UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, Plaintiff, v. ALEX M. AZAR, III, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No.: 1:19-cv-01672-GLR

PLAINTIFF'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Rule undeniably expands both the substance and the enforcement of "conscience protections" under 25 different statutes. Rather than defend this expansion on the merits, HHS denies that the Rule changes the landscape at all and asserts that "the Rule merely implements and clarifies those important preexisting conscience protections enacted by Congress." Def. Opp. 1.[1] This is wrong, as the administration's boast of "new" conscience protections confirms. And it is fatal to HHS's defense of the Rule. HHS expanded conscience protections without statutory authority and without support in the AR. The Rule violates existing federal law protecting patient rights to health care, and it violates constitutional law. The Rule must be vacated in its entirety.

ARGUMENT

I. The Rule Vastly Expands the Scope and Enforcement of the "Federal Conscience Statutes."

HHS considers it "[r]emarkabl[e]" that the City "do[es] not challenge the underlying Federal Conscience Statutes" as part of its APA challenge. Def. Opp. 1. But the very purpose of the APA is to ensure that "*administration* of [Congress's] own statutes" is "judicially confined to the scope of authority granted or the objectives specified." *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986) (quoting S. Rep. No. 752, 79th Cong., 1st Sess., 26 (1945)).[2] The City challenges HHS's broad new *Rule*, which is neither coterminous with the Federal Conscience Statutes, nor a mere clarification of those narrow, clearly delineated statutes.

[1] The City refers to Plaintiff's Motion for Preliminary Injunction (Dkt. 14-1) as "PI Motion"; Defendant's Opening Summary Judgment Brief (Dkt. 44) as "Def. Br."; Plaintiff's Opening Summary Judgment Brief (Dkt. 50-1) as "Pl. Br."; Defendants' Opposition and Reply (Dkt. 92) as "Def. Opp."

[2] All emphases in the brief are added unless otherwise indicated.

A. The Rule's text clearly expands the Federal Conscience Statutes.

HHS's assertion that the "challenged definitions in the Rule reflect the unambiguous meaning of the terms in the Federal Conscience Statutes" is easily refuted. Def. Opp. 5. As set forth in the City's prior briefing, PI Motion 22-24; Pl. Br. 25-30, and in Section II.C, *infra*, the Rule *expands* the substantive scope of carefully-delineated statutory provisions beyond their longstanding meaning, which providers have relied upon and complied with for decades. Among other expansions, the Rule: (1) permits any worker in the healthcare arena to refuse to perform ordinary job duties with any "specific, reasonable, and articulable connection to furthering" a procedure, no matter how removed; (2) radically expands the list of individuals and entities qualifying as a "health care entity"; (3) expands "referral" to include any communication with a "reasonably foreseeable outcome" of "assist[ing] a person in" obtaining or receiving funding for an objected-to procedure; and (4) curtails healthcare providers' ability to make accommodations for objecting entities. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170, 23,186, 23,263-264 (May 21, 2019); *see also* Def. Opp. Ex. 1 (comment stating that "the proposed regulations *define* particular statutory terms with *commendable breadth*").

The Rule expressly anticipates that it will increase denials of care. In response to comments expressing "concerns about expanding protection to HIV treatment, pre-exposure prophylaxis, and infertility treatment," HHS confirmed that the Rule encompasses such refusals, stating: "In the event that the Department receives a complaint with respect to HIV treatment, pre-exposure prophylaxis, or infertility treatment, the Department would examine the facts and circumstances of the complaint to determine whether it falls within the scope of the statute in question *and these regulations*." 84 Fed. Reg. 23,182; *see also id.* 23,189, 23,205 (HHS would consider refusals to refer LGBT persons or treat gender dysphoria on a "case-by-case basis"). There is ample evidence

in the AR that the expanded definitions will harm LGBTQ individuals' efforts to obtain counseling, PrEP, infertility care, treatments related to gender dysphoria, and HIV treatment. *See*, *e.g.*, Pl Br. 14 n.12.[3]

Facilitating refusals of care to transgender individuals is an *intended* consequence of the Rule. Troublingly, HHS cited as a justification for the Rule *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017), a case in which a transgender man alleged that he had been denied a hysterectomy because of his gender identity.[4] 84 Fed. Reg. 23,176 & n.27. HHS's brief confirms its view that a refusal by a correctional facility worker to provide "hormone therapy to incarcerated transgender persons could potentially relate to the Federal Conscience Statutes." Def. Opp. 19 n.5.

