organizations are at a loss as to how to reconcile the proposed regulation and Title VII given the dearth of litigation on the subject and the lack of explanation in the proposed regulation. The Equal Employment Opportunity Commission (EEOC) addressed this problematic intersection in its public comment in response to the 2008 regulation that had the substantively identical legal problem, noting that "Introducing another standard under the Provider Conscience Regulation for some workplace discrimination and accommodation complaints would disrupt this judicially-approved balance and raise challenging questions about the proper scope of workplace accommodation for religious, moral or ethical beliefs." In this public comment the EEOC concluded that, "Title VII should continue to provide the legal standards for deciding all workplace religious accommodation complaints. HHS's mandate to protect the conscience rights of health care professionals could be met through coordination between EEOC and HHS's Office for Civil Rights, which have had a process for coordinating religious discrimination complaints under Title VII for over 25 years." We agree with the EEOC.

3. **The proposed regulation lacks safeguards to ensure patients would receive emergency care as required by federal law (EMTALA) and ethical standards.**

The proposed regulation is dangerously silent in regards to ensuring patient wellbeing. The lack of consideration of patients' rights is evidenced by the fact that the proposed regulation contains no provision to ensure that patients receive legally available, medically warranted treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs remain paramount, and that they are able to receive both accurate information and quality health services.

The proposed regulation also fails to address potential conflicts with emergency care requirements. Under the Emergency Medical Treatment and Active Labor Act (EMTALA), a hospital receiving government funds and providing emergency services is required also to provide medical screening and stabilizing treatment to a patient who has an emergency medical condition (including severe pain or labor). However, the proposed regulation contains a blanket right of refusal for physicians, with no discussion of their duties under EMTALA or how conflicts should be resolved.

AAMC's EMTALA policy states, "All patients to whom this Policy applies shall receive an initial screening examination by Qualified Medical Personnel and appropriate treatment within the capabilities of Anne Arundel Medical Center without regard to age, race, color, religion, national origin, sex, sexual orientation, ability to pay, payer, physical or mental condition or handicap." Similar language exists in other AAMC policies, including our Patient Rights and discrimination policies.

Conclusion

Simply put, this proposed regulation is bad policy and will hurt our patients and communities. Hospitals and health systems exist to treat patients and provide them with access to the information they need for treatment. Entities that serve patients must be committed to respecting both the values of health care workers and the patients and the communities they serve in a way that allows for the delivery of care. The sweeping exemption and its undefined boundaries of the proposed regulation will have a chilling effect on the provision of life saving and medically necessary healthcare.

Sincerely,

Maulik Joshi, DrPH
Executive Vice President, Integrated Care Delivery and Chief Operating Officer
Anne Arundel Medical Center
2000 Medical Parkway
Annapolis, MD 21401

Exhibit 30

Anti-Defamation League®

BY E-MAIL

March 26, 2018

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

Re: Docket HHS-OCR-2018-0002

On behalf of the Anti-Defamation League, we are writing to offer our comments on the proposed 45 CFR Part 88, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," as outlined at 83FR 3880 ("Proposed Rule" or "Part 88").

For more than a century, the Anti-Defamation League (ADL) has been an active advocate for religious freedom for all Americans – whether in the majority or minority. Among ADL's core beliefs is strict adherence to the separation of church and state effectuated through both the Establishment Clause and the Free Exercise Clause of the First Amendment. We believe a high wall of separation between government and religion is essential to the continued flourishing of religious practice and belief in America, and to the protection of all religions and their adherents.

ADL believes that true religious freedom is best achieved when all individuals are able to practice their faith or choose not to observe any faith; when government neutrally accommodates religion, but does not favor any particular religion; and when religious belief is not used to harm or infringe on the rights of others by government action or others in the public marketplace.

The "play in the joints" between the Establishment Clause and Free Exercise Clause allows and, in many instances, mandates government to accommodate the religious beliefs and observances of citizens. Religious accommodation, however, has its limitations. The United States government should not sanction discrimination or harm in the name of religion. The right to individual religious belief and practice is fundamental. But there should be no license to discriminate or to do harm with government authority.

As noted in the background for this Proposed Rule, healthcare providers – whether individuals or entities – already have robust statutory religious or moral exemptions from performing abortions or sterilization procedures, or complying with advanced directives, and in certain international programs, they have even broader exemptions ("Statutory Exemptions").[1] Provided that the health and safety of patients are safeguarded, such

[1] *See* The Church Amendments, 42 U.S.C. 300a-7; The Coats-Snowe Amendment, 42 U.S.C. 238n; Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d) (the Weldon Amendment) and at Div. H, Tit. II, sec. 209; Patient Protection and Affordable Care Act related to assisted suicide 42 U.S.C. 18113; 42 U.S.C. 1395cc(f), 1396a(w)(3), and 14406; 22 U.S.C. 7631(d); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. J, Tit. VII, sec. 7018 (Helms Amendment).

accommodations are appropriate for doctors, nurses, and others, who actually may be called on to perform these medical procedures or services.

The Proposed Rule, however, crosses the line from providing appropriate accommodations to allowing individuals or entities with incidental or tangential relationships to such procedures or services to detrimentally impose their religious or moral beliefs on patients and other third parties. It does so in two ways. First, Part 88 provides excessively broad and vague definitions of persons, entities, and activities covered by Statutory Exemptions. Second, it includes an excessively broad interpretation of Statutory Exemptions the enforcement of which is delegated to the Office of Civil Rights ("OCR").

As a result, Part 88 would impede access to federally-supported healthcare and in particular have a disparate impact on women, LGBTQ people and religious minorities. It thereby would undermine the mission of OCR, which is to "... enforce laws against discrimination based on race, color, national origin, disability, age, sex, and religion by certain health care and human services." Moreover, the Proposed Rule and the accompanying creation of a new OCR division to implement it convey the distinct message that enforcement of civil rights protections for such groups is secondary.

The Proposed Rule Provides Excessively Broad Definitions of Persons and Entities Covered by Statutory Exemptions

The "Descriptions of the Proposed Rule" ("Rule Descriptions") advise that the term "Entity" means a person or any legal entity whether private or public, and the definition of "Health Care Entity" is not definitive. Rather, it includes examples of covered persons or entities such as "...an individual physician or other health care professional, health care personnel, ... a hospital, a laboratory, an entity engaging in biomedical or behavioral research, ... a or health insurance plan ... , or any other kind of health care organization." However, these examples are "... an illustrative, not an exhaustive list." Additionally, while Part 88 contains a definition of "Health Program or Activity," which will be discussed, *infra*, it does not appear to contain a definition of "health care."

With respect to employees of or other persons associated with Entities or Health Care Entities, the Rule Descriptions provide the following definitions for the terms "Workforce" and "Individual." Workforce means:

> *employees, volunteers, trainees, contractors, and other persons whose conduct in the performance of work for an entity or health care entity is under the direct control of such entity or health care entity, whether or not they are paid by the entity or health care entity, as well as health care providers holding privileges with the entity or health care entity.*

The term "Individual" means "a member of the workforce of an entity or health care entity," including "... volunteers, trainees, or other members or agents of a covered entity, broadly defined, when the conduct of the person is under the control of such entity" (emphasis added).

The Statutory Exemptions are intended to cover persons, who actually may be called on to perform medical procedures. Yet, based on these definitions, virtually any person, including volunteers, who work, for example, at a federally-funded or supported hospital, pharmacy, medical or nursing school, nursing home, or "any other kind of health care organization" would be covered by Statutory Exemptions. Simply put, any person performing work for such a facility

– whether paid or unpaid – would be encompassed by the Proposed Rule irrespective of their non-medical job description or role. That unnecessarily-inclusive definition would compromise and harm the rights of third parties.

The Proposed Rule Provides Excessively Broad Definitions of Activities Covered by Statutory Exemptions

The Rule Descriptions advise that term "Healthcare Program or Activity … 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" (emphasis added). Part 88 does not define the meaning of "health-related services" or "service related to health or wellness."

These terms must be read in conjunction with two other definitions: "Assist in the Performance" and "Referral or Refer for." The Rule Descriptions advise that the Department of Health and Human Services ("HHS") intends Assist in the Performance to "… to provide broad protection for individuals, consistent with the plain meaning of the statutes …" because "[t]he 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 (emphasis added). To this end, the term applies "… to activities with an articulable connection to the procedure, health service, health service program, or research activity in question."

Furthermore, "Referral or Refer for" includes

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

Based on these definitions a person who performs work for a federally-supported healthcare facility could refuse, without penalty, to perform their responsibilities for any service related to health or wellness that has an indirect or possible articulable connection to a statutorily-covered procedure, including providing any information about or how to obtain a procedure.

