Exhibit 100

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LEGISLATIVE OFFICE

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

Submitted electronically

AMERICAN CIVIL LIBERTIES UNION
WASHINGTON
LEGISLATIVE OFFICE
915 15th STREET, NW, 6TH FL
WASHINGTON, DC 20005
T/202.544.1681
F/202.546.0738
WWW.ACLU.ORG

FAIZ SHAKIR
DIRECTOR

NATIONAL OFFICE
125 BROAD STREET, 18TH FL.
NEW YORK, NY 10004-2400
T/212.549.2500

OFFICERS AND DIRECTORS
SUSAN N. HERMAN
PRESIDENT

ANTHONY D. ROMERO
EXECUTIVE DIRECTOR

ROBERT REMAR
TREASURER

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

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

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

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

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

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

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

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

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

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

[3] *See id.* at 18.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Appears to provide immunities for health care institutions and professionals who refuse to provide complete information to patients about their condition and treatment options;
- Would result in patients being denied, or delayed in getting, health care to the extent the Rule requires health care facilities to employ people who refuse to perform core functions of their jobs;
- Purports to create new "exemptions," that would leave patients who rely on federally-subsidized health care programs, such as Title X family planning services, unable to obtain services those programs are required by law to provide;
- Creates confusion about whether hospitals can refuse to provide, and bar its staff from providing, emergency care to pregnant women who are suffering miscarriages or otherwise need emergent abortion care; and
- Invites health care providers to discriminate against individuals based on who they are by, for example, refusing to provide otherwise available services to a patient for the sole reason that the patient is transgender.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. The Proposed Rule Fosters Discrimination.

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

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

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

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

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

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

* * *

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

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

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

A. Examples of Impermissible Church Amendment Expansions.

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

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

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

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

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

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

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

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

B. Examples of Impermissible Coats-Snowe Amendment Expansions.

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

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

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

C. Examples of Impermissible Weldon Amendment Expansions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* * *

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

Sincerely,

Louise Melling Deputy Legal Director	Faiz Shakir National Political Director

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

Exhibit 101

GREATER NEW YORK HOSPITAL ASSOCIATION
555 WEST 57TH STREET, NEW YORK, NY 10019 • T (212) 246-7100 • F (212) 262-6350 • WWW.GNYHA.ORG • PRESIDENT, KENNETH E. RASKE

March 27, 2018

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

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

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

Dear Mr. Severino:

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

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

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

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

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

> In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections.[1]

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

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

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

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

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

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[1] "The Limits of Conscientious Refusal in Reproductive Medicine," *ACOG Committee Opinion*, no. 385 (November 2007; *reaffirmed 2016*)

[2] N. Berlinger, B. Jennings, S. Wolf, *The Hastings Center Guidelines for Decisions on Life Sustaining Treatment and Care Near the End of Life* (Oxford University Press, 2013), 17.

[3] Ibid.

GNYHA

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

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

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

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

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

Comments on Specific Regulatory Proposals

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

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

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

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

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

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"Assist in the Performance"

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

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

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

"Discriminate" or "Discrimination"

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

Compliance Requirements

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

GNYHA

Enforcement Authority

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

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

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

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

Thank you for taking our comments into consideration.

Very Truly Yours,

Kenneth E. Raske
President

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

Exhibit 102

March 27, 2018

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

Re: Docket No.: HHS- OCR - 2018—0002, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority; Proposed Rule issued January 26, 2018

Dear Mr. Severino:

The Massachusetts Health & Hospital Association (MHA), on behalf of its member hospitals, health systems, physician organizations, and allied healthcare providers appreciates this opportunity to offer comments related to the Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) proposed rule regarding certain statutory conscience protections.

At the outset it is important to note that the Massachusetts provider community has consistently worked with our medical staff to ensure that personal views that are raised and discussed within various levels of care are respected as they relate to providing care and treatment of our patients and our communities that we serve. The adoption of the conscience protections for health care professionals within the federal affordable care act was similar to requirements that have been adopted within both Massachusetts statues as well as healthcare licensure requirements. In particular, healthcare providers have had the ability to raise religious concerns related to care and treatment, during which the facility or clinic will work with the provider to determine how to accommodate those concerns as well as ensure continued care and treatment for the patients.

However, the Massachusetts provider community also has a strong commitment to ensuring that all patients are able to access emergent, urgent, and medically necessary care. In Massachusetts, it is standard policy for all hospitals and health system to not discriminate in the delivery of emergent, urgent, and medical necessary care on the basis of the patient's race, color, national origin, citizenship, alienage, religion, creed, sex, sexual orientation, gender identity, age, or disability. As a result, we are concerned about possible conflicts that may result in the enforcement of the proposed regulations by OCR given conflicting state laws and regulations. To that end, we provide the following comments for consideration by OCR to reflect hospital and other healthcare provider's obligations under specific state requirements.

OCR Enforcement of Provider Conscience Rights:
While MHA and our members are considerate of a healthcare provider's ability to determine the medical necessity and treatment options for patients, hospitals and health system also recognize the individual clinician's religious rights (as their conscience rights) related to participating in various care and treatment.

In keeping with the principle that the conscience (or religious) protections should be treated akin to an individuals' civil rights, MHA urges OCR to ensure that the enforcement policies and practices applicable to the conscience protections are comparable to the long-standing policies and practices applicable when guaranteeing other civil rights protections for employees and staff. OCR should not invent new, distinct, or additional policies and practices that add unnecessary complexity and burden or prefer conscience protections over other civil rights.

Specifically, OCR should use existing civil rights frameworks as the model for the conscience protections at issue, such as evaluating facts and circumstances to determine whether a hospital has done all it reasonably can to accommodate religious conscience objections of individual medical staff. This not only would place the conscience protections on a level playing field with other civil rights, but would ensure that the conscience protections are guaranteed through an enforcement framework that already has proven effective in analogous civil rights contexts. We would urge not sanctioning a healthcare provider (the hospital or health care system) for failing to accommodate the moral or religious beliefs of an employee or medical staff where, despite being on notice of his or her right to do so, the individual did not give the hospital or health care system advance notice of his or her religious beliefs.

Again it is important to note that under existing federal and state laws/regulations, healthcare facilities already provide reasonable accommodation for employees who disclose their sincerely held religious beliefs. This type of framework has successfully protected employees, including those of hospitals and health systems, from religious discrimination. For this reason we would urge OCR to keep the framework for review based on the requirement of reasonably accommodating the sincerely held religious beliefs of employees and medical staff. The regulation should not be expanded to include moral objections without creating a framework for considering such concern that is not based on existing state laws or regulations.

Conflict with Existing Provider Licensure and Standards of Care:
We would also strongly urge OCR to consider the current requirements that healthcare providers have under existing Centers for Medicare and Medicaid Services (CMS) conditions of participation as well as other federal and state requirements. There are specific requirements related to the delivery of care and treatment for all patients by a provider who is receiving federal and state funding through Medicare, state Medicaid programs (like the Massachusetts MassHealth program), and the Social Security Act. More specifically, Massachusetts providers are required under state law and regulations to meet specific access requirements for low income patients under the Health Safety Net program. In addition state licensure requirements for a facility and individual professional licensure requirements also stipulate the care and treatment of a patient regardless of their race, color, national origin, citizenship, alienage, religion, creed, sex, sexual orientation, gender identity, age, or disability.

We strongly urge OCR to recognize the potential conflicting requirements under existing federal and state laws and regulations that would prevent the enforcement of a provider conscience regulation as outlined in the draft regulations. If strictly enforced as drafted, we are also concerned that many providers would be out of compliance with the requirements outlined above

impacting provider eligibility for reimbursement under the federal and state public programs. For these reasons we urge OCR to consider the government's interests in not only ensuring fundamental fairness but also avoiding inappropriate disruption of health services that are funded by federal and state resources.

Increase of Unnecessary Regulatory Burdens:
In the proposed rule, MHA would also request OCR to consider the increased regulatory burdens of both the certification of compliance as well as the proposed notice requirements.

Healthcare providers, such as hospitals and health systems, already have to sign cost reports and other documents with CMS that indicate that the facility is in compliance with all applicable federal rules and regulations. These include applicable civil rights laws, access to care standards, and operational requirements issued by a multitude of federal Health and Human Services (HHS) agencies. The provider community strongly feels that in addition to the four stated exceptions for providing compliance with the regulations, providers should also be able to utilize existing certification requirements that express the facilities adherence to federal regulatory requirements under HHS. Requiring a detailed analysis and certification for this specific rule may result in the slippery slope of requiring similar certifications for all other rules and requirements issued by HHS. This would add to the overall paperwork burden and unnecessary use of resources by providers that should be focused on patient care.

MHA is also opposed to the requirement of having a separate HHS notice requirement. Hospitals in particular are already required to provide a multitude of forms and notices to patients when they arrive for services (inpatient or outpatient) that create substantial confusion for patients and caregivers. We would strongly urge that COR instead allow providers to use those notices that are developed in various states that take into consideration the key messages of the provider conscience religious considerations, but tailored to each state specific standards. Adding in additional notice requirements that are contradictory to the state requirements is confusing to patients which lead to delays in care. In addition, duplicative notifications increase costs in signage, postage, and other materials. So we urge OCR to reconsider their approach and allow notices to be based on state specific requirements.

Thank you for considering our comments. Should you have any questions about the points raised in this letter, please do not hesitate to contact me at (781) 262-6034 or agoel@mhalink.org.

Sincerely,

Anuj K. Goel, Esq.
Vice President, Legal and Regulatory Affairs

Exhibit 103

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

March 27, 2018

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

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

To whom it may concern:

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

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

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

These are our concerns:

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

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

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

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

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

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

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

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

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

Conclusion

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

Sincerely,

Maulik

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

Exhibit 104

THE DISABILITY COALITION

A Coalition of Persons with Disabilities, Family Members, and Advocates

In Santa Fe:
P.O. Box 8251
Santa Fe, New Mexico 87504-8251
Telephone: (505) 983-9637

In Albuquerque:
3916 Juan Tabo Boulevard, NE
Albuquerque, NM 87111
Telephone: (505) 256-3100

Reply to: Santa Fe office

March 27, 2018

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

Re: Department of Health and Human Services, Office for Civil Rights RIN 0945–ZA03, Proposed Regulation on "Protecting Statutory Conscience Rights in Health Care", Docket No. HHS-OCR-2018-0002

The Disability Coalition of New Mexico is a broad coalition of persons with disabilities, family members and advocates for the rights of people with disabilities of all kinds, including physical, mental, developmental, intellectual, and sensory. We submit these comments in opposition to the proposed rule on "Protecting Statutory Conscience Rights in Health Care" ("the Proposed Rule") published in the Federal Register by the Department of Health and Human Services (DHHS) on January 26, 2018. 83 Fed.Reg. 3880.

Our central concern is that the Proposed Rule will allow or even promote discrimination specifically on the basis of disability. However, we note that persons with disabilities would also be subject to increased discrimination on non-disability-specific bases that they share with other individuals, such as discrimination related to reproductive health services or end-of-life care, or that based on sexual orientation or gender identity.

People with disabilities already face significant barriers to obtaining the health care they need, in the form of such obstacles as inaccessible medical offices and equipment, providers who do not understand or address the needs of persons living with disabilities, or those who do not value the lives of individuals with disabilities to the same degree as those of the "able-bodied". The Proposed Rule would compound those problems by giving license to an extremely broad range of people involved – however tangentially – in the provision of health care services to impose

their individual beliefs on patients, to the extent of entirely depriving them of access to necessary services.

Refusals to provide care are often based on subjective beliefs about the quality of life that a person with a disability experiences – or will experience if allowed to live. For example, life-saving care may be denied to a newborn because treating providers believe that the child's quality of life as an individual with a disability is not worth saving. Or care may be withheld from someone who has been severely injured in an automobile accident based on the belief that his quality of life going forward does not merit providing life-saving services. Or a person with an intellectual disability may be denied services based on a belief that the person does not deserve the same access to services that a person with "normal" functional capacity would receive. The Proposed Rule would give free rein to providers to impose these beliefs on their patients, exacerbating the already difficult situation that people with disabilities face in obtaining health care services.

Health care providers already enjoy ample protection from being forced to participate in services that violate their religious beliefs. The Proposed Rule would constitute an enormous broadening of those protections, to the detriment of patients in need of care.

1. The Proposed Rule would allow any person's individual belief to be the basis of an exemption from providing needed care to a patient, regardless of whether the belief is based on religious precepts.
2. The exemption would extend well beyond clinicians directly involved in the provision of health care services, and allow anyone with any "articulable connection" to service provision to refuse participation. 83 Fed.Reg. at 3892 (preamble) and 3923 (proposed 45 CFR §88.2). For example, a hospital administrator could refuse to process paperwork to admit a patient for a procedure disfavored by that employee, a cafeteria worker could refuse to bring a meal to a patient receiving services the worker does not agree with, or a technician could refuse to prepare equipment to be used in a procedure.
3. The "health care entities" protected under the Proposed Rule would include an extremely broad range of organizations beyond those directly engaged in the provision of health care services. The proposed definition expressly includes, for example, research organizations, insurance plans, and "plan sponsor[s]" such as employers, and goes on to state that the proposed list is intended to be merely illustrative and is not exhaustive. 83 Fed.Reg. at p. 3893 (preamble) and 3924 (proposed 45 CFR §88.2). The extent to which entities or individuals with only the most tangential tie to the care would be permitted to block provision of that care is breath-taking.
4. A provider refusing to participate would be under no obligation to give the patient information on or referral to alternate sources of care that would enable the individual to obtain needed services, or to facilitate the patient's transfer to such a provider. Withholding such information from a patient is a gross violation of the trust relationship that should exist between provider and patient and could lead to serious harm to a patient who is thereby prevented from accessing needed care from an alternative source after a "conscience-based" refusal.