B. HHS previously concluded that the expanded definitions in the Rule were overbroad and inconsistent with the Federal Conscience Statutes.

HHS itself concluded in 2011 that the definitions it now proposes to reinstate were "overbroad in scope" and inconsistent with the intent of the Federal Conscience Statutes. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9969 (Feb. 23, 2011) (the "2011 Rule"). HHS confirmed that:

> The 2008 Final Rule may have caused confusion as to whether the Federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs. The Federal provider conscience statutes were intended to protect health care providers from being forced to *participate in medical procedures* that violated their moral and religious beliefs. They were *never intended*

[3] *See also, e.g.*, Ex. 51 (AR140635 at 140639); Ex. 52 (AR138013); Ex. 53 (AR59389); Ex. 54 (AR106); Ex. 55 (AR6649); Ex. 56 (AR7577); Ex. 57 (AR8890); Ex. 58 (AR9247); Ex. 59 (AR9506); Ex. 60 (AR10053); Ex. 61 (AR135903); Ex. 62 (AR134884); Ex. 63 (AR134797); Ex. 64 (AR136181) This is a sampling of hundreds of individual and organizational comments in the AR concretely identifying how the Rule's expanded definitions will increase denials of necessary health care for LGBTQ individuals.

[4] A California court recently held that Minton alleged a cognizable claim for denial of "full and equal access to health care treatment." *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Sept. 17, 2019) (noting that it is permissible to burden religious exercise where necessary to ensure full and equal access to medical treatment). *See also* Ex. 31 (AR135450) (discussing *Minton*).

> *to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable*.

Id. at 9973-74. HHS has given the Court no reason to turn a blind eye to that reasoned conclusion.

C. The Rule imposes new compliance and enforcement provisions.

Finally, the Rule vastly expands OCR's enforcement authority. The new Rule gives OCR: (1) "discretion in choosing the means of enforcement"—including for noncompliance with the *new* assurance and certification requirements; (2) authority to conduct "compliance reviews" regardless whether a complaint has been filed; and (3) authority to investigate complaints "whether or not the particular complainant is a person or entity protected by Federal conscience and anti-discrimination laws." 84 Fed. Reg. 23,221-222; 45 C.F.R. § 88.7(b)(c). The Rule allows OCR, in "coordination with the funding component," to terminate not only the federal award at issue, but *all* federal funds administered by HHS, 84 Fed. Reg. 23,272; 45 C.F.R. § 88.7(i)(3).

In short, HHS's assertion that the Rule does not "meaningfully differ[] from the Federal Conscience Statutes" and merely "applies existing procedures for administering federal awards," Def. Opp. 1, 8, does not withstand even mild scrutiny.

II. HHS Lacks Statutory Authority for its Legislative Rulemaking.

As set forth above, HHS has engaged in *substantive, legislative* rulemaking—not mere administration. The Rule purports to interpret and implement the Church, Coats-Snowe, and Weldon Amendments, the ACA, and approximately 20 other statutes. 84 Fed. Reg. 23,170. But HHS identifies no legislative authority for expanding the scope of the Federal Conscience Statutes or imposing new substantive compliance requirements and enforcement mechanisms. Because HHS's rulemaking lacks authority, no deference is due. *See, e.g.*, *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation

of administrative authority."). Even if HHS had authority to expansively interpret the Federal Conscience Statutes—as a matter of law it does not—its definitions are unreasonable.