Application of the Proposed Rule's Definitions to 45 CFR Part 88's Interpretation of Statutory Exemptions Will Impede Access to Healthcare

The Proposed Rule's definitions operating in conjunction with its interpretation of substantive Statutory Exemptions could impede access to or deny federally-funded or supported healthcare. And the harm caused by enforcement of the Proposed Rule would disparately impact women, LGBT people, and religious minorities.

For example, with respect to federally supported healthcare within the United States, here are some examples of the harms that could result:

- An administrator at the only healthcare provider in a rural area could refuse to perform intake or process paperwork for a woman who must terminate her pregnancy due to an ectopic pregnancy or who is getting a tubal ligation. Similarly, the administrator could refuse to do the same for a transgender person, who is undergoing gender reassignment surgery because the surgery requires a hysterectomy. At the same provider, the only administrator or receptionist on shift could refuse to provide a referral to or any information about a health clinic that provides abortions.
- An administrator at a healthcare provider, even one that does not provide abortions or sterilization procedures, could refuse to disclose the provider's policy on these procedures based on the sincerely-held belief that the person seeking the information will either obtain the procedure at the contacted provider or at an alternative provider, which offers these procedures.
- A lab technician could refuse to perform any tests for a patient who will undergo an abortion, sterilization procedure, hysterectomy, or gender reassignment surgery.
- A hospital maintenance worker or contractor directed by the healthcare provider could refuse to perform any upkeep or construction work on an operating room or other facility that is used for abortions, sterilization procedures or hysterectomies.
- A hospital orderly could refuse to provide wheelchair service to a patient who is getting a hysterectomy or gender reassignment surgery.
- An administrator or employee of an insurance company that provides federally funded Medicare or Medicaid insurance policies could refuse to disclose to a prospective purchaser of insurance whether policies cover sterilization, gender reassignment surgery or services related to advance directives.
- At a federally supported medical school, an administrator could refuse to register students based on the sincerely-held belief that they will obtain medical training on abortion, sterilization, gender reassignment surgery, or advance directives, and will perform or assist with such procedures or services during or after their training. Or an employee of such a school's bookstore could refuse to sell medical books to students that provide information on abortion, sterilization or advance directives based on the sincerely-held belief that providing these books will train students to prospectively perform such procedures or services.

In the international arena, Part 88 could have an even wider detrimental impact. Pursuant to the Proposed Rule "[a]ny entity" that receives federal financial assistance for HIV/AIDS prevention, treatment or care under section 104A of the Foreign Assistance Act of 1961 shall not "endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the applicant has a religious or moral objection, as a condition of assistance" (emphasis added).

Thus, with respect to programs funded under section 104A, a health care organization, doctor, nurse or administrator, for example, could not be penalized for refusing, based on religious or moral objection, to treat or offer services to LGBT people, Muslims or other religious minorities, or sex workers.

The Proposed Rule Raises Significant Constitutional Issues

The U.S. Supreme Court "'has long recognized that government may (and sometimes must) accommodate religious practices.'" *See Corp. of Presiding Bishop v. Amos*, 483 U.S. 327, 334. (1987) (citations omitted). However, it cautioned that "[a]t some point, accommodation may devolve into "an unlawful fostering of religion.'" *Id* at 334-35.

Indeed, religious accommodations that unduly burden third parties violate the Establishment Clause. *See Sherbert v. Verner*, 374 U.S. 398 (1963); see also *Estate of Thornton* v. *Caldor*, 472 U.S. 703, 710 (1985). More recently, the Court has found that for statutory exemptions under the Religious Land Use and Institutionalized Persons Act, 42 U.S.C. § 2000cc et seq., to comport with the Establishment Clause, reviewing courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries." *See Cutter v.Wilkinson*, 544 U.S. 709, 720 (2005).

Furthermore, in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), every member of the Court authored or joined an opinion recognizing that detrimental effects on nonbeneficiaries must be considered when evaluating requests for accommodations under the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb et seq. *See Hobby Lobby*, 134 S. Ct. at 2760 ("Nor do we hold * * * that * * * corporations have free rein to take steps that impose 'disadvantages . . . on others' or that require 'the general public to pick up the tab.'" (brackets omitted)); *id.* at 2781 n.37 ("It is certainly true that in applying RFRA 'courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries.'"); *id.* at 2787 (Kennedy, J., concurring) (religious exercise must not "unduly restrict other persons * * * in protecting their own interests"); *id.* at 2790 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting) ("Accommodations to religious beliefs or observances * * * must not significantly impinge on the interests of third parties."); *see also Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., joined by Sotomayor, J., concurring) (Court's recognition of right to accommodation under RLUIPA was constitutionally permissible because "accommodating petitioner's religious belief in this case would not detrimentally affect others who do not share petitioner's belief").

The Proposed Rule goes well beyond a religious accommodation that safeguards the health and safety of patients while exempting doctors, nurses, and medical professionals, who actually may be called on to perform abortions, sterilization, or other medical procedures, or to comply with advance directives. Rather, as detailed above, Part 88 broadly allows a wide swath of non-medical personnel far removed from these procedures or services to detrimentally impose their particular religious beliefs about them on innocent third parties. The Proposed Rule therefore raises serious constitutional issues because the broad exemptions provide a license to discriminate and would unduly burden – or, in some instances – deny patient access to federally-supported healthcare services.

We urge you to recall the Proposed Rule for modifications in light of these serious policy and constitutional arguments.

Sincerely,

Jonathan A. Greenblatt
CEO

David L. Barkey
Southeastern & National
Religious Freedom Counsel

Michael Lieberman
Washington Counsel

Exhibit 31

AAMC

Association of
American Medical Colleges
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www.aamc.org

Via Electronic Submission *(www.regulations.gov)*

March 26, 2018

Roger Severino
Director, Office of Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care, HHS (HHS-OCR-2018-0002)

Dear Mr. Severino:

The Association of American Medical Colleges (AAMC or Association) welcomes the opportunity to comment on the Department of Health and Human Services (HHS' or the Agency's) proposed rule titled *Protecting Statutory Conscience Rights in Health Care, HHS*, 83 *Fed. Reg.* 3880 (January 26, 2018).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Our members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, we serve the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. As will be described in detail below, should the rule be finalized as proposed, it will result in harm to patients, undermine standards of medical professionalism, and raise serious concerns regarding individuals' rights that are protected by other federal and state laws. **Therefore, we urge the Department to withdraw the proposed regulation.**

The Needs of Patients Should Be Put First

Ethical and moral issues within the context of health care are among the most challenging that we face. They require a careful balance between the rights of the health care professional to avoid behavior that violates his/her moral or ethical code, and the rights of a patient to receive lawful health care services that are safe and medically appropriate. In some circumstances, it is difficult to maintain this balance. When that happens, the health and the rights of the patient, who is in the more vulnerable position, must be given precedence. Those who choose the profession of medicine are taught repeatedly during their medical school and residency training that, in the end, their duty to care for the patient must come first, before self. For example, the American Medical Association *Principles of Medical Ethics* state, "A physician shall, while caring for a patient, regard responsibility to the patient as paramount." This does not mean that a physician or other health care provider must act in violation of his or her own moral code,

but it does mean that a physician has the duty to provide information and to refer the patient to other caregivers without judgment.[1]

Julie Cantor wrote about the need for a balance towards professionalism in her article, "Conscientious Objection Gone Awry – Restoring Selfless Professionalism in Medicine" (New England Journal of Medicine, April 9, 2009), which is cited in this proposed rule instead as evidence of rampant discrimination against those who wish to practice women's health. Rather than promote discrimination against health care professionals, Dr. Cantor calls on those who "freely choose their field" to evaluate their beliefs in relation to their specialties and whether they are able to provide all legal options for care. "As gatekeepers to medicine, physicians and other health care providers have an obligation to choose specialties that are not moral minefields for them. … Conscience is a burden that belongs to that individual professional; patients should not have to shoulder it."

There Is No Demonstrable Need for the Proposed Rule

As we stated when we commented on the original 2008 Federal Health Care Conscience Rule, no individual or entity in this country has the option to pick and choose the laws to which he/she will adhere. Every health care provider and entity already has the obligation to comply with all applicable federal laws. The Department has offered little evidence that this has not been the case. The Office of Civil Rights has received just forty-four complaints since it was designated with authority to enforce the Church, Coats-Snow, and Weldon Amendments. The paucity of complaints does not provide compelling evidence of a need for the expansion of OCR's authority, or the need for changes in the current regulations.