In addition to its extremely broad scope, we have many other concerns about the Proposed Rule, including the following:

1. The Proposed Rule would improperly give the religious, moral or ethical beliefs of health care providers (or other individuals distantly associated with the provision of care) primacy over those of the patient. The Proposed Rule goes well beyond protecting the religious and moral beliefs of health care providers and allows those providers (and others with even a tenuous connection to provision of services) to impose their beliefs on their patients and other third parties.

2. The Proposed Rule would improperly give the religious, moral or ethical beliefs of providers primacy over medical standards of care. All patients have the right to expect that they will be treated in accordance with such generally accepted standards and should not be deprived of that appropriate treatment based on individual provider beliefs.

3. The Proposed Rule would protect the rights of providers to refuse to provide care, but does nothing to protect providers whose consciences call on them to provide services. For example, a physician would have the right to refuse to provide abortion services, but another physician whose moral convictions called for her to provide an abortion as a necessary service for a patient would not have the same protection for her beliefs and could be subjected to retaliation, disciplinary action or outright denial of her right to act on her beliefs by providing appropriate medical care. In so doing, the Proposed Rule appears to privilege some moral convictions as worthy of protection over others that are deemed to be unworthy of such safeguards.

4. The disclosure requirements in the Proposed Rule are inadequate. While it would require health care entities to notify patients of the provider's right to refuse services, it requires no notification of the types of care or services that will be denied. This could lead to a patient unknowingly finding herself in a position where she will be denied services, to her detriment. For example, a patient may mistakenly believe that a full-service hospital offers sterilization services, only to find out that she cannot obtain a tubal ligation at the time she delivers her baby but must instead undergo a second surgical procedure at a separate facility at another time.

5. The Proposed Rule goes beyond protecting the religious and moral beliefs of providers and would constitute government authorization for discrimination.

6. The Proposed Rule would conflict with existing law and does not clarify how its provisions would interact with those other provisions.

a) The Proposed Rule would create a conflict with the Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1295dd. That statute requires that a hospital must screen patients to determine the existence of an emergency condition and must provide necessary services to stabilize the individual's condition or, in appropriate cases, transfer the patient to another provider for care. The Proposed Rule appears to encourage providers to flout EMTALA by denying care, disregarding the requirements to screen and stabilize, and refusing to arrange for transfer to an appropriate provider. The Proposed Rule (including the preamble) published in the Federal Register makes neither any mention of EMTALA or any attempt to clarify the intended interaction of the Proposed Rule's provisions with statutory obligations under EMTALA.

b) Title VII of the 1964 Civil Rights Act requires reasonable accommodations for the religious beliefs or practices of employees, including those of health care entities, unless the accommodation imposes a undue burden on the entity's operations. The Proposed Rule would go well beyond such accommodations and thereby put employers in the position of operating within two different and inconsistent sets of rules. As with EMTALA, the Proposed Rule published in the Federal Register neither mentions nor addresses Title VII.

Finally, the Proposed Rule appears to authorize an unconstitutional establishment of religion. Freedom of religion, as enshrined in the U.S. Constitution, is the right to free exercise of one's own religion and is not a license to impose one's religious beliefs on others or to engage in discrimination against others based on one's own beliefs. The U.S. Supreme Court has warned that accommodation of religious beliefs may, if taken too far, become an "unlawful fostering of religion", *Corp. of Presiding Bishop v. Amos*, 483 U.S. 327, 334-35 (1987), and that religious accommodations that unduly burden others are not protected by the Constitution's Establishment Clause. See *Sherbert v. Verner*, 374 U.S. 398 (1963); see also *Burwell v. Hobby Lobby*, 573 U.S. ___,134 S. Ct. 2751 (2014). The Proposed Rule would authorize individuals and institutions involved in the provision of health care to impose their private beliefs on others who do not share those beliefs and thus unduly burden those other persons, and is therefore unconstitutional.

We strongly urge the Department to withdraw the Proposed Rule. Thank you for your consideration of these comments.

Sincerely,

Ellen Pinnes
for The Disability Coalition
EPinnes@msn.com

Exhibit 105

March 27, 2018

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

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

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

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

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

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

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

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

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

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

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

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Family Planning Program, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.

[2] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

[3] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

[4] *See, e.g.*, Rule *supra* note 1, at 180-185.

[5] *See* NFPRHA *supra* note 34.

[6] *See id.*

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

Sincerely,

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

Exhibit 106

March 27, 2018

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

Re: RIN 0945-ZA03

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

Dear Secretary Azar:

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

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

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

Application of Proposals in Emergency Situations

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

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

202-728-0610
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[1] 42 U.S. Code § 1395dd - Examination and treatment for emergency medical conditions and women in labor

[2] ACEP Code of Ethics for Emergency Physicians; Approved Jan 2017; https://www.acep.org/clinical---practice-management/code-of-ethics-for-emergency-physicians

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

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

Definition of Referrals

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

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

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

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

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

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

Requirement to Submit Written Assurances and Certifications of Compliance

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

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

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

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

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

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

Notice Requirement

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

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

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

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

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

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

Sincerely,

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

Exhibit 107

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VIA ELECTRONIC SUBMISSION AT REGULATIONS.GOV

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM
RIN 0945-ZA03
Hubert H. Humphrey Building, Room 209F
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0945-ZA03
Comments on DHHS Notice of Proposed Rulemaking Concerning "Protecting Statutory Conscience Rights" in Health Care; Delegations of Authority

Dear Director Severino:

The National Immigration Law Center ("NILC") submits the following comments to the federal Department of Health and Human Services ("Department") and its Office for Civil Rights ("OCR") in opposition to the proposed regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (83 Fed, Reg. 3880 (Jan. 26, 2018)).

NILC specializes in the intersection of health care and immigration laws and policies, providing technical assistance, training, and publications to government agencies, labor unions, non-profit organizations, and health care providers across the country. For over 30 years, NILC has worked to promote and ensure access to health services for low-income immigrants and their family members.

As an organization focused on defending and advancing the rights of low income immigrants, we are deeply concerned with the ways in which these regulations fail to account for the significant burden that will fall disproportionately on immigrants and all people of color. Immigrant women and immigrants who identify as Lesbian, Gay, Bisexual, Transgender, and Queer ("LGBTQ") already experience severe health disparities and discrimination, conditions that will be exacerbated by the proposed rule, resulting in in poorer health outcomes.

LOS ANGELES (Headquarters)
3450 Wilshire Blvd. Box #108 – 62
Los Angeles, CA 90010
213 639-3900
213 639-3911 fax

WASHINGTON, DC
1121 14th Street, NW, Suite 200
Washington, DC 20005
202 216-0261
202 216-0266 fax

www.nilc.org

We object to the proposal that OCR direct its limited resources toward the subject of this rule, and to the newly created "Conscience and Religious Freedom Division" in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. Immigrant communities rely on OCR to enforce regulations implementing the Title VI protection that individuals with Limited English Proficiency (LEP) are not subject to discrimination based on national origin. [1] According to the Pew Research Center 49 percent of foreign born individuals are not proficient English speakers (data from the 2010 Census and 2013-15 American Community Surveys).[2] Yet OCR's enforcement of the Title VI protection is inadequate, with the result that LEP patients have been consistently shown to receive lower quality health care than English-proficient patients on various measures: understanding of treatment plans and disease processes, satisfaction, and incidence of medical errors resulting in physical harm.[3] For these reasons, NILC calls on the Department and OCR to withdraw the proposed rule in its entirety.

I. The proposed regulation would divert OCR from its agency mission by shifting resources that should be used to address the rights of populations subject to acute discrimination and health disparities.

The proposed regulation would inappropriately favor the supposed protection of individuals with certain religious and moral convictions at the expense of protections against the kind of documented experiences of discrimination leading to health disparities which OCR is designed by statute to address, notably under Title VI and Section 1557 of the Patient Protection and Affordable Care Act ("ACA").[4] With its origin in protecting against this type of discrimination, the agency must look closely at how any changes would affect this mission before creating new regulations.

As many other commentators will likely note, discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.[5] Numerous federal courts have found that

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[1] 42 U.S.C. §2000d (stating that "no person in the United States shall, on the grounds of race, color, or national origin" be subject to discrimination in federally funded program), § 200d-1 (authorizing the establishment of the regulations and offices for civil rights within federal agencies to enforce prohibitions on discrimination).

[2] Gustavo López and Kristen Bialik, *Key findings about U.S. immigrants*, PEW RESEARCH CENTER (May 3, 2017), http://www.pewresearch.org/fact-tank/2017/05/03/key-findings-about-u-s-immigrants.

[3] Alexander R. Green, MD, MPH, and Chijioke Nze, Language-Based Inequity in Health Care: Who Is the "Poor Historian"?, *AMA Journal of Ethics*. March 2017, Volume 19, Number 3: 263-271.

[4] 42 U.S.C. § 18116 (tasking HHS with enforcing a number of civil rights laws which ban discrimination on additional discriminations, such as gender).

[5] *See, e.g.*, *EEOC v. R.G. & G.R. Harris Funeral Homes*, No. 16-2424 (6th Cir. Mar. 7, 2018).

federal sex discrimination statutes reach these forms of gender-based discrimination.[6] In 2012, the Equal Employment Opportunity Commission ("EEOC") likewise held that "intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII."[7] This is a serious civil rights violation that OCR, under Section 1557 of the ACA, should be addressing.

The agency must therefore consider the impact on these populations in considering whether the proposed regulation is an appropriate action for the agency. As national advocates focused on the health of immigrants, NILC urges OCR and the Department to consider how particular sectors of the immigrant population would be harmed by this rule. Immigrants are among the most disproportionately uninsured people in the United States, a harm which is compounded by disparities in health disparities among women and LGBTQ persons. The uninsured rates for citizens (9 percent) is nearly half of lawfully present immigrants (17 percent), even though many of the latter are eligible for health coverage programs but not enrolled. In fact, according to the Kaiser Family Foundation, a larger percentage of unenrolled citizens have a factor making them ineligible for coverage or financial assistance (38 percent) than lawfully present immigrants (31 percent).[8] This is compounded by dynamics of an individual's race and sexual orientation: among adult women, 15.2 percent of those who identified as lesbian or gay reported being unable to obtain medical care in the last year due to cost, as compared to 9.6 percent of straight individuals.[9] These are documented health disparities, which OCR can and should be doing more to investigate under Section 1557 of the ACA.

II. The proposed regulation would harm the health outcomes of immigrant women and women of color by allowing further divergence of access to certain services for these populations.

Among individuals with access to health care, women's race and immigration status play a role in how they receive health services, access which would be harmed further by this rule. According to a recent report, doctors often fail to inform black women of the full range of reproductive health options regarding labor or delivery possibly due to

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[6] *See, e.g.*, *Smith v. City of Salem*, 378 F.3d 566, 572-75 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act). *See also* Statement of Interest of the United States at 14, *Jamal v. Saks*, No. 4:14-cv-02782 (S.D. Tex. Jan. 26, 2015).

[7] *Macy v. Holder*, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12 (Apr. 20, 2012).

[8] *Health Coverage of Immigrants*, KAISER FAMILY FOUNDATION (Dec. 13, 2017), https://www.kff.org/disparities-policy/fact-sheet/health-coverage-of-immigrants.

[9] Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT'L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.

stereotypes about black women's sexuality and reproduction.[10] Young black women noted that they were shamed by providers when seeking sexual health information and contraceptive care in part, due to their age, and in some instances, sexual orientation.[11] Moreover, the Centers for Disease Control and Prevention reports that black mothers experience maternal mortality at three times the rate of whites.[12]

New research also shows that women of color in many states disproportionately receive their care at Catholic hospitals.[13] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs), which provide guidance on wide range of hospital matters, including reproductive health care. In practice, the ERDs prohibit the provision of emergency contraception, sterilization, abortion, fertility services, and some treatments for ectopic pregnancies. Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals and as a result, women were delayed care or transferred to other facilities, risking their health.[14] The proposed rule will give health care providers, such as Catholic hospitals, a license to opt out of evidence-based care that the medical community endorses. If this rule were to be implemented, more women, particularly women of color, will be put in situations where they will have to decide between receiving compromised care or seeking another provider to receive quality, comprehensive reproductive health services. For many, this choice does not exist.

This problem is particularly acute for immigrant, Latina women and their families who often face cultural and linguistic barriers to care, especially in rural areas.[15] These women often lack access to transportation and may have to travel great distances to get the care

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[10] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at* https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.
[11] *Reproductive Injustice*, *supra* note 10, at 16-17.
[12] Centers for Disease Control and Prevention, Trends in Pregnancy-Related Deaths, available at https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html
[13] Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, Pub. Rights Private Conscience Project (2018), *available at* https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[14] Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[15] Michelle M. Casey et al., *Providing Health Care to Latino Immigrants: Community-Based Efforts in the Rural Midwest,* AM. J. PUB. HEALTH (2011), *available at* http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1709.

they need.[16] In rural areas there may simply be no other sources of health and life-preserving medical care. When these women encounter health care refusals, they have nowhere else to go. This is the kind of discrimination OCR should be protecting against.

III. The proposed regulation would allow OCR to turn a blind eye to the rampant discrimination faced by LGBTQ individuals, which would cause particular harm to LGBTQ immigrants.

