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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	NO. 2:19-cv-00183-SAB DECLARATION OF PAUL CRISALLI IN SUPPORT OF STATE OF WASHINGTON'S MOTION FOR PRELIMINARY INJUNCTION NOTED FOR: July 17, 2019 With Oral Argument at 1:30 p.m.

I, Paul Crisalli, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I am over the age of 18 and have personal knowledge of all the facts stated herein.

2. I am an Assistant Attorney General with the Washington State Attorney General's Office and counsel of record for the State of Washington in this matter.

3. Attached hereto as Exhibit A is a true and correct copy of comments from Attorneys General of New York, *et al.* Obtained from: https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70188.

4. Attached hereto as Exhibit B is a true and correct copy of comments from California Dep't of Justice. Obtained from: https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70182.

5. Attached hereto as Exhibit C is a true and correct copy of N.Y. City Comm'n on Human Rights, *et al.* Obtained from: https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71028.

6. Attached hereto as Exhibit D is a true and correct copy of comments from Am. Acad. of Pediatrics. Obtained from: https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71022.

7. Attached hereto as Exhibit E is a true and correct copy of comments from Am. Coll. Of Obstetricians & Gynecologists. Obtained from: https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70647.

8. Attached hereto as Exhibit F is a true and correct copy of comments from Inst. for Policy Integrity. Obtained from: https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72071.

DATED this 24th day of June, 2019, at Seattle, WA.

PAUL CRISALLI
Assistant Attorney General

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DECLARATION OF SERVICE

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

DATED this 24th day of June, 2019, at Seattle, Washington.

s/ Paul Crisalli
PAUL CRISALLI, WSBA #40681
Assistant Attorney General

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Exhibit A

ATTORNEYS GENERAL OF NEW YORK, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, NEW JERSEY, NEW MEXICO, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, VIRGINIA, WASHINGTON

March 27, 2018

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

Re: Proposed Rule: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority [Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03]

The undersigned State Attorneys General submit these comments to urge the Department of Health and Human Services ("HHS") to withdraw the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the "Proposed Rule").[1] HHS has proposed to codify a sweeping and overbroad right that would allow individuals and entire institutions to deny lawful and medically necessary care to patients for "religious, moral, ethical, or other reasons." This Proposed Rule is unsupported by the federal health care conscience laws it purports to implement; conflicts with federal statutes regarding emergency health care, religious accommodations, and comprehensive family planning services; undermines the States' health care policies and laws; would lead to status-based discrimination against patients; and would violate both the Spending Clause and the Establishment Clause of the United States Constitution. The Proposed Rule impermissibly seeks to coerce state compliance with its unlawful requirements by threatening to terminate billions of dollars in federal health care funding if at any point HHS determines that a state has failed—or even "threatened" to fail—to comply with the Proposed Rule's extensive mandates.

If adopted, the Proposed Rule would effectuate a substantial change in the delivery of health care, and it would do so at the expense of not only employers and states, but also of patients whose access to medically necessary care would be seriously threatened by the Proposed Rule. At a time when many Americans are struggling to obtain affordable health care, the Proposed Rule would reduce access to health care by allowing a vast new set of individuals and institutions to opt out of providing that care. It would also unnecessarily decrease the information patients receive about their health care options, undermining their ability to choose the best options for their own health care. It would impose particularly onerous burdens on marginalized patients who already

[1] 83 Fed. Reg. 3880 (Jan. 26, 2018).

confront discrimination in obtaining health care. It would do so needlessly because existing federal and state laws already provide a time-tested, established framework that balances respect for religious freedom with the rights and needs of patients, employers, and states.

The Proposed Rule prioritizes providers over patients. If implemented, the Proposed Rule will enable health care workers to refuse to provide life-saving care without notice to their employers—and to the detriment of patients—and impose massive burdens on both private and public institutions. As officials of States entrusted with the power to protect the health, safety, and welfare of the public, we urge that the Proposed Rule be withdrawn.

I. Background

The Proposed Rule purports to implement a litany of federal statutes concerning conscience objections in health care.[2] Several of these statutes concern behavior by state governments. Generally speaking, the statutes concerning state behavior relate to the procedures of: abortion and sterilization; assisted suicide, euthanasia, and mercy killing; and counseling and referral. [3]

(A) Three Long-standing Statutes Concern Objections to Abortion and Sterilization.

The Church Amendments, originally passed in the 1970s and now codified at 42 U.S.C. § 300a-7, provide in relevant part that:

1. the receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act does not obligate any individual "to perform or assist in the performance of any sterilization procedure or abortion" if doing so would be contrary to the individual's religious beliefs or moral convictions;
2. entities that receive a grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act cannot discriminate against physicians or health personnel because they assisted in a sterilization procedure or abortion, because they refused to participate in a sterilization procedure or abortion on the grounds of religious beliefs or moral

[2] 83 Fed. Reg. at 3881-86.

[3] Additional statutes that may apply to states that are not discussed in this section include: 29 U.S.C. § 669(a)(5)-1 (concerning occupational illness examinations and tests); 42 U.S.C. §§ 290bb-36(f), 5106i (concerning medical service or treatment, including suicide assessment, early intervention, and treatment services, for youth whose parents or guardians object based on religious beliefs or, in certain cases, moral objections); 42 U.S.C. §§ 1320a-1, 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), 1397j-1(b), 5106ia(2)-1 (concerning certain exemptions from law and standards for religious nonmedical health care institutions and "an elder's right to practice his or her religion through reliance on prayer alone for healing" in certain cases); and 42 U.S.C. § 1396s(c)(2)(B)(ii) (concerning pediatric vaccination).

convictions, or because of their religious beliefs or moral convictions regarding sterilization or abortion;

3. entities that receive a grant or contract for biomedical or behavioral research cannot discriminate against physicians or health personnel because they assisted in any lawful health service or research activity, because they refused to do so on the grounds of religious beliefs or moral convictions, or because of their religious beliefs or moral convictions regarding the service or activity;
4. HHS's funding of a health service program or research activity does not obligate any individual to "perform or assist in the performance of" any part of that health service program or research activity if contrary to the individual's religious beliefs or convictions; and
5. entities that receive a grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 cannot discriminate against applicants for training or study based on "the applicant's reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions."

The Coats-Snowe Amendment, passed in 1996 and codified at 42 U.S.C. § 238n, prohibits state governments that receive federal funds, among others, from discriminating against:

1. any health care entity that refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions;
2. any health care entity that refuses to make arrangements for any of the activities specified in paragraph (1); or
3. any health care entity that attends (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

The Weldon Amendment, an appropriations rider first passed in 2004 and that has been attached to the Labor, Health and Human Services, Education, and Related Agencies Appropriations Act every year since, states in relevant part that none of the funds appropriated in the Act may be made available to any state government if it discriminates against any "institutional or individual health care entity" because it "does not provide, pay for, provide coverage of, or refer for abortions."[4]

[4] The citation for the 2017 appropriations bill's Weldon Amendment is Consolidated Appropriations Act of 2017, Public Law 115-31, 131 Stat. 135, 562.

(B) Two Statutes Concern Objections to Assisted Suicide, Euthanasia, and Mercy Killing.

Section 1553 of the Affordable Care Act, codified at 42 U.S.C. § 18113, proscribes state governments that receive federal funding under the Affordable Care Act from discriminating against an "individual or institutional health care entity on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing."[5]

A statutory provision applying to state-administered Medicaid programs, 42 U.S.C. § 14406, clarifies that the advanced directives requirements applicable to those programs, codified at 42 U.S.C. § 1396a(w), do not require a provider, organization, or employee of a provider or organization "to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing or to apply to or to affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing."

(C) A Medicaid Managed Care Organization Statute Concerns Objections to Counseling or Referral.

A statutory provision related to state-administered Medicaid programs, 42 U.S.C. § 1396u-2(b)(3)(B), explains that a Medicaid managed care organization is not required "to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds" and "makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service."

II. The Proposed Rule Exceeds HHS's Authority under the Referenced Statutes by Adopting Excessively Broad Definitions of Statutory Text.

The Proposed Rule states that "the statutory provisions and the regulatory provisions contained in [the Proposed Rule] are to be interpreted and implemented broadly to effectuate their protective purposes."[6] In HHS's attempt to broaden what it views as the referenced statutes' purposes, however, it has ventured far beyond the text of those statutes and the bounds of the statutory authority Congress delegated to it. HHS has done this by proposing excessively broad definitions of statutory terms, at least one of which is already more narrowly defined by the statutes themselves.

[5] 42 U.S.C. § 18113(a).

[6] 83 Fed. Reg. at 3923.

(A) The Proposed Rule's Definition of "Assist in the Performance" Is Excessively Broad.

The Proposed Rule aims to enforce "[f]ederal health care conscience and associated anti-discrimination laws," which allow certain individuals and entities to "refuse to perform, assist in the performance of, or undergo" health care services or research "to which they may object for religious, moral, ethical, or other reasons."[7] In implementing this aim, the Proposed Rule adopts a definition of **"assist in the performance"** that is untethered from and unsupported by the statutory text. HHS proposes that this common-sense phrase actually "means to participate in any program or activity with an *articulable connection* to a procedure, health service, health program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes but is not limited to counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity."[8]

The Proposed Rule's overly broad definition of "assist in the performance"—which requires only an "articulable connection" to a procedure, health service, health program, or research activity—is intended to capture acts with only a remote connection to a given medical procedure. Indeed, it expressly includes "counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity." This strained definition is much broader than that contemplated by Congress, as evidenced by the text of the statutes the Proposed Rule purports to implement. Indeed, the statutory text when read as a whole demonstrates that Congress made clear textual distinctions when discussing the performance of a medical procedure and other services, such as counseling. This Proposed Rule blurs that Congressionally-adopted distinction. For example, the first four subsections of the Church Amendments refer to the performance or assistance in the performance of a particular activity or activities.[9] The fifth and last, however, applies to "reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations…."[10] When Congress intended to include activities such as counseling in its mandates, it did so. Likewise, the Coats-Snowe Amendment extends to those who refuse "to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions," among others, indicating that Congress again knew how to—and did—include training and referrals in its mandates when it desired to do so.[11] The Weldon Amendment is yet another example of how Congress's drafting decisions reflect its intent, as the Amendment reaches entities that do not "provide, pay for, provide coverage of, or refer for abortions."[12] Congress mentions "referral" separate and apart from "assistance in the

[7] 83 Fed. Reg. at 3923.

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

[9] 42 U.S.C. §§ 300a-7(b)-(d).

[10] 42 U.S.C. § 300a-7(e).

[11] 42 U.S.C. § 238n(a)(1); *see also* 42 U.S.C. § 238n.

[12] Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 562.

performance" in at least five other statutory provisions that the Proposed Rule claims to implement and to which HHS seeks to apply this definition.[13] Such an application to these statutes would make the statutory text superfluous and flout the authority delegated to HHS by Congress.

(B) The Proposed Rule's Definition of "Health Care Entity" Is Excessively Broad.

The Proposed Rule would apply the protections of the referenced statutes not only to individual health care professionals, but also to other "health care entities" on the basis of their "religious, moral, ethical, or other" objections.[14] The Proposed Rule's definition of **"health care entity"** extends far broader than the statutory text it professes to interpret, including "health care personnel" beyond health care professionals like doctors and nurses, laboratories, and health plan sponsors, issuers, and third-party administrators. The Coats-Snowe Amendment, the Weldon Amendment, and the Affordable Care Act each define "health care entity," and none of the statutory definitions is as broad as the one contemplated by the Proposed Rule.[15]

None of the statutory definitions, for example, include "health care personnel" as a category distinct from "an individual physician or other health care professional." Including "health care personnel" in conjunction with the broad definition of "assist in the performance" could force an employer to plan its employee schedules around not only doctors and nurses who may be asked to perform or assist in the performance of a procedure, but also around a receptionist who may otherwise have to schedule an appointment for that procedure. This would not only impose significant burdens on employers, but it would also write out of the statutory texts altogether those specific activities and procedures to which the statutes apply. The definition of "health care professional," on the other hand, is already appropriately defined under at least two of the statutes referenced by the Proposed Rule.[16]

Moreover, none of the statutory definitions include "a laboratory" or "a plan sponsor, issuer, or third-party administrator." The addition of laboratories is unrelated to the procedures targeted by any of the referenced statutes, and their inclusion could lead to the refusal of all manner of routine testing, including pregnancy testing, because of an "articulable connection" to an objected-to procedure. Most importantly, the addition of plan sponsors (typically employers), plan issuers (such as insurance companies), and third-party administrators (which perform claims processing and administrative tasks as opposed to actual health care services), enlarges the number of entities affected by the Proposed Rule in ways that are unnecessary, not contemplated by the

[13] 22 U.S.C. § 7631(d)(1)(B) (President's Emergency Program for AIDS Relief); 42 U.S.C. § 1395w-22(j)(3)(B) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization); 42 U.S.C. § 18023(b)(4) (Affordable Care Act); 42 U.S.C. § 18023(c)(2)(A)(i)-(iii) (Affordable Care Act); Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 539 (Medicare Advantage).

[14] 83 Fed. Reg. at 3923.

[15] 42 U.S.C. § 238n(c)(2) (Coats-Snowe); 42 U.S.C. § 18113(b) (Affordable Care Act); Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 562 (Weldon Amendment).

[16] 42 U.S.C. § 1395w-22(j)(3)(D) (Medicare+Choice) (including physicians, specialists, physician assistants, nurses, and social workers, among others); 42 U.S.C. § 1396u-2(b)(3)(C) (Medicaid managed care organization) (same).

statutes, and not sensible. These new categories of "health care entit[ies]," particularly when combined with the excessively broad definition of "assist in the performance," could lead to objections by human resources analysts, customer service representatives, data entry clerks, and numerous others who believe that analyzing benefits, answering a benefits-related question, or entering a pre-authorization for an objected-to procedure, for example, is assisting in the performance of that procedure. It is difficult to estimate the immense scope of administrative difficulty that this definition could cause at facilities nationwide, and the Proposed Rule offers no reasonable explanation for these new categories of "health care entit[ies]." In fact, there is no judicious interpretation of "health care entity" that includes every employer who offers a health care plan because 49% of Americans have employer-provided health insurance.[17] This definition applied to the Weldon Amendment could also prohibit a state government from requiring an employer to provide insurance coverage for lawful abortions.

(C) The Proposed Rule's Definition of "Referral or Refer For" Is Excessively Broad.