Accreditation Organizations Require Medical Students and Residents to Be Taught to Respond to the Many Health Care Needs of a Diverse Patient Population and Respect a Medical Student or Resident's Decision to Not Receive Training in Abortions

Starting with undergraduate medical education and continuing through residency training, physicians are taught that they will be practicing medicine in a multi-cultural, multi-ethnic world in which patients and their families hold diverse viewpoints on many complex ethical issues that affect health care. Their education also occurs in an atmosphere that acknowledges that as health care providers, physicians themselves bring a diversity of religious and moral views on health care issues to their work. Such disparate views are examined during the educational process during a physician's initial training and throughout the individual's professional development.

Belying the concern that medical schools and training program are discriminating against medical students and residents for their religious views are the accreditation requirements of the Liaison Committee for Medical Education (LCME), which accredits all US medical education programs leading to the MD degree, and the Accreditation Council for Graduate Medical Education (ACGME), which accredits residency programs that seek to attract a wide variety of individuals into medicine. Both organizations have standards that are designed to ensure that the education of physicians provides an environment that embraces diversity of views and values for both health care providers and patients. For instance, the LCME requires that "[t]he selection of individual [medical] students must not be influenced by any political or financial factors."

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[1] American Medical Association Council on Ethical & Judicial Affairs, "Code of Medical Ethics Opinion 1.1.7" https://www.ama-assn.org/delivering-care/physician-exercise-conscience

Additional requirements include the following:

> A medical school does not discriminate on the basis of age, creed, gender identity, national origin, race, sex, or sexual orientation.
>
> A medical school ensures that the learning environment of its medical education program is conducive to the ongoing development of explicit and appropriate professional behaviors in its medical students, faculty, and staff at all locations and is one in which all individuals are treated with respect. The medical school and its clinical affiliates share the responsibility for periodic evaluation of the learning environment in order to identify positive and negative influences on the maintenance of professional standards, develop and conduct appropriate strategies to enhance positive and mitigate negative influences, and identify and promptly correct violations of professional standards.
>
> A medical school develops effective written policies that address violations of the code, has effective mechanisms in place for a prompt response to any complaints, and supports educational activities aimed at preventing inappropriate behavior. Mechanisms for reporting violations of the code of professional conduct are understood by medical students, including visiting medical students, and ensure that any violations can be registered and investigated without fear of retaliation. (Standards, Publications, & Notification Forms. LCME. lcme.org/publications. Accessed March 2018).

Further, the LCME's June 2017 Rules of Procedure regarding medical school accreditation state that:

> Medical education programs are reviewed solely to determine compliance with LCME accreditation standards. LCME accreditation standards and their related elements are stated in terms that respect the diversity of mission of U.S. medical schools, including religious missions.

The LCME also recognizes the need for medical students to learn how to care for a diverse patient population. For example,

> The faculty of a medical school ensure that the medical curriculum provides opportunities for medical students to learn to recognize and appropriately address gender and cultural biases in themselves, in others, and in the health care delivery process. The medical curriculum includes instruction regarding the following:
>
> - The manner in which people of diverse cultures and belief systems perceive health and illness and respond to various symptoms, diseases, and treatments
> - The basic principles of culturally competent health care
> - The recognition and development of solutions for health care disparities
> - The importance of meeting the health care needs of medically underserved populations
> - The development of core professional attributes (e.g., altruism, accountability) needed to provide effective care in a multidimensional and diverse society

Similarly, the ACGME states that:

> Residents are expected to demonstrate sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation.

> Clinical learning environments (CLEs) need to ensure that their residents and fellows learn to recognize health care disparities and strive for optimal outcomes for all patients, especially those in potentially vulnerable populations. As front-line caregivers, residents and fellows are a valuable resource for formulating strategies on these matters. They can assist the CLEs in addressing not only low-income populations, but also those that experience differences in access or outcome based on gender, race, ethnicity, sexual orientation, health literacy, primary language, disability, geography, and other factors.
>
> The diverse, often vulnerable, patient populations served by CLEs also provide an important opportunity for teaching residents and fellows to be respectful of patients' cultural differences and beliefs, and the social determinants of health.
>
> In considering patient outcomes, it is important to note that patients at risk for disparities are likely to require differences in care that are tailored to their specific needs—based not only on their biological differences, but also on other social determinants of health (e.g., personal social support networks, economic factors, cultural factors, safe housing, local food markets, etc.).

The ACGME's Common Program Requirements state that "Programs must provide a professional, respectful, and civil environment that is free from mistreatment, abuse, or coercion of students, residents, faculty and staff. Programs, in partnership with their Sponsoring Institutions, should have a process for education of residents and faculty regarding unprofessional behavior and a confidential process for reporting, investigating, and addressing such concerns. (Standard VI.B.6)

In regard to women's healthcare, both accrediting organizations are clear that a program cannot require training in abortion procedures. The ACGME's Program requirements specific to obstetrics and gynecology state "Residents who have a religious or moral objection may opt-out and must not be required to participate in training in or performing induced abortions." The profession of medicine seeks to embrace within its ranks individuals from diverse racial/ethnic, cultural, religious and socioeconomic backgrounds. Such diversity of backgrounds helps to ensure that physicians will understand and be sympathetic to the traditions, values, and beliefs of their patients and provide competent care.

The Proposed Rule Is Overly Expansive In Its Reach and Is Incongruous with Medical Professionalism

The proposed rule is overly expansive, allowing physicians and others to avoid engaging in any activity "with an articulable connection" to the objectionable procedure, "include[ing] counseling, referral, training, and other arrangements for the procedure." It then proposes a definition of referral that expands the general understanding of referral to include "the provision of *any* information…when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or *possible outcome of the referral*." (emphasis added). The refusal of a physician or other health care professional to provide a patient with information, or to give a patient a referral to a provider where the desired care is available, risks limiting the patient's access to health care. Allowing health care professionals to engage in behavior that could harm patients is incongruous with the standards of medical professionalism that are the core of a physician's education and the practice of medicine.

Similarly, the proposed regulation would interpret the term "assist in the performance" to include "any activity with an articulable connection to a procedure, health service, or research activity[.]" The proposed regulation states that this definition is intended to be broad, and not limited to direct involvement with a procedure, health service, or research activity. For example, this broader definition could apply to an employee whose task is to clean a room where a particular procedure took place. Such a

broad view is unnecessary particularly since the employee has the option to seek employment elsewhere while the patient may have only one place where he/she can receive care.

The Proposed Rule Will Do Harm to Lower Income Americans, Racial and Ethnic Minorities, the LGBTQ Community, and Patients in Rural Areas

The proposed rule would allow physicians and others to avoid engaging in any activity "with an articulable connection" to the objectionable procedure, "includ[ing] counseling, referral, training, and other arrangements for the procedure." This broad reach will create or exacerbate inequities in health care access for Americans whose access may already be limited due to their geographic residence or financial means. For rural- and frontier-dwelling Americans who reside in a health professional shortage area, access to certain services might functionally cease to exist as a result of this proposed rule: seeking care in distant locales might be too burdensome or expensive. This holds, too, for lower income Americans who lack the financial means to seek out care for procedures when their primary physicians decline to provide services.

Racial and ethnic minority women have reported experiencing race-based discrimination when receiving family planning care.[2] The proposed rule may exacerbate this problem and the consequences that follow for women and their children. Research has associated unintended pregnancy with several adverse maternal and child health outcomes, such as delayed prenatal care, tobacco and alcohol use during pregnancy, delivery of low birthweight babies[3], and poor maternal mental health.[4] These negative health outcomes are more prevalent in racial and ethnic minority communities likely would worsen under the proposed rule.

For the lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities, the proposed rule may further exacerbate heath care access disparities. It is well documented that LGBTQ Americans currently experience discrimination in health care settings, erecting a barrier to accessing health care services.[5] This proposed rule would codify what many within and beyond the LGBTQ communities will view as state-sanctioned discrimination, and allow providers to refuse care or appropriate referrals solely on the basis of their patients' sexual orientation or gender identity. This stands in stark opposition to OCR's stated goal to "protect fundamental rights of nondiscrimination."