A. HHS's "housekeeping" and "monitor[ing]" authority does not authorize substantive expansion of the Federal Conscience Statutes.

HHS invokes 5 U.S.C. § 301 and other "regulations regarding the administration of funding instruments" as its authority for "complaint investigation *or defining relevant terms*." Def. Br. 21; Def. Opp. 3. But Section 301 "authoriz[es] what the APA terms 'rules of agency organization procedure or practice' as opposed to 'substantive rules.'"[5] *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979). The Supreme Court distinguished regulating "the way in which requests for information are to be dealt with" from "claim[ing] authority to withhold information." *Id.* at 310 n.41 (citing legislative history). The Rule goes well beyond delegating authority to receive complaints: HHS redefines the scope of the Federal Conscience Statutes and arrogates to itself the authority to impose draconian "consequences" for noncompliance with those new, unauthorized conditions. Def. Opp. 4. While the 2011 Rule addresses "the way in which [complaints] are to be dealt with,"[6] the 2019 Rule's expansion of enforcement authority is akin to "authority to withhold" and, as such, is far outside the scope of housekeeping. *Chrysler Corp.*, 441 U.S. at 310 n.4.

HHS tries to justify the Rule by arguing that it is "required under the Federal Conscience Statutes to apply certain conditions to federal awards."[7] Def. Opp. 4. But the Rule doesn't apply existing conditions—it establishes entirely *new* "conditions" with no basis in the Federal

[5] The Rule is plainly "substantive" under the APA. It has all the "hallmark[s] of a legislative rule": it underwent notice and comment, and its "interpretation of [key statutory terms] as well as the compliance procedures impose obligations on covered entities." *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 46 (D.D.C. 2014) (explaining why rule is legislative, not interpretive).

[6] The City is not challenging OCR's authority to receive complaints. Def. Opp. 3.

[7] The City did not "abandon" but rather expressly addressed the argument that HHS cannot rely on grant and funding authority for the Rule. Def. Opp. 3. *See* Pl. Br. 23.

Conscience Statutes. HHS cannot invoke funding regulations to alter the substantive parameters of Federal Conscience Statutes.

B. HHS lacks any other authority to expand the Federal Conscience Statutes.

HHS contends that "several statutory provisions explicitly grant HHS sufficient regulatory authority here" and cites three provisions of the ACA (42 U.S.C. §§ 18023, 18041, 18113), two narrow provisions of the Social Security Act (42 U.S.C. §§ 1302, 1315a), and one provision of the Public Health Services Act (PHSA) regarding certification of laboratories (42 U.S.C. § 263a). As HHS acknowledges, "[t]he great majority of the Federal Conscience Statutes that the Rule implements, of course, are not part of the ACA." Def. Br. 31. *None* of the laws HHS invokes grant it authority to interpret the Church, Coats-Snowe, or Weldon Amendments at the heart of the Rule.

HHS says that *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28 (D.D.C. 2014) ("*PRMA*"), does not apply because in that case the agencies "lacked authority under any of the statutes to which they pointed." Def. Opp. 5. That is wrong. The court in *PRMA* considered a scenario similar to the one here—where "HHS has strung together … specific grants of authority" from different statutory provisions, which the court found "do not authorize the orphan drug rule implemented." 43 F. Supp. 3d at 39. The court rejected a "limited grant of rulemaking authority in *an entirely different statute*" as the basis for the rule. *Id.* at 40 (emphasis in original). The court also considered express delegations of authority under the two statutes at issue—the PHSA and the 340B program. It found the first lacking because it related to "administration … not the *implementation* of the [PHSA]" and found the second lacking because it was related to "resolving disputes." *Id.* at 39, 42-43 (emphasis in original). The court invalidated the Rule at *Chevron* step one. *Id.* at 45.