Finally, several of the federal health care conscience statutes prohibit discrimination against health care providers who elect not to provide "referrals" or "refer for" objected-to procedures. The Proposed Rule defines **"referral or refer for"** in an unjustified and unreasonable manner, allowing a health care provider to refuse to provide "any information" by "any method" that could provide "any assistance" to an individual when obtaining an objected-to procedure is a "possible outcome" of the information.[18] Based on this definition, a health care professional would not be required to refer a woman to Planned Parenthood for prenatal care—even if it were the only option she could afford—because abortion is a "possible outcome of the referral." Likewise, a health care professional would not be required to refer a woman for the treatment of an extensive ovarian or other reproductive system cancer because sterilization is a "possible outcome of the referral." The Proposed Rule's expansive definition would serve to drastically decrease access to information about health care services and access to those services themselves and to undermine the States' interest in ensuring access to health care to their citizens.

III. The Proposed Rule is Contrary to Federal Law—Resulting in Harm to Patients.

(A) The Proposed Rule Conflicts with the Emergency Medical Treatment and Labor Act (EMTALA).

While the Proposed Rule asserts the primacy of provider conscience, it contains no protections to ensure that patients have adequate access to necessary health care in emergencies. In fact, the Proposed Rule does not reference the treatment of patients in emergency situations at all. This places the Proposed Rule in direct conflict with the Emergency Medical Treatment and

[17] *Health Insurance Coverage of the Total Population (2016),* Kaiser Family Foundation, https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Mar. 12, 2018).

[18] 83 Fed. Reg. at 3924.

Labor Act ("EMTALA"),[19] a federal law requiring hospitals to provide for emergency care. The absence of an explicit recognition of the EMTALA requirements in the Proposed Rule could jeopardize patient lives. EMTALA defines the term "emergency medical condition" to include:

> a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy….[20]

Yet, under the Proposed Rule, a woman suffering an ectopic pregnancy, for example, could be turned away from her nearest provider and forced to locate a doctor willing and available to provide her with an appropriate treatment before it is too late. The Proposed Rule's impact on access to emergency care would likely be particularly dangerous in the rural areas of the States where an alternative provider may be difficult—or even impossible—to find in the necessary timeframe.

This reduction in access to emergency care is not supported by the statutes upon which the Proposed Rule purports to be based. Indeed, Representative Weldon stated shortly after his Amendment's passage that the law was not intended to reach emergency abortions and that EMTALA requires critical-care health facilities to provide appropriate treatment to women in need of emergency abortions, the Weldon Amendment notwithstanding. Representative Weldon explained:

> The Hyde-Weldon amendment is simple. It prevents Federal funding when courts and other government agencies force or require physicians, clinics and hospitals and health insurers to participate in *elective* abortions. …It simply prohibits coercion *in nonlife-threatening situations*. …It ensures that in situations where a mother's life is in danger a health care provider must act to protect the mother's life. In fact, Congress passed the Federal Emergency Medical Treatment and Active Labor Act (EMTALA) forbidding critical-care health facilities to abandon patients in medical emergencies, and requires them to provide treatment to stabilize the medical condition of such patients—particularly pregnant women.[21]

Moreover, at least one of the statutes referenced in the Proposed Rule is clear that it shall not be "construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1395dd of this title (popularly known as "EMTALA")."[22]

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[19] 42 U.S.C. § 1395dd.

[20] 42 U.S.C. § 1395dd(e)(1)(A).

[21] 151 Cong. Rec. H176-77 (Jan. 25, 2005) (statement of Rep. Weldon) (emphases added).

[22] 42 U.S.C. § 18023(d).

Any proper rule implementing this statute, as well as the others referenced, must explicitly ensure that patients receive emergency medical treatment.

(B) The Proposed Rule Conflicts with the Affordable Care Act.

The Affordable Care Act prohibits the Secretary of Health and Human Services from promulgating any regulation that:

1. creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
2. impedes timely access to health care services;
3. interferes with communications regarding a full range of treatment options between the patient and the provider;
4. restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
5. violates the principles of informed consent and the ethical standards of health care professionals; or
6. limits the availability of health care treatment for the full duration of a patient's medical needs.[23]

The Proposed Rule violates nearly every one of these proscriptions. First, by not clarifying that emergency medical care is mandatory under federal law, the Proposed Rule creates unreasonable barriers to timely access to appropriate medical care. Second, by disavowing principles of informed consent in its broad definitions of "assist in the performance" and "referral or refer for," the Proposed Rule interferes with "communications regarding a full range of treatment options between the patient and the provider," "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," and "violates the principles of informed consent and the ethical standards of health care professionals."[24] The Proposed Rule's violation of these federal protections is unlawful. It is also unnecessary given that the States already have systems in place to protect religious freedom while ensuring access to health care and compliance with federal law.[25]

(C) The Proposed Rule Does Not Properly Account for the Costs It Seeks to Impose on Patients.

The Proposed Rule also fails to comply with the requirement that federal agencies accurately assess the costs and benefits of their proposed regulations whenever possible.[26] HHS

[23] 42 U.S.C. § 18114.

[24] *Id.*

[25] *See infra* Section V.

[26] The Proposed Rule states that "The Department has examined the impacts of the proposed rule as required under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 13771 on Reducing Regulation

estimates that the first year of this rule would cost the economy, mostly in the already highly-regulated health care industry, $312.3 million, and years two through five would cost the economy $125.5 million annually. This estimate fails to include or account for, in any measure, the potentially substantial monetary costs of the health consequences resulting from the denials of care that would inevitably follow the Proposed Rule's unlawful expansion of the referenced statutes. At least some of these costs would likely be borne by states. For example, for each pregnant teen who is not referred to affordable prenatal care for fear that abortion is a "possible outcome of the referral," the subsequent health care for that teen and her child (if carried to term) could cost a state Medicaid program $2,369 to $3,242, depending on when the care was ultimately initiated.[27]

Moreover, as "Non-quantified Costs" of the Proposed Rule, HHS lists only vaguely and briefly: "Any ancillary costs resulting from a protection of conscience rights,"[28] while ignoring the impact on patient care. It does not list the loss of health or human dignity caused when a health care professional denies care to someone facing an emergency medical issue or with some other medical need. It does not list the emotional and other harm inherent in going forward with a medical procedure and later discovering that a better option was available—an option that a health care professional decided not to disclose at the time of treatment. It does not list the loss of the Constitutional right to abortion that will occur when women are denied information about termination of pregnancy before the procedure can no longer be lawfully performed.[29]

IV. The Proposed Rule is Contrary to Federal Law and Unconstitutional—Resulting in Harm to Employers.

(A) The Proposed Rule Conflicts with Title VII of the Civil Rights Act of 1964.

The Proposed Rule defines "discriminate or discrimination" without explaining how it interacts with existing laws protecting employees from discrimination on the basis of religion. For example, Title VII of the Civil Rights Act of 1964 ("Title VII") prohibits discrimination in employment on the basis of religious beliefs.[30] Its protection also extends to "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional

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and Controlling Regulatory Costs (January 30, 2017), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354, 5 U.S.C. 601-612), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-04), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), the Assessment of Federal Regulation and Policies on Families (Pub. L. 105-277, section 654, 5 U.S.C. 601 (note)), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520)." 83 Fed. Reg. at 3901-02.

[27] William J. Hueston, et al., *How Much Money Can Early Prenatal Care for Teen Pregnancies Save?: A Cost-Benefit Analysis*, 21 J. Am. Bd. Family Med. 184 (2008). Women who are denied abortions based on existing legal restrictions are also more likely to receive public assistance than women who obtain abortions—both shortly after the denial and for years afterward. *See* Diana Greene Foster, et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407 (2018).

[28] Table 1—Accounting Table of Benefits and Costs of All Proposed Changes, 83 Fed. Reg. at 3902.

[29] *See An Overview of Abortion Laws*, Guttmacher Inst. (last updated Mar. 20, 2018), https://www.guttmacher.org/state-policy/explore/overview-abortion-laws (last visited Mar. 26 2018).

[30] 42 U.S.C. § 2000e-2(a).

religious views."[31] Title VII, unlike the Proposed Rule, states that employers are not obligated to accommodate employees' religious beliefs to the extent that such an accommodation would cause "undue hardship" on the employer.[32] This carefully constructed balancing test, which is conducted on a case by case basis, recognizes that employers should not be forced to sacrifice their principal obligations—to their business, their patients, and their other employees—in order to accommodate the religious beliefs of one employee. Moreover, at least one of the statutes referenced in the Proposed Rule is clear that it shall not "alter the rights and obligations of employees and employers under [T]itle VII of the Civil Rights Act of 1964."[33] Any proper rule implementing this statute, as well as the others referenced, must ensure that employers are not faced with undue hardships in accommodating employee beliefs.

By contrast, the Proposed Rule ignores the "undue hardship" test and instead contains a blanket prohibition on "discrimination." This blanket prohibition could be interpreted to prevent the transfer of an employee to another area of a health care entity or a different shift even if the employee's beliefs prevent the employee from performing the essential functions of the initial position. When applied without any reference to employer or patient needs, this broad definition of discrimination could be interpreted to require a health care entity to hire someone who cannot deliver health care services that are critical to the health care entity's mission or risk sanction. For example, even a small women's health clinic could be in violation of the Proposed Rule for refusing to hire a doctor who would not perform, or a receptionist who would not schedule, a tubal ligation. Congress did not intend to so constrain health care providers as to force them to abandon patient care—or their missions and businesses altogether.[34]

(B) The Proposed Rule Conflicts with Title X of the Public Health Service Act of 1970.

Family planning projects funded through Title X are required to counsel pregnant patients about all health care options, including abortion, and provide referrals for those options if requested.[35] The Proposed Rule ignores Title X and, in fact, conflicts with its requirements. Specifically, the Proposed Rule defines discrimination to include the utilization of:

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[31] 29 C.F.R. § 1605.1.

[32] 42 U.S.C. § 2000e(j). The New York State Human Rights Law also requires the accommodation of religious beliefs "unless, after engaging in a bona fide effort, the employer demonstrates that it is unable to reasonably accommodate the employee's or prospective employee's sincerely held religious observance or practice without undue hardship on the conduct of the employer's business." N.Y. Human Rights L. § 296(10).

[33] 42 U.S.C. § 18023(c)(3).

[34] *See* 151 Cong. Rec. H176-77 (Jan. 25, 2005) (statement of Rep. Weldon) ("The amendment does not apply to willing abortion providers. Hyde-Weldon allows any health care entity to participate in abortions in any way they choose.").

[35] *See* Title X, Public Health Service Act of 1970 § 1001, 42 U.S.C. § 300; Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135, 521 (2017) ("all pregnancy counseling shall be nondirective"); 42 C.F.R. § 59.5(a)(5) (requiring that a family planning project offer pregnant women the opportunity to be provided information and counseling regarding prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination). *Id.* (dictating that a family planning project, "[i]f requested to provide such information and counseling, provide

> any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that tends to subject individuals or entities protected under this part to any adverse effect described in this definition….[36]

An "adverse effect" as referenced in this definition includes the denial of grants or contracts or any other benefits or privileges.[37] Thus, a state could be unable to select Title X sub-recipients on the basis of their willingness to counsel about and refer for abortions. Application of the definition of "discriminate or discrimination" without any reference to states' Title X obligations leaves states with a Hobbesian choice: they can either withhold federal family planning dollars from organizations unwilling to provide "non-directive" pregnancy counseling about (and potential referral to) all of the health care options—in direct contravention of the Proposed Rule—or provide such funding—in direct contravention of Title X. Like the Weldon Amendment, Congress passes the non-directive pregnancy counseling requirement applicable to Title X in appropriations measures each year and did so as recently as last year.[38] Congress surely did not intend in 2017 that the non-directive pregnancy counseling requirement be nullified by a new agency interpretation of statutes predating this Congressional action.

(C) The Proposed Rule Violates the Establishment Clause.

The Proposed Rule's failure to consider the needs of patients or employers, including those governed by Title X, in its mandates implies that health care professionals have an unprecedented absolute right to religious accommodation, which is incompatible with the United States Constitution. Indeed, the Proposed Rule does not include any provision for balancing or accounting for a patient's right to care or an employer's commitment to deliver that care. Laws that compel employers to "conform their business practices to the particular religious practices of . . . employees" violate the Establishment Clause.[39] In *Estate of Thornton v. Caldor*, the Supreme Court invalidated a law providing employees with the absolute right not to work on their chosen Sabbath in part because the law unfairly and significantly burdened the employers and fellow employees who did not share the employee's Sabbath. "The First Amendment ... gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities."[40] The Court found the law "unyielding[ly] weight[ed]" the interests of Sabbatarians "over all other interests" and was invalid under the Establishment Clause.[41] To the extent that the Proposed Rule requires businesses to accommodate their employees' religious

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neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.").

[36] 83 Fed. Reg. at 3923-24.

[37] *Id.*

[38] Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135, 521 (2017).

[39] *Estate of Thornton v. Caldor*, 472 U.S. 703, 709 (1995).

[40] *Id*. at 710 (quoting *Otten v. Baltimore & Ohio R.R. Co*., 205 F.2d 58, 61 (1953)).

[41] *Id*.

beliefs at all costs, it is directly analogous to the law successfully challenged in *Caldor* and thus contravenes the First Amendment.

V. The Proposed Rule Undermines State Policies Regarding Health Care and Would Require States to Violate Their Own Laws.

HHS states that while the Proposed Rule "is expected to affect State and local governments, the anticipated effect is not substantial."[42] The States disagree. In order to ensure access to care for their citizens, the States have enacted laws to guarantee emergency and medically necessary care as well as informed consent. State laws also protect the religious freedom of employees while respecting the business necessities of their employers. These important, sometimes competing needs have been carefully balanced in various ways in each of the States. The Proposed Rule upsets these delicate and long-standing balances and ignores the needs of patients and employers.

First, as noted above, the Proposed Rule does not so much as mention the provision of emergency health care, which can require abortions or other procedures to which a health care professional may object. In addition to conflicting with federal law requiring emergency medical care,[43] the Proposed Rule is at odds with state law that requires the provision of emergency medical care.[44] In many states, mandatory emergency care includes the provision of emergency contraception to survivors of sexual assault.[45] In addition to mandating emergency care, several state regulations also prohibit health care professionals from abandoning a patient in medical need without first arranging for the patient's care.[46] The Proposed Rule ignores the requirement of emergency or medically necessary care under federal or state law,[47] seemingly leaving the provision of this care solely to chance.

Second, the Proposed Rule does not allow for state laws that already facilitate the accommodation of religious or moral objections, balancing conscience protection with patients' rights to access care. For example, several states have laws allowing an individual to refuse to

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[42] 83 Fed. Reg. at 3918.

[43] *See supra* Section III.

[44] *E.g.*, N.Y. Pub. Health Law § 2805-b.