LGBTQ people continue to face discrimination in many areas of their lives, including health care, on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[17] A survey conducted by Lambda Legal found that in 2009, lesbian, gay, and bisexual immigrants and immigrants living with HIV reported higher levels of discrimination than non-immigrant individuals, and the numbers were especially high for immigrants of color.[18] In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.[19] They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.[20]

There are documented outcomes of discrimination against LGBTQ people:

- Twenty-nine percent of transgender individuals experienced a health care provider's refusal to see them on the basis of their perceived or actual gender identity, and 29 percent experienced unwanted physical contact from a health care provider.[21]

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[16] NAT'L LATINA INST. FOR REPROD. HEALTH & CTR. FOR REPROD. RIGHTS, NUESTRA VOZ, NUESTRA SALUD, NUESTRO TEXAS: THE FIGHT FOR WOMEN'S REPRODUCTIVE HEALTH IN THE RIO GRANDE VALLEY, 7 (2013), *available at* http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[17] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).

[18] *LGBT Immigrants and Immigrants living with HIV*, LAMBDA LEGAL, https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-insert_lgbt-immigrants-and-immigrants-living-with-hiv.pdf.

[19] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.

[20] *Id.*

[21] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018),

- 23 percent of respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[22]
- According to one survey, 8 percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.[23]
- Almost ten percent of lesbian, gay, or bisexual respondents reported that they had been denied necessary health care expressly because of their sexual orientation.[24]

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences.[25] LGBTQ people still face discrimination and often avoid care due to fear of discrimination. This discrimination based on lack of competent care is only furthered when the addition of language and cultural differences exist.

This is the kind of discrimination that OCR has been successful in opposing, and it must continue to do so. As data obtained by the Center for American Progress shows, when the agency was enforcing its regulation against these forms of discrimination from 2012-16, it was effective at identifying discrimination, including 30 percent of cases that were based on denial of care because of gender identity, not related to gender transition.[26] The proposed rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBTQ persons. Refusals also implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else, and OCR should ensure that this happens.

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https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.

[22] NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey* 5 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf [hereinafter *2015 U.S. Transgender Survey*].

[23] Mirza, *supra* note 21.

[24] LAMBDA LEGAL, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* 5 (2010), *available at* .http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.

[25] Medical schools often do not provide instruction about LGBTQ health concerns that are not related to HIV/AIDS. Jen Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S*, KAISER FAMILY FOUND.12 (2017), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.

[26] Mirza, et al., note 21.

IV. The proposed rule is overly broad, vague, and will cause confusion

NILC supports the comments submitted by the National Health Law Program, particularly in their analysis of the ways in which the proposed rule is broad, vague, and will cause confusion in the health care delivery system. The regulations as proposed would introduce broad and poorly defined language to the existing law that already provides ample protection for the ability of health care providers to refuse to participate in a health care service to which they have moral or religious objections. The regulations dangerously expand the application of the underlying statutes by offering an extremely broad definition of who can refuse to provide health services and what they can refuse to do.

While the proposed regulations purport to provide clarity and guidance in implementing existing federal religious exemptions, in reality they are vague and confusing. This lack of clarity may make it more difficult for people experiencing discrimination to understand and enforce their rights. This concern is particularly relevant to immigrant populations who have limited English proficiency and may be unfamiliar with the U.S. health care system.

V. Conclusion

NILC opposes the proposed rule as it expands religious refusals in a way that fails to protect immigrant women and LGBTQ immigrants from discrimination, to the detriment of patients' health and well-being. The outcome of this regulation will harm communities who already lack access to care and endure discrimination. For these reasons, we urge the agency to withdraw the rule in its entirety.

Thank you for your attention to our comments. If you have any questions, reach out to Matthew Lopas at lopas@nilc.org or 202-609-9962.

Sincerely,

Matthew Lopas
Health Policy Attorney
National Immigration Law Center

Exhibit 108

March 27, 2018

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

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

Dear Secretary Alex Azar,

The New York State Lesbian, Gay, Bisexual, and Transgender (LGBT) Health & Human Services Network (The Network), a coalition of 72 LGBT-serving organizations across New York State, strongly opposes the proposed rule titled, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," as published by the Office for Civil Rights in the January 26, 2018 Federal Register.

The Network's mission is to address and eliminate LGBT-related health disparities and empower LGBT communities to access affordable and culturally informed health services, resulting in a stronger and safer healthcare environment for all LGBT people. This regulation would permit and promote discrimination by healthcare providers, under the guise of moral or religious protections. In particular, we are concerned that this regulation would formally and explicitly allow health care providers to deny healthcare services to LGBT people who already face health disparities due to discrimination and bias in healthcare.

The Network strongly urges against the proposed Protecting Statutory Conscience Rights in Health Care rule for three (3) main reasons: 1) religious liberty cannot override patient autonomy or anti-discrimination principles; 2) this regulation would contribute to increased levels of discrimination for already medically vulnerable communities, particularly LGBT communities; and 3) this regulation does not reflect the viewpoint of the majority of voters.

Religious liberty cannot override patient autonomy or anti-discrimination principles. Religious exemption policies like this one would allow health care workers to prioritize their

own religious beliefs above patient care. These regulations allow providers to base the course of a patient's medical treatment on their own personal beliefs, not on what is best for the patient's health and circumstances. The proposed rule "ensure[s] that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate," however, medical providers are already protected and supported through their code of ethics and law. The United State Equal Employment Opportunity Commission (EEOC) protects medical providers in the workplace; they can already refuse to provide treatment that violates their religious, moral, or ethical values under religious discrimination & reasonable accommodation, as long as this does not place undue hardship on the employer.[1]

Additionally, the American Medical Association (AMA) Principles of Medical Ethics states that, "A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care." Medical providers already can choose not to provide care based on moral, religious, or other objections. However, formalizing this code of ethics into law would legally permit discrimination and prevent patients who have experienced refusal of care from pursuing legal action. It is the government's duty to ensure that all people have access to healthcare services, free from discrimination. While this regulation claims to protect religious freedom, it is actually a thinly veiled attempt to devalue women and LGBTQ people.

This regulation would contribute to increased levels of discrimination for already medically vulnerable communities, particularly LGBT communities. LGBT people often experience difficulty finding affirming and competent care. In the 2015 United States Trans Survey, 33% of transgender and gender non-conforming people reported having at least one negative experience related to being transgender, such as verbal harassment, refusal of treatment, or having to teach the health care provider about transgender people to receive appropriate care, with increased rates for people of color.[2] Medical negligence and mistreatment led to the death of Robert Eads, a transgender man with ovarian cancer whom over 20 different doctors refused to treat; one provider claimed the diagnosis should make Robert Eads "deal with the fact that he is not a real man."[3]

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[1] United States. Equal Employment Opportunity Commission. (1992). *EEOC compliance manual*. Washington, DC: U.S. Equal Employment Opportunity Commission.
[2] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality.
[3] Lambda Legal. (2013). *Transgender Rights Toolkit: Overcoming Health Care Discrimination*. New York: Lambda Legal

Furthermore, 50% of LGB people and 90% of transgender people believe there are not enough medical personnel who are properly trained to care for them. Over 50% of LGB and 85% of transgender people indicated that overall community fear or dislike of people like them is a barrier to care.[4] This proposed rule would likely exacerbate the fear, mistreatment, harassment, and barriers to care for this already vulnerable population.

This regulation does not reflect the viewpoint of the majority of voters. In a March 2017 nationally representative survey done on behalf of the National Women's Law Center, 61% of voters showed opposition to religious exemption laws. In particular, voters express strong concerns that religious exemption laws do not allow patients to access to optimal medical care, information, and referrals without interference. The majority of constituents (60%) also emphasize that hospitals, medical providers, or public health programs that receive public funding should not be allowed to deny medical care based on religious beliefs. [5] Given that religious exemption policies are not supported by the majority of voters, they should not be implemented.

In closing, The Network strongly opposes the proposed regulation, Protecting Statutory Conscience Rights in Health Care. The Office for Civil Rights has a duty to ensure that LGBTQ individuals are not targeted with this discriminatory regulation.

We appreciate the opportunity to provide these comments. Please contact Corey Westover, the Director of The Network, at cwestover@gaycenter.org or 646.358.1733 with any questions or concerns.

Sincerely,
The New York State LGBT Health & Human Services Network

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[4] Lambda Legal. (2010). *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV*. New York: Lambda Legal.
[5] Greenberg Quinlan Rosner Research. (2017). *Voters Oppose Religious Exemption Laws: Findings from a National Survey of Voters*. Washington, DC: Greenberg Quinlan Rosner Research.

Members of The Network who oppose the proposed ruling,
"Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"

ACR Health - Q Center
Albany Damien Center
Ali Forney Center
Alliance for Positive Health
Apicha Community Health Center
Audre Lorde Project
Bassett Healthcare Network - The Gender Wellness Center
Binghamton University - Lesbian and Gay Family Building Project/Pride and Joy Families
Callen-Lorde Community Health Center
Community Awareness Network for a Drug-Free Life and Environment (CANDLE)
Chinese American Planning Council - Project Reach
Community Health Action of Staten Island
Cortland LGBT Resource Center
CRUX Climbing
DBGM, Inc.
Destination Tomorrow
Empire Justice Center - LGBT Rights Project
Gay & Lesbian Youth Services of Western New York
GMHC
Grand Street Settlement
GRIOT Circle, Inc.
Harm Reduction Coalition
Hetrick-Martin Institute
Hispanic AIDS Forum - Latino Pride Center
Hudson Valley LGBTQ Community Center
In Our Own Voices
Institute for Human Identity (IHI)
Latino Commission on AIDS
Long Island Crisis Center - Pride for Youth
Long Island Gay and Lesbian Youth (LIGALY)
Long Island LGBT Center
Make the Road New York - LGBTQ Program
Metropolitan Community Church of New York
Montefiore Medical Center- Adolescent AIDS Program
Mount Sinai - Institute for Advanced Medicine
New York City Anti-Violence Project

New York Legal Assistance Group (NYLAG) - LGBT Law Project
New York Transgender Advocacy Group (NYTAG)
Northwell Health - Center for Transgender Care
Out Alliance
Planned Parenthood Mohawk Hudson
Planned Parenthood of the North Country New York - LGBTQ Services, Education, & Outreach
Planned Parenthood of the Southern Finger Lakes - Out For Health
Pride Center of Staten Island
Pride Center of the Capital Region
Pride Center of Western New York
Princess Janae Place, Inc.
Queens Community House- Queens Center for Gay Seniors/Generation Q
Queens LGBT Community Center (Q-Center)
Rainbow Access Initiative
Rainbow Heights Club
Rockland County Pride Center
Safe Horizon - Streetwork Project
SAGE
SAGE Long Island
SAGE Upstate
Southern Tier AIDS Program - Identity Youth
St. Lawrence University - SAFE Project
State University of New York (SUNY) - The HEAT Program
Sylvia Rivera Law Project
The Legal Aid Society - LGBT Law and Policy Initiative
The Lesbian, Gay, Bisexual, Transgender Community Center
The LOFT: LGBT Community Services Center
Translatina Network
The National LGBT Cancer Network
The Trevor Project
Transgender Legal Defense and Education Fund (TLDEF)
Trillium Health
Unity Fellowship Breaking Ground
Urban Justice Center - Peter Cicchino Youth Project

Exhibit 109

March 27, 2018

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

Re: NPRM on Religious Exemptions for Health Care Entities (RIN 0945-ZA03)

To Whom It May Concern:

The National Center for Transgender Equality (NCTE) submits the following comments to express our strong opposition to expanding exemptions for health care entities based on religious or moral objections.

Founded in 2003, NCTE is one of the nation's leading social justice organizations working for life-saving change for the over 1.5 million transgender Americans and their families. Over our years of advocacy, we have time and again seen the harmful impact that discrimination in health care settings has on transgender people and their loved ones, including discrimination based on religious or moral disapproval of who transgender people are and how they live their lives. Our experience has shown us that discrimination against transgender people in health care—whether it is being turned away from a doctor's office or emergency room, being denied access to basic care, or being mistreated and degraded simply because of one's transgender status—is widespread and creates significant barriers to care. The sweeping and excessive expansions to religious and moral exemptions sought by this rule go far beyond established law and threaten to severely exacerbate the barriers to care that transgender people and other vulnerable patient populations face.

We deeply respect and value freedom of religion, which is already protected by our Constitution, numerous federal statutes, and existing Department regulations. But refusing or obstructing access to medical care is a perversion of that cherished principle. In health care, patients must come first. By opening the door to health care refusals that go far beyond those permitted under federal law, this rule is harmful, unnecessary, and unsupported by federal law, and it would undermine the critical purposes of the Department's programs and the civil rights laws it is responsible for enforcing.

Simply put, the proposed rule is contrary to law and would harm patients. We urge the Department to reject this harmful and unnecessary rule.

I. Expanding religion-based exemptions can exacerbate the barriers to service access that transgender people and other vulnerable populations face.

For many Americans, including transgender Americans, discrimination in health care settings remains a grave and widespread problem and contributes to a wide range of health disparities. The proposed rule

1133 19th Street NW
Suite 302
Washington, DC 20036

202-642-4542
www.TransEquality.org

would exacerbate this urgent problem by encouraging actions that deny or obstruct access to timely medical care.