The Proposed Rule Adds Burdensome Requirements That Have No Commensurate Benefit

The Department and this Administration have undertaken major efforts to reduce regulatory burden, such as "Reducing Regulation and Controlling Regulatory Costs" (Executive Order 13771, issued January 30, 2017), "Enforcing the Regulatory Reform Agenda" (Executive Order 13777, issued February 24, 2017), the Centers for Medicare & Medicaid's "Patient over Paperwork" initiative (launched October 2017, in an effort to reduce unnecessary burden), and several Requests for Information regarding administrative burden. The burden associated with complying with the proposed rule runs counter to this goal. Moreover, the investment in resources that would be required for a large teaching health care system to

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[2] Thorburn S, Bogart LM. "African American women and family planning services: perceptions of discrimination." *Women Health*. 2005;42(1):23–39.
[3] Institute of Medicine (US) Committee on Unintended Pregnancy; Brown SS, Eisenberg L, editors. "The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families. National Academies Press (US); 1995. 3, *Consequences of Unintended Pregnancy*. Available from: https://www.ncbi.nlm.nih.gov/books/NBK232137/
[4] Herd P et al., "The implications of unintended pregnancies for mental health in later life," *American Journal of Public Health*, 2016, 106(3):421–429.
[5] Cahill, S. "LGBT Experiences with Health Care," *Health Affairs* Vol. 36, No.4. 2017. Available from: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0277

ensure compliance and monitoring of all of the proposed requirements would be even more onerous and reduce funds available for the core missions of teaching, patient care, and research.

The Department proposes to modify existing civil rights clearance forms (or develop similar forms in the future), and notes that it might require submission of these documents annually and incorporate by reference in all other applications submitted that year. The receipt of any federal funds already requires the compliance with all federal laws and regulations; assurances and attestations to compliance are routine. OCR has not made clear why there is a need for additional assurance and certification.

The Department also proposes notice requirements, which includes notice on the funding recipient's website, in prominent and conspicuous physical locations where other notices to the public and notices to the recipient's workforce are customarily posted. The notice is to be posted by April 26, 2018, or for new recipients, within 90 days of becoming a recipient. Even if the rule is finalized by April 26, and no changes are made in the notice requirement, it is unreasonable to expect current recipients to comply by that date.

The rule also proposes that if a sub-recipient is found to have violated federal health care conscience and associated anti-discrimination laws, the recipients "shall be subject to the imposition of funding restrictions and other appropriate remedies." Requiring the imposition of funding restrictions should be dependent on the facts and circumstances of a particular case; however, by using the word "shall" there seems to be no discretion in whether this penalty is appropriate. If the rule is finalized, the AAMC asks that OCR clearly make the penalty optional by using "may" instead of "shall."

The AAMC strongly urges the Department to withdraw the proposed rule. Alternatively, the rule should be re-proposed and narrowed in scope to, at a minimum, appropriately balance the needs of patients with the needs of health care providers who have freely chosen their profession.

If you would like additional information, please contact Ivy Baer, Senior Director and Regulatory Counsel, at 202-828-0499 or ibaer@aamc.org.

Sincerely,

Janis M. Orlowski, MD MACP
Chief, Health Care Affairs

Exhibit 32

March 27, 2018

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) opposes the Department of Health and Human Services proposed rule, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, which seeks to permit discrimination by providers in all aspects of health care without adequately protecting patients from discrimination in accessing health care services. This proposed rule is not necessary to protect the rights of providers. The existing rule issued in 2011 adequately protects the conscience of providers and patients.

As a membership organization of nurses dedicated to improving and promoting the health of women and newborns and strengthening the nursing profession, AWHONN asserts that nurses have the professional responsibility to provide nonjudgmental nursing care to all patients, either directly or through appropriate and timely referrals. However, AWHONN recognizes that some nurses may have religious or moral objections to participating in certain reproductive health care services, research, or associated activities. Therefore, AWHONN supports the existing protections afforded under federal law for a nurse who refuses to assist in performing any health care procedure to which the nurse has a moral or religious objection so long as the nurse has given appropriate notice to his or her employer.

AWHONN considers access to affordable and acceptable health care services a basic human right. With regard to the nurse's role in meeting the health care needs of patients, AWHONN advocates that nurses adhere to the following principles:

- Nurses should not abandon a patient, nor should they refuse to care for someone based on personal preference, prejudice, or bias.
- Nurses have the professional responsibility to provide impartial care and help ensure patient safety in emergency situations and not withdraw care until alternate care is available, regardless of the nurses' personal beliefs.
- At the time of employment, nurses are professionally obligated to inform their employers of any values or beliefs that may interfere with essential job functions. Nurses should ideally practice in settings in which they are less likely to be asked to assist in care or procedures that conflict with their religious or moral beliefs.

By permitting providers to refuse to refer patients based on the provider's religious beliefs or moral convictions, the proposed rule carries severe consequences for patients, making it difficult for many individuals to access the care they need.

The proposed rule will undermine critical federal health programs delivered through the Title X Family Grants. The Proposed Rule would seemingly allow health care entities to receive grants and contracts under Title X, while refusing to provide key services required by those programs.[1] For instance, Congress

[1] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's*

has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[2] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[3] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[4] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub recipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[5] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[6]

The Proposed Rule will carry severe consequences for providers and undermine the provider-patient relationship. AWHONN asserts that any woman's reproductive health care decisions are best made by the informed woman in consultation with her health care provider. AWHONN believes these personal and private decisions are best made within a health care system whose providers respect the woman's right to make her own decisions according to her personal values and preferences and to do so confidentially. Therefore, AWHONN supports and promotes a woman's right to evidence-based, accurate, and complete information and access to the full range of reproductive health care services. AWHONN opposes legislation and policies that limit a health care provider's ability to counsel women as to the full range of options and to provide treatment and/or referrals, if necessary.

Title VII of the Civil Rights Act of 1964 protects workers (applicants and employees) from employment discrimination based on race, color, religion, sex, national origin, or participation in certain protected activities. With respect to religious protection, Title VII applies to most U.S. employers and requires reasonable accommodation of the religious beliefs, observances, and practices of employees when requested, unless such accommodation would impose undue hardship on business operations. These protections do and should continue to apply to nurses and other health care professionals.

A nurse should retain the right to practice in his or her area of expertise following a refusal to participate in an abortion, sterilization, gender reassignment surgery, or any other procedure. This refusal should not jeopardize the nurse's employment or subject him or her to harassment. In addition, one's moral and ethical beliefs should not be used as criteria for employment, unless they preclude the nurse from fulfilling essential job functions. AWHONN asserts that these rights should be protected through written

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Family Planning Program, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.
[2] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[3] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[4] *See, e.g.*, Rule *supra* note 1, at 180-185.
[5] *See* NFPRHA *supra* note 34.
[6] *See id.*

institutional policies that address reasonable accommodations for the nurse and describe the institution's required terms of notice to avoid patient abandonment.

Sincerely,

Seth A. Chase, MA
Director, Government Affairs
Association of Women's Health, Obstetric & Neonatal Nurses (AWHONN)
1800 M Street NW
Suite 740 South
Washington, DC 20036

Exhibit 33

Aurora Health Care®

750 W. Virginia Street
Milwaukee, WI 53204

www.AuroraHealthCare.org

March 27, 2018

Mr. Roger Severino
Director, Office for Civil Rights (OCR)
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Director Severino:

On behalf of Aurora Health Care, Inc. (Aurora), we appreciate the opportunity to submit comments regarding the Department of Health and Human Services (HHS) proposed rule regarding federal conscientious and religious objection protections for health care workers.

Aurora is a not-for-profit integrated health care provider based in Milwaukee, Wisconsin, serving over 100 communities in the eastern third of the state through 15 hospitals, a physician practice comprised of 1,432 physicians, 72 pharmacies, Wisconsin's largest home health organization, and one of the state's largest intern and resident programs. As evidenced by more than 300 active clinical trials, Aurora is dedicated to delivering innovations to provide the best possible care today, and to define the best care for tomorrow.

Aurora's Provides Quality Health Care to Diverse and Unique Patient Populations in the Many Different Communities We Serve

Aurora's caregivers touch the lives of millions of diverse patients across a large geographical area, which provides us with an opportunity to improve the health outcomes of the unique patient populations we serve.

In this comment letter, Aurora is pleased to share our feedback with HHS regarding how its proposed rule would impact our integrated delivery system's ability to tackle some of the most serious health care issues facing our nation today, including combatting the alarming opioid abuse epidemic raging right here in Wisconsin, reducing chronic illnesses, eliminating health disparities and expanding access to high-quality care for vulnerable patients. Unfortunately, these complex and pervasive challenges are particularly endemic in Wisconsin, where significant patient populations live in highly urban or highly rural, low-income and underserved communities.

Therefore, any HHS proposed regulation should be assessed and evaluated by how it would impact access to care for our most vulnerable patient populations in these underserved communities.

Aurora Respects Our Health Care Professionals' Moral and Religious Beliefs

At Aurora, we respect our health care professionals' moral and religious beliefs and their conscience-based objections to certain activities. We stand by our policy to "make reasonable accommodations for requests to be excluded from activities that are in conflict with sincerely held religious, ethical or moral beliefs."