The rulemaking authority upon which HHS relies for this Rule is even less compelling than that in *PRMA*. ACA Section 1553, which relates to assisted suicide, simply designates OCR "to receive complaints of discrimination based on this section." 42 U.S.C. § 18113(d). This is exactly the kind of "administrative" authority *PRMA* rejected as a basis for substantive rulemaking such as redefining key statutory terms.[8] 43 F. Supp. 3d at 39. And Church, Coats-Snowe, and Weldon delegate *no* authority to HHS. *PRMA* expressly rejected HHS's attempt to use 42 U.S.C. § 1302 (governing Medicare and Medicaid) to issue rules pursuant to the PHSA. 43 F. Supp. 3d at 41 & n.13. HHS cannot recycle that failed effort here to expand the substantive provisions of Church, Coats-Snowe, Weldon, and the ACA.[9]

Finally, HHS has no support for its conclusory assertion that it has "implicit" authority to redefine conscience protections in the Federal Conscience Statutes. Def. Opp. 6. HHS identifies no "gap left, implicitly or explicitly, by Congress" in the self-enforcing, narrowly delineated statutes. *Id.* (quoting *Morton v. Ruiz*, 415 U.S. 199, 231 (1974)). In fact, HHS admitted there are none. Def. Br. 50 (Federal Conscience Statutes "clearly provide[] unambiguous notice to funding recipients of the Statutes' anti-discrimination provisions."); Pl. Br. 22-25. The circumstances

[8] *Gonzales v. Oregon,* 546 U.S. 243 (2006) is also instructive. There the Supreme Court considered a rulemaking under the Controlled Substances Act, which *expressly* gave the Attorney General rulemaking power in "two specific areas"—"dispensing of controlled substances" and rules "necessary and appropriate for the efficient execution of his functions under this chapter." *Pharm. Research*, 43 F. Supp. 3d at 37 (quoting *Gonzales*, 546 U.S. at 259). The Supreme Court vacated a rule defining "legitimate medical purpose" not to include assisted suicide under the CSA, on the ground that the CSA did not grant "this broad authority to promulgate rules." *Id.* at 38 (quotation omitted). Here, HHS identifies no express delegation of authority to interpret or implement Church, Coats-Snowe, or Weldon.

[9] HHS does not even attempt explain how the other narrow and largely administrative provisions it cites give it authority to "implement[]" and "interpret" the substantive conscience protections. For example, HHS does not explain how 42 U.S.C. § 18041, requiring HHS to establish exchanges under the ACA, gives it authority to expand substantive conscience protections. *See* Def. Opp. at 4 n. 1. It does not grant that authority under the ACA, and it certainly does not grant authority as to 20 other statutes in the Rule, including Church, Coats-Snowe, and Weldon.

present in *Morton*—a 140-year history of agency promulgation of rules and policies and an "explicit[]" delegation of authority to the Secretary—are manifestly absent here.

C. HHS's definitions are unreasonable.

Because HHS lacks any authority for "interpreting" the statute, the Rule fails at *Chevron* step one, and there is no need to assess reasonableness. *PRMA*, 43 F. Supp. 3d at 45. Even where authority exists, however, an agency interpretation that is "inconsistent with the design and structure of the statute as a whole does not merit deference." *Util. Air Regulatory Grp. v. E.P.A.*, 573 U.S. 302, 321 (2014). HHS's definitions are incompatible with the text of the statutes it purports to interpret and with the robust legislative framework protecting conscience objections *and* patient rights to nondiscriminatory health care—*not* elevating the former over the latter.

Church, Coats-Snowe, and Weldon are narrowly tailored to address specific procedures—abortion, sterilization, and assisted suicide—in specifically delineated contexts, e.g., in Church Amendment Section (d), behavioral and biomedical research.[10] Pl. Br. 26-30. They are "unambiguous," Def. Br. 50, and Congress evinced no intent to read them "expansively."