[45] *See, e.g.*, MGL c. 111, s. 70E (requiring the provision of information about emergency contraction and emergency contraception to survivors of sexual assault); N.J.S.A. 26:2H-12.6c (same); N.Y. Pub. Health Law § 2805-p (same); Wash. Rev. Code § 70.41.350 (same). *See also* 410 ILCS 70/2.2(b) (similar).

[46] Conn. Gen. Stat. § 19a-580a ("An attending physician or health care provider who is unwilling to comply with the wishes of the patient …, shall, as promptly as practicable, take all reasonable steps to transfer care of the patient to a physician or health care provider who is willing to comply with the wishes of the patient…."); 8 NYCRR § 29.2 (noting unprofessional conduct includes "abandoning or neglecting a patient or client under and in need of immediate professional care, without making arrangements for the continuation of such care…"); Wash. Admin. Code § 246-840-700; Wash. Admin. Code § 246-817-380; Wash. Admin. Code § 246-808-330. *See also* N.J.S.A. 45:14-67.1 (requiring a pharmacy to fill lawful prescriptions without undue delays despite employee objections); Wash. Admin. Code § 246-869-010 (same).

[47] States are required to define medically necessary care for their Medicaid plans. 42 C.F.R. § 438.210(a)(5). The Proposed Rule, however, would undermine the ability of states to use these federally-mandated definitions of medically necessary care to select Medicaid providers.

assist in a non-emergency abortion as long as the individual notifies the employer in advance.[48] This type of state law facilitates accommodations such as "staffing or scheduling practices that respect an exercise of conscience rights under Federal law."[49] The Proposed Rule, however, states that "OCR will regard as presumptively discriminatory any law, regulation, policy, or other such exercise of authority that has as its purpose, or explicit or otherwise clear application, the targeting of religious or conscience-motivated conduct." Thus, HHS would regard these laws, which are targeted at religious or conscience-motivated conduct—but only to accommodate it—as presumptively discriminatory. Given that all federal health care funding could be terminated for any "threatened failure to comply" with the Proposed Rule, states are faced with either having no such laws (or even policies for their own hospital systems), which would threaten efficient health care administration and the provision of care, or losing all federal funding to provide that care.

Third, the Proposed Rule does not acknowledge or recognize the import of patient informed consent, which is protected by the Affordable Care Act and state law. The Proposed Rule does not require that a patient be informed that a health care provider is refusing to counsel them about, or refer them to, certain health care services. States such as New York and Massachusetts mandate informed consent for patients to ensure that patients can make their own informed medical decisions.[50] In other states, the failure to inform patients of possible alternative treatments increases the risk of malpractice liability for the health care providers involved in the patients' care and the health care facility at which the care is performed.[51] The complexity of identifying which members of a large health care team have objections to providing full informed consent—and about which topics—not only risks delay in necessary care, but increases the risk of liability for health care providers and facilities. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which consisted of leading experts in research, law, medicine, and medical ethics, issued a seminal 1982 report on the ethical and legal implications of informed consent that concluded that patients must be provided with "all relevant information regarding their condition and alternative treatments."[52] Other federal laws recognize the importance of informed consent, including two of the statutes that the Proposed Rule professes to implement. These statutes require plans that refuse "to provide, reimburse for, or provide coverage of a counseling or referral service" on the basis of a moral or religious objection to "make[] available information on its policies regarding such service to prospective enrollees before

[48] *See, e.g.*, Conn. Regs. § 19–13–D54(f); 720 ILCS 510/13; MGL c. 112 s. 12I; N.Y. Civ. Rights L. § 79-1. *See also* Wash. Rev. Code § 48.43.065 (protecting right of provider, carrier, or facility to refrain from participating in provision or payment for specific service they find objectionable, but requiring advanced notice); Wash. Rev. Code § 70.47.160 (same); Wash. Admin. Code § 284-43-5020 (requiring carriers to file plan ensuring timely access to services).

[49] 83 Fed. Reg. at 3913.

[50] MGL c. 111, s. 70E; N.Y. Pub. Health L. § 2805-d. *See also* 720 ILCS 510/13 ("If any request for an abortion is denied [because of a conscience objection], the patient shall be promptly notified.")

[51] *See, e.g.*, Wash. Rev. Code § 7.70.050.

[52] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship, Washington, DC: U.S. Government Printing Office, 1982, https://repository.library.georgetown.edu/handle/10822/559354.

or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service."[53] Both laws also provide that they shall not "be construed to affect disclosure requirements under State law."[54] The Proposed Rule seeks not only to write the disclosure requirement out of these two statutes but also to take power from the states that Congress has expressly reserved to them. An agency action that seeks to preempt state laws without the proper Congressionally delegated authority is unlawful.[55]

VI. The Proposed Rule's Funding Termination Scheme Exceeds HHS's Statutory Authority and Is Unconstitutional.

(A) The Proposed Rule Exceeds HHS's Statutory Authority by Threatening to Terminate All Federal Health Care Funding to Recipients for Any "Failure or Threatened Failure" to Comply.

The Proposed Rule seeks to impose new and unnecessary conditions on billions of federal health care dollars that states rely on to ensure access to care for patients. The Proposed Rule emphasizes its intention to terminate a "variety of financing streams" for *any* failure—or *threatened* failure—to comply with any of the statutes referenced, and it does so without so much as defining the term "threatened failure."[56] HHS does provide a non-exclusive list of "examples" of financing streams that it proposes should be dependent on the states' ability to avoid a vague and non-defined "threatened failure" to comply with the Proposed Rule. This list expressly includes reimbursement for health-related activities provided by programs including: Medicaid and the Children's Health Insurance Program; public health and prevention programs; HIV/AIDS and STD prevention and education; substance abuse screening; biomedical and behavioral research at state institutions of higher education; services for older Americans; medical assistance to refugees; and adult protection services to combat elder justice abuse.[57]

HHS states that "Congress has exercised the broad authority afforded to it under the Spending Clause to attach conditions on Federal funds for respect of conscience…."[58] Indeed, the relevant statutes condition funding from specific sources to specific requirements and prohibitions. For example, the first two of the five requirements of the Church Amendments condition only grants, contracts, loans, or loan guarantees under the Public Health Service Act, the Community

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[53] 42 U.S.C. § 1395w-22(j)(3)(B) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization).

[54] 42 U.S.C. § 1395w-22(j)(3)(C) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization).

[55] *See Texas v. United States*, 95 F. Supp. 3d 965, 980-81 (N.D. Tex. 2015) (enjoining a U.S. Department of Labor rule implementing the Family and Medical Leave Act on the ground that compliance with the rule would require the plaintiff states to violate their own state laws and that the rule exceeded the agency's congressionally delegated authority).

[56] 83 Fed. Reg. at 3905, 3931.

[57] 83 Fed. Reg. at 3905.

[58] 83 Fed. Reg. at 3889.

Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act.[59] The third Church Amendment requirement conditions only grants or contracts "for biomedical or behavioral research," the fourth applies to HHS's funding of a particular health service program or research activity, and the fifth conditions funds similar to those conditioned by the first two.[60] Many of the referenced statutes have a similar framework.[61] The Proposed Rule ignores the sources of funds Congress has conditioned upon obedience to each statute, instead threatening to terminate *all* federal health care funding to recipients for *any* failure—or *threatened* failure—to comply with any of the statutes referenced.[62] These sanctions far exceed HHS's statutory authority,[63] and if acted upon, would unjustifiably terminate sources of funding that states rely on to provide critical, and sometimes life-saving, health services to their citizens.

Moreover, the Proposed Rule's funding termination provisions require no administrative process before HHS terminates all federal health care funding for a state or other entity. Under the Proposed Rule, HHS can terminate all federal health care funding solely upon its determination that "there appears to be a failure or threatened failure to comply" with either the referenced statutes or the Proposed Rule itself.[64] It can do so even if only a state's sub-recipient—not the state itself—is accused of wrongdoing.[65] It can also do so while a state or other entity is attempting to resolve the matter informally.[66]

(B) The Proposed Rule Violates the Spending Clause.

As noted in Section VI(A), *supra*, there is no statutory authority for HHS's assertion of a vast new power to terminate broad swaths of federal health care funding that are unrelated to the program funds that Congress has expressly conditioned. If, however, Congress did delegate to HHS the authority to terminate *all* federal health care funding to the states on the basis of a failure or threatened failure to comply with any of the referenced statutes, such an action would violate the Spending Clause.

Congress may use the Spending Clause power to condition grants of federal funds upon the states taking certain actions that Congress could not otherwise require them to take, but this

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[59] 42 U.S.C. §§ 300a-7(b)-(c)(1).

[60] 42 U.S.C. §§ 300a-7(c)(2)-(e).

[61] *E.g.*, 22 U.S.C. § 7631(d) (President's Emergency Program for AIDS Relief); 42 U.S.C. §§ 1395w-22(j)(3)(A)-(B) (Medicare+Choice); 42 U.S.C. §§ 1396u-2(b)(3)(A)-(B) (Medicaid managed care organization); 42 U.S.C. § 18113 (Affordable Care Act).

[62] 83 Fed. Reg. at 3931.

[63] *See County of Santa Clara v. Trump*, 250 F. Supp.3d 497, 530-532 (N.D. Cal. 2017) (enjoining executive order regarding sanctuary cities in part because order violated separation of powers by attempting to exercise Congress's spending power in its enforcement).

[64] *Id.*

[65] 83 Fed. Reg. at 3929.

[66] 83 Fed. Reg. at 3931.

power is not without limit.[67] Importantly, if Congress seeks to condition the states' receipt of federal funds, it "must do so unambiguously."[68] Conditions on federal grants can also be barred if they are unrelated "to the federal interest in particular national projects or programs."[69] Additionally, "the financial inducement offered by Congress" cannot be "so coercive as to pass the point at which pressure turns into compulsion."[70] The Proposed Rule would violate each of these limits on Congress's exercise of the Spending Clause power.

In the first instance, the vague notion of a "threatened failure to comply" offends the requirement that Congress must unambiguously state the prohibited conduct that will trigger the loss of funding under its Spending Clause power.[71] Additionally, because the Proposed Rule conflicts with other federal laws, the states risk all of their federal health care funding by merely complying with (other) federal law—leaving them no unambiguously compliant course of action. For example, if a pregnancy counselor at a public health department that receives Title X funds objects to providing counseling about or referral to abortion services, the facility will have to decide whether to 1) transfer that employee in violation of the Proposed Rule or 2) allow that employee not to counsel about or refer to these services in violation of Title X. Should it choose the first option, it could lose all of its federal health care funding; should it choose the second option, it could lose all of its federal Title X funding.

Next, the funding that HHS proposes it should be allowed to terminate, on the basis of a "threatened failure to comply" with the Proposed Rule, includes programs, like the Children's Health Insurance Plan, that are entirely unrelated to the federal interest in protecting conscience objections to a narrow category of procedures, such as abortion and sterilization.[72]

Last, the Supreme Court has already held that Congress's imposition of new, unrelated conditions on an amount *less* than the amount of funding at stake under the Proposed Rule was so coercive as to be likened to a "gun to the head."[73] In *National Federation of Independent Business v. Sebelius*, the Supreme Court reasoned that a Congressional threat to a state's Medicaid funding was unconstitutional because it was so coercive as to deprive states of any meaningful choice whether to accept the condition attached to receipt of federal funds.[74] The Proposed Rule would eliminate not only states' Medicaid funding, but a host of other federal health care funding as well.

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[67] *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 578 (2012).

[68] *Id.* at 576.

[69] *South Dakota v. Dole*, 483 U.S. 203, 207 (1987) (internal citation omitted).

[70] *Sebelius*, 567 U.S. at 580 (internal citation and quotation marks omitted).

[71] *Dole*, 483 U.S. at 207.

[72] 83 Fed. Reg. at 3905.

[73] *Sebelius*, 567 U.S. at 581.

[74] *Id.* at 579-585.

VII. The Proposed Rule Will Increase Discrimination, Limit Health Care Providers, and Harm Patients.

The States maintain a quintessential interest in the civil rights and health of their residents, an interest alternately described as quasi-sovereign and within those police powers reserved to them.[75] The States have considered the Proposed Rule in light of their twin duties to protect civil rights and the public health, and believe that it harms both patients and health care providers. Despite HHS's stated interest in "a society free from discrimination,"[76] the Proposed Rule substantially increases the risk of discrimination against patients on the basis of, *inter alia*, sex, sexual orientation, or gender identity. The Proposed Rule also risks having a chilling effect upon health care providers in a manner that will likely harm patients and vulnerable populations. Both of these anticipated harms arise from the unnecessary and unsupported breadth and scope of the Proposed Rule.

(A) The Proposed Rule Will Increase Status-Based Discrimination Against Patients.

The statutes referenced in the Proposed Rule in no way permit entities or health care personnel to deny care to a patient based on his or her status, *e.g.*, a patient's status as lesbian, gay, bisexual, or transgender. Rather, those statutes set forth narrowly tailored exemptions to the provision of specific procedures, irrespective of a patient's status.[77] Against this backdrop of narrow statutory protections allowing health care workers to opt out of certain procedures and services, HHS seeks to expand the scope of the referenced statutes, its regulatory footprint, and its own power. As set forth in Section II, *supra*, the Proposed Rule defines the terms "assist in the performance" and "health care entity" in ways that broaden the scope of the referenced statutes, vastly expand the number of individuals potentially eligible to assert a "religious, moral, ethical, or other" objection, and dramatically increase the types of services to which they may object. This expanded universe of individuals who can refuse to provide patient care or perform activities with an "articulable connection" to patient care, combined with the enormous sanctions faced by states and other entities if they do not allow for these exemptions, raises the specter of heightening status-based discrimination against existing patient populations.

The States have serious concerns, for example, that an expanded universe of potential conscience objectors may seek to use the statutory tether of a "sterilization procedure" to deny care to transgender patients. Transgender people regularly experience discrimination within the health care industry, resulting in substantial health disparities with the non-transgender

[75] *See, e.g.*, *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 488 (1987) (acknowledging state police power and interest in public health); *Snapp v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 609 (1982) (acknowledging state interest in eradicating the "political social, and moral damage" resulting from "invidious discrimination"); *Mackey v. Montrym*, 443 U.S. 1, 17 (1979) (acknowledging state interest in public health and safety).

[76] 83 Fed. Reg. at 3903.