A. Transgender people face widespread discrimination in health care settings.

An estimated 0.6% of the U.S. adult population is transgender, representing 1.4 million adults over the age of 18, as well as hundreds of thousands of young Americans.[1] The medical and scientific community overwhelmingly recognizes that a person's innate experience of gender is an inherent aspect of the human experience for all people, including transgender people.[2] For example, the American Psychological Association states that having "deeply felt, inherent" gender identity that is different from the gender one was thought to be at birth is part of "healthy and normative" range of variation in human development found across cultures and across history.[3] The Department has previously recognized that "variations in gender identity and expression are part of the normal spectrum of human diversity."[4]

Many, though not all, transgender people experience a medical condition known as gender dysphoria. Gender dysphoria is a serious medical condition that is codified in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM 5), which defines it as clinically significant distress or impairment related to an incongruence between one's experienced gender and the gender one was thought to be at birth.[5] Like anyone, transgender people need preventive care to stay healthy and acute care when they become sick or injured. Some may also need medical care to treat gender dysphoria. Under the treatment protocol widely accepted by the medical community, medically necessary treatment for gender dysphoria may require steps to help an individual transition from living as one gender to another.[6] This treatment, sometimes referred to as "transition-related care," may include

[1] Andrew R. Flores et al., *How Many Adults Identify as Transgender in the United States?* (2016), http://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf. *See also* Jody L. Herman et al. *Age of Individuals who Identify as Transgender in the United States* (2017), https://williamsinstitute.law.ucla.edu/wp-content/uploads/TransAgeReport.pdf (estimating that 0.7% of people in the United States between the ages of 13 and 17, or 150,000 adolescents, are transgender).

[2] *See, e.g.*, Am. Psychological Ass'n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 AMERICAN PSYCHOLOGIST 832, 834-35 (2015), https://www.apa.org/practice/guidelines/transgender.pdf; Brief of American Academy of Pediatrics, American Psychiatric Association, American College of Physicians, and 17 Additional Medical and Mental Health Organizations in Support of Respondent, *G. G. v. Gloucester County Sch. Bd.*, No. 16-274 8–9 (Sup. Ct. *filed* March 2, 2017) (affirming that "[e]veryone—whether they are transgender or cisgender—develops awareness of their gender identity along a 'pathway'" with typical stages and that transgender identity is a normal variation of this development); Human Rights Campaign, Am. Acad. of Pediatrics, & Am. College of Osteopathic Pediatricians, *Supporting & Caring for Transgender Children* (2016), https://assets2.hrc.org/files/documents/SupportingCaringforTransChildren.pdf; World Prof. Ass'n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* 16 (7th ed. 2011), https://www.wpath.org/publications/soc.

[3] Am. Psychological Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, *e*, 70(9):832, 834-35 (2015).

[4] Substance Abuse & Mental Health Servs., *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth* 1 (2015), https://store.samhsa.gov/shin/content/SMA15-4928/SMA15-4928.pdf.

[5] Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders* 452 (5th ed. 2013).

[6] *See generally* World Prof. Ass'n for Transgender Health, *supra* note 2; Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM 3869 (2017). *See also* Am. Medical Ass'n, *AMA Policies on GLBT Issues, Patient-Centered Policy H-185.950, Removing Financial Barriers to Care for Transgender Patients* (2008), http://www.imatyfa.org/assets/ama122.pdf (recognizing WPATH *Standards* as "internationally accepted"); Am. Psychiatric Ass'n, *Position Statement on Discrimination Against Transgender and Gender Variant Individuals* (2012),

counseling, hormone therapy, and/or a variety of possible surgical treatments, depending on the individualized needs of each patient.[7] It is the overwhelming consensus among major medical organizations—including the American Medical Association,[8] the American College of Physicians,[9] the American Psychological Association,[10] the American Psychiatric Association,[11] the American Academy of Family Physicians,[12] the Endocrine Society,[13] the American College of Obstetricians and Gynecologists,[14] and the World Professional Association for Transgender Health[15]—that transition-related treatments are medically necessary, effective, and safe when clinically indicated to alleviate gender dysphoria. For example, the American Psychiatric Association "[a]dvocates for removal of barriers to care…for gender transition treatment," emphasizing that "[s]ignificant and long-standing medical and psychiatric literature exists that demonstrates clear benefits of medical and surgical interventions to gender variant individuals seeking transition" and "[a]ccess to medical care (both medical and surgical) positively impacts the mental health of transgender and gender variant individuals."[16] Numerous studies and meta-analyses have demonstrated the significant benefits of transition-related care in the treatment of gender dysphoria.[17] Indeed, transition-related treatments are the only treatments that have been demonstrated to be effective in treating gender dysphoria.[18]

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http://www.dhcs.ca.gov/services/MH/Documents/2013_04_AC_06d_APA_ps2012_Transgen_Disc.pdf (citing WPATH *Standards*); Am. Psychological Ass'n, *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination* (2008), http://www.apa.org/about/policy/transgender.aspx (same).

[7] *See* World Prof. Ass'n for Transgender Health, *supra* note 2 at 16.

[8] Am. Medical Ass'n, *supra* note 6.

[9] Am. College of Physicians, *Lesbian, Gay, Bisexual and Transgender Health Disparities: A Policy Position Paper from the American College of Physicians*, 163 ANNALS OF INTERNAL MEDICINE 135, 140 (2015).

[10] Am. Psychological Ass'n, *supra* note 6.

[11] Am. Psychiatric Ass'n, *supra* note 6.

[12] Am. Acad. of Family Physicians, *Resolution No. 1004: Transgender Care* (2012), https://www.aafp.org/dam/AAFP/documents/about_us/special_constituencies/2012RCAR_Advocacy.pdf.

[13] Hembree et al., *supra* note 6.

[14] Am. College of Obstetricians & Gynecologists, *Committee Opinion No. 512: Health Care for Transgender Individuals*, 118 OBSTETRICS & GYNECOLOGY 1454 (2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.

[15] World Prof. Ass'n for Transgender Health, *supra* note 2.

[16] Am. Psychiatric Ass'n, *supra* note 6.

[17] *See, e.g.*, Ashli A. Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*. J SEXUAL MEDICINE (Jan. 17 2018); Gemma L. Witcomb et al., *Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services*, J. AFFECTIVE DISORDERS (Feb. 2018) Cecilia Dhejne et al., *Mental Health and Gender Dysphoria: A Review of the Literature*, 28 INT'L REV. PSYCHIATRY 44 (2016); William Byne et al., *Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder*, 41 ARCHIVES OF SEXUAL BEHAVIOR 759 (2012); Marco Colizzi, Rosalia Costa, & Orlando Todarello, *Transsexual Patients' Psychiatric Comorbidity and Positive Effect of Cross-Sex Hormonal Treatment on Mental Health: Results from a Longitudinal Study*, 39 PSYCHONEUROENDOCRINOLOGY 65 (2014); Audrey Gorin-Lazard et al., *Hormonal Therapy is Associated with Better Self-Esteem, Mood, and Quality of Life in Transsexuals*, 201 J. NERVOUS & MENTAL DISORDERS 996 (2013); M. Hussan Murad et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 CLINICAL ENDOCRINOLOGY 214 (2010); Griet De Cuypere et al., *Sexual and Physical Health After Sex Reassignment Surgery*, 34 ARCHIVES OF SEXUAL BEHAVIOR 679 (2005); Giuloio Garaffa, Nim A. Christopher, & David J. Ralph, *Total Phallic Reconstruction in Female-to-Male Transsexuals*, 57 EUROPEAN UROLOGY 715 (2010); Caroline Klein & Boris B. Gorzalka, *Sexual Functioning in Transsexuals Following Hormone Therapy and Genital Surgery: A Review*, 6 J. SEXUAL MEDICINE 2922 (2009).

[18] *See, e.g.*, Substance Abuse & Mental Health Servs., *supra* note 3.

Despite the medical consensus regarding the necessity of transition-related care, many transgender people have struggled to get access to medically necessary care—including care recommended to treat gender dysphoria, as well as medical care for unrelated conditions. Numerous studies have documented the widespread and pervasive discrimination experienced by transgender people and their families in the health care system. For example, the 2015 U.S. Transgender Survey, a national study of nearly 28,000 transgender adults in the United States, found that:

- Just in the year prior to taking the survey, one-third (33%) of respondents who saw *any health care provider* during that year were turned away because of being transgender, denied treatment, physically or sexually assaulted in a health care setting, or faced another form of mistreatment or discrimination due to being transgender.[19]
- In the year prior to taking the survey, nearly one-quarter (22%) of respondents who visited a *drug or alcohol treatment program* where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender.[20]
- In the year prior to taking the survey, 14% of respondents who visited a *nursing home or extended care facility* where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender.[21]
- In the year prior to taking the survey, one-quarter (25%) of respondents *experienced a problem with their health insurance* related to being transgender. This included being denied coverage for treatments for gender dysphoria as well as being denied coverage for a range of unrelated conditions simply because they are transgender.[22]
- In the year prior to taking the survey, 23% of respondents *avoided seeking medical care* when they needed it because of fear of being mistreated, and 33% avoided seeking necessary health care because they could not afford it.[23]

The 2015 U.S. Transgender Survey also revealed patterns of marked health disparities affecting respondents. Respondents were approximately five times more likely than the general population to have been diagnosed with HIV, with elevated rates among people of color and in particular among Black transgender women, who were over 60 times more likely to be living with HIV than the general population.[24] Standard questions based on the K-6 Kessler Psychological Distress Scale revealed that transgender respondents were approximately eight times more likely than the general population to have experienced serious psychological distress in the month prior to taking the survey.[25] Further, respondents were nearly twelve times more likely to have attempted suicide in the previous year than the general population.[26] Rates of suicide attempts and psychological distress were particularly high among respondents who had faced barriers to accessing medical care and anti-transgender discrimination in health care and other settings.

[19] Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey* 96–97 (2016), www.ustranssurvey.org/report.
[20] *Id.* at 216.
[21] *Id.* at 219.
[22] *Id.* at 95.
[23] *Id.* at 98.
[24] *Id.* at 122.
[25] *Id.* at 105.
[26] *Id.* at 112.

Similarly, a nationally representative 2017 study found that transgender respondents faced high rates of discrimination in health care settings.[27] Out of those who had visited a doctor or health care provider in the previous year:

- Nearly one-third (29%) reported that a health care provider refused to see them because of their actual or perceived gender identity.
- One in eight (12%) said that a health care provider refused to provide them with care related to gender dysphoria.
- More than one in five (21%) said that a health care provider used harsh or abusive language when treating them.
- Nearly one-third (29%) experienced unwanted physical contact or sexual assault by a health care provider.

For many transgender people, especially those living outside of metropolitan areas, simply finding a different provider is not a viable option. Many transgender respondents to the 2017 study reported that it would be very difficult or impossible for them to find alternative providers to get the care they need if they were turned away by a health care provider. For example, nearly one-third (31%) of transgender respondents said it would be "very difficult" or "not possible" to find the same type of service at a different hospital and 30% said it would be "very difficult" or "not possible" to find the same type of service at a different community health center or clinic.[28]

Health disparities facing transgender people have been recognized in a major 2011 report of the National Academy of Medicine (then the Institute of Medicine),[29] and by the Department's Healthy People 2020 initiative.[30] These disparities do not reflect inherent pathology; as the American Psychiatric Association has stated, "[b]eing transgender or gender variant implies no impairment in judgment, stability, reliability, or general social or vocational capabilities; however, these individuals often experience discrimination due to a lack of civil rights protections for their gender identity or expression."[31] Discrimination and barriers to care exacerbate the marked health disparities affecting transgender individuals,[32] including by increasing transgender people's risk factors for poor physical and mental

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[27] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[28] *Id.*

[29] Inst. of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.

[30] Dep't of Health & Human Servs., *Healthy People 2020: LGBT Health Topic Area* (2015), http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health ("LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights.")

[31] Am. Psychiatric Ass'n, *supra* note 6.

[32] See, e.g., Ilan H. Meyer et al., *Demographic Characteristics and Health Status of Transgender Adults in Select US Regions: Behavioral Risk Factor Surveillance System, 2014*, 107 AM. J. PUB. HEALTH 582 (2017); Joint Comm'n, *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide* (2011), http://www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf.

health[33] and driving high rates of HIV.[34] Numerous studies have found that when transgender people are supported in their environment, including by accessing the health care they need without discrimination, the health disparities they experience decrease substantially.[35]

As leading medical organizations such as American Medical Association[36] and the American Psychological Association[37] have emphasized, robust laws protecting patients from discrimination are essential in addressing these disparities and reducing the barriers to care facing millions of Americans, including transgender Americans, while expanding religious exemptions can dangerously exacerbate those barriers to care. In response to the Department's recent Request for Information regarding "Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding," numerous medical organizations expressed concerns with expanding religious exemptions in health care, including the American Psychiatric Association,[38] the American Psychological Association,[39] the American Medical Association,[40] the American Academy of Pediatrics,[41] and the American Academy of Nursing.[42]

B. Other vulnerable populations, including women, lesbian, gay, and bisexual people, communities of color, people with disabilities, and people with limited English proficiency, struggle to access adequate care.

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[33] Ctrs. for Disease Control & Prevention, *Lesbian, Gay, Bisexual, and Transgender Health* (2014), http://www.cdc.gov/lgbthealth/about.htm.

[34] Ctrs. for Disease Control & Prevention, *HIV and Transgender Communities* (2016), https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-transgender-brief.pdf.

[35] *See, e.g.*, Lily Durwood, Katie A. McLaughlin, & Kristina R. Olson, *Mental Health and Self-Worth in Socially Transitioned Transgender Youth*, 56 J. AM. ACAD. CHILD ADOLESC. PSYCHIATRY 116 (2017); Kristina R. Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities*, 137 PEDIATRICS (2016); Annelou L. C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 PEDIATRICS (2014).

[36] Am. Medical Ass'n, *Letter to Director Roger Severino* (Sept. 1, 2017), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2017-09-01_Letter-to-Severino-re-Section-1557-Identity-Protection.pdf.

[37] Am. Psychological Ass'n, Comment Letter on Request for Information on Patient Protection and Affordable Care Act: Reducing Regulatory Burdens and Improving Health Care Choices to Empower Patients (July 12, 2017), https://www.regulations.gov/document?D=CMS-2017-0078-2528.