HHS ignores, for example, Sen. Church's statement that the "amendment is meant to give protection to the *physicians, to the nurses, to the hospitals themselves, if* they are religious affiliated institutions." 119 Cong. Rec. S9595 (Dec. 22, 1973). Nothing in Church (or Weldon, or Coats-Snowe) suggests Congress intended to allow any employee in the healthcare arena to opt out of providing care for individuals based on any religious or moral objection. Yet the Rule's definition

[10] Contrary to HHS's assertion that the Church Amendments cover "a broad range of activity," Def. Opp. 9, the legislative history confirms that Church (d), 42 U.S.C. § 300a-7(d), applies in narrow circumstances. Church (c) and (d) were added in 1993 when Congress passed The National Research Act, Public Law 93-348, and were accepted by the Conference Committee with the express limitation that they apply "only to entities that receive grants or contracts for biomedical or behavioral research under programs administered by the Secretary." H.R. Conf. Rep. 93-1148.

of "assist in the performance" authorizes exactly that. *See* 84 Fed. Reg. at 23,186 ("Scheduling an abortion or preparing a room… are necessary parts of the process" and, therefore, constitute "assistance"); *id.* 23,205 (covering treatment for gender dysphoria). As set forth in Section IV.B *infra*, HHS in 2011 concluded that the Federal Conscience Statutes did not allow this. HHS has not justified its new reading of legislative intent.

HHS's new definition of "health care entity" is an unjustified expansion of an *explicitly defined term*. Even if, as HHS contends, Congress's lists are "non-exhaustive," HHS's additions must be consistent with the others in the list. *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010). HHS does not and cannot explain how expanding the list from "physicians" and "health care professionals" to ***all*** "health care *personnel*," and adding pharmacists,[11] 84 Fed. Reg. 23,264, is consistent with carefully-calibrated lists in Weldon, Coats-Snowe, and the ACA. *Cf. Samantar*, 560 U.S. at 319 ("careful calibration of remedies among the listed types of defendants suggests that Congress did not mean to cover other types of defendants never mentioned in the text.").

HHS's Rule creates a single new definition of "discrimination" to be employed across 25 different statutes, which govern diverse, limited contexts. Def. Opp. 10. As discussed in Section III.B, *infra*, the definition, which contains no "undue hardship" exception, *directly* conflicts, for example, with ACA Section 1303(c)'s prohibition on interfering with the employer-employee relationship under Title VII. In defending the sweeping definition, HHS *emphasizes* that there is "no universal definition of discrimination that governs all federal statutes" and that the definition contains a "*non-exhaustive list*" of scenarios. Def. Opp. 9-10, 12 (emphasis in HHS brief). That

[11] The National Community Pharmacist Association itself noted that "pharmacists are not the intended provider" under the statutes and urged OCR to rescind the Proposed Rule as in excess of statutory authority." Ex. 65 (AR147879).

only *highlights* the overbreadth. That *additional* scenarios may constitute discrimination makes the definition more unreasonable and impedes providers' ability to comply.

The Rule's expansion of the term "referral" from its understood technical meaning in the healthcare context to a far more sweeping definition also lacks justification.[12] HHS's refrain that the definition "consists of a *non-exhaustive list* of items that *may* constitute 'referral,'" Def. Opp. 12, is no restriction at all and no comfort to providers attempting to comply.

Even if HHS had the authority to issue these expansive definitions, they cannot be squared with the text of the statutes or Congress's intent.

III. The Rule Violates Existing Federal Law Protecting Patients' Rights.

A. ACA Section 1554 prohibits HHS from "promulgat[ing] any regulation" that "creates any unreasonable barriers," or "impedes timely access" to health care.

Notably, HHS's opposition *does not dispute* that the Rule creates "unreasonable barriers" and "impedes access" under ACA Section 1554. 42 U.S.C. § 18114. Instead, HHS rejects (and characterizes as "extraordinary") the assertion that Section 1554, which specifically addresses *HHS*'s ability to "*promulgate any regulation*" restricts HHS's authority to issue the Rule. Def. Opp. 13. HHS claims that interpreting Section 1554 to mean what it says would "render meaningless … many Federal Conscience Statutes" and "mean that HHS could not put any restrictions on Medicare or Medicaid funding through regulations." *Id.* This parade of horribles lacks any basis in reality.