Aurora Does Not Tolerate Discrimination Towards Our Patients and Those Seeking Medical and Behavioral Health Care

At the same time, we respect our patients' rights and do not tolerate discrimination against patients. To that point, we also stand by our policy that "patients are given reasonable access to care in a safe setting without regard to race, creed, color, national origin, ancestry, religion, sex, sexual orientation, gender identity, marital status, age, disability or source of payment."

At Aurora, we seek to provide culturally competent care to every patient we serve. We are committed to fostering a culture of inclusion that embraces and nurtures our patients, colleagues, partners, physicians and communities. Patients and their caretakers come to Aurora from a wide range of backgrounds, and many of these patients have serious or multiple health challenges. Providing the right care demands sensitivity to their diverse needs. Diversity is at the very heart of Aurora's important mission of providing patient-centered care.

Aurora's Existing Policies Strike an Appropriate Balance between Caregivers and Patients

It is Aurora's position that our existing policies strike the right balance between caregiver and patient rights. Any new and additional protections for conscientious and religious objections for health care workers have the real potential of throwing off this necessary balance and negatively impacting patient access to care. Aurora's medical centers and clinics are, at times, the only connection to health care in some of Wisconsin's most rural communities. And in both rural and urban areas, we continually strive to remove barriers to health care access. The proposed rule regarding conscience objections in health care could negatively impact this critical access in an unjustified way.

Additional Federal Government Intervention is Unnecessary

It also is Aurora's position that additional protections are unnecessary because, as a health care organization, we already have a strong commitment to respecting the moral, ethical and religious beliefs of both its health care professionals and patients. This commitment is grounded in part by professional codes of ethics. The American Medical Association upholds that a physician's duties to inform[1] and refer[2] remain in situations where conscience objections

[1] "Providing information about treatment options the physician sincerely believes are morally objectionable or about how the patient might obtain objected-to treatment elsewhere is morally distant from what the physician's deeply held beliefs tell him or her is wrong. Providing information is sufficiently distant that the risk to physician integrity is outweighed by the professional obligation to inform, given the strong ethical import of informed consent. Physicians can avoid any taint of complicity by notifying prospective patients prior to initiating a patient-physician relationship about interventions or services that conscience prohibits the physician from offering." American

could worsen or limit access to treatments or health care. Aurora respects that no two patient-physician relationships are exactly alike, and that physicians must follow their individual consciences in weighing matters of professional integrity. At Aurora, clinical ethics consultation is available to health care professionals to assist in balancing these values commitments. It is our experience that a health care professional will pursue a balanced course of action that both aligns with their conscience and respects the patient's need for treatment or health care. For example, health care professionals often determine it is their responsibility to both provide information about and refer for services they personally find morally objectionable. There is not a need for the federal government to intervene with this process. Additional federal regulatory burdens could disrupt the existing patient-physician relationship which is critical to unlocking the potential of patient-driven value care.

Regulatory Relief Needed to More Effectively Address the Nation's Complex Health Challenges

Aurora appreciates HHS' current focus on eliminating and preventing additional regulatory burdens in the Medicare program and America's health care system to allow integrated networks and providers to spend more time and resources tackling the nation's most pervasive health challenges and not on paperwork. Excessive red tape not only stands as a barrier to care, but as a key driver of cost. Reducing unnecessary regulatory burdens would not only provide relief and free up limited precious resources to allocate to the most urgent and acute health needs, but would also provide an opportunity to make care more patient-centered than ever before.

Proposal Would Significantly Increase Regulatory Burdens for Delivery Systems and Providers

Unfortunately the HHS proposed rule would place significant new regulatory burdens on hospitals and their caregivers instead of reducing them. The proposed rule follows an announcement of a new Conscience and Religious Freedom Division within the HHS Office for Civil Rights (OCR) which will be tasked with enforcing these new regulations. Under the proposed rule, OCR would have new authority to initiate compliance reviews, conduct investigations, and use enforcement tools to address violations of the new rule. Under this new authority, OCR could conduct an investigation even if a formal complaint has not been filed.

In addition, the proposed rule would require recipients of federal funds to submit an assurance and certification of their compliance and to notify protected individuals and entities of their rights. Notification would require posting on Aurora's website, as well as a physical location within each of our facilities. Aurora would also need to maintain records to verify compliance with the proposed rule. The proposed rule also recommends designating an additional employee and

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Medical Association Council on Ethical and Judicial Affairs, "Physician Exercise of Conscience" (2014), page 6, https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/i14-ceja-physician-exercise-conscience.pdf.

[2] See especially: "The greater the likelihood or severity of harm, the stronger the physician's duty to facilitate in some way the patient's access to needed care, even in the face of becoming in some measure complicit in what the physician believes is wrong," and "terminating the relationship is ethically permissible only when timeliness of care is not a factor and the physician adheres to ethical guidelines for terminating the relationship." For more, see: AMA CEJA, "Physician Exercise of Conscience," page 7.

resources responsible for compliance, the adoption of internal grievance procedures, and the preparation of internal compliance reports as best practices.

The need to comply with the proposed rule will unfortunately impose additional unnecessary federal regulatory burdens on providers and require resources and focus being diverted away from patient-driven and value-based care.

Addressing the Underlying Socioeconomic Contributors to Chronic Diseases

The complex but pervasive relationship between socioeconomic status and health outcomes is unfortunately highly visible throughout underserved communities across America where people living at or below the poverty line have a greater likelihood of having one or more chronic health conditions. This dynamic is playing out in Milwaukee where the city has higher than state average rates of infant mortality, obesity, sexually transmitted diseases, cancer (breast, cervical, lung, and prostate), violence, teen pregnancy, childhood lead poisoning, and mortality due to unintentional injuries. Chronic health problems - such as obesity, diabetes, heart disease and hypertension - are endemic to Milwaukee's underinsured and uninsured populations.

Any new federal regulation that would intentionally or unintentionally impede our most vulnerable patient populations from seeking and accessing care has the potential to further exacerbate both the human suffering and financial tolls being inflicted by these deadly but preventable chronic conditions.

Barriers to Accessing Behavioral Health Services

The proposed rule regarding federal conscientious and religious objections for health care workers could have significant negative unintended consequences for underserved and vulnerable patients in urgent need of critical access to behavioral and mental health care.

Wisconsin is faced with a severe shortage of behavioral health specialists right at the same time an alarming opioid overdose epidemic rages across the state. According to a recent report from the Centers for Disease Control and Prevention, Wisconsin saw the largest one-year rise across the entire nation in increased opioid overdoses, with opioid-related ED visits increasing by 109% from 2016 to 2017.

One in five Americans suffers from a diagnosable, treatable mental health condition. Minority groups — including African Americans, Hispanics, Asian Americans and Native Americans — are more likely to experience the risk factors that can cause mental health issues. Most notably, poverty contributes to the development of problems such as depression, anxiety and post-traumatic stress disorder (PTSD). They are also considerably under-represented when it comes to receiving mental health treatment.

Moreover, research suggests that lesbian, gay, bisexual, and transgender (LGBT) individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and

human rights. Discrimination against LGBT persons has been associated with high rates of psychiatric disorders, substance abuse, and suicide.[3]

Given that mental and behavioral health resources for the general patient population are woefully inadequate in our state, we strongly urge policymakers to especially consider the potential any new regulation would have for underserved patients who are also seeking this type of care.

Conclusion

Aurora Health Care appreciates the opportunity to comment on the proposed rule regarding federal conscientious and religious objection protections for health care workers.

We strongly urge HHS to avoid implementing any policies that would result in denying care to specific groups of people.

Should you have any questions, please feel free to give me a call at (414) 299-1878 or contact Anthony Curry at (414) 299-1657.

Thank you in advance for your consideration.

Sincerely,

Cristy Garcia-Thomas
Chief Experience Officer
Aurora Health Care

[3] Office of Disease Prevention and Health Promotion. (2016). Lesbian, gay, bisexual, and transgender health. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health

Exhibit 34

BEND THE ARC
jewish action

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

We appreciate this opportunity to provide comments in response to this NPRM. Bend the Arc Jewish Action is the largest national Jewish social justice organization focused exclusively on domestic policy. As Jews, we care deeply about the freedom of religion and as such are deeply concerned about this proposed rule which creates a framework that distorts essential protections for religious freedom to justify discrimination. Accordingly, we urge the Department to withdraw it.

This rule would create a blanket exemption to allow hospitals, insurance companies, health care providers, and support staff to refuse patients care or even referrals for care. We reject the use of religion to deny essential health care services to people without ensuring that such individuals receive the care they need. We feel a moral imperative to ensure that patients receive the health care they request without delay and to oppose the Administration's proposal that could allow religion to be used to deny patients' access to critical health care.