[38] Am. Psychiatric Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 22, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-10700.

[39] Am. Psychological Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 21, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-8429.

[40] Am. Medical Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 17, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-7327https://www.regulations.gov/document?D=HHS-OS-2017-0002-7327.

[41] Am. Acad. of Pediatrics, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 21, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-12098.

[42] Am. Academy of Nursing, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 24, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-11760.

Similarly, a wide range of vulnerable communities face routine discrimination and barriers to care. While the Department's primary focus should be on eliminating these barriers to care, its proposed rule does the opposite and threatens to exacerbate them.

For example, despite the substantial progress made after the enactment of the Affordable Care Act, health care discrimination against women remains rampart.[43] Many health plans continue to exclude treatments that are primarily required by women, such as coverage of pregnancy-related conditions.[44] In many parts of the country, access to reproductive health services is sparse, and some hospitals refuse to treat patients experiencing miscarriages, ectopic pregnancies, and other conditions affecting reproductive health, even when the condition is emergent or the patient has nowhere else to go.[45] Even among providers who do offer reproductive health services, many refuse to provide them to women who are unmarried or who do not conform to sex stereotypes, or subject women to harassment and mistreatment.[46] Women are also more likely than men to receive substandard care for conditions such as heart disease or chronic pain,[47] which further limits women's options when seeking a provider who will meet their needs.

Gender disparities in health care disproportionately affect women of color. Women of color are particularly likely to experience discrimination and harassment in health care.[48] Research has found that women of color face significant barriers to reproductive care: for example many respondents were neglected by medical staff, received inadequate or misleading information about the range of treatment options they had for labor and delivery, or were stigmatized and shamed by medical providers based on racial stereotypes.[49] In many states, women of color are more likely than white women to receive their care at Catholic hospitals, whose ethical directives regarding reproductive care often prevent patients from receiving treatment consistent with medical standards of care.[50] Inadequate access to reproductive care is one of the main drivers in persistent racial disparities in maternal mortality—with Black women being three to four times more likely to die in childbirth than white women[51]—as well as higher rates of

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[43] *See, e.g.*, Nat'l Women's Law Ctr., *Turning to Fairness* (2012), https://nwlc.org/wp-content/uploads/2015/08/nwlc_2012_turningtofairness_report.pdf.

[44] *See, e.g.*, Nat'l Women's Law Ctr., *NWLC Section 1557 Complaint: Sex Discrimination Complaints Against Five Institutions*, http://www.nwlc.org/resource/nwlc-section-1557-complaint-sex-discrimination-complaints-against-five-institutions (Section 1557 complaints filed against five institutions that exclude pregnancy coverage).

[45] *See, e.g.*, Nat'l Women's Law Ctr., *Health Care Refusals Harm Patients: The Threat to Reproductive Health Care* (2014), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2015/08/refusals_harm_patients_repro_factsheet_5-30-14.pdf.

[46] *Id.*

[47] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. AM. HEART ASS'N 1 (2015); Jennifer A. Kent, Vinisha Patel, & Natalie A. Varela, *Gender Disparities in Health Care*, 79 MOUNT SINAI J. MED. 555 (2012); Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29 J. LAW, MED. & ETHICS, 13 (2001); Inst. of Med., *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* 75–77 (2011).

[48] Nat'l Public Radio, Robert Wood Johnson Foundation, & Harvard T. H. Chan School of Public Health, *Discrimination in America: Experiences and Views of American Women* (2017), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/21/2017/12/NPR-RWJF-HSPH-Discrimination-Women-Final-Report.pdf.

[49] Ctr. for Reproductive Rights, Nat'l Latina Inst. for Reproductive Health, & SisterSong Women of Color Reproductive Justice Collective, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf.

[50] Kira Shepherd & Katherine Franke, *Bearing Faith: The Limits of Catholic Health Care for Women of Color* (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[51] Ctr. for Reproductive Rights et al., *supra* note 49.

cervical cancer and HIV among women of color.[52] People of color of all genders often face prohibitive barriers to care: for example, people of color are significantly more likely to be uninsured,[53] and people of color in rural America are also more likely to live in an area with a shortage of health professionals, leaving many with no alternatives if they are refused care.

People with disabilities also continue to face discriminatory barriers to care, including physical barriers in health care settings, mistreatment by health care providers, and the unavailability or inaccessibility of health care providers who are competent in meeting their health care needs. These barriers are often especially heighted for people with disabilities who live or spend much of their time in provider-controlled settings, including Medicaid-funded Home and Community-Based Services, where they receive supports and services for daily living, including assistance with dressing, grooming, bathing, transportation to social and health-related appointments, and participating in recreational activities. These services can be intensely intimate and implicate a person's right to pursue and maintain romantic relationships, build a family, and make basic decisions about one's life. In such settings, expansive religious exemptions that encourage aides to interfere with someone's health care can be extremely harmful for the health of a person with a disability and their ability to exercise their right to basic self-determination.

Lesbian, gay, and bisexual people (LGB) experience frequent discrimination when accessing health-related services. For example, a recent study found that 8% of LGB respondents reported that a doctor or other health care provider refused to see them because of their sexual orientation, and 7% experienced unwanted physical contact by a health care provider.[54] Many LGB people, especially those in rural areas, report that finding an alternative provider if they are refused treatment or harassed would be very difficult or even impossible.[55] Additionally, many LGB people struggle to access reproductive and sexual health services, including fertility services and HIV prevention treatments such as pre-exposure prophylaxis (PrEP). Inadequate access to care contributes to significant health disparities affecting the LGB

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[52] *See, e.g.*, Ctrs. for Disease Control & Prevention, *Cervical Cancer Rates by Rates and Ethnicity* (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm; *HIV Among Women* (March 9, 2018), https://www.cdc.gov/hiv/group/gender/women/index.html (noting that at the end of 2015, 59% of women living with diagnosed HIV were Black, 19% were Latina, and 17% were white, and that Black women were more likely to contract HIV through sexual contact than white women).

[53] Kaiser Family Found., *Uninsured Rates for the Nonelderly by Race/Ethnicity* (2016), https://www.kff.org/uninsured/state-indicator/rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[54] Mirza & Rooney, see *supra* note 27. *See also* Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf; Ning Hsieh & Matt Ruther, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities in Access to Care,* 36 HEALTH AFFAIRS 1786 (Oct. 2017), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.0455?journalCode=hlthaff; Human Rights Watch, *All We Want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States* (2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[55] Mirza & Rooney, see *supra* note 27 (finding that 18% of LGBT people overall and 41% of LGBT people living outside of metropolitan areas report that it would be "very difficult" or "impossible" to find equivalent treatment at another hospital if they were to be turned away).

population,[56] including higher prevalence of disabilities and chronic conditions,[57] certain cancers,[58] cardiovascular disease,[59] and depression, anxiety, and other mental health conditions.[60] Barriers to accessing care also contribute to high rates of HIV infection among gay and bisexual men, who account for 56% of all people living with HIV in the United States and 70% of new HIV infections.[61]

C. Transgender people and other vulnerable communities already face barriers to care based on the personal beliefs of health care workers or administrators.

The personal beliefs of health care providers, administrators, and others in the health care industry have too often been used to deny individuals access to health care and other critical services—a problem that can be significantly worsened by expanding existing exemptions. For example, religious or moral disapproval has been invoked to refuse to provide infertility and reproductive care,[62] treat patients with HIV,[63] treat a newborn because of her parents' same-sex relationship,[64] and provide emergency services and other care for people who are suffering miscarriages.[65] Religious objections have also been invoked to deny transgender people access to medical care—both care related and unrelated to gender transition—or subject transgender people to degrading or abusive treatment in medical settings. Consider the following examples:

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[56] *See generally* Dep't of Health & Human Servs., *supra* note 30.

[57] David J. Lick, Laura E. Durso, & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERSPECTIVES ON PSYCHOLOGICAL SCIENCE 521 (2013), http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities.

[58] *Id.*; Jennifer Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the U.S.* (2016), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.

[59] *Id.*

[60] *Id.*; Human Rights Campaign et al., *Health Disparities Among Bisexual People* (2015), http://hrc-assets.s3-website-us-east-1.amazonaws.com//files/assets/resources/HRC-BiHealthBrief.pdf.

[61] Ctrs. for Disease Control & Prevention, *CDC Fact Sheet: HIV Among Gay and Bisexual Men* (2017), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf.

[62] Casey Ross, *Catholic Hospitals are Multiplying, Boosting Their Impact on Reproductive Health*, SCIENTIFIC AMERICAN (Sept. 14, 2017), https://www.scientificamerican.com/article/catholic-hospitals-are-multiplying-boosting-their-impact-on-reproductive-health-care; Nat'l Women's Law Ctr., *supra* note 45; *see also North Coast Women's Care Medical Grp., Inc. v. San Diego County Superior Court*, 189 P.3d 959, 959 (Cal. 2008).

[63] *See, e.g.*, Complaint, *Simoes v. Trinitas Reg'l Med. Ctr.*, No. UNNL-1868-12 (N.J. Super. Ct. *filed* May 23, 2012); Nat'l Women's Law Ctr., supra note 45.

[64] Abby Phillip, *Pediatrician Refuses to Treat Baby with Lesbian Parents and There's Nothing Illegal About It*, WASH. POST (Feb. 19, 2015), https://www.washingtonpost.com/news/morning-mix/wp/2015/02/19/pediatrician-refuses-to-treat-baby-with-lesbian-parents-and-theres-nothing-illegal-about-it; *see also* Amicus Brief of Lambda Legal Defense and Education Fund et al., *Masterpiece Cakeshop et al. v. Colo. Civil Rights Comm'n et al.*, No. 16-111, 17–19 (Sup. Ct. *filed* Oct. 30, 2017).

[65] Am. Civil Liberties Union, *Health Care Denied: Patients and Physicians Speak out About Catholic Hospitals and the Threat to Women's Health and Lives* (2016), https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied; Nat'l. Women's Law Ctr., *Denied Care When Losing a Pregnancy: Pharmacies Refuse to Fill Needed Prescriptions* (Apr. 16, 2015), http://www.nwlc.org/our-blog/denied-care-when-losing-pregnancy-pharmacies-refuse-fill-needed-prescriptions; Nat'l Women's Law Ctr., *Below the Radar: Health Care Providers' Religious Refusals Can Endanger Pregnant Women's Lives and Health* (2011), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2015/08/nwlcbelowtheradar2011.pdf; Samantha Lachman, *Lawsuits Target Catholic Hospitals for Refusing to Provide Emergency Miscarriage Management*, HUFFINGTON POST (June 10, 2016), https://www.huffingtonpost.com/entry/catholic-hospitals-miscarriage-management_us_5759bf67e4b0e39a28aceea6.

> As my being transgender is a relevant piece of medical information…I revealed this information to [the doctor] when he entered the treatment room. His immediate response was, "I believe the transgender lifestyle is wrong and sinful." … The rest of the time between the examination and him writing the prescription, he asked questions about how transgender women find sexual intimacy. As he had yet to hand over the prescription, I felt compelled by the power dynamic to provide answers to questions I would normally tell an asker are none of his or her business.… [I]t was very creepy having this conversation with this person, and I felt I had the filthy end of the stick and was being subordinated by this doctor because he felt he could. – Karen S.[66]

> My Dignity Health insurance covered my hormones (because my doctor did not specifically note it as trans-related), and scheduled my top surgery before suddenly cancelling their coverage. Someone at their company had "connected the dots" and realized I was seeking transition-related services, which they denied due to their company's Catholic values. I was forced to pay for the surgery out of pocket, destroying my family's finance and putting me in considerable debt.[67]

> I was told by [mental health] professionals that I can only be "fixed" by "accepting Jesus" and denying who I really am when I sought assistance with beginning transition.[68]

In addition, the personal beliefs of hospital administrators and other health care workers have been used to interfere with doctors' exercise of their medical judgment. Some hospitals have invoked their religious affiliation to not only refuse to provide emergency care related to miscarriages, transition-related medical care, and other needs, but also to prevent doctors from providing those treatments at the hospital, in spite of those doctors' best medical judgment.[69] For example, in 2016 a New Jersey hospital approved and scheduled Jionni Conforti's hysterectomy, then abruptly cancelled the procedure at the last minute and refused to allow his surgeon to perform it when an administrator discovered the patient was transgender despite his doctor's determination that the procedure was medically necessary.[70] These practices are especially concerning in light of the rapidly growing number of religiously affiliated hospitals. For example, the number of Catholic hospitals—which represent the largest denomination in the health care field—has increased by 22% since 2001, and Catholic hospitals now own one in six hospital beds across the country.[71] Catholic hospitals must follow religious directives that often restrict the provision of certain treatments, including for emergency contraception, sterilization, abortion, fertility services, and ectopic

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[66] Amicus Brief of Transgender Legal Defense and Education Fund et al., *Masterpiece Cakeshop et al. v. Colo. Civil Rights Comm'n et al.*, No. 16-111, 11 (Oct. 30, 2017).
[67] This quotation has been excerpted from a story shared by a 2015 U.S. Transgender Survey respondent after completing of the survey.
[68] This quotation has been excerpted from a story shared by a 2015 U.S. Transgender Survey respondent after their completion of the survey.
[69] For example, complaints have been filed against Catholic hospitals for refusing to allow doctors to provide care to transgender patients that the doctors are regularly allowed to provide for non-transgender people. *See, e.g.*, Complaint, *Hastings v. Seton Med. Ctr.*, No. CGC-07-470336 (Cal. Sf. Super. Ct. Dec. 19, 2007) (case settled). *See also Health Care Denied*, *supra* note 65.
[70] *Conforti v. St. Joseph's Healthcare System*, No. 2:17-cv-00050-JLL-JAD (D.N.J. filed Jan. 5, 2017).
[71] Lois Uttley & Christine Khaikin, *Growth of Catholic Hospitals: 2016 Update of the Miscarriage of Medicine Report* (2016), http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW_Update-2016-MiscarrOfMedicine-report.pdf?token=54%2Fj8Gp90FWPtm7ExSkDGRuC77o%3D.