[77] *See, e.g.*, 42 U.S.C. § 300a-7(b)(1) (Church Amendment) (referring to "performance of any sterilization *procedure or abortion*" (emphasis added)).

population.[78] This discrimination includes both denials of care related to gender transition as well as denials of care for routine medical issues—*e.g.*, physicals, treatment for the flu, or care for diabetes—completely unrelated to their transgender status.[79] In some instances, this discrimination has occurred in emergency medical settings in which prompt and effective care for patients is urgent and its absence could be life-threatening.[80] Similarly, the States also have concerns that an expanded universe of conscience objectors could seek to use the Proposed Rule to deny medical care to male patients who seek pre- or post-exposure prophylactic medications to prevent HIV infection based upon those men's actual or perceived sexual orientation.[81] Any regulatory expansion of statutory conscience exceptions that results in status-based discrimination would fundamentally undermine patient health and the interest of the States in preserving that health within their borders.

(B) The Proposed Rule Will Have a Chilling Effect Upon Health Care Providers, Further Harming Patients.

The Proposed Rule would also inhibit the provision of health care in a manner that harms public health and likely falls more heavily on the shoulders of vulnerable populations. Not only does the Proposed Rule vastly expand the scope of individuals who may lodge conscience-based objections to the provision of medical procedures and other services with an "articulable connection" to those procedures,[82] it also exceeds its statutory authority in intending to cut off all federal health care funding for any failure or threatened failure to comply with the Proposed Rule.[83] This regulatory combination is an especially dangerous one that is likely to have a chilling effect upon health care providers. Health care providers faced with a potentially limitless universe of conscience objections from any employee, including members of the janitorial or secretarial staff, have strong incentives to cease offering procedures like abortion or gender transition-related

[78] *See, e.g.*, Grant, Jaime M., et al., *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey*, (Nat'l Ctr. Transgender Equal./Nat'l Gay & Lesbian Task Force, Washington, D.C.), 2011 ("2011 Report"), at 6; James, Sandy E., et al., *The Report of the 2015 U.S. Transgender Survey*, (Nat'l Ctr. Transgender Equal., Washington D.C.), 2016 ("2016 Report"), at 103-07.

[79] *See* 2011 Report, at 6 (noting that 19% of survey respondents reported being refused medical care due to their transgender or gender non-conforming status); 2016 Report, at 96-97 (noting that 15% of survey respondents reported a health care provider asking unnecessary or invasive questions about their transgender status unrelated to the reason for their visit; 8% of respondents reported a provider's denial of transition-related care; and 3% of respondents reported a denial of care unrelated to gender transition).

[80] *See, e.g.*, *Rumble v. Fairview Health Servs.*, 2015 U.S. Dist. LEXIS 31591 (D. Minn. Mar. 16, 2015) (detailing emergency room physician's actions toward transgender man in suit brought under Affordable Care Act and Minnesota Human Rights Law).

[81] *See, e.g.*, Donald G. McNeil, Jr., *He Took a Drug to Prevent AIDS. Then He Couldn't Get Disability Insurance*, N.Y. Times (Feb. 12, 2018), *available at*: https://www.nytimes.com/2018/02/12/health/truvada-hiv-insurance.html (last visited Mar. 26, 2018).

[82] *See supra* Section II.

[83] *See supra* Section VI(A).

therapies or surgeries in order to avoid any possibility of the loss of all federal health care funding, including Medicaid funding, which could literally close a health care provider's doors.

Such a net reduction in the medical care offered by health care providers would harm the public health in each of the States. Additionally, because the Proposed Rule generally targets health care services supported by federal funds, its impact would be felt most by low-income patients who are far less likely to have alternative health care services available after a provider ceases to provide certain medical care or procedures. Further, patients reliant upon federal funding for the provision of health care are disproportionately non-white: 21% black and 25% Hispanic, as compared to those communities' respective proportions of 13.3% and 17.8% in the United States population. Consequently, any chilling effect the Proposed Rule has upon health care providers' decisions to offer abortion or other procedures will be borne disproportionately by minority populations.[84]

VIII. Conclusion

If adopted, the Proposed Rule will harm patients by increasing discrimination and decreasing the provision of health care and information about health care. It will harm the Constitutional rights of the States and their residents. It will needlessly and carelessly upset the balance that has long been struck in federal and state law to protect the religious freedom of providers, the business needs of employers, and the health care needs of patients. Accordingly, we urge HHS to withdraw the Proposed Rule.

Respectfully submitted,

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New York Attorney General

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[84] *Compare Medicaid Enrollment by Race/Ethnicity*, Kaiser Family Foundation, https://www.kff.org/medicaid/state-indicator/medicaid-enrollment-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Mar. 23, 2018), *and Quick Facts: United States*, United States Census Bureau, https://www.census.gov/quickfacts/fact/table/US/PST045216 (last visited Mar. 23, 2018).

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Exhibit B

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March 27, 2018

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

RE: Comments on Proposed Rule: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (Jan. 26, 2018), RIN 0945-ZA03

Dear Secretary Azar:

I write today to urge the U.S. Department of Health and Human Services (HHS) to withdraw the Proposed Rule: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 Fed. Reg. 3,880 (Jan. 26, 2018), RIN 0945-ZA03 ("Proposed Rule" or "Rule"). This Proposed Rule would impede access to care and create barriers to patients' exercise of their rights. Further, it undermines HHS's mission to "enhance the health and well-being of all Americans, by providing for effective health and human services."

As California's Attorney General, I have a constitutional duty to protect Californians, by safeguarding their health and safety, and defending the State's laws. Cal. Const., art. V, § 13. This Rule is an unlawful attempt by the Administration to proceed without congressional authority and is in conflict with the Constitution and multiple existing laws. If implemented, it will have significant negative impacts on States; their residents, including women, LGBTQ individuals, and other marginalized populations; and numerous entities in the State that receive federal healthcare funding. Thus, I urge that the Rule be withdrawn.

Among its many problems, the Proposed Rule threatens the removal of *all* federal healthcare funds from recipients, including the State, deemed not in compliance with the Rule. Jeopardizing this funding would have significant effects on California families as these funds support public healthcare programs and public health initiatives.

The Rule would also create rampant confusion about basic patient rights and federally entitled healthcare services, while discouraging providers from providing safe, legal care. The Rule not only permits any individual, entity, or provider to deny basic healthcare services—

including emergency care—but also discharges a provider from the duties to cite evidence to support the denial of services, to notify a supervisor of the denial of services, and to provide notice or alternative options to patients that may want to seek services from another provider. There is little evidence that in drafting the Rule, HHS considered the impact to patients. 83 Fed. Reg. at 3,902; *Id*. at 3,902-3,918 (failing to mention, let alone quantify the impact of this Rule on patients). Moreover, the effects of the Proposed Rule would be widespread as it implicates "*any* program or activity with an *articulable connection* to a procedure, health service, health program, or research activity," 83 Fed. Reg. at 3,923. The consequences of this overbroad Rule will disproportionately affect the most vulnerable populations, and in particular, could have a chilling effect on those seeking to exercise their constitutionally protected healthcare rights.

a. The Proposed Rule Targets the State of California and its Interests in Protecting its Residents, Healthcare Industry, and Consumer Protections

The Proposed Rule particularly aims to upend and target California's concerted efforts to balance the rights of patients and providers. The Rule suggests that further federal guidance is needed because of an increase in lawsuits against state and local laws; however, HHS puts forth little actual evidence. In targeting California's carefully crafted laws, the Rule tramples on the rights of patients and takes aim at California specifically.

First, the Rule references two pending federal lawsuits stemming from the California Department of Managed Health Care's (DMHC) August 22, 2014 letters issued to health plans regarding abortion coverage. 83 Fed. Reg. at 3,889 (citing *Foothill Church v. Rouillard*, No. 2:15-cv-02165-KJM-EFB, 2016 WL 3688422 (E.D. Cal. July 11, 2016); *Skyline Wesleyan Church v. Cal. Dep't of Managed Health Care*, No. 3:16-cv-00501 (S.D. Cal. 2016)). Then, noting that HHS's Office of Civil Rights (OCR) previously closed three complaints against DMHC, the Rule states that OCR's finding that the Weldon Amendment had not been violated by California law requiring that health plans include coverage for abortion "no longer reflects the current position of HHS, OCR, or the HHS office of the General Counsel." 83 Fed. Reg. at 3,890. This reversal in the agency's interpretation of the Weldon Amendment is apparently based on a misreading of the law, and is arbitrary and capricious. 5 U.S.C. § 706; *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974); *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010). Moreover, HHS cites no authority that permits it to reverse its position in this manner. Later, the Proposed Rule—apparently referencing California's Reproductive Freedom, Accountability, Comprehensive Care, and Transparency (FACT) Act—announces that even requiring a clinic to post notices mentioning the existence of government programs that include abortion services would be considered a referral for abortion under the Weldon Amendment and Section 1303 of the Affordable Care Act.[1] 83 Fed. Reg. at 3,895. Such a broad definition of "refer for" is

[1] Section 1303 prohibits the use of certain Federal funds to pay for abortion coverage by qualified health plans. 42 U.S.C. § 18023(b)(2)(A). However, Section 1303 permits an issuer to charge and collect $1 per enrollee per month for coverage of abortion services so long as the

unsupported by the plain language of these statutes, and is thus outside of HHS's delegated authority. *See infra* at 3-4.

HHS's attempt to redefine the law threatens California's sovereign and quasi-sovereign interests in regulating healthcare, criminal acts, and California-licensed entities and professionals. *See also New York v. United States*, 505 U.S. 144, 155-56 (1992); Cal. Bus. & Prof. Code §§ 101, 101.6, 125.6 (providing that a California licensee is subject to disciplinary action if he or she refuses to perform the licensed activity or aids or incites the refusal to perform the licensed activity by another licensee because of another person's sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status); 733 (a California licensee "shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient"); 2761; Cal. Penal Code § 13823.11(e) and (g)(4); Cal. Health & Saf. Code §§ 10123.196, 1367.25, 123420(d); Cal. Civ. Code § 51; *No. Coast Women's Care Med. Group, Inc. v. San Diego County Superior Court*, 44 Cal.4th 1145 (2008). "[T]he structure and limitations of federalism . . . allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (internal quotation marks and citation omitted).

Furthermore, the estimated costs and benefits of the Rule do not justify it, but rather reveal it to be greatly wasteful of public funds. HHS admits that OCR has received only 44 complaints over the last 10 years of alleged instances of violations of conscience rights. 83 Fed. Reg. at 3,886. Yet, as HHS further admits, it will cost nearly $1.4 billion over the first years to implement the Rule, and for the affected entities to comply with the new assurance and certification requirements. *Id.* at 3,902, 3,912-13. Meanwhile, HHS disclaims any ability to quantify the benefits. *Id.* at 3,902, 3,916-17.

In undercutting important patient protections and creating barriers to care, the Proposed Rule not only oversteps on policy grounds, but also has numerous legal deficiencies. Below I address many, but by no means all, of these deficiencies.

b. The Proposed Rule Exceeds Congressional Authority

As a threshold matter, the Proposed Rule exceeds the authority of the statutes it cites, and therefore violates the Administrative Procedure Act. 5 U.S.C. § 706. Nothing in the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, or other statutes permits HHS to redefine the terms used in these underlying statutory schemes. Yet the Proposed Rule has characterized numerous terms, including "assist in the performance," "health care entity," and "referral or refer for," so broadly as to materially alter well-established statutory language.

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funds are deposited in a separate account, maintained separately, and used only for abortion services.

For example, contrary to the implementing statutes, the Proposed Rule suggests that "assist in the performance" encompasses participating in "any" program or activity with an "articulable connection" to a procedure, health service, health program, or research activity, including "counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity." 42 Fed. Reg. at 3,923. Only the Church Amendments refer to "assist in the performance" of an activity, and nothing in that statutory scheme envisions the broad definition in the Proposed Rule. 42 U.S.C. § 300a-7. That Congress specifically references "to counsel" in a separate Church Amendment provision, "training" in the Coats-Snowe Amendment, and "refer for" in the Weldon Amendment confirms that the Proposed Rule's definition of "assist in the performance" should not include these additional activities. Reading and interpreting the statutes in these ways will allow for unlawful refusals of care.

Similarly, "health care entity" is defined in the Coats-Snowe Amendment, the Weldon Amendment, and the Affordable Care Act, yet the Proposed Rule goes beyond these definitions to include "health care personnel," as distinct from a "health care professional," such as a doctor or nurse. 42 Fed. Reg. at 3,924. Therefore, it appears that, under the Proposed Rule, even someone like a receptionist at a doctor's office could refuse to provide services, including making an appointment for a patient, based on his or her moral objections. By expanding "health care entity" to cover personnel, "health care professional" is rendered superfluous, contrary to the rules of statutory interpretation. Additionally, the Proposed Rule's definition of "health care entity" is overbroad, given that it includes "a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan." 42 Fed. Reg. at 3,924. In short, the Rule's redefinition of "health care entity" is arbitrary and capricious, as it runs counter to OCRs' previous, well-reasoned interpretation of the term.

The Proposed Rule's definition of "referral or refer for" is particularly broad, suggesting that "any method," even posting of notices, would be considered a "referral." 42 Fed. Reg. at 3,924. These new exceptions created by the Rule are not envisioned by any federal statute, and would permit healthcare professionals to elude the scope of state laws protecting a patient's rights to healthcare services.

c. The Proposed Rule is Contrary to Law

The Rule also violates the U.S. Constitution in several respects, including conflicting with the Spending Clause, the Due Process Clause, the Establishment Clause, and Separation of Powers. Furthermore, the Rule conflicts with several federal statutes. 5 U.S.C. § 706.

The Proposed Rule violates the Spending Clause because it (a) coerces states and their entities to follow the Proposed Rule or lose billions of dollars in federal funds; (b) is vague and does not provide adequate notice of what specific action or conduct, if engaged in, will result in the withholding of federal funds; (c) constitutes post-acceptance conditions on federal funds; and (d) is not rationally related to the federal interest in the particular program that receives federal funds. *See NFIB v. Sebelius*, 567 U.S. 519, 582-83 (2012); *Pennhurst State Sch. and Hospital v.*

Halderman, 451 U.S. 1, 17 (1981) (If Congress desires to condition the States' receipt of federal funds, it "must do so unambiguously . . . enabl[ing] the States to exercise their choice knowingly, cognizant of the consequences of their participation"); *South Dakota v. Dole*, 483 U.S. 203 (1987); *Massachusetts v. United States*, 435 U.S. 444, 461 (1978) (plurality op.) (conditioning federal grants illegitimate if unrelated "to the federal interest in particular national projects or programs"). The Rule is tantamount to "a gun to the head." *NFIB*, 567 U.S. at 581. If California opts out of complying with the Rule (or even "[i]f there appears to be a failure or threatened failure to comply"), it "would stand to lose not a relatively small percentage" of its existing federal healthcare funding, but all of it. *Id*.; 83 Fed. Reg. at 3,931.