By making it easier to use moral and religious objections to discriminate and hamper access to critical medical care and services, this rule will disproportionately burden women and LGBTQ individuals. We are particularly concerned that the rule will negatively impact reproductive health care, including access to abortion and contraceptive care, as well as necessary transition-related care for transgender individuals. Moreover, since the rule governs all entities or individuals that benefit from federally funded health care programs or activities, this rule will allow taxpayer dollars to subsidize discriminatory behavior and certain religious viewpoints.

Specifically, we raise the following concerns about the proposed rule:

- **The rule creates an unacceptable blanket exemption for religious or moral objections with no concern for other interests:** Religious freedom is a fundamental American value. Yet this essential freedom has always been understood to have boundaries. We support religious accommodations that are carefully crafted to maintain the freedom to exercise faith without infringing on other important rights and freedoms. In fact, the First Amendment requires that when creating a religious exemption, the government must account for the burdens an exemption would impose on others. This understanding of religious freedom also reflects a tenet of our faith: We should treat others fairly, as we would like to be treated.

  This proposed rule, however, appears to allow religious and moral conviction claims to trump any and all other interests. The rule gives complete deference to a hospital's or provider's religious objection to providing or referring for a certain medical service,

ignoring the government's significant interests in maintaining broad access to health care, an individual's ability to obtain certain medical services, and our nation's longstanding commitment to extant civil rights protections. This rule instead creates what amounts to a blanket exemption, casting aside other important rights and ignoring the need to carefully craft accommodations.

For instance, Title VII of the Civil Rights Act of 1964 requires employers to reasonably accommodate employees' or applicants' sincerely held religious beliefs, observances, and practices, unless doing so would impose an "undue hardship" on an employer. When a health care worker requests an accommodation, Title VII ensures that employers consider how to balance an accommodation with obligations to serve patients, protect coworkers, ensure public safety, and abide by other legal requirements. The proposed rule, however, establishes an entirely different and conflicting standard.

- **The scope of the proposed rule is sweeping and would permit a wide range of individuals and entities to refuse to provide a broad spectrum of services:** The proposed rule would greatly expand the individuals and entities that may invoke religious beliefs or moral convictions to refuse to provide, directly or indirectly, essential services and care. The proposed rule not only applies to medical professionals like doctors and nurses, but also extends to support staff, volunteers, trainees, contractors, and others who work at a health care entity. The set of entities that may receive an exemption is also broad: it includes organizations offering insurance plans and "plan sponsors," an expansion which might ultimately protect businesses unrelated to the provision of health care.

  In addition, the proposed rule also extends to referrals for care. Depending on location or circumstance, this may functionally block people from obtaining vitally needed services. This rule creates a vast scope for objections or objectors that will endanger many individuals' ability to access the care or services they need.

- **Many health care providers are called by their faith to uphold a duty to their patients.** The proposed rule ignores that many providers' religious and moral convictions prompt them to prioritize their patients' health. Providers should be able to give patients sound information about treatment choices so patients can make informed decisions about their care. And providers should be able to deliver health care, including abortion and transition-related care.

As advocates for religious freedom, we are alarmed by the proposed rule. Categorical exemptions like these distort and degrade religious freedom, endangering the wide support that carefully crafted religious accommodations have long enjoyed in our country. This rule takes great liberties in reinterpreting extant civil rights law and religious exemptions. We urge you to rescind this proposed rule.

Exhibit 35

BJC HealthCare

Via Electronic Submission (www.regulations.gov)

March 27, 2018

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

RE: HHS-OCR-2018-0002: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority Proposed Rule

Dear Secretary Azar,

I write you today on behalf of BJC Healthcare ("BJC") in St. Louis, an integrated health system employing approximately 30,000 people in a variety of roles covering the full spectrum of healthcare services across a diverse geography. BJC supports the religious and conscience rights of all people and organizations, and we appreciate this opportunity to submit related public comment on this Proposed Rulemaking ("the proposals").[1] We are concerned that the proposed regulatory regime places unnecessary additional administrative and other burdens upon employers, while also inadequately considering the rights of patients and responsibilities of health care entities ("employers") to provide appropriate and necessary patient care, in part because it creates potential inconsistencies between existing, well-established bodies of federal and state anti-discrimination law. We would encourage adopting the following recommendations to create a more effective, efficient and consistent approach:

- Adopt or adapt the language and definitions related to religion/conscience-based discrimination to mirror those found in Title VII of the Civil Rights Act of 1964 and amended by the Equal Employment Opportunity Act of 1972 (42 USC 2000e) ("the Acts").[2] In particular:
  - Adopt the "accommodation" and "undue hardship" concepts found in the Acts' definition of "religion" at 42 USC 2000e(j).
  - Forego incorporating a "disparate impact" analysis as contemplated in the proposals.[3] The interpretation of the "disparate impact" analysis varies among the federal circuit courts and states, and the inclusion of such analysis in the final rule may lead to unintended confusion and inconsistent application.

[1] "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," 83 FR 3880, January 26, 2018. Available at https://www.gpo.gov/fdsys/pkg/FR-2018-01-26/pdf/2018-01226.pdf.
[2] 42 USC 2000e—Definitions is available here: https://www.govinfo.gov/content/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap21-subchapVI-sec2000e.pdf. This definition was added by Public Law 92-261, available here: https://www.govinfo.gov/content/pkg/STATUTE-86/pdf/STATUTE-86-Pg103.pdf. The statutory requirements are implemented into the regulatory code at 29 CFR 1605—Guidelines on Discrimination Because of Religion, available here: https://www.govinfo.gov/content/pkg/CFR-2017-title29-vol4/pdf/CFR-2017-title29-vol4-part1605.pdf.
[3] See 83 FR 3893, left column, linked in note 1 above.

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BJC HealthCare

- Expand the proposed 45 CFR 88.8—Relationship to Other Laws[4]
  - Defer to the religious anti-discrimination protections of state and locals governments if/when stronger than federal protection.[5]
  - Permit healthcare providers and employers to follow state enforcement and compliance regimes when doing so would result in equal or greater protections and/or equal or lesser burden on providers and employers. For example:
    - Waive proposed federal Certification and Notice requirements when a state or federal law already contains substantially similar requirements.[6]
    - Defer any OCR investigations to relevant state agencies when possible.

We believe the above recommendations will meet HHS's goals of protecting individual rights regarding religion/conscience, while minimizing providers and employers regulatory burden of doing so and ensuring the ability of health care providers to provide appropriate and necessary care to patients in need. Thank you for your consideration. Please let me know if you have any questions or BJC can otherwise assist your agency in this or any other matter.

Sincerely,

David L. McCune
Vice President
Corporate Compliance Department
BJC HealthCare

[4] See brief discussion in the Proposal at 83 FR 3899, with proposed formal language for 45 CFR 88.8 at 83 FR 3931, linked in Note 1 above.

[5] See for example RsMO 188.100 et. seq regarding employments discrimination related to abortions in particular, available here, http://revisor.mo.gov/main/ViewChapter.aspx?chapter=188. RSMO 213.055 addresses unlawful employment practices more problem, including as relates to Religion, available here: http://revisor.mo.gov/main/ViewChapter.aspx?chapter=213. See also Missouri's 13 CSR 60-3.050 for regulatory policy on religious discrimination in employment, available here: https://www.sos.mo.gov/cmsimages/adrules/csr/current/8csr/8c60-3.pdf.

[6] See "Assurances and Certifications" as proposed at 45 CFR 88.4 and discussed starting at 83 FR 3896, and "Notice," as proposed at 45 CFR 88.5 and discussed starting at 83 FR 3897.

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Exhibit 36

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 37

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, S.W.
Washington, D.C. 20201

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

To Whom It May Concern:

I am writing on behalf of Boston Medical Center (BMC), a private, not-for-profit, 487-bed, academic medical center located in Boston, Massachusetts, in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. BMC is the primary teaching affiliate for Boston University's School of Medicine. It is the busiest trauma and emergency services center and the largest safety net hospital in New England. BMC is dedicated to providing accessible health care to everyone. 57% of its patients are from under-served populations and 32% of patients do not speak English as a primary language. Seeing more than one million patient visits a year in over 70 medical specialties and subspecialties, BMC physicians are leaders in their fields with the most advanced medical technology at their fingertips and working alongside a highly-skilled nursing and professional staff. BMC's mission is to provide exceptional care, without exception to all patients. BMC's staff is committed to providing quality care to every patient and family member with respect, warmth and compassion.