pregnancies.[72] Providers at such hospitals often find that they are unable to provide the standard of care for treatments such as miscarriage managements,[73] and one study of physicians working at religiously affiliated hospitals found that nearly one in five (19%) experienced a conflict between the religious directives of their hospital and their ability to practice in accordance with medical standards and their clinical judgment.[74]

Religious beliefs have also been invoked to justify refusals to provide critical human services for lesbian, gay, bisexual, and transgender (LGBT) individuals and families, as well as unmarried parents. The potential for harmful discrimination justified by religious beliefs is further illustrated by countless cases of religion being cited as a basis for denial of service or humiliating treatment toward LGBT people in restaurants, hotels, retail stores, and by individual government employees.[75]

For many patients, such refusals do not merely represent an inconvenience: in many cases, they can result in necessary or even emergent care being delayed or denied outright, putting their health and in some instances their lives at risk. These refusals are particularly dangerous in situations where individuals have limited options, such as in emergencies, when needing specialized services, in many rural areas,[76] or in areas where religiously affiliated hospitals are the primary or sole hospital serving a community.[77]

Expanding exemptions beyond established law as the proposed rule attempts to do—and encouraging service providers receiving federal funds to discriminate against intended program beneficiaries—would aggravate these harms even further. Permitting a broader range of service providers that receive taxpayer money to use a religious or moral litmus test to determine which services they provide and who receives care would result in many patients in need being denied access to medical care and other essential

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[72] *See* U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* (2009), http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf; Lois Uttley et al., *Miscarriage of Medicine: The Growth of Catholic Hospitals and the Threat to Reproductive Health Care* (2013), http://static1.1.sqspcdn.com/static/f/816571/24079922/1387381601667/Growth-of-Catholic-Hospitals-2013.pdf?token=O2KPmDeCHsArsY1wqp0wEBigKC4%3D.

[73] Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458.

[74] Debra B. Stulberg et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, 25 J. GENERAL INTERNAL MED. 725–30 (2010), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970.

[75] *See, e.g.*, Amicus Brief of Lambda Legal Defense and Education Fund et al., *Masterpiece Cakeshop,* No. 16-111 (documenting instances of discrimination against LGBT people, including discrimination based on religious objections, in a variety of settings); Amicus Brief of National LGBTQ Task Force, et al., *Masterpiece Cakeshop,* No. 16-111; Amicus Brief of Transgender Legal Defense and Education Fund et al., *Masterpiece Cakeshop*, No. 16-111 (same); Amicus Brief of Transgender Law Center et al., *Masterpiece Cakeshop,* No. 16-111, 12–13 (Sup. Ct. filed Oct. 30, 2017) (same).

[76] People living in rural areas often struggle to access care due to a variety of factors, including physician shortages, financial and geographic barriers to transportation, and a lack of available specialists who can meet their needs. *See, e.g.*, Martin MacDowell et al., *A National View of Rural Health Workforce Issues in the USA*, 10 RURAL REMOTE HEALTH 1531 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483; Carol Adaire Jones et al., *Health Status and Health Care Access of Farm and Rural Populations,* U.S. DEP'T OF AGRIC. ECON. RESEARCH SERV. (2009), https://www.ers.usda.gov/publications/pub-details/?pubid=44427; Thomas A. Arcury et al., *The Effects of Geography and Spatial Behavior on Health Care Utilization among the Residents of a Rural Region*, 40 HEALTH SERVS. RESEARCH 135 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130; Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources,* 20 J. OF WOMEN'S HEALTH 1743 (Nov. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216064.

[77] *See e.g., Health Care Denied, supra* note 65; Uttley et al., *supra* note 72.

services—jeopardizing the welfare of many intended HHS program recipients and compromising the Department's ability to meet its legal obligations and fulfil its mission.

II. Expanding exemptions undermines the Department's mandate to protect the health and well-being of all Americans.

Reducing discrimination and other barriers to accessing health care services, as well as reducing the accompanying health disparities, is core to the Department's mission and its obligations under laws authorizing its programs. Weakening protections and limiting program access by expanding religion-based exemptions fundamentally runs contrary to this mission.

The Department's core mission is to "enhance and protect the health and well-being of all Americans…by providing for effective health and human services."[78] The foremost purpose of the Department is to provide for services and supports for individuals and communities who need them—a purpose that is statutorily prescribed by Congress in the statutes authorizing many of the Department's programs.[79] Ensuring that beneficiaries of Department programs and other patients have fair and equal access to services and reducing barriers to those services is an inseparable and necessary component of this responsibility. The Department's ability to ensure equal, nondiscriminatory access to services would be significantly weakened by the proposed rule. In order to meet its legal obligations and its statutory mission, HHS must prioritize the needs and rights of patients over those of organizations seeking federal funds. Creating new or expanded exemptions for recipients of federal funds at the cost of patients' access to health services prevents the Department from meeting its responsibilities to HHS program beneficiaries and patients around the country.

Protecting religious freedom is an important value, and many health care providers with deeply held religious or moral beliefs have played important roles in addressing our nation's health care needs. Yet the driving force of this value is the core constitutional principle of separation of church and state—a principle that is fundamentally undermined by the expansion of religious exemptions in health care. Health care providers, entities, and grantees should be allowed—and *are* allowed under current practices and policies—to maintain their distinct religious identities when providing health care services, so long as they comply with generally applicable requirements, including nondiscrimination laws, that exist to protect patients. Protecting the right to practice religion does not require the sweeping expansion of religion-based exemptions that this proposed rule attempts to implement, which would amount to government-funded discrimination and subvert HHS' mission and compelling interest in promoting public health and wellbeing.

III. The exemptions proposed in the rule go far beyond what the applicable statutes permit and exceed the Department's authority.

[78] Dep't. of Health & Human Servs., *About HHS* (2017), https://www.hhs.gov/about/index.html.

[79] *See, e.g.*, 34 U.S. Code § 11201 (establishing Runaway and Homeless Youth programs because "youth who have become homeless or who leave and remain away from home without parental permission… are urgently in need of temporary shelter and services").

The Department has the authority and responsibility to enforce laws as they are written, including laws creating and delimiting religious and moral exemptions. This rule, however, proposes exemptions that are far broader than permitted under the statutes that the Department cites. By redefining key terms, eliminating important limitations and requirements included in the law, and applying statutes outside of their intended scope, the proposed rule attempts to significantly expand existing exemptions. The Department does not have the statutory authority to expand or create new religious exemptions to its statutorily prescribed programs beyond the exemptions permitted by statutes. Reading additional exceptions into a statute where Congress already contemplated and enumerated specific ones, contrary to fundamental principles of statutory construction, is in excess of the statutory authority provided in the laws the Department seeks to enforce.[80]

A. The Department's regulation proposes an impermissible and harmful reinterpretation of the Church Amendments.

The Department's rule proposes a reinterpretation of the Church Amendments that broadens their impact far beyond what the statute permits, potentially allowing a range of refusals that would severely compromise patients' access to medically necessary care.

Redefinition of "assist in the performance"

One of the most concerning transformations proposed by this regulation is the reinterpretation of what it means to "assist in the performance" of a procedure. In the 2008 rule, the Department defined the term as the participation in "any activity with a reasonable connection" to a procedure to which an individual objects.[81] This definition itself is so broad that it could be applied to services and forms of "assistance" even beyond those contemplated by Congress when the law was enacted. The current rule, however, attempts to expand the application of the Church Amendments even further than the 2008 rule did by defining the statutory term to mean "any activity with an *articulable* connection" to a procedure to which an individual objects.[82]

Although the preamble claims that this definition "mirrors the definition used for the term in the 2008 Rule,"[83] the definition is in fact an attempt to radically expand potential refusals. By allowing health care workers to refuse to engage in activities with a merely "articulable" connection to the service to which a provider or entity has an objection, the proposed rule opens the door to refusals to perform activities whose asserted nexus to the procedure being objected to is greatly attenuated and patently unreasonable, as long as it can be put into words.[84] Individuals wishing to obstruct access to care could seek to invoke

[80] *See, e.g., U.S. v. Smith*, 499 U.S. 160 (1991).
[81] 45 C.F.R. § 88 (2008).
[82] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3923 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88) [hereinafter Proposed Rule].
[83] *Id.* at 3892.
[84] *Compare, e.g., Erzinger v. Regents of Univ. of Cal.*, 137 Cal. App. 3d 389, 394 (Ct. App. 1982), *cert. denied* 462 U.S. 1133 (1983) ("The proscription [of the Church Amendments] applies only when the applicant must participate in acts

the rule to refuse to perform functions whose connection to a sterilization or abortion is extremely remote—such as bringing a meal to a patient after a procedure, handling scheduling tasks that may include booking follow-up appointments for sterilization or abortion procedures, or preparing a patient room. The proposed definition may also be invoked by health care workers or entities who refuse to treat unrelated conditions simply because a patient has had an abortion or sterilization procedure or may have one in the future. For example, it may be invoked by a cardiologist, oncologist, or even an emergency room doctor—as well as nurses, other medical staff, and administrative staff—to refuse to treat a patient for an unrelated condition because they object to asking about or taking into account an abortion or sterilization procedure that a patient has had in the past or intends to have in the future.

Implied redefinition of "sterilization"

The expanded exemptions proposed in the rule might even be construed to permit refusals related to medical treatments that are needed to treat a disease or disorder that may have a merely *incidental* effect of impacting fertility, including certain types of treatments for gender dysphoria. Although the Church Amendments were never intended to reach such medical treatments, the breadth and vagueness of several provisions in the proposed rule may be interpreted to support such an application. For example, twice in the proposed rule, the Department cites *Minton v. Dignity Health*, a case involving denial of care for gender dysphoria, as a purported example of a violation of existing religious exemptions.[85] In this case, a hospital abruptly canceled a hysterectomy for a patient, Evan Minton, after discovering he was transgender and that the procedure was recommended to treat gender dysphoria. The procedure was cancelled in spite of Mr. Minton's doctor's objections and previous determination that the treatment was medically necessary.[86] The same hospital routinely permitted Mr. Minton's physician and other physicians to perform hysterectomies—and in fact, his doctor performed another hysterectomy at the hospital for a non-transgender patient on the very same day that Mr. Minton's hysterectomy was scheduled[87]—but it refused to allow Mr. Minton's procedure to be performed because hospital administrators asserted a religious objection to the use of the procedure to treat gender dysphoria. While Mr. Minton was fortunate to be able to reschedule his procedure—with the same surgeon—at another hospital, many patients who are so abruptly refused care are not so lucky and may face medical complications from delayed treatment.

Applying the Church Amendments in this context—as the Department's citation to the *Minton* case implies—would exceed and contradict the plain meaning of the statute. Like treatments for many other conditions, certain treatments for gender dysphoria, such as hormone treatments and certain surgeries, can have an incidental effect of temporarily or permanently reducing fertility and in some cases eliminating fertility entirely. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. Similarly, a range of other conditions have treatments that can lead to sterilization. For example, forms of chemotherapy and certain other cancer treatments can and in some cases will necessary lead to permanent sterilization, and many medications, including a variety of antibiotic and seizure control medications, can also have an incidental effect of reducing or eliminating fertility. If religious or moral exemptions related to sterilization were construed to encompass treatments

related to the actual performance of abortions or sterilizations. Indirect or remote connections with abortions or sterilizations are not within the terms of the statute.").

[85] Proposed Rule, 83 Fed. Reg. at 3888–89.

[86] Complaint at 6–7, *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. *filed* Apr. 19, 2017).

[87] *Id.* at 2.

that have an incidental effect of affecting fertility, this reinterpretation could lead to refusals that substantially exceed the plain language of the statute and open the door for patients to be denied a dangerously wide range of medically necessary treatments.

Application to other services other than abortion or sterilization

We are also concerned that the proposed rule's sweeping and ambiguous language, in conjunction with the preamble, may lead to an expansive misinterpretation of sections (c)(2) and (d) of the Church Amendments that may encourage refusals of *any* health care service for a religious or moral reason, even those with no connection to sterilization or abortion at all—far exceeding the longstanding application of this statute.[88] This ambiguity may lead covered entities to believe that they can refuse to provide or refer for any service—such as vaccines, psychiatric medication, infertility treatments, and HIV-related care—that is inconsistent with their personal beliefs, jeopardizing the health of numerous Americans. It may also lead covered entities to believe that they can refuse to provide services based on objections about who the patient is: it can encourage, for example, a provider who has a moral or religious objections to providing services for LGBT people, women, people with disabilities, or people of color to refuse to treat them at all, regardless of the treatment they require.

B. The proposed rule impermissibly expands the Coats-Snowe and Weldon Amendments.

Redefinition of "referral"

We are deeply troubled by the Department's proposal to reverse its long-standing interpretation of the application of the Weldon Amendment. We are particularly concerned about the Department's attempt to radically redefine what it means to provide a referral for a patient. There is no legal basis to support the proposed transformation of the term from its plain meaning as it is used in medicine—that is, transferring the care of a patient to a particular health care provider[89]—to "the provision of *any* information…pertaining to a health care service" so long as the health care entity believes that the health care service is a "possible outcome" of providing that information.[90] This breathtakingly broad definition attempts to exempt providers not only from transferring care to another health provider, but from supplying information that has even an exceedingly remote connection to a procedure they object to, so long as they simply believe that it is *not impossible* that doing so may lead the patient to receive the objected-to treatment—even if they do not believe that it is likely or plausible. For example, it may embolden a health care provider to refuse to inform a woman about a pregnancy complication she is experiencing, even if it can be treated, based on their belief that it is *possible* though unlikely she will opt to terminate the pregnancy. While the Department claims that statutory language—such as references to "referring for" an abortion or "making arrangements to provide referrals"—suggests that Congress

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[88] *See, e.g.*, *Elbaum v. Grace Plaza of Great Neck*, 148 A.D.2d 244, 255–56 (N.Y. App. Div. 1989) (finding that a nursing home's reliance on the Church Amendments to justify refusal to remove feeding tube was "misplaced" because the statute only pertains to sterilization and abortion procedures).