[12] The medical regulatory backdrop makes clear that Congress intended the word "referral" to have its normal meaning in the healthcare setting—for a provider to direct a patient to another provider. *See, e.g.*, Medicare.gov, *Glossary-R*, https://www.medicare.gov/ glossary/r (last visited Oct. 2, 2019) (defining referral as "[a] written order from your primary care doctor for you to see a specialist or get certain medical services"); Ctrs. for Medicare & Medicaid Serv., *Glossary*, https://go.cms.gov/2LN4RE1 (last visited Oct. 2, 2019) ("referral is defined as an actual document obtained from a provider in order for the beneficiary to receive additional services.").

First, as the City explained, Section 1554 does not affect "Federal Conscience *Statutes*"—it speaks only to HHS's *regulatory* authority. Pl. Br. 19. *Second*, Section 1554 limits only "unreasonable" barriers and, thus, does not limit all restrictions under Medicare, Medicaid, or any other regulatory authority. *Third*, even if Section 1554 were limited to regulations under the ACA, as HHS argues, Def. Br. 31, it would limit HHS's authority here: HHS invokes as its *primary* authority for the Rule several provisions of the ACA, including Sections 18023, 18041, and 18113. Def. Opp. 5. As set forth in Section II.B, *supra*, these sections do not grant HHS authority to expand other Federal Conscience Statutes, a "great majority" of which are not the ACA. Def. Br. 31. But HHS certainly cannot simultaneously invoke authority under the ACA *and* ignore Section 1554's restriction on its authority to "promulgate any regulation" restricting access to care.

Nor does Section 1303(c)(2) nullify Section 1554. Section 1303(c)(2) confirms that the ACA shall not be "construed to have any effect on *Federal laws* regarding—(i) conscience protection." Section 1554 does not restrict "Federal law" regarding conscience protection—it governs rulemaking. There is no need to look at the ACA's legislative history to conclude that Section 1303 speaks to legislation, whereas Section 1554 speaks to regulation. The plain text—Section 1303(c) referring to "Application of State and Federal laws regarding abortion"[13] and Section 1554 referring to HHS authority "promulgate any regulation"—answers the question.

B. The Rule conflicts with ACA Section 1303(c) and EMTALA.

Far from giving HHS free reign to expand conscience protections, as HHS contends, Def. Opp. 4, Section 1303 *restricts* HHS's authority under the ACA and confirms that the Rule is contrary to Federal law. Section 1303 states that it shall not "alter the rights and obligations of

[13] *United States v. Mitchell*, 39 F.3d 465 (4th Cir.1994) analyzed the term "contrary to law," not the term "State and Federal laws," and is therefore inapposite.

employees and employers under title VII of the Civil Rights Act of 1964" or "relieve any health care provider from providing emergency services … including … [as required by] EMTALA." The Rule runs afoul of both prohibitions.

The Rule's expansive definition of "discrimination" (for which HHS's only purported rulemaking authority is the ACA) does exactly what Section 1303 forbids—it "alter[s] the rights and obligations of employees and employers under title VII" by eschewing any "undue hardship" exception to an employer's obligation to make accommodations. The Federal Conscience Statutes are silent on the issue of "undue hardship." HHS is not free to expand those statutes under the authority of the ACA in a manner that "alter[s] the rights and obligations of employees and employers under title VII."