Providing quality, consistent patient care is a priority at our hospital. Through its commitment to serve everyone, BMC offers numerous outreach programs and services. BMC offers Interpreter Services in over 250 Languages, 24 hours a day. We are proud of the diversity of our patients and employees and hold strong in our belief that many faces create our greatness. BMC has a long history of caring for lesbian, gay, bi-sexual, transgender and gender queer (gender non-conforming) (LGBTQ) patients. In 2016 BMC proudly established its Center for Transgender Medicine and Surgery (CTMS), which is the first medical center in New England to provide a comprehensive transgender health care program and is a leader nationally in the delivery of transgender medical care. BMC recognizes that the transgender patient population has been severely marginalized because of discrimination and bias, which

has resulted in significant health disparities for this group. The 2015 U.S. Transgender Survey Report, prepared by the National Center for Transgender Equality, found that one-third of the survey respondents reported having at least one negative health care related experience because of being transgender and nearly one-fourth, of the almost 28,000 respondents, did not seek health care due to a fear of mistreatment by health care providers because of being transgender. As a result of the historical harm and mistreatment faced by transgender people, many health care institutions throughout the United States are providing more targeted health care services for transgender and LGBQ patients and thereby working towards decreasing the health care disparities for LGBTQ patients that are still pervasive throughout the United States.

The Department of Health and Human Services' Proposed Rule "Protecting Statutory Conscience Rights in Health Care", as currently drafted, has the potential to significantly detract from the progress made and increase the health disparities faced by the LGBTQ patient population. First, the proposed rule, under the notion of religious protection, overreaches with an embedded catch-all provision that essentially states that no entity shall discriminate against a physician or other health care personnel for refusing to perform "**any lawful health service"** on grounds that "it is contrary to [the health care provider's] religious beliefs or moral convictions." (Proposed Rule §88.3(a)(2)(v)). **This provision is too broad.** Second, both federal and state laws already protect individual health care employees from discrimination on the basis of their religious beliefs. For example, to be in compliance with the existing federal and Massachusetts laws, BMC has a policy, as do many other hospitals, that establishes a procedure to excuse an employee from participating in a patient's care or treatment when the prescribed care or treatment conflicts with the employee's values, ethics, or religious beliefs. The existing protections are meaningful and familiar to health care providers who have navigated these personal obligations alongside their commitment to providing seamless, respectful health care to patients. There is no need to augment the existing protections. Third, HHS' proposed regulation creates a complex, burdensome notice and reporting process for organizations and hospitals that is not only unnecessary and threatens to undermine the continuity of patient care, but also results in significant additional costs at a time when we as a society are trying to bring down the cost of health care in the United States. Finally, the proposed rule does not address what should happen in emergency departments or emergent care situations in which a patient's life is in danger. There are specific requirements under the federal Emergency Medical and Labor Treatment Act (EMTALA) that prohibit hospitals with emergency departments from refusing to treat people based on their insurance status or ability to pay. EMTALA requires hospitals to provide "an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available in emergency departments, to determine whether or not an emergency medical condition exists." (42 C.F.R. 489.24(a)(1)(i)). The proposed rule is silent on how EMTALA's requirements can be reconciled with its catch-all provision. **For these reasons and as further explained below, we urge the Department to withdraw the proposed rule.**

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1. **The proposed rule attempts to inappropriately broaden religious exemptions in a way that would deny patients medically necessary care and could lead to discrimination against entire patient groups.**

Hospitals and health care organizations are in the business of providing health care services and information to patients and communities. The broad and undefined nature of the proposed rule gives individual providers' beliefs priority over life-saving patient care and threatens to prevent the provision of services to patients in need. The lack of definition, structure, and guidelines will leave health care providers without standards and structures to guide the provision of necessary care to the most vulnerable populations, including LGBTQ people.

The broad scope of the proposed rule's catch-all provision and the health care workers it applies to will make it possible for some providers to deny certain treatments or to decline to see certain patients. The proposed rule contemplates extending the interpretation of existing statutory exemptions, for procedures such as abortion and sterilization, far beyond the current standards. Forty-five states, including Massachusetts, have state laws that protect health care providers who object to participating in abortion procedures and several states also include protections for providers who do not want to participate in sterilization procedures.[1] Massachusetts General Law Ch. 112 §12I provides a protocol through which a health care provider shall not be discriminated against for not participating in a patient's care or treatment related to abortion and sterilization. These type of state laws and the existing federal laws (Church Amendment, Coats-Snowe Amendment and the Weldon Amendment) already provide health care provider protection. Hospital policies throughout the country should reflect compliance with their state and federal laws. For example, BMC has a policy that delineates a protocol so that an employee "shall not be required to participate in tubal ligations, vasectomies, abortions, or any other procedures that conflict with his/her ethical principles unless the patient's life is in immediate danger." The BMC policy is tailored to address specific procedures that may be contrary to a provider's religious beliefs or ethical principles, it also makes a reference to "any other procedure" that may conflict with a provider's ethical principle and outlines a specific method (in writing) by which a provider can request to be relieved from certain patient care duties, while taking patient safety into consideration. The existing protections are sound and protect the religious beliefs and moral convictions of BMC's health care providers, as well as ensure that necessary patient care is provided.

[1] "*Refusing to Provide Health Services*" Published on *Guttmacher Institute* (https://www.guttmacher.org.) March 1, 2018. See https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services

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Roger Sevirino, Director of HHS' Office of Civil Rights stated in an interview that "The way these conscience claims work is that providers do not deny service to patients because of identities. What happens is providers choose not to provide or engage in certain procedures at all."[2] The problem with this approach is that the scope of what procedures are covered by the proposed rule are not clear. The proposed rule certainly emphasizes abortion, sterilization and assisted suicide, but Section 88.3 (a)(2)(v) is a catch-all provision that essentially empowers any physician or other health care personnel "to refuse to perform or assist in the performance of such service or activity on the grounds that doing so would be contrary to his or her religious beliefs or moral convictions, or because of his or her religious beliefs or moral convictions."

Under HHS' proposed rule a provider could be seen as empowered to refuse to provide **any** health care service or information for a religious or moral reason – extending beyond abortion and sterilization procedures, to other types of procedures in general and other areas of health care services, such as the provision of Pre-Exposure Prophylaxis (PrEP), infertility care, hormone therapy and other non-surgical gender transition-related services, and possibly even HIV treatment under the auspices of "any" service. The language of the proposed rule extends beyond specific procedures to health care services in general. This is problematic because, as drafted, the catch-all provision could also be viewed as protecting a health care provider who refuses to treat a transgender person for a condition that is completely unrelated to a gender transition procedure, such as providing treatment for a broken leg, cancer care, the flu or appendicitis, if the health care provider asserts that caring for a transgender person is contrary to his/her moral conviction. The language of this proposed rule potentially authorizes discrimination by health care providers towards an entire patient group regardless of the procedure, treatment or service that is needed.

2. **The proposed rule conflicts with Title VII and fails to inform hospitals of the boundaries of the rule when the exemption may cause an undue hardship on the hospital.**

Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e) already requires employers to reasonably accommodate the sincerely-held religious beliefs, observances, and practices of its applicants and employees, when requested, unless the accommodation would impose an undue hardship on business operations, which is defined as more than a *de minimis* cost. The proposed regulation fails to mention Title VII and the balancing of employee rights and provider hardships. BMC and other hospitals and health organizations are at a loss as to how to reconcile the proposed rule and Title VII given the dearth of litigation on the subject and the lack of explanation in the proposed rule.

[2] *"New Trump Initiatives: A win for anti-abortion activists, protections for "conscience" objections"* By Jessica Ravitz, CNN, January 19, 2018.

The Equal Employment Opportunity Commission (EEOC) addressed this problematic intersection in its public comment in response to the 2008 Federal Health Care Conscience Rule that had the substantively identical legal problem, noting that: "Introducing another standard under the Provider Conscience Regulation for some workplace discrimination and accommodation complaints would disrupt this judicially-approved balance and raise challenging questions about the proper scope of workplace accommodation for religious, moral or ethical beliefs." In this public comment the EEOC concluded that, "Title VII should continue to provide the legal standards for deciding all workplace religious accommodation complaints. HHS's mandate to protect the conscience rights of health care professionals could be met through coordination between EEOC and HHS's Office for Civil Rights, which have had a process for coordinating religious discrimination complaints under Title VII for over 25 years." On this point, Boston Medical Center agrees with the EEOC.

3. The proposed rule creates additional and unnecessary cost for hospitals.

The proposed rule requires each hospital to make routine assurances, certifications and employee and public notifications related to compliance with its requirements. The Proposed Rule's Notice Requirement, § 88.5, requires that notices concerning the Federal Health Care Conscience and Associated Anti-Discrimination Protections be placed on hospital websites, posted in prominent and conspicuous physical locations in every department where notices to the public and notices to their workforce are customarily posted. This section also makes reference to including the notification in personnel manuals, employment applications and student handbooks. The costs associated with these requirements are unnecessary because most hospitals, including BMC, already have policies and references in employee manuals that respect religious freedoms and offer relief to employees from patient care duties that conflict with an individual's religious beliefs or ethical principles.