It violates the Due Process Clause, as well, because it is unconstitutionally vague and permits OCR to immediately withhold billions of federal funding, if there "appears to be a failure" to comply, or just an apparent "threatened" failure to comply, and there is no review process. 83 Fed. Reg. at 3,931; *see Mathews v. Eldridge*, 424 U.S. 319, 349 (1976) ("The essence of due process is the requirement that a person in jeopardy of serious loss be given notice of the case against him and opportunity to meet it.") (internal alterations and quotations omitted); *Goldberg v. Kelly*, 397 U.S. 254 (1970). To satisfy due process, the law must (1) "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly," and (2) "provide explicit standards for those who apply them." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). This Proposed Rule does not meet either of these requirements.

The Rule also constitutes an undue burden on a woman's decision to terminate her pregnancy before viability. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016); *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992) (plurality op.). The net effect of this rule will result in women being denied access to crucial information and even necessary treatment, including lawful abortions.

The Proposed Rule violates the Establishment Clause by accommodating religious beliefs to such an extent that it places an undue burden on third parties—patients. *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985); *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005) ("[A]n accommodation must be measured so that it does not override other significant interests"); *Santa Fe Indep. Sch. Dist. v. Doe*, 530 U.S. 290 (2000); *Lee v. Weisman*, 505 U.S. 557 (1992). Furthermore, the Proposed Rule constitutes excessive government entanglement with religion. *Larkin v. Grendel's Den*, 459 U.S. 116, 122-27 (1982); *Williams v. California*, 764 F.3d 1002, 1015 (9th Cir. 2014); *see also Larson v. Valente*, 456 U.S. 228, 244 (1982); *Kiryas Joel Village Sch. Dist. v. Grument*, 512 U.S. 687, 703 (1994) ("[G]overnment should not prefer . . . religion to irreligion").

Last, the Proposed Rule violates the Separation of Powers. U.S. Const. art. I, § 8, cl. 1; *Dole*, 483 U.S. at 206; *Clinton v. City of New York*, 524 U.S. 417, 438 (1998). Although *Congress* may attach conditions to receipt of federal funds, the executive branch cannot "amend[] parts of duly enacted statutes" after they become law, including to place conditions on

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

In addition to these Constitutional violations, the Proposed Rule conflicts with several federal statutes and is written so broadly it could implicate others. First, the Proposed Rule clashes with several provisions of the Affordable Care Act, most notably section 1554, which prohibits the Secretary of HHS from creating barriers to healthcare, and section 1557, which prohibits discrimination in health programs or activities. 42 U.S.C. §§ 18114, 18116 (2015). Second, the Proposed Rule fails to reconcile its provisions with Title VII and the body of case law that has developed with regard to balancing religious freedoms and consumer rights. 42 U.S.C. § 2000e-2(e); *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 830 (9th Cir. 1999); *Peterson v. Hewlett Packard Co.*, 358 F.3d 599, 606-607 (9th Cir. 2004); *Opuku-Boateng v. State of California*, 95 F.3d 1461 (9th Cir. 1996). Third, the Proposed Rule contravenes Title X of the Public Health Services Act, 42 U.S.C. §§ 300-300a-6, which provides federal funding for family-planning services. Lastly, the Proposed Rule disregards the Emergency Medical Treatment & Labor Act (EMTALA), commonly known as the Patient Anti-Dumping Act, enacted by Congress in response to growing concern about the provision of adequate medical services to individuals, particularly the indigent and the uninsured, who sought care from hospital emergency rooms. 42 U.S.C. § 1395dd(a) (1986); *Jackson v. East Bay Hosp.*, 246 F.3d 1248, 1254 (9th Cir. 2001) (citation omitted).

To reiterate, the Proposed Rule fails to account for its potential impact on States and their citizens. The Rule will have damaging, irreparable repercussions for certain patient populations including women, LGBTQ individuals, and others. Even if OCR concludes, after an investigation, that a provider should have provided certain services that were denied for claimed religious or moral reasons, it will be too late for the patient who was wrongly deprived of that necessary care. As California knows from experience, OCR could take years to conduct an investigation; however, any correction at the end of that process would be inadequate for the patient whose healthcare has been compromised. This will be made worse by providers who are fearful of the federal government's enforcement of the Rule and threatened loss of funds, and who instead of treating a patient or providing a referral, will simply chose not to provide particular services, reducing access to care.

For the reasons set forth above, California strongly opposes the Proposed Rule and urges that it be withdrawn.

Sincerely,

XAVIER BECERRA
Attorney General of California

Exhibit C

NYC

March 27, 2018

Via electronic submission

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

To Whom It May Concern:

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

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

The Proposed Rule Will Harm Patients

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

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

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

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

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

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

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

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

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

The Proposed Rule Will Lead to Discrimination Against Already Vulnerable Populations

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

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

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

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

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

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

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

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

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

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

We urge HHS to rescind the proposed rule.

Sincerely,

Steven Banks
Commissioner
New York City Department of
Social Services

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

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

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

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

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

Exhibit D

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
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Department of Health and Human Services, Office for Civil Rights
RIN 0945-ZA03
Docket ID No. HHS-OCR-2018-0002

Dear Director Severino:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 66,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, I write to provide input for the Notice of Proposed Rulemaking (NPRM) regarding Protecting Statutory Conscience Rights in Health Care.

America's pediatricians represent all faiths and serve children and families of all faiths. The free exercise of religion is an important societal value, which must be balanced against other important societal values, such as protecting children from serious harm and ensuring child health and well-being.

All children need access to appropriate, evidence-based health services to ensure they can grow, develop, and thrive. The inability to receive needed health care services can have a profound impact on the health of children. The AAP publishes policies and reports based on the best available scientific evidence that are designed to ensure children receive the health and social services they need. The AAP urges the U.S. Department of Health and Human Services (HHS) to ensure that health providers follow evidence-based or evidence-informed practices such as those published by professional medical organizations like the AAP. As HHS considers expanding conscience protections and the enforcement thereof, we respectfully offer these suggestions to ensure that HHS policy facilitates optimal access to services that support healthy children and families.

Introduction

Some health care professionals and health care organizations do morally object to particular services or treatments and refuse to provide them. Possible examples of such conscientious objection in pediatric practice include refusals to prescribe contraception, specifically emergency contraception[i]; perform routine neonatal male circumcision[ii]; or administer vaccines developed with virus strains or cell lines derived from voluntarily aborted human fetuses.[iii] Such objections may limit patients' access to information or treatment, and given this, the implementation of such objections is an important issue.

There are morally important reasons to protect the individual's exercise of conscience. Conscience is closely related to integrity. Performing an action that violates one's conscience undermines one's sense of integrity and self-respect and produces guilt, remorse, or shame.[iv,v] Integrity is valuable, and harms associated with the loss of self-respect should be avoided. This view of conscience provides a justification for respecting conscience independent of particular religious beliefs about conscience or morality. Claims of conscience are generally negative (the right to not perform an action) rather than positive (the right to perform an action).[vi]

Nevertheless, constraints on claims of conscience can be justified on the basis of health care professionals' role responsibilities and the power differential created by licensure. Health care professionals – and other health care entities – fulfill a particular societal role with associated expectations and responsibilities. For example, health care professionals' primary focus should be on their patients' rather than their own benefit. These role expectations are based in part on the power differential between health care professionals' and patients, which is the result of the providers' knowledge and patients' conditions. Role obligations are generally voluntarily accepted; therefore, health care professionals' claims of conscientious objection may justifiably be limited.

The AAP supports a balance between the individual physician's moral integrity and his or her fiduciary obligations to patients. **A physician's duty to perform a procedure within the scope of his or her training increases as the availability of alternative providers decreases and the risk to the patient increases.** Physicians should work to ensure that health care-delivery systems enable physicians to act according to their consciences and patients to obtain desired and appropriate health care. When an entire health care organization—and not just one provider—objects to providing a specific service, the availability of alternative providers naturally decreases even further.

However, physicians have a duty to disclose to patients and prospective patients standard treatments and procedures that they refuse to provide but are normally provided by other health care professionals. Physicians have a moral obligation to inform their patients of relevant alternatives as part of the informed-consent process. Physicians should convey information relevant to the patient's decision-making in a timely manner, using widely accepted and easily understood medical terminology, and should document this process in the patient's medical record. Physicians who consider certain treatments immoral or who claim a conscience or religious objection have a duty to refer patients who desire these treatments in a timely manner when failing to do so would harm the patients. Such physicians must also provide appropriate

ongoing care in the interim. These same obligations should be applicable to all recipients of federal funds for the provision of health care.

HHS's NPRM must not induce any health care entity, as defined in the NPRM, to abrogate its moral responsibilities of serving patients. The AAP strongly warns of harms to children's health should HHS not require providers, grantees, or any other entities subject to the NPRM to fulfill the moral obligation to:

- Ensure that patients obtain desired and appropriate health care;
- Disclose to patients and prospective patients standard treatments and procedures that they refuse to provide which are normally provided by other health care professionals;
- Inform patients of alternative providers as part of the informed-consent process;
- Provide information relevant to the patient's decision-making in a timely manner, using widely-accepted and easily-understood medical terminology, and document this process in the patient's medical record; and
- Refer patients who desire these treatments in a timely manner when failing to do so would harm the patients. Such entities must also provide appropriate ongoing care in the interim.

Specific Concerns Regarding the NPRM's Potential Impact on Child Health and Wellbeing

Institutional discrimination/HHS grantees/Medicaid and CHIP coverage/access

The Academy believes that the United States can and should ensure that all children, adolescents, and young adults from birth through the age of 26 years who reside within its borders have affordable access to high-quality and comprehensive health care, regardless of their or their families' incomes. Public and private health insurance should safeguard existing benefits for children and take further steps to cover the full array of essential health care services recommended by the AAP, including reproductive health and pregnancy-related services. CMS funds critical programs to support adolescent health, reduce unintended pregnancy, and provide reproductive health care, and these programs and services are critical to the health of adolescents and adults. The AAP urges HHS to ensure that no individual accessing services through a public health insurance is denied access to essential care.

As HHS considers potential changes to regulations and policy guidance to encourage the provision of grants and contracts to faith-based organizations, we urge you to ensure that federal policy does not undermine children's access to needed care and services. This includes a focus on upholding federal statutory safeguards for Medicaid beneficiaries that ensure access to qualified providers and appropriate and meaningful services. The AAP believes it essential that all states should uphold this fundamental protection affording access to any qualified, willing provider from which a beneficiary wishes to seek care. This essential protection is critical to the health of adolescents and young adults.

Vaccines

The Academy strongly supports all children and their families following the recommended childhood vaccination schedule.[vii] Routine childhood immunizations against infectious diseases are an integral part of our public health infrastructure and childhood immunization is one of the greatest accomplishments of modern medicine. In the United States 2009 birth cohort, routine childhood immunization will prevent approximately 42,000 early deaths and 20 million cases of disease, saving $13.5 billion in direct costs and $68.8 billion in societal costs.[viii] For children born in the United States between 1994 and 2013, "vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the course of their lifetimes."[ix]

However, vaccines are not 100% effective in all individuals receiving them. Certain infants, children, and adolescents cannot safely receive specific vaccines because of age or specific health conditions. These individuals benefit from the effectiveness of immunizations through a mechanism known as community immunity (also known as "herd" immunity). Community immunity occurs when nearly all individuals for whom a vaccine is not contraindicated have been appropriately immunized, minimizing the risk of illness or spread of a vaccine-preventable infectious agent to those who do not have the direct benefit of immunization. Although there is variance for levels of immunization required to generate community immunity specific to each disease and vaccine, it is generally understood that population immunization rates of at least 90% are required, as reflected in the Healthy People 2020 goals.[x] Certain highly contagious diseases, such as pertussis and measles, require a population immunization rate of ≥95% to achieve community immunity. But despite the importance of vaccines to children's health—and public health overall—some religious adherents object to their use.[xi]

For example, some religious adherents object to vaccines for chicken pox, hepatitis A, hepatitis B, polio, and measles, mumps and rubella (MMR) because they all have an attenuated connection to fetal-tissue research conducted in the 1960's.[xii] While the individual doses of these vaccines are not produced using fetal tissue, nor do they contain fetal tissue, the listed vaccines are grown in human cell cultures developed from two cell lines that trace back to two fetuses, both of which were legally aborted for unrelated medical reasons in the early 1960s. In addition, some object to the vaccine against the human papillomavirus (HPV). Certain strains of HPV can cause a variety of cancers, most notably cervical cancer.[xiii] Each year, approximately 11,000 women in the United States are diagnosed with cervical cancer – and almost half that number die from it.[xiv] Because HPV is often transmitted through sexual contact, and because the HPV vaccine is most effective when administered before the patient comes in contact with the virus, medical experts and organizations – including the AAP – recommend that the HPV vaccine be administered at 11 or 12 years of age.[xv] But because HPV can be transmitted sexually, some religious objectors oppose the vaccine on the basis that it allegedly encourages teens to engage in premarital sex, and that the correct way to limit transmission is through abstinence.[xvi]

In addition, all 50 states, the District of Columbia, and Puerto Rico have regulations requiring proof of immunization for child care and school attendance as a public health strategy to protect children in these settings, and to secondarily serve as a mechanism to promote timely immunization of children by their caregivers. Although all states and the District of Columbia

have mechanisms to exempt school attendees from specific immunization requirements for medical reasons, the majority also have a heterogeneous collection of regulations and laws that allow nonmedical exemptions, including those based on one's religious beliefs, from childhood immunizations otherwise required for child care and school attendance.

The AAP supports regulations and laws requiring certification of immunization to attend child care and school as a sound means of providing a safe environment for attendees and employees of these settings. The AAP also supports medically indicated exemptions to specific immunizations as determined for each individual child. The AAP views nonmedical exemptions to school-required immunizations as inappropriate for individual, public health, and ethical reasons and advocates for their elimination.[xvii] HHS policy should support organizations focused on advancing public health, a critical component of which is vaccination. We urge HHS not to make any policy changes that would provide grants or contracts to organizations that advocate for or adhere to vaccine policies not based on the best available evidence and science.

Unfortunately, we have seen the impact when immunization rates decline. In 2015, the United States experienced a large, multi-state outbreak of measles linked in part to exposures at Disneyland in California. The outbreak likely started from a traveler who became infected with measles and then visited the amusement park while infectious. Most of those infected were intentionally unvaccinated, some of them did not know their vaccination status, and a minority of them were vaccinated. Once outbreaks get started even vaccinated people can be affected because no vaccine is 100 percent effective. Analysis by CDC scientists showed that the measles virus type in this outbreak (B3) was identical to the virus type that caused the large measles outbreak in the Philippines in 2014.