[89] *See, e.g.*, American Acad. of Family Physicians, *Consultations, Referrals, and Transfers of Care* (2017), https://www.aafp.org/about/policies/all/consultations-transfers.html ("A referral is a request from one physician to another to assume responsibility for the management of one or more of a patient's specific problems…. This represents a temporary or partial transfer of care to another physician for a particular condition.")

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

intended for this term to be interpreted broadly,[91] the definition that it proposes extends so far beyond the plain meaning of the term that it amounts to a radical revision of the statutory language that undermines rather than effectuates Congress' intent.

Redefinition of "health care entity"

The Department's broad redefinition of the term "health care entity" also ignores Congress' clear intent to limit the entities affected by these statutes. For example, the Coats-Snowe Amendment defines "health care entity" as an "individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions."[92] In contrast, the Department has proposed a far-reaching definition of this term, applicable to all statutes, that combines definitions from multiple statutes.[93] This attempt to supplant the varying statutory definitions of this term with a catch-all list creates confusion about the health care entities that must comply with each statute. It also disregards the congressional intent to cabin the application of each statute, evidenced by the fact that Congress took the time to create separate definitions for each statute rather than to create a universally applicable definition of the term, and by its deliberate decision to include some types of health care entities in each definition while excluding others.

C. The proposed rule impermissibly expands exemptions for Medicare and Medicaid organizations.

The essential care that Medicaid and Medicare programs provide to many Americans are already riddled with expansive exemptions for grantees and other participants, leaving many beneficiaries with no avenue to receive the care they need.[94] It is deeply concerning, therefore, that the proposed rule attempts to expand several exemptions applicable to these programs beyond the statutory language, including the counseling and referral provisions of 42 U.S.C. 1396u-2(b)(3)(B) and 42 U.S.C. 1395w-22(j)(3)(B) and the provisions of the Consolidated Appropriations Act of 2017 related to Medicare Advantage. Expanding religious exemptions in the manner proposed both exceeds the Department's authority and undermines its statutorily prescribed mission to serve beneficiaries and facilitate their access to needed medical care.

Redefinition of "referral"

First, we are troubled by the impact that the expansive redefinition of "referral" could have on patient care for Medicaid and Medicare Advantage recipients. In the context of the counseling and referral

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[91] *Id.* at 3895.

[92] 42 U.S.C. § 238n(c)(2). *See also* Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009).

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

[94] *See, e.g.,* Amy Littlefield, *How a Catholic Insurer Built a Birth Control Obstacle Course in New York*, REWIRE NEWS (Jan. 26, 2017), https://rewire.news/article/2017/01/26/catholic-insurer-built-birth-control-obstacle-course-new-york (describing the refusal of New York's largest Medicaid plan to cover a range of services based on religious objections). *See also* Catholic Health Association of the United States, *Catholic Health Care in the United States* (2018), https://www.chausa.org/docs/default-source/default-document-library/cha_2018_miniprofile7aa087f4dff26ff58685ff00005b1bf3.pdf?sfvrsn=2 (noting that Catholic hospitals, which are required to comply with ethics guidelines that limit access to reproductive and other care, reported one million Medicaid discharges in 2017).

provisions, the proposed rule may be interpreted as allowing Medicaid managed care organizations and Medicare Advantage organizations not only to refuse to cover a counseling or referral service that they object to, but also to refuse to cover or provide for any provider-patient communication that they believe can *possibly* lead to a service to which they object, no matter how remote the connection. Similarly, this novel definition of "referral" suggests that the Consolidated Appropriations Act of 2017 exempts not only Medicare Advantage organizations who refuse to refer for abortions in the natural reading of the term—that is, to transfer care of the patient to another provider—but also those who refuse to provide or cover the provision of any information that they believe can possibly lead to a patient obtaining an abortion. This attempt to rewrite the statutory language is unsupported by statutory language or congressional intent and threatens the health and safety of the program beneficiaries whom these programs are required to serve.

Attempt to transform a statutory construction provision into a freestanding exemption

Further, the proposed rule misinterprets the counseling and referral provisions of 42 U.S.C. § 1396u-2(b)(3)(B) and 42 U.S.C. § 1395w-22(j)(3)(B) by turning a statutory construction provision into a freestanding religious exemption. The Department's proposed exemption relies on narrow provisions that are intended only to qualify the statutes' prohibition on interference with doctor-patient communications. The provisions that the Department cites are pulled from a section whose primary purpose is to prohibit covered entities from interfering with a health care provider's ability to advise an enrollee about their health status or available treatments, regardless of whether those treatments are covered.[95] These provisions clarify a limitation to that prohibition: namely, that a covered entity's refusal to cover a procedure or service does not constitute interference with doctor-patient communication under this section. These provisions are not intended to create a general religious exemption for Medicaid MCOs and Medicare Advantage organizations, but rather they are statutory construction clauses that explain specifically how the prohibition on interference with communication is meant to be construed. Congress' limited intent when enacting these statutes is underscored not only by the plain language of this subsection, which clearly qualifies only a specific requirement of the statute, but also by the choice to explicitly label 42 U.S.C. § 1396u-2(b)(3)(B) as "Construction." The proposed rule, however, disregards the congressional intent evidenced in the statutory language and isolates this section from its context, misrepresenting its limited scope and instead presenting it as a standalone religious exemption that allows Medicaid managed care organizations and Medicare Advantage organizations to refuse to cover any counseling or referral service that they disapprove of.

Omission of critical, patient-protective statutory language

[95] 42 U.S.C. 1396u-2(b)(3)(A) ("Subject to subparagraphs (B) and (C), under a contract under section 1396b(m) of this title a medicaid managed care organization (in relation to an individual enrolled under the contract) shall not prohibit or otherwise restrict a covered health care professional…from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the contract…."); 42 U.S.C. 1395w-22(j)(3)(A) ("Subject to subparagraphs (B) and (C), a Medicare Choice organization (in relation to an individual enrolled under a Medicare Choice plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional…from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan….").

Additionally, the proposed rule omits requirements, enumerated in both 42 U.S.C. § 1396u-2(b)(3)(B) and 42 U.S.C. § 1395w-22(j)(3)(B), that organizations that decline to cover certain treatments notify enrollees of their policy. The statutory construction clauses do not exempt an organization merely on the basis that it has a religious or moral objection to covering a service: it also requires, as a condition of the exemption, that the organization "make 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."[96] The Department's omission of this requirement from its proposed rule will create confusion regarding organizations' legal obligations to disclose their policies to potential and current enrollees and may lead to or encourage noncompliance with the law. Without sufficient enforcement of notification requirements, potential enrollees may be unable to make an informed choice about their health care, and current enrollees may find themselves unable to access care that they would reasonably expect to be covered.

Similarly, the proposed rule misrepresents the exemption provided to entities participating in Medicare Advantage in the Consolidated Appropriations Act of 2017, omitting requirements in the law that ensure that enrollees and the Department itself are notified of objections to covering abortions. The proposed rule asserts that an exemption exists when an "entity will not provide, pay for, provide coverage of, or provide referrals for abortions."[97] In contrast, the statute itself provides an exemption when "the entity *informs the Secretary* that it will not provide, pay for, provide coverage of, or provide referrals for abortions."[98] By excising this important language, the Department may create ambiguity about covered entities' obligations to notify the Department of its objections to covering abortions—a requirement that is necessary to allow the Department to meet its statutory obligation to "make appropriate prospective adjustments to the capitation payment" to entities declining to cover abortions.[99] The statute, furthermore, explicitly states that "a Medicare Advantage organization described in this section shall be responsible for informing enrollees where to obtain information about all Medicare covered services"[100]—a notification requirement that the proposed rule omits, potentially creating confusion regarding a Medicare Advantage organization's responsibilities to inform enrollees about the scope of their coverage.

IV. The proposed exemptions run counter to numerous federal and state laws and raise serious constitutional questions.

A. *Conflict with the Establishment Clause of the Constitution*

Expanding religious exemptions in the manner proposed may run afoul of constitutional restrictions on the scope of religious exemptions. The Supreme Court has noted that there are limits to permissible accommodations based on religious beliefs, and that "at some point, accommodation may devolve into an unlawful fostering of religion."[101] To comply with the Constitution, "an accommodation must be

[96] 42 U.S.C. 1396u-2(b)(3)(B)(ii); 42 U.S.C. 1395w-22(j)(3)(B)(ii).
[97] Proposed Rule, 83 Fed. Reg. at 3926.
[98] Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, Tit. II, sec. 209 (emphasis added).
[99] *Id.*
[100] *Id.*
[101] *Corp. of the Presiding Bishop v. Amos*, 483 U.S. 327, 334-35 (1986) (internal quotation marks omitted).

measured so that it does not override other significant interests"[102] or "impose unjustified burdens on other[s],"[103] and any "detrimental effect on any third party" must be seriously considered.[104] The exemptions proposed in the rule—which would allow many providers and entities to take taxpayer dollars and then refuse to provide a range of needed medical services—would *by definition* impose significant burdens on many intended HHS program recipients. The rule, however, includes no discussion or consideration of the impact its proposed exemptions may have on patients and other third parties, and in fact undermines important statutory limitations on those exemptions that are intended to prevent or mitigate the harms patients may face, thereby raising serious constitutional concerns.

B. *Conflict with federal statutes*

Additionally, many of the exemptions proposed in the rule may conflict with a range of patient protections included in other federal laws. While these protections are subject to the religious exemptions provided under federal law, they are not subject to exemptions whose scope exceeds federal law, including the expanded exemptions proposed in this rule. Adopting an interpretation of religious exemption laws that conflicts with the requirements of other federal laws would compromise the Department's ability to enforce existing law as required. Further, doing so will cause confusion for covered entities about how to navigate seemingly inconsistent obligations under different laws, and subject them to increased liability.

Emergency Medical Treatment and Active Labor Act (EMTALA)

For example, if the proposed rule is implemented, it can subject hospitals to standards that conflict with their obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA), which requires hospitals that have a Medicare provider agreement and an emergency department to provide medical screening and stabilizing treatments to patients in emergency conditions (including labor).[105] The proposed rule contemplates no exceptions to the broad, automatic exemptions it promotes, such as exceptions for emergencies or life-threatening conditions. A hospital could therefore reasonably interpret the proposed rule as requiring it to exempt essential personnel from providing, for example, comprehensive care for a patient experiencing emergent pregnancy-related complications, even when doing so means that the hospital is unable to provide the patient with stabilizing care, in violation of its obligations under EMTALA. The Department provides no guidance about how a hospital can comply with the expanded refusal rights suggested by this proposed rule in cases where doing so would result in an EMTALA violation—potentially putting the hospital in the impossible position of having to somehow satisfy two conflicting requirements. Indeed, the preamble underscores the potential conflict between EMTALA and the Department's approach when it criticizes an American College of Obstetrics and Gynecologists statement reaffirming that physicians must provide emergency care when a safe transfer

[102] *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005); *see also Estate of Thornton v. Caldor, Inc.* 472 U.S. 703, 709-10 (1985) ("unyielding weighting" of religious interests of those taking exemption "over all other interests" violates Constitution).
[103] *Cutter*, 544 U.S. at 726; *see also Texas Monthly, Inc. v. Bullock*, 480 U.S. 1, 18 n.8 (1989) (religious accommodations may not impose "substantial burdens on nonbeneficiaries").
[104] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014) (citing *Cutter*, 544 U.S. at 720). Indeed, every member of the Court, whether in the majority or in dissent, reaffirmed that religious accommodations cannot unduly burden third parties. *See id.* at 2786–87 (Kennedy, J., concurring); *id.* at 2790, 2790 n.8 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting). *See also Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
[105] 42 U.S.C. § 1395dd.

is not possible, regardless of their personal beliefs. The preamble suggests that this position—a simple recitation of a widely accepted legal and professional obligation for physicians—is "evidence of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious or moral convictions" and its implementation "could constitute a violation of Federal health care conscience laws."[106]

Affordable Care Act

The proposed rule is also inconsistent with several provisions of the Affordable Care Act, including Section 1554 and Section 1557. Section 1554 prohibits the Department from promulgating any regulation that "creates any unreasonable barriers to…appropriate medical care" or "impedes timely access to health care services"; that "restricts the ability of health care providers to provide full disclosure of all relevant information to patients" or interferes with their ability to communicate about "a full range of treatment options"; that "violates the principles of informed consent and the ethical standards of health care professionals"; or that "limits the availability of health care treatment for the full duration of a patient's medical needs."[107] This proposed rule violates each and every one of these requirements. Additionally, by pursuing broad exemptions that would likely result in discrimination against patients, the proposed rule conflicts with Section 1557 of the Affordable Care Act, which prohibits discrimination in health care on the basis of race, national origin, disability, age, and sex,[108] and runs counter to clear congressional intent evidenced in this section and throughout the ACA to protect the rights of patients and reduce barriers to accessing health care.