Furthermore, according to the proposed rule's preamble (Table 4: Summary of Costs) the estimated financial burden for the proposed rule will be $312.3 million in the first year and $125.5 million, annual recurring costs, during years two to five. The total estimated burden for compliance with this proposed rule, over its first five years, is $814.3 million dollars; over three-quarters of a billion dollars. This is an exorbitant amount of money for the facilities within the health care industry to spend at a time when there are calls to action and efforts being made to bring down the cost of health care throughout the United States. The return on investment will not justify the estimated burden, especially since there are already protections in place at the federal and state level related to conscience objections to participating in procedures such as abortion, sterilization and assisted suicide.

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4. The proposed rule lacks safeguards to ensure patients would receive emergency care as required by federal law and ethical standards.

The proposed rule is dangerously silent in regards to ensuring patient wellbeing. The lack of consideration of patients' rights is evidenced by the fact that the proposed rule contains no provision to ensure that patients receive legally available, medically warranted treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs remain paramount, and that they are able to receive both accurate information and quality health services.

The proposed rule also fails to address potential conflicts with emergency care requirements. Under the Emergency Medical Treatment and Active Labor Act (EMTALA) (42 U.S.C. § 1395dd), a hospital receiving government funds and providing emergency services is required to provide medical screening and stabilizing treatment to a patient who has an emergency medical condition (including severe pain or labor) (42 U.S.C. § 1395dd(a) and (b)). However, the proposed regulation contains a blanket right of refusal for physicians, with no discussion of their duties under EMTALA or how conflicts should be resolved. In fact, the proposed rule's preamble specifically identifies as problematic the 2016 American Congress of Obstetricians and Gynecologists reaffirmation of its ethics opinion that providers have an obligation to provide care regardless of the provider's personal moral objections if a referral is not possible or would negatively impact the patient's health. This reaffirmation is a tenet of providing necessary care for all who are in need. The requirements of EMTALA must be reconciled with the elements of the proposed rule, since EMTALA contains significant civil penalties (up to $50,000 for each violation) to prevent hospitals and physicians from disregarding their duties in treating all patients in similar manner (42 U.S.C. § 1395dd(d)(1)).

Conclusion

BMC is committed to providing exceptional care, without exception to everyone in our community. Hospitals and health systems exist to treat patients and provide them with access to the information they need for treatment. Entities that serve patients must be committed to respecting both the values of health care workers and the patients and the communities they serve in a way that allows for the delivery of care. BMC respects the dignity and rights of its diverse employees and patients. Our vision is to meet the health needs of the people of Boston and beyond by providing high quality comprehensive care to all, particularly mindful of the needs of vulnerable populations. HHS's proposed rule would stymie our ability to do this. The sweeping catch-all provision and the undefined boundaries of this proposed rule will have a chilling effect on the provision of life saving and medically necessary health care, result in significant unnecessary costs and contradict existing federal and state laws. BMC strongly urges the Department to withdraw the proposed rule. Alternatively, the rule should be re-proposed and (1) narrowed in scope to, at a minimum, remove the broad and vague catch-all language found in §88.3, (2) be drafted in a way that it does not contradict or is silent towards existing federal

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laws, such as Title VII and EMTALA and (3) should not include an expensive and burdensome notification and certification protocol.

If you would like additional information, please contact Melissa Shannon, Vice-President of Government Affairs at (617) 638-6732 or melissa.shannon@bmc.org or Wendoly Ortiz Langlois, Associate General Counsel at (617) 638-7901 or wendoly.langlois@bmc.org.

Sincerely,

Kate Walsh

Kate Walsh
President and Chief Executive Officer
Boston Medical Center

Exhibit 38

XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

1300 I STREET, SUITE 125
P.O. BOX 944255
SACRAMENTO, CA 94244-2550
Public: (916) 445-9555

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

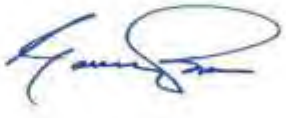
receipt of federal funds. *Clinton*, 524 U.S. at 439. HHS's attempt to broaden those statutes is thus a violation of the Separation of Powers.

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 39

STATE OF CALIFORNIA
DEPARTMENT OF INSURANCE
EXECUTIVE OFFICE
300 CAPITOL MALL, SUITE 1700
SACRAMENTO, CA 95814
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www.insurance.ca.gov

Dave Jones, Insurance Commissioner

Submitted via www.regulations.gov

March 27, 2018

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

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

Dear Secretary Azar:

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

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

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

Impacts of the Proposed Rule

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

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

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

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

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

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

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

The Rule Exceeds Legal Authority

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

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

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

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

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

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

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

Weldon Amendment Overreach

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

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

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

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

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

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

Adverse Impact on Consumers

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

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

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

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

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

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

The Rule Imposes a Substantial Regulatory Burden

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

[3] James, S.E., Herman, J.L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016) *The Report of the 2015 U.S. Transgender Survey*, National Center for Transgender Equality, p.10
[4] Office of Disease Prevention and Health Promotion (ODPHP), Healthy People 2020, *Lesbian, Gay, Bisexual, and Transgender Health*, retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health

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

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

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

Sincerely,

Dave Jones

DAVE JONES
Insurance Commissioner

[5] 72 Fed. Reg. at 9971

Exhibit 40

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, S.W.
Washington, D.C. 20201

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

To whom it may concern:

I am writing on behalf of the California LGBT Health and Human Services Network in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. The California LGBT Health and Human Services Network is a statewide coalition of over 60 non-profit providers, community centers, and researchers working collectively to advocate for state level policies and resources that will advance LGBT health. We strive to provide coordinated leadership about lesbian, gay, bisexual, transgender, and queer (LGBTQ) health policy in a proactive, responsive manner that promotes health and wellness as part of the movement for LGBT equality.

The proposed rule goes far beyond the scope of the underlying statutes, and strays from the original purpose of the Office of Civil Rights (OCR). OCR was created to uphold the principle that all people in the United States have a right to receive health care in a nondiscriminatory manner. OCR has always been an office focused on protecting the rights of consumers and increasing access to health care. The proposed rule would stray from this core tenet of OCR, and instead restrict consumers access to nondiscriminatory health care.

The enforcement actions outlined against recipients of federal funds and subrecipients alike will have the likely impact of encouraging discrimination by health care entities. This new proposal from HHS encourages health care providers to abandon the principle of "first, do no harm" in favor of their personal beliefs. This puts transgender patients, people who need reproductive health care, and many others at risk of being denied necessary and even life-saving

care. The proposed enforcement measures are likely illegal and will result in great costs the health care industry, and to individual patients.

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need.[1] In the past year, out of respondents to the 2015 U.S. Transgender Survey who saw a health care provider, one-third were denied treatment, turned away, or mistreated.[2] Accessing quality, culturally competent care and overcoming outright discrimination is even a greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder and for some people nearly impossible. By expanding the definition of a health care entity, this rule will likely make it more difficult for patients and consumers to access comprehensive and affirming sexual health care.

The proposed rule is in conflict with existing state and local nondiscrimination protections. Even in California, where we have taken proactive steps to increase accessing to affirming health care – that is available in a patient's spoken language, is developmentally appropriate, and culturally responsive – many LGBTQ people still struggle to find supportive and knowledgeable providers. And yet, this proposed rule would have us go backwards. The proposed rule tramples on California's efforts to protect patients' health and safety, including through the California Insurance Gender Nondiscrimination Act, and other rules that have made it clear that all people the right to access coverage for medically necessary care regardless of their gender identity or gender expression.[3] By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. It therefore is disingenuous for the Department to claim that the proposed rule "does not impose substantial direct effects on States," "does not alter or have any substantial

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[1] *See, e.g.*, Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), www.ustranssurvey.org/report; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[2] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality.

[3] *See, e.g.*, California Department of Managed Health Care, *Letter No. 12-K: Gender Nondiscrimination Requirements* (April 9, 2013), http://translaw.wpengine.com/wp-content/uploads/2013/04/DMHC-Director-Letter-re-Gender-NonDiscrimination-Requirements.pdf.

direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.

The proposed rule goes far beyond established law, appears to have been developed in a rushed and arbitrary manner, and most importantly will put the health and potentially even the lives of patients at risk. We urge you to withdraw the proposed rule.

Sincerely,

Amanda Wallner

Director, California LGBT Health and Human Services Network