Another measles outbreak occurred in Minnesota in the spring and summer of 2017, primarily concentrated within the Somali-American community. At the start of the outbreak, only about 42 percent of Somali-Minnesota 2-year-olds were vaccinated, largely due to many parents in the Somali-American community holding unfounded fears that the measles-mumps-rubella (MMR) vaccine causes autism. In a community with previously high vaccination coverage, the sudden drop in MMR vaccination rates resulted in a coverage level low enough to sustain widespread measles transmission in the community following introduction of the virus. Over the course of the outbreak, more than 8,000 people in Minnesota were exposed to measles, 500 were asked to stay home from work or school, 79 people were confirmed with measles, 73 of which were children under 10 years old, and 71 of the cases were in people who were unvaccinated for measles.[xviii]

In addition, each year, more than 200,000 individuals are hospitalized and 3,000-49,000 deaths occur from influenza-related complications.[xix] Serious morbidity and mortality can result from influenza infection in any person of any age. Rates of serious influenza-related illness and death are highest among children younger than 2 years old, seniors 65 years and older, and people of any age with medical conditions that place them at increased risk of having complications from influenza, such as pregnant women and people with underlying chronic cardiopulmonary, neuromuscular, and immunodeficient conditions. Hospital-acquired influenza has been shown to have a particularly high mortality rate, with a median of 16% among all patients and a range of 33% to 60% in high-risk groups such as transplant recipients and patients in the ICU.[xx]

Transmission from an infected, previously healthy child or adult begins as early as 1 day before the onset of symptoms and persists for up to 7 days; infants and immunocompromised people may shed virus even longer. Some infected people remain asymptomatic yet contagious.[xxi]

Because of the numbers cited above, the AAP also supports mandatory influenza immunization for all health care personnel as a matter of patient safety. Voluntary programs have failed to increase immunization rates to acceptable levels. Large health care organizations have implemented highly successful mandatory annual influenza immunization programs without significant problems. Mandating influenza vaccine for all health care personnel nationwide is ethical, just, and necessary. As such, we urge HHS not to make any policy changes that would weaken existing measures to immunize health care personnel and protect patients from vaccine-preventable infectious diseases.

Mental Health Services

Suicide affects young people from all races and socioeconomic groups, although some groups have higher rates than others. American Indian/Alaska Native males have the highest suicide rate, and black females have the lowest rate of suicide. Sexual minority youth (ie, lesbian, gay, bisexual, transgender, or questioning) have more than twice the rate of suicidal ideation compared to the average of all other children in the same age range.[xxii] The 2013 Youth Risk Behavior Survey of students in grades 9 through 12 in the United States indicated that during the 12 months before the survey, 39.1% of girls and 20.8% of boys felt sad or hopeless almost every day for at least 2 weeks in a row, 16.9% of girls and 10.3% of boys had planned a suicide attempt, 10.6% of girls and 5.4% of boys had attempted suicide, and 3.6% of girls and 1.8% of boys had made a suicide attempt that required medical attention.[xxiii]

The leading methods of suicide for the 15- to 19-year age group in 2013 were suffocation (43%), discharge of firearms (42%), poisoning (6%), and falling (3%).[xxiv] Particular attention should be given to access to firearms, because reducing firearm access may prevent suicides. Firearms in the home, regardless of whether they are kept unloaded or stored locked, are associated with a higher risk of completed adolescent suicide.[xxv,xxvi] However, in another study examining firearm security, each of the practices of securing the firearm (keeping it locked and unloaded) and securing the ammunition (keeping it locked and stored away from the firearm) were associated with reduced risk of youth shootings that resulted in unintentional or self-inflicted injury or death.[xxvii]

Youth seem to be at much greater risk from media exposure than adults and may imitate suicidal behavior seen on television.[xxviii] Media coverage of an adolescent's suicide may lead to cluster suicides, with the magnitude of additional deaths proportional to the amount, duration, and prominence of the media coverage.[xxix] A prospective study found increased suicidality with exposure to the suicide of a schoolmate.[xxx] Newspaper reports about suicide were associated with an increase in adolescent suicide clustering, with greater clustering associated with article front-page placement, mention of suicide or the method of suicide in the article title, and detailed description in the article text about the individual or the suicide act.[xxxi] More research is needed to determine the psychological mechanisms behind suicide clustering.[xxxii,xxxiii] The National

Institute of Mental Health suggests best practices for media and online reporting of deaths by suicide.[xxxiv]

Families and children, from infancy through adolescence, need access to mental health screening and assessment and a full array of evidence-based therapeutic services to appropriately address their mental and behavioral needs. In particular, adolescents, including LGBTQ youth, need non-judgmental treatment for mental health disorders. The AAP strongly urges HHS not to permit entities to infringe upon such treatment including through the use of "conversion" or "reparative therapy" which is never indicated for LGBTQ youth (add endnote from the LGBTQ section).

Sexual Assault

Sexual assault includes any situation in which there is nonvoluntary sexual contact, with or without penetration and/or touching of the anogenital area or breasts, that occurs because of physical force, psychological coercion, or incapacitation or impairment (e.g., secondary to alcohol or drug use). Sexual assault also occurs when victims cannot consent or understand the consequences of their choice because of their age or because of developmental challenges.[xxxv] National data show that teenagers and young adults ages 12 to 34 years have the highest rates of being sexually assaulted of any age group.[xxxvi] Annual rates of sexual assault were reported in 2012 (for 2011) by the U.S. Department of Justice to be 0.9 per 1000 persons 12 years and older (male and female).[xxxvii]

When an adolescent discloses that an acute sexual assault has occurred, it is incumbent on the health care provider to provide a nonjudgmental response. A supportive environment may encourage the adolescent to provide a clear history of what happened, agree to a timely medical and/or forensic evaluation, and engage in counseling and education to address the sequelae of the event and to help prevent future sexual violence. It is important to obtain the history of what happened from the adolescent, when possible. As in any other medical encounters, the physician should learn about relevant past medical and social history. Physicians should consider the possibility that the adolescent could be a victim of human trafficking and commercial sexual exploitation and ask appropriate questions, such as "Has anyone ever asked you to have sex in exchange for something you wanted?"[xxxviii] In addition, the physician should address the physical, psychological, and safety needs of the adolescent victim of sexual violence and be aware that responses to sexual assault can vary. The health care provider should address the adolescent's immediate health concerns, including any acute injuries, the likelihood of exposure to sexually transmitted infection (STIs), the possibility of pregnancy, and other physical or mental health concerns. Treatment guidelines for STIs from the CDC[xxxix] include recommendations for comprehensive clinical treatment of victims of sexual assault, including emergency contraception and HIV prophylaxis. Sexual assault is associated with a risk of pregnancy; 1 study reported a national pregnancy rate of 5% per rape among females 12 to 45 years of age.[xl,xli,xlii,xliii,xliv] Pregnancy prevention and emergency contraception should be addressed with every adolescent female, including rape and sexual assault victims. The discussion can include the risks of failure of the preventive measures and options for pregnancy management. It is critical that no entities, whether individual health care providers or organizations, be sanctioned by HHS in limiting the range of options that a pediatrician may discuss with sexual assault victims.

Global Health

The President's Emergency Plan for AIDS Relief (PEPFAR), the U.S. government's effort to prevent and treat HIV and AIDS worldwide, already includes a broad conscience clause (Leadership Act Section 301(d)) that allows participating organizations to deny patients information or care. This includes barrier means of contraception (e.g., condoms), which are one of the mainstays of HIV prevention. The NPRM would apply provisions of the Church Amendments to other global health programs funded by the Department, thereby allowing global health providers and entities to refuse individuals the care in contexts where suitable alternatives may be hard to find or nonexistent.

Sexuality Education and Reproductive Health

Pediatricians are an important source of health care for adolescents and young adults, especially younger adolescents, and can play a significant role in continuously addressing sexual and reproductive health needs during adolescence and young adulthood. Office visits present opportunities to educate adolescents on sexual health and development; to promote healthy relationships and to discuss prevention of sexually transmitted infections (STIs) including HIV, unintended pregnancies, and reproductive health-related cancers; to discuss planning for the timing and spacing of children, planning for pregnancy, and delivering preconception health care, as appropriate; and to address issues or concerns related to sexual function and fertility.[xlv] Pediatricians can help adolescents sort out whether they feel safe in their relationships as well as how to avoid risky sexual situations. Pediatricians also can facilitate discussion between the parent and adolescent on sexual and reproductive health.[xlvi] Pediatricians are in an important position to identify patients who are at risk for immediate harm (e.g., abuse, sex trafficking) and work collaboratively as part of a team of professionals from a number of disciplines to address these needs.

Sixty-five percent of reported *Chlamydia* and 50% of reported gonorrhea cases occur among 15- to 24-year-olds.[xlvii] Teen-aged birth rates in the United States have declined to the lowest rates seen in 7 decades yet still rank highest among industrialized countries. Pregnancy and birth are significant contributors to high school dropout rates among female youth; only approximately 50% of teen-aged mothers earn a high school diploma by 22 years of age versus approximately 90% of females who did not give birth during adolescence.[xlviii] Child sex trafficking and commercial sexual exploitation of children (CSEC) is increasingly being identified as a public health problem in the United States, and victims of sex trafficking and CSEC may present for medical care for a variety of reasons related to infections, reproductive issues, and trauma and mental health.[xlix]

The AAP believes that all children and adolescents should have access to developmentally appropriate, evidence-based, comprehensive, and medically accurate human sexuality education that empowers them to make informed, positive, and safe choices about healthy relationships, responsible sexual activity, and their reproductive health. This includes information about methods of contraception and sexual consent, as well as information that affirms gender identity and sexual orientation. The Academy supports approaches to sexual and reproductive health that are based on evidence and medical consensus. As such, the AAP recommends that pediatricians counsel their patients to use the most effective methods of contraception, starting with long-

acting reversible contraception such as implants and intrauterine devices. The AAP also strongly encourages the delivery of sexuality education that is based on modern conceptions of human sexuality. Access to accurate reproductive health care and sexual health information is critical to the overall development and well-being of children and adolescents.

The Academy's policy statement on Sexuality Education for Children and Adolescents recognizes that the development of healthy sexuality depends on forming attitudes and beliefs about sexual behavior, which can be influenced by religious concerns in addition to ethnic, racial, cultural, and moral ones. It is imperative that the administration of programs that pertain to reproductive health and education be done with respect for a multiplicity of religious values and belief systems, while prioritizing adolescents' right to accurate sexual health information.

The federal government oversees several programs that fund the delivery of evidence-based sexuality education. These programs help states implement innovative approaches to preventing unintended teen pregnancy, HIV, and other sexually transmitted infections, as well as youth development and adulthood preparation. The AAP urges HHS to continue to prioritize the funding of evidence-based or evidence-informed models in the administration of these programs, and to ensure that federal dollars for these programs are granted to organizations that meet the criteria laid out in these federal programs. The AAP also urges HHS to ensure that all programs that provide access to reproductive health care services prioritize access to the most effective methods of contraception.

Contraception

Pediatricians play an important role in adolescent pregnancy prevention and contraception. Nearly half of US high school students report ever having had sexual intercourse.[l] Each year, approximately 750 000 adolescents become pregnant, with more than 80% of these pregnancies unplanned, indicating an unmet need for effective contraception in this population.[li][lii]

Although condoms are the most frequently used form of contraception (52% of females reported condom use at last sex), use of more effective hormonal methods, including combined oral contraceptives (COCs) and other hormonal methods, was lower, at 31% and 12%, respectively, in 2011.[liii] Use of highly effective long-acting reversible contraceptives, such as implants or intrauterine devices (IUDs), was much lower.[liv] Adolescents consider pediatricians and other health care providers a highly trusted source of sexual health information.[lv][lvi] Pediatricians' long-term relationships with adolescents and families allow them to ask about sensitive topics, such as sexuality and relationships, and to promote healthy sexual decision-making, including abstinence and contraceptive use for teenagers who are sexually active. Additionally, medical indications for hormonal contraception, such as dysmenorrhea, heavy menstrual bleeding or other abnormal uterine bleeding, acne, and polycystic ovary syndrome, are often uncovered during adolescent visits. A working knowledge of contraception will assist the pediatrician in both sexual health promotion and treatment of common adolescent gynecologic problems. Contraception has been inconsistently covered as part of insurance plans. However, the Institute of Medicine has recommended contraception as an essential component of adolescent preventive care,[lvii] and the Patient Protection and Affordable Care Act of 2010 (Pub L No. 111–148) requires coverage of preventive services for women, which includes contraception, without a copay.[lviii,lix]

Abortion

Ensuring that adolescents have access to health care, including reproductive health care, has been a long-standing objective of the AAP.[lx] Timely access to medical care is especially important for pregnant teenagers because of the significant medical, personal, and social consequences of adolescent childbearing. The AAP strongly advocates for the prevention of unintended adolescent pregnancy by supporting comprehensive health and sexuality education, abstinence, and the use of effective contraception by sexually active youths. For 2 decades, the AAP has been on record as supporting the access of minors to all options regarding undesired pregnancy, including the right to obtain an abortion. Membership surveys of pediatricians, adolescent medicine specialists, and obstetricians confirm this support.[lxi,lxii,lxiii]

In the United States, minors have the right to obtain an abortion without parental consent unless otherwise specified by state law. State legislation that mandates parental involvement (parental consent or notification) as a condition of service when a minor seeks an abortion has generated considerable controversy. U.S. Supreme Court rulings, although upholding the constitutional rights of minors to choose abortion, have held that it is not unconstitutional for states to impose requirements for parental involvement as long as "adequate provision for judicial bypass" is available for minors who believe that parental involvement would not be in their best interest.[lxiv, lxv] Subsequently, there has been renewed activity to include mandatory parental consent or notification requirements in state and federal abortion-related legislation.

The American Medical Association, the Society for Adolescent Health and Medicine, the American Public Health Association, the American College of Obstetricians and Gynecologists, the AAP, and other health professional organizations have reached a consensus that a minor should not be compelled or required to involve her parents in her decision to obtain an abortion, although she should be encouraged to discuss the pregnancy with her parents and/or other responsible adults.[lxvi,lxvii,lxviii,lxix,lxx,lxxi,lxxii] These conclusions result from objective analyses of current data, which indicate that legislation mandating parental involvement does not achieve the intended benefit of promoting family communication but does increase the risk of harm to the adolescent by delaying access to appropriate medical care or increasing the rate of unwanted births.