Title VII of the Civil Rights Act of 1964

Further, the proposed rule's approach, which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers, conflict with the well-established standard under other federal laws, such as Title VII of the Civil Rights Act, creating confusion and increased liability for hospitals and other health care employers. As the Supreme Court has long held, Title VII requires that employers reasonably accommodate employees' religious exercise unless doing so would impose undue hardship on the employer, ensuring that the employer can consider the effect that an accommodation would have on clients, patients, co-workers, and its own operations, as well as factors such as public safety, patient health, and other legal obligations.[109] A standard that appears to allow for none of these considerations, and instead appears to require broad and automatic exemptions regardless of the consequences, would create confusion for employers and undermine the federal government's

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[106] Proposed Rule, 83 Fed. Reg. at 3887–3888 (criticizing an American College of Obstetrics and Gynecologists ethics committee that reaffirms a physicians' duty to provide emergency care when transfer is not feasible and suggesting that it is "evidence of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious or moral convictions" and "could constitute a violation of Federal health care conscience laws").

[107] 42 U.S.C. § 18114.

[108] 42 U.S.C. § 18116.

[109] *See, e.g., Ansonia Bd. of Educ. v. Philbrook*, 479 U.S. 60, 70 (1986) ("In enacting [Title VII], Congress was understandably motivated by a desire to assure the individual additional opportunity to observe religious practices, but it did not impose a duty on the employer to accommodate at all costs"). *See also, e.g., Wilson v. U.S. West Communications*, 58 F.3d 1337 (8th Cir. 1995) (affirming that Title VII requires reasonable accommodation employee only when the accommodation does not create an undue hardship on the employer); *Noesen v. Med. Staffing Network, Inc.*, 2006 WL 152996, at *4 (W.D. Wis. June 1, 2006), *aff'd* 232 F. App'x 581 (7th Cir. 2007); *Grant v. Fairview Hosp. & Healthcare Servs.*, 2004 WL 326694 at *4 (D. Minn. Feb. 18, 2004).

ability to properly enforce federal laws.[110] Such a standard could require health care employers to hire individuals who refuse to do essential components of their job. For example, it could require small hospitals to staff their emergency rooms with employees who are unwilling to provide emergency treatment to pregnant or transgender patients even when doing so makes it impossible for the hospital to provide life-saving care to patients or comply with other legal obligations such as under EMTALA. Similarly, this standard could require a clinic that is funded under Title X—and that is therefore statutory required to provide non-directive pregnancy options counseling[111]—to employ medical or administrative staff who refuse to discuss or even simply schedule appointments for pregnancy counseling, even when doing so prevents the clinic from serving its patients or complying with other laws.

C. *Conflict with state and local laws*

Finally, the proposed rule threatens to interfere with the enforcement of hundreds of state and local laws—including laws that protect patients from malpractice and discrimination, laws requiring providers to disclose important information to patients, and laws that prohibit unfair insurance practices and set other minimum standards for private insurance or Medicaid programs. The Department's claims that "this rulemaking does not impose substantial direct effects on States or political subdivision of States" and "does not implicate" federalism concerns under Executive Order 13,132[112] are, as a factual matter, false: as the Department itself recognizes in the preamble, the principles and requirements espoused in its proposed rule conflict with many state and local laws,[113] and the Department challenges several state laws and policies throughout its preamble.[114] While the Department argues that it is merely enforcing existing law and thus minimally impacts state and local governments, its proposed rule in fact represents a significant and unwarranted expansion of existing federal laws—an expansion that is fundamentally at odds with the prevailing interpretation on which many state and local governments have relied when enacting laws to protect their residents.

V. The proposed rule erodes core tenets of the medical system.

The propose rule undermines longstanding ethical and legal principles of informed consent. Informed consent—a fundamental principle of patient-centered care—relies on the disclosure of medically accurate information by providers in order to allow patients to make competent and voluntary decisions about their medical treatment.[115] Health care providers must provide information that is accurate and sufficient to allow a patient to provide informed consent to a course of treatment or lack of treatment, and a health care provider's refusal to provide adequate information can constitute a violation of both medical

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[110] Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel raised concerns about potential conflict with established Title VII standards and emphasized that Title VII should remain the legal standard for determining religious accommodations. Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html

[111] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

[112] Proposed Rule, 83 Fed. Reg. at 3919.

[113] *Id.* at 3888.

[114] *See, e.g., id.* at 3886.

[115] *See, e.g.*, Tom Beauchamp & James Childress, *Principles of Biomedical Ethics* (4th ed. 1994).

standards of care[116] and legal standards.[117] The proposed rule, however, encourages providers to flout their obligations to provide patients with necessary medical information. By encouraging health care providers and entities to refuse to provide key information and disregarding statutory requirements that patients be given notice that they may not receive complete and accurate information, the proposed rule degrades trust and open communication between doctors and patients and prevents patients from being able to make an informed decision about their health care.

For example, by proposing to expand the definition of "referral" to the provision of *any* information by a health care worker who believes that it could *possibly* lead a patient to obtain a treatment to which they object, the Department encourages health care providers to withhold critical information about available treatments, their risks and benefits, or even the patient's diagnosis. As discussed above, the proposed rule even omits statutory requirements that health care entities inform patients of their objections to certain treatments or policies of refusing to provide or cover them. By omitting these notification requirements from its proposed rule, the Department creates confusion about what information health care providers must give to patients about their or their employees' religious or moral objections and encourages entities to ignore these obligations. Especially in light of studies indicating that most patients are unaware that religiously affiliated health care institutions might refuse to provide treatments based on religious objections, [118] the Department's apparent reluctance to fully enforce disclosure requirements jeopardizes patients' ability to make informed decisions about their health care.

VI. The Department's failure to follow required rulemaking procedures and base its rule on available evidence suggests an arbitrary and capricious process.

The Department failed to follow normal rulemaking procedures in issuing the proposed rule in several respects and to consider important evidence regarding the rule's impact. Together with the fact that the rule exceeds the Department's statutory authority, runs counter to existing laws, and undermines the constitutional and other legal rights of patients, this rushed and inadequate rulemaking procedure strongly suggests a violation of the Administrative Procedure Act.[119]

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[116] *See, e.g., The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent*, 14 AM. MED. J. ETHICS 555-56 (2012), http://journalofethics.ama-assn.org/2012/07/coet1-1207.html ("The physician's obligation is to present the medical facts accurately to the patient.... The physician has an ethical obligation to help the patient make choices from among therapeutic alternatives consistent with good practice."); Am. Nurses Ass'n, *Code of Ethics for Nurses with Interpretive Statements* (2001), https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html ("Patients have the moral and legal right to determine what will be done with their own person; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens, and available options in their treatments...."); Am. Pharmacists Ass'n, *Code of Ethics for Pharmacists* (1994).

[117] *See., e.g., Brownfield v. Daniel Freeman Marina Hosp.*, 256 Cal. Rptr. 240 (Ct. App. 1989).

[118] Ensuring that disclosure requirements are rigorously enforced is particularly important in light of research indicating that most patients are unaware that some religiously affiliated health care entities may refuse to provide treatments based on their religious beliefs. *See, e.g.,* Nadia Sawicki, *Mandating Disclosure of Conscience-Based Limitations on Medical Practice*, 42 AM. J. LAW & MED. 85 (2016), http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.

[119] The Administrative Procedure Act instructs a reviewing court to hold agency actions as unlawful when they are found to be "(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence...; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court." 5 U.S.C. § 706.

A. Failure to include the rule in the Department's Unified Regulatory Agenda

First, under longstanding Executive Orders governing the rulemaking process, proposed rules must first appear in the agency's Regulatory Agenda.[120] Executive Order 13,771, signed by President Trump, reaffirms that "no regulation shall be issued by an agency if it was not included on the most recent version or update of the published Unified Regulatory Agenda…unless the issuance of such regulation was approved in advance in writing by the Director" of the Office of Management and Budget.[121] We are aware of no circumstance that would justify the Director approving an exception to this normal process in this instance. We are concerned that the failure of the Department to comply with these requirements reflects a hasty development of the rule that lacked sufficient review of its impact and factual and legal basis.

B. Failure to conduct a meaningful federalism analysis

The Department also failed to comply with the requirements of Executive Order 13,132, which requires agencies to conduct a thorough review of any federalism implications of its regulations, including by identifying effects the regulation would have on existing state and local laws and on the ability of states to exercise power in realms traditionally reserved for them, as well as identifying and in some cases providing funding for costs that would be incurred by state and local governments.[122] The Department's cursory review of federalism implications meets none of those basic requirements. Its conclusion that the regulation has *no* federalism implications is directly contradicted the Department's own statements that its regulation could upend numerous existing state and local laws and policies, require changes to state programs such as Medicaid, and limit the manner in which many states can regulate health care in the future.[123] Regardless of the merits of the Department's interpretation of existing federal law, it is required to make a fact-based federalism assessment that recognizes these impacts of the regulation on state and local laws.

C. Failure to assess the costs of denied or delayed health care

Additionally, the Department failed to comply with Executive Order 13,563, which permits agencies to propose a rule only after conducting an accurate assessment of costs and benefits, and after reaching a reasoned determination that the benefits outweigh the costs and that the regulations are tailored "to impose the least burden on society."[124] While the Department considered the substantial financial costs that its new notification requirements may have on certain health care entities, it failed to even attempt to assess the most significant cost its rule would have if adopted: the cost incurred by patients whose access to care may be denied, delayed, or limited, including substantial financial and health-related costs to patients, to health care entities, and to government-funded health programs. Neglecting to take this cost into consideration or even acknowledge it—despite the Department's past recognition of the pervasiveness of barriers to health care faced by many patients[125]—is suggestive of an arbitrary and

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[120] *E.g.*, Exec. Order No. 13,771, 82 Fed. Reg. 9339, 9340 (Jan. 30, 2017); Exec. Order No. 12,866, 58 Fed. Reg. 190 (Oct. 4, 1993).
[121] *Id.*
[122] Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).
[123] *See, e.g*, Proposed Rule, 83 Fed. Reg. at 3886–3888.
[124] Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011).
[125] *See, e.g.*, Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (2016).

capricious process that entirely failed to consider a crucially important aspect of the issued addressed in the rule.

D. Failure to adequately consider comments from the Department's closely related RFI

We are further concerned that the timing of the publication of the proposed rule reflects an insufficient consideration of public comments to the Department's recent Request for Information on a closely related topic, "Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding." The Department completed its comment period on the Request for Information in November 24, only two months before the publication of this rule, and received over 12,000 comments—the vast majority of which were not posted publicly until mid-December.[126] Many, if not most, of these public comments focused on the precise topic of this proposed rule: religious exemptions for health care workers and institutions. Yet despite the clear and close connection between the RFI and the proposed rule, the brief period of time between them suggests that it is unlikely that the proposed rule reflects a serious, reasoned analysis of the many comments the Department received on the RFI.

This hasty rule development stands in sharp contrast with the typical process for HHS and other agency rules, which commonly spans over several months or years instead of only a few weeks. An illustrative example is the Department's rulemaking process implementing Section 1557 of the Affordable Care Act, which began with a Request for Information in 2013, a proposed rule in 2015, and a final rule in 2016 issued after thorough consideration of more than 25,000 public comments.[127] Given that this proposed rule invokes dozens of distinct statutes, affects numerous areas of both health care service provision and coverage, and imposes sweeping and burdensome new notice and certification requirements—all without any change in the governing statutory or case law—it deserves at least as much deliberation.

VII. Expanding religion-based exemptions is unnecessary.

In addition to raising legal and constitutional questions, an expansion of religion-based exemptions is unnecessary as a matter of policy. Federal statutes and existing regulations, including the existing OCR conscience rule, already provide a broad range of special exemptions for health care providers or entities with religious or moral objections to many services, and these exemptions provide more than adequate protections, as evidenced by the large number of faith-based organizations that have received and continue to receive federal grants and other federal funding.

Among the laws and regulations that protect health care entities, in addition to the statutes cited by the proposed rule, is the Religious Freedom Restoration Act (RFRA). RFRA protects any grantee from any government action (including a denial or limitation of a grant or contract) that substantially burdens their exercise of religion, unless the government can meet the high burden of demonstrating that the action is narrowly tailored to serve a compelling interest. The protections in RFRA are more than sufficient to ensure that faith-based organizations and providers with religious or moral objections to certain procedures can receive case-by-case accommodations, as appropriate, to have a fair opportunity to

[126] Dan Diamond, *HHS Defends Withholding Comments Critical of Abortion, Transgender Policy*. POLITICO (Dec. 18, 2017), https://www.politico.com/story/2017/12/18/hhs-faith-based-rule-withholding-comments-236759.
[127] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. at 31,376.

receive federal funds. Existing Department regulations explicitly acknowledge that their requirements are subject to limitations under RFRA and other federal laws.[128]

Conclusion

We strongly urge the Department to refrain from expanding health care refusal rights as proposed in this rule. Doing so would undermine vulnerable populations' access to essential health services and compromise the Department's ability to meet its responsibilities to legal beneficiaries and its legal obligations. Protecting religious freedom is important, and a range of existing laws and regulations already provide more than adequate protections for individuals and entities with religious or moral objections to providing specific services. It is therefore unwise and unnecessary for the Department to put patients at risk by allowing them to be mistreated or denied care using the federal dollars that are intended to help them. Moreover, the proposed rule is contrary to law in numerous respects. We strongly urge the Department to abandon this unnecessary, untenable, and harmful proposed rule and instead maintain the existing 2011 rule on the topic, while preserving OCR's primary focus on enforcing the civil rights and privacy rights of patients.

Thank you for your consideration.

[128] *See, e.g.*, 45 C.F.R. pt. 92 §92.2(b)(2).

CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Leif Overvold
Leif Overvold