Beliefs about abortion are deeply personal and are shaped by class, culture, religion, and personal history, as well as the current social and political climate. The AAP acknowledges and respects the diversity of beliefs about abortion. The AAP affirms the value of parental involvement in decision-making by adolescents and the importance of productive family communication in general. The AAP is foremost an advocate of strong family relationships, and holds that parents are generally supportive and act in the best interests of their children. We strongly urge HHS policy not to enable entities to infringe on the ability of parents and children to act in their best interests.

Medical Neglect

The AAP asserts that every child should have the opportunity to grow and develop free from preventable illness or injury. Children also have the right to appropriate medical evaluation when it is likely that a serious illness, injury, or other medical condition endangers their lives or threatens substantial harm or suffering. Under such circumstances, parents and other guardians have a responsibility to seek medical treatment, regardless of their religious beliefs and preferences. The AAP emphasizes that all children who need medical care that is likely to prevent substantial harm or suffering or death should receive that treatment.[lxxiii]

The U.S. Constitution requires that government not interfere with religious practices or endorse particular religions. However, these constitutional principles do not stand alone and may, at times, conflict with the independent government interest in protecting children. Government obligation arises from that interest when parental religious practices subject minor children to possible loss of life or to substantial risk of harm. Constitutional guarantees of freedom of religion do not permit children to be harmed through religious practices, nor do they allow religion to be a valid legal defense when an individual harms or neglects a child. As HHS considers the implementation, expansion, and enforcement of religious objections to medical care, we urge you to avoid policy changes that would result in financial support for organizations that encourage or engage in faith-based medical neglect.

Religious Nonmedical Health Care Institutions

Medicare and Medicaid cover care provided at religious nonmedical health care institutions (RNHCIs) and exempt these institutions from medical oversight requirements.[lxxiv] RNHCIs provide custodial rather than skilled nursing care. Given patients' exemptions from undergoing medical examinations, it is not possible to determine whether patients of RNHCIs would otherwise qualify for benefits.[lxxv,lxxvi] Because providing public funding for unproven alternative spiritual healing practices may be perceived as legitimating these services, parents may not believe that they have an obligation to seek medical treatment. Although the AAP recognizes the importance of addressing children's spiritual needs as part of the comprehensive care of children, it opposes public funding of religious or spiritual healing practices.[lxxvii]

Newborn Hearing Screening

Although most infants can hear normally, 1 to 3 of every 1,000 children are born with some degree of hearing loss.[lxxviii] Without newborn hearing screening, it is difficult to detect hearing loss in the first months and years of an infant's life. About half of the children with hearing loss have no risk factors for it. Newborn hearing screening can detect possible hearing loss in the first days of a child's life. If a possible hearing loss is found, further tests will be done to confirm the results. When hearing loss is confirmed, treatment and early intervention should start as soon as possible. Studies show that children with hearing loss who receive appropriate early intervention services by age 6 months usually develop good language and learning skills. That is why the AAP recommends that all babies receive newborn hearing screening before they go home from the hospital. We would thus strongly urge HHS to support hearing screenings for all newborns, without exception.

Unaccompanied Children

Children, unaccompanied and in family units, seeking safe haven in the United States often experience traumatic events in their countries of origin, during their journeys to the United States, and throughout the difficult process of resettlement. Upon arriving in the U.S., unaccompanied immigrant children are transferred to the custody of HHS's Office of Refugee Resettlement (ORR) and placed in shelters, many of which are run by faith-based organizations. Children, especially those who have been exposed to trauma and violence, should not be placed in settings that do not meet basic standards for children's physical and mental health and that expose children to additional risk, fear, and trauma. Children in federal custody and in the custody of sponsors, whether unaccompanied or accompanied, should receive timely, comprehensive medical care, including reproductive services and abortion care, that is culturally and linguistically sensitive by medical providers trained to care for children.[lxxix] This care should be consistent throughout all stages of the immigration processing pathway.

Recent actions by the Office of Refugee Resettlement in the case of "Jane Doe" are quite troubling. No woman or girl should face political interference in their health care decisions, including while she is in an ORR shelter, or held in any federally-funded detention facility. Safe, legal abortion is a necessary component of women's health care. When abortion care is illegal or highly restricted, women resort to unsafe means to end an unwanted pregnancy, including self-inflicted abdominal and bodily trauma, ingestion of dangerous chemicals, self-medication with a variety of drugs, and reliance on unqualified abortion providers. By obstructing basic access to safe and legal abortion, ORR is risking the health and lives of women and adolescents in its custody. ORR's action also appears to be a violation of the terms of the *Flores v. Reno* Settlement Agreement.

We urge HHS to ensure that no grantee of the federal government be permitted to deny any child, especially a child who has been exposed to trauma and violence, access to timely, comprehensive medical care, including reproductive services and abortion care.

Adoption and Foster Care

The AAP supports families in all their diversity, because the family has always been the basic social unit in which children develop the supporting and nurturing relationships with adults that they need to thrive. Children may be born to, adopted by, or cared for temporarily by married couples, nonmarried couples, single parents, grandparents, or legal guardians, and any of these may be heterosexual, gay or lesbian, or of another orientation. Children need secure and enduring relationships with committed and nurturing adults to enhance their life experiences for optimal social-emotional and cognitive development. Scientific evidence affirms that children have similar developmental and emotional needs and receive similar parenting whether they are raised by parents of the same or different genders.[lxxx] If two parents are not available to the child, adoption or foster parenting remain acceptable options to provide a loving home for a child and should be available without regard to the sexual orientation of the parent(s).[lxxxi] We urge HHS not to permit entities to discriminate against prospective or current adoptive or foster parents on the basis of sexual orientation of the parents.

LGBTQ Children

All children and adolescents deserve the opportunity to learn and develop in a safe and supportive environment. Lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth face high rates of bullying and other factors that contribute to health disparities such as higher rates of depression and suicidal ideation, higher rates of substance use, and more sexually transmitted and HIV infections.[lxxxii] Supportive and affirming communities, schools, friends and families can buffer all young people – especially LGBTQ youth – from negative experiences and outcomes while simultaneously promoting positive health and well-being.[lxxxiii] Policies that single-out or discriminate against LGBTQ youth are harmful to social-emotional health and may have lifelong consequences.[lxxxiv] All health care entities receiving federal funding, including those that are faith-based, should be welcoming to children who are members of the LGBTQ community.

The AAP advocates for policies that are gender-affirming for children – an approach that is supported by other medical professional organizations. In 2016, the AAP joined with other organizations to produce the document, "Supporting & Caring for Transgender Children," a guide for community members and allies to ensure that transgender young people are affirmed, respected, and able to thrive.[lxxxv] Section 1557 of the ACA contains essential nondiscrimination provisions for LGBTQ youth including prohibitions for discrimination on the basis of gender identity. These protections should be maintained and all covered entities, including faith-based organizations, should be required to comply.

All children and adolescents deserve the opportunity to learn and develop in a safe and supportive environment. “Conversion” or “reparative therapy” is never indicated for LGBTQ youth.[lxxxvi] This type of therapy is not effective and may be harmful to LGBTQ individuals by increasing internalized stigma, distress, and depression.[lxxxvii] We urge HHS to refrain from supporting entities who do not treat LGBTQ youth as they do all others, who discriminate or condone discrimination against them, their families, or LGBTQ parents, or who support, condone, or provide “conversion” or “reparative therapy”.

Child Welfare Services

Children in foster care have such unique vulnerabilities and health disparities that the AAP classifies them as a population of children with special health care needs. Children in foster care face greater health needs because of their experiences of complex trauma, including abuse, neglect, witnessed violence, and parental substance use disorders (SUD). Children in foster care have typically experienced multiple caregivers, impacting their ability to form a safe, stable, and nurturing attachment relationship with a caregiver. One third of children in foster care have a chronic medical condition, and 60 percent of those under age 5 have developmental health issues.[lxxxviii , lxxxix] Up to 80 percent of children entering foster care have a significant mental health need.[xc] Ensuring access to appropriate and trauma-informed services is critical to meeting the needs of this vulnerable population.

In FY 2016, the number of children entering foster care increased to over 270,000, up from 251,352 in FY 2012. This is the fourth year in a row that removals have increased after declining over the past decade. Parental substance use was a factor for the removal in over a third of those

cases, second only to neglect as a factor for placement in foster care. Of note, infants represented nearly a fifth of all removals from families to foster care, totaling 49,234 in FY 2016. A total of 437,465 children were in foster care on the last day of FY 2016.[xci] As the opioid epidemic continues to contribute to rising foster care placements, we need federal policies that support child and family healing and that provide a sufficient number of nurturing, high-quality foster and adoptive families.

Children fare best when they are raised in families equipped to meet their needs. Child welfare services can support the intensive family preservation services and parental SUD treatment needed to help families heal when it is possible to keep children together with their parents. When out-of-home placements are necessary for a child's health and safety, access to quality parenting from foster or kinship care providers can support a child's healing. High-quality foster parent training and recruitment is essential to ensure sufficient access to families with the necessary background and training in trauma, child development, and parenting skills. In light of the ongoing opioid epidemic and its impact on rising foster care placements, there is a significant need to expand recruitment broadly to meet growing need and to also better support and retain foster families and kinship caregivers.

Given the uniquely vulnerable health needs of children in foster care, and the need for expanded capacity for foster and adoptive homes, the AAP recommends that HHS not make any changes in federal child welfare policy that would result in discrimination against LGBTQ children and youth in foster care, or LGBTQ families seeking to serve as foster or adoptive parents. Faith-based organizations play an important role in providing child welfare services and families to provide nurturing homes for children. However, no federal policy changes should allow for discrimination against children or families in child welfare services on the basis of religion, sexual orientation, or gender identity. All children who enter the child welfare system should receive compassionate, high-quality, and trauma-informed care and support services.

HHS should not support entities involved in child welfare services that engage in discrimination against children or families based on sexual orientation, gender identity, marital status, or faith.

Conclusion

The AAP wishes to underscore its recognition of the important role of religion in the personal, spiritual, and social lives of many individuals, including health providers. Balancing that role with efforts to ensure children have appropriate access to needed health and social services is critical to meeting their health needs and supporting their health and wellbeing. As HHS considers potential changes to regulations and policy guidance to encourage the provision of grants and contracts to faith-based organizations, we urge you to ensure that federal policy does not undermine children's access to needed care and services.

Thank you again for the opportunity to provide feedback on this important issue. If you have any questions, please reach out to Ami Gadhia in our Washington, D.C. office at 202/347-8600 or agadhia@aap.org.

Sincerely,

Colleen A. Kraft MD, FAAP
President
CAK/avg

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Exhibit E

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Office of the President
Haywood Brown, MD, FACOG

March 27, 2018

VIA ELECTRONIC SUBMISSION

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

Re: RIN 0945-A03; Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

The American College of Obstetricians and Gynecologists (ACOG) writes in response to the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (Proposed Rule), published in the Federal Register on January 26, 2018 by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).

The creation of the Proposed Rule, coupled with the creation of a new division within OCR – the "Conscience and Religious Freedom Division" – suggests a concerning expansion of OCR's authority in a way that threatens to restrict access for patients seeking medical care and support. We are concerned that the Proposed Rule and new office will encourage some providers and institutions to place their personal beliefs over their patients' medical needs, a move that can have real-world, potentially life-and-death consequences for patients. ACOG opposes this expansion and calls on HHS and OCR to immediately withdraw the Proposed Rule.

ACOG believes that respect for an individual's conscience is important in the practice of medicine, and recognizes that physicians may find that providing indicated care could present a conflict of conscience. ACOG is committed to ensuring all women have unhindered access to health care and opposes all forms of discrimination.[i]

As outlined in the American Medical Association's Code of Medical Ethics, responsibility to the patient is paramount for all physicians. ACOG holds that providers with moral or religious objections should ensure that processes are in place to protect access to and maintain a continuity of care for all patients. If health care providers feel that they cannot provide the standard services that patients request or require, they should refer patients in a timely

manner to other providers. In an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care. Conscientious refusals should be limited if they constitute an imposition of religious or moral beliefs on patients, negatively affect a patient's health, are based on scientific misinformation, or create or reinforce racial or socioeconomic inequalities. The Proposed Rule disregards these rigorous standards of care established by the medical community.

The Proposed Rule demonstrates political interference in the patient-physician relationship. Institutions, facilities, and providers must give patients the full range of appropriate medical care to meet each patient's needs as well as relevant information regarding evidence-based options for care, outcomes associated with different interventions, and, in some cases, transfer to a full-service facility. Communication is the foundation of a positive patient-physician relationship and the informed consent process.[ii,iii] By allowing providers to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to make the health care decision that is right for them. All patients should be fully informed of their options.[iv]

ACOG evaluates policies based on the standard of "first, do no harm" to patients, and the result of the Proposed Rule could be just the opposite. Across the country, refusals of care based on personal beliefs have kept women from needed medical care.[v]

The Proposed Rule expands existing conscientious refusal laws by allowing any entity involved in a patient's care to claim a conflict of conscience, from a hospital board of directors to an individual who schedules procedures, and by allowing the refusal of "any lawful health service or activity."[vi] This threatens patients' access to all health care services, including vaccinations and blood transfusions.

ACOG believes that the top priority in any federal rulemaking must be ensuring access to comprehensive, evidence-based health care services. Access to comprehensive reproductive health care services is essential to women's health and well-being.[vii] ACOG urges HHS and OCR to put patients first and withdraw the Proposed Rule.

Sincerely,

Haywood L. Brown, MD, FACOG
President
American College of Obstetricians and Gynecologists

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[i] American College of Obstetricians and Gynecologists. Statement of Policy: Racial Bias. Feb 2017. *Accessed online:* https://www.acog.org/-/media/Statements-of-Policy/Public/StatementofPolicy93RacialBias2017-2.pdf?dmc=1&ts=20180326T1531018088

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[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).

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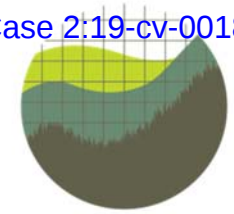
Exhibit F



Institute for Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

March 27, 2018

VIA ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services

Attn: Office for Civil Rights

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

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law[1] respectfully submits the following comments to the Department of Health and Human Services ("HHS" or "the Department") regarding its proposed rule on statutory conscience protections in health care ("Proposed Rule").[2] Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

Our comments focus, first, on HHS's failure to provide a reasoned explanation for disregarding relevant prior findings and, second, on serious errors and oversights in the Department's Regulatory Impact Analysis for the Proposed Rule. Specifically, we note the following:

- HHS disregards, without explanation, concerns that it raised in its 2011 rulemaking on conscience protections ("2011 Rule"), such as the possibility that an overly broad conscience protections rule would interfere with patients' ability to offer informed consent and the possibility that an overly broad rule would lead providers to believe—mistakenly—that statutory conscience protections allow them to discriminate against certain types of patients.
- HHS's Regulatory Impact Analysis ignores the Proposed Rule's potentially substantial indirect costs, such as reduced access to health care for patients and increased personnel expenses for providers.
- The Regulatory Impact Analysis fails to assess the distributional impacts of the Proposed Rule.
- The Regulatory Impact Analysis underestimates the number of entities covered by the Proposed Rule's assurance and certification requirement and, as a result, understates the Proposed Rule's direct compliance costs.

[1] This document does not purport to present New York University School of Law's views, if any.

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

I. HHS Fails to Provide a Reasoned Explanation for Disregarding Findings It Made in the 2011 Rule.

This is not HHS's first rulemaking on conscience protections. In 2008, the Department finalized a regulation ("2008 Rule") that, among other things, purported to clarify the scope of conscience protections under the Church Amendments, Section 245 of the Public Health Service Act, and the Weldon Amendment by expansively defining certain statutory terms.[3] HHS subsequently rescinded all of the 2008 Rule's definitions in the 2011 Rule, citing concerns about their potential to (1) compromise patients' ability to offer informed consent, (2) cause confusion about the scope of statutory protections, and (3) inadvertently encourage providers to discriminate against certain categories of patients.[4]

When an agency amends, suspends, or repeals a rule, the agency must provide "a reasoned explanation . . . for disregarding facts or circumstances that underlay or were engendered by the prior policy."[5] Underlying the 2011 Rule was a conclusion by HHS that expansive definitions of statutory terms would compromise patients' ability to offer informed consent and foster confusion and discrimination. Accordingly, before it can adopt the Proposed Rule, which defines statutory terms even more broadly than the 2008 Rule did, the Department must acknowledge its prior concerns about expansive definitions and explain either why those concerns are not implicated by the definitions proposed here or why the Proposed Rule is justified despite those concerns. In the absence of such an explanation, the Proposed Rule is arbitrary and capricious.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Compromise Patients' Ability to Provide Informed Consent

When it rescinded the majority of the 2008 Rule in 2011, HHS did so, in part, to "clarify any mistaken belief that [the 2008 Rule] altered the scope of information that must be provided to a patient by their provider in order to fulfill informed consent requirements."[6] The 2011

[3] Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072, 78,073 (Dec. 19, 2008) (hereinafter "2008 Rule").

[4] Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9973-74 (Feb. 23, 2011) (hereinafter "2011 Rule").

[5] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).

[6] 2011 Rule, 76 Fed. Reg. at 9973.

Rule emphasized that making a patient aware of all available health care options is "crucial to the provision of quality health care services."[7]

The Proposed Rule is likely to limit patients' awareness of their health care options to an even greater extent than the 2008 Rule would have.[8] For example, the Proposed Rule suggests that a provider has no obligation to offer patients a disclaimer regarding health care procedures to which the provider has a religious or moral objection.[9] In other words, providers need not warn patients that they are not being informed of all available treatment options. And yet HHS fails even to acknowledge its 2011 finding that a conscience protections rule could not properly "alter[ ] the scope of information that must be provided to a patient,"[10] much less explain why the Department no longer holds that view.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Cause Confusion About the Scope of Statutory Protections

The 2011 Rule highlighted commenters' concern that the definitions in the 2008 Rule "were far broader than scope of the federal provider conscience statutes."[11] In rescinding those definitions, the Department noted its agreement that the definitions "may have caused confusion regarding the scope" of statutory protections.[12]

Definitions included in the Proposed Rule are even broader than those adopted in 2008. For example, whereas the 2008 Rule interpreted statutory protections against "assist[ing] in in the performance" of an objectionable procedure to encompass any action with a "reasonable" connection to that procedure,[13] the Proposed Rule requires only an "articulable" connection to the procedure.[14] But the Proposed Rule nevertheless fails to acknowledge HHS's prior finding as to the potential for broad definitions to cause confusion. Nor does the Department explain why the Proposed Rule is justified in spite of this potential for confusion.

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[7] *Id.*

[8] Proposed Rule, 83 Fed. Reg. at 3924.

[9] *See id.* at 3894-95 (defining "referral or refer for" to include "disclaimers," and noting that referral was not defined in the 2008 Rule).

[10] 2011 Rule, 76 Fed. Reg. at 9973.

[11] *Id.*

[12] *Id.*

[13] 2008 Rule, 73 Fed. Reg. at 78,097.

[14] Proposed Rule, 83 Fed. Reg. at 78,090-91.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Encourage Discrimination Against Categories of Patients

HHS's 2011 decision to rescind the definitions in the 2008 Rule was also motivated by concern that the definitions would lead providers to believe, incorrectly, that statutory protections extended not just to refusals to perform particular procedures, but also to refusals to care for particular types of patients. As the Department explained in the 2011 Rule, statutory conscience protections "were never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable."[15] But the Department agreed with commenters that the 2008 Rule could nevertheless give the impression that "Federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs."[16] As a result, HHS feared that the 2008 Rule could reduce access to "a wide range of medical services, including care for sexual assault victims, provision of HIV/AIDS treatment, and emergency services."[17]

Again, the definitions in the Proposed Rule are even broader than those that caused the Department concern in 2011 and are thus likely to give rise to the same harmful misimpressions about the scope of statutory conscience protections. But the Department neither acknowledges its prior concerns regarding the inadvertent encouragement of discrimination nor explains why proceeding with the Proposed Rule is reasonable despite those concerns.

II. HHS Fails to Consider the Proposed Rule's Indirect Costs

A rational cost-benefit analysis considers both the direct *and* indirect effects of a proposed rule. To that end, Executive Order 12,866 requires agencies to consider not just "direct cost . . . to businesses and others in complying with the regulation," but also "any adverse effects" the rule might have on "the efficient functioning of the economy, private markets . . . health, safety, and the natural environment."[18] Longstanding guidance on regulatory impact analysis from the White House Office of Management and Budget similarly instructs agencies to "look beyond the direct benefits and direct costs of [their] rulemaking and consider any important

[15] 2011 Rule, 76 Fed. Reg. at 9973-74.

[16] *Id.* at 9973.

[17] *Id.* at 9974.

[18] E.O. 12,866 § 6(a)(3)(C)(ii).

ancillary benefits and countervailing risks."[19] The Supreme Court, too, has made clear that "'cost' includes more than the expense of complying with regulations" and that "any disadvantage could be termed a cost."[20]

Despite HHS's clear obligation to consider indirect consequences, the Regulatory Impact Analysis for the Proposed Rule assesses only direct compliance costs and ignores the ways in which the Proposed Rule is likely to reduce patients' access to health care and increase providers' personnel expenses.

HHS Fails to Consider Costs to Patients from the Express Denial of Medical Services

For a variety of reasons, the Proposed Rule is likely to reduce the availability and consumption of medical services, negatively affecting patient health and wellbeing. As discussed in Section I of these comments, the Proposed Rule's expansive definitions of statutory terms are likely to lead some providers to adopt a much broader interpretation of statutory conscience protections than Congress intended. This, in turn, will increase the frequency with which patients are denied care due to a provider's religious or moral objections. Such denials can impose a variety of costs—financial, physical, and psychological—on patients.

At minimum, a patient denied care must incur the cost of seeking out an alternative provider. Assuming patients typically choose the most convenient healthcare provider available, a second-choice provider may be farther away than the first. Traveling farther away, the patient loses time and money spent on transportation, and may be required to request time off from work or pay for childcare services. For some patients, these costs may be insurmountable.

Furthermore, some patients who are denied care may be too discouraged to seek out alternative sources of healthcare services. These patients may eschew treatment altogether, leading to negative health consequences.

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[19] Office of Mgmt. & Budget, Circular A-4 (2003), https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.

[20] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015); *see also Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin.,* 956 F.2d 321, 326-27 (D.C. Cir. 1992) (striking down fuel-efficiency rule for failure to consider indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (holding that EPA was required to consider the indirect safety effects of substitute options for car brakes when banning asbestos-based brakes under the Toxic Substances Control Act).

Finally, the Proposed Rule may discourage some patients from seeking medical services in the first place, simply because they *fear* being rejected by a provider. This assumption is reciprocal to the Department's assumption that some potential healthcare providers are currently (absent the Proposed Rule) discouraged from entering the profession because they fear they will be discriminated against for their religious and moral convictions.[21]

HHS Fails to Consider Costs to Patients from the Undisclosed Denial of Medical Services

The Proposed Rule's likely health costs extend beyond patients who are (or who fear that they will be) expressly denied care. As explained in Section I of these comments, the Proposed Rule encourages providers not merely to refuse to provide referrals for procedures or services to which they object, but also to refuse to warn patients that the provider is declining to recommend such treatments. A patient who does not realize she is being denied information about a particular health care option might choose an alternative that is less beneficial to her health or wellbeing.[22]

HHS Fails to Consider Indirect Personnel Costs for Providers

In addition to imposing health costs on patients, the Proposed Rule may indirectly increase personnel costs for some health care entities. For example, if the Proposed Rule causes support staff at a given health care facility to decline to perform services that they previously performed (or to decline to treat patients whom they previously treated), the facility will need to pay for additional labor to meet the same level of demand.

[21] Proposed Rule, 83 Fed. Reg. at 3916.

[22] The Department solicits comment on methodologies that can be used to quantify ancillary health costs. There are a number of ways to assess such impacts, including: retrospective cohort studies (e.g., studying the conditions of women's health in the 1960's and 1970's when information on abortion was limited); cohort studies in other countries or states where abortion counseling and referral is restricted; prospective cohort studies (i.e., a pilot program testing the regulation on a subset of the population); self-report surveys administered to a sample population of women (assessing, for example, their awareness of the existence of and details of abortions procedures); estimations of the potential effects by using statistics in the current environment as indicators; or any other of a number of epidemiological and other studies that are routinely performed by public health professionals when evaluating policies that affect public health.

III. HHS Fails to Consider the Proposed Rule's Distributional Impacts

Executive Order 12,866 requires agencies to "consider . . . distributive impacts" that will result from a proposed regulatory action.[23] In addition to failing to take the aforementioned ancillary costs into consideration, the Department has failed to consider how these costs will burden certain groups disproportionately. The Department's failure to consider such distributional impacts is particularly egregious given that it lists the promotion of "a society free from discrimination" as one of the chief benefits of the Proposed Rule.[24] HHS cannot rationally tout the Proposed Rule's potential to reduce discrimination against religious health care providers while ignoring its potential to increase discrimination against other groups.[25]

Specifically, the Department should consider whether and to what extent the Proposed Rule will disproportionately burden the following subpopulations:

- Immigrant Women: Recent immigrants may be less well informed on the availability of reproductive health care in the U.S., and therefore in greater need of the counselling and referral services that the Proposed Rule covers.

- Rural Women: Increasing the incidence of health care providers refusing to provide counseling or referrals may create a greater problem for women who live in rural areas than for women at large, due to the increased search and travel costs associated with finding an alternative provider in rural areas.

- Low-Income Women: Women with lower incomes have fewer resources available to allocate to transportation and child care. If refused counseling or referral services, these women may suffer greater costs when seeking alternative health care providers. The refusal may even result in an insurmountable obstacle to obtaining the health service sought.

- Women of Color: Women of color disproportionately earn lower incomes and live in underserved areas. If refused counseling or referrals, these women may experience greater burdens to seek alternative health care providers.

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[23] E.O. 12,866 § 6(b)(5).

[24] Proposed Rule, 83 Fed. Reg. at 3903.

[25] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (noting that "reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions"); *Sierra Club v. Sigler*, 695 F.2d 957, 979 (5th Cir. 1983) (an agency "cannot tip the scales . . . by promoting [an action's] possible benefits while ignoring [its] costs.").

- LGBTQ Individuals: As discussed in Section I, the Proposed Rule, like the 2008 Rule, may lead health care workers to believe they can permissibly refuse to provide any type of medical service to gay or transgender individuals (or their families) based on moral or religious objections. Such refusals would decrease the quantity and quality of health care available to that population.

- Individuals with HIV/AIDS: Similarly, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical service to individuals with HIV/AIDS. Again, such refusals would decrease the quantity and quality of health care available to that population.

- Interracial/Interfaith Families: Finally, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical services to interracial or interfaith families because they morally object to such relationships. As with LGBTQ patients and HIV-positive patients, this misimpression could result in reduced access to health care for interracial and interfaith families.

IV. HHS Underestimates the Number of Entities Affected by the Proposed Rule and, as a Result, Underestimates the Proposed Rule's Compliance Costs

In addition to overlooking the Proposed Rule's indirect costs, HHS also underestimates the Proposed Rule's *direct* costs. Section 88.4 of the Proposed Rule requires certain recipients of HHS funding "to submit written assurances and certifications of compliance" with statutory conscience protections.[26] In calculating compliance costs for this assurance and certification requirement, the Department estimates that the requirement would apply to between 94,279 and 152,519 individuals and entities.[27] But that estimate excludes a large number of individuals and entities that, under a plain reading of the Proposed Rule, would in fact be required to submit assurances and certifications.[28]

HHS assumes that "all physicians" will be exempt from complying with the assurance and certification requirement, either because they do not accept HHS funds or because they "meet the proposed criteria for exemption . . . in proposed § 88.4(c)(1)."[29] But § 88.4(c)(1) exempts physicians and physician offices only if they (1) participate in Medicare Part B and

[26] Proposed Rule, 83 Fed. Reg. at 3896.

[27] *Id.* at 3910.

[28] *Id*. at 3910, 3915.

[29] *Id.* at 3909-10.

(2) "are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism."[30] It is patently unreasonable for the Department to assume that this exemption encompasses every physician who receives HHS funds. Some physicians, for example, accept both Medicare *and* Medicaid funding.

HHS makes a similar error in estimating the number of individuals and entities that would be exempt from the assurance and certification requirement due to § 88.4(c)(2), which exempts recipients of funding under certain grant programs administered by the Administration for Children and Families that have a purpose unrelated to health care provision or medical research. The Department assumes that "all persons and entities that provide child and youth services . . . [and] all entities providing services for the elderly and persons with disabilities . . . would fall within this exemption."[31] As with the exemption for physicians, however, the § 88.4(c)(2) exemption is unavailable if HHS money is accepted from any other source. It seems unlikely that *no* entities that provide services for children, the elderly, or the disabled receive HHS funding from *any* source other than non-healthcare-related grant programs administered by the Administration for Children and Families.

Because it underestimates the number of entities that will be obligated to comply with the Proposed Rule's assurance and certification requirement, HHS also underestimates the Proposed Rule's total compliance costs.

Respectfully,

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Theodore Gifford
Jack Lienke
Jason A. Schwartz

[30] *Id.* at 3929.

[31] *Id.* at 3910.