The Rule also impermissibly "relieve[s] any health care provider from providing emergency services as required by State or Federal law, including [under EMTALA]" in violation of Section 1303(d) and EMTALA itself. As the Fourth Circuit has stated, EMTALA's "core purpose is to get patients into the system who might otherwise go untreated and be left without a remedy because traditional medical malpractice law affords no claim for failure to treat" and "to deal with the problem of patients being turned away from emergency rooms for non-medical reasons." *Bryan v. Rectors & Visitors of Univ. of Virginia*, 95 F.3d 349, 351 (4th Cir. 1996). The Rule runs counter to this "core purpose" by authorizing an individual to "fail[] to treat" an individual in an emergency situation based on an objection to that person's identity or the treatment sought. A violation of EMTALA would result if even a single ambulance driver refused care—and the Rule confirms that "EMTs and paramedics are treated like other health care professionals under this definition." 84 Fed. Reg. 23,188. HHS's refusal to treat emergencies differently creates

an irreconcilable, non-hypothetical conflict between EMTALA and the Rule. HHS has offered no explanation of how it could apply EMTALA and the Rule harmoniously.

This is a problem borne of the *Rule*'s expanded definition of "assist in the performance" and "discriminate and discrimination," which together expand conscience protections to individuals even tangentially involved in a procedure and prevent providers from finding reasonable accommodations. It is not, as HHS contends, a conflict between EMTALA and the Federal Conscience Statutes themselves.

C. The Rule conflicts with ACA Section 1557.

HHS incorrectly reads Section 1303(c)(2) to elevate "federal conscience protections" and to nullify Section 1557's non-discrimination mandate—which is not at all what Section 1303(c)(2) says. Section 1303(c) requires no effect on "Federal laws regarding conscience protection" *and* "No effect on Federal civil rights law." 42 U.S.C. § 18023. HHS's insistence that federal conscience protections (statutory or regulatory) trump all other statutory protections against discrimination in health care is the central flaw in the Rule and a reason to vacate it.

IV. HHS's Unexplained Policy Reversal and Disregard for Patients' Rights Was Arbitrary and Capricious.

HHS's argument that the Rule is not arbitrary and capricious is replete with platitudes—for example, HHS "provided 'a rational connection between the facts found and the choice made [and] supported each challenged aspect of the Rule with sound and detailed reasoning." Def. Opp. 15-16. These assertions are unsupported by anything in the AR and rely heavily on HHS's now-discredited assertion that the change in policy is justified by the "recent, documented instances of alleged and demonstrated conscience discrimination." *Id.* at 16.

A. The Administrative Record refutes HHS's justification for the Rule.

HHS's attempt to rehabilitate its reliance on an increase in complaints as a justification for the Rule fails. HHS asserts that a "sizeable number of complaints did implicate the relevant statutes" and cites a total of *eight* complaints, bringing the total up to, at most, 11 complaints in the AR. Def. Opp. at 18 n. 4. Again, this falls far short of what HHS represented as "the reasons for this rule"—that "[d]uring FY 2018 … OCR received ***343 complaints alleging conscience violations***." 84 Fed. Reg. 23,229. HHS cannot escape that it "offered an explanation for its decision that runs counter to the evidence before the agency," rendering the Rule arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins*., 463 U.S. 29, 43 (1983); *accord Casa De Maryland v. U.S. Dep't of Homeland Sec.,* 924 F.3d 684, 703 (4th Cir. 2019) ("[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself."). The disconnect between HHS's justification and the AR warrants vacating the Rule.

B. HHS's contention that the 2011 Rule was inadequate or confusing is contrary to the Administrative Record.

While an agency is entitled to "rebalance old facts to arrive at the new policy," it is not entitled to "ma[k]e factual findings directly contrary to the [prior rule] and expressly rel[y] on those findings to justify the policy change." *Organized Vill. of Kake v. U.S. Dep't of Agric*., 795 F.3d 956, 968 (9th Cir. 2015). HHS does not even argue that it is giving more weight to particular facts. It instead asserts that the 2011 Rule "created confusion." Def. Opp. 16. That is the opposite of HHS's conclusion in 2011 that the "2008 Final Rule may have caused confusion as to whether the Federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs." 76 Fed. Reg. 9973-74.

HHS's few citations to the AR do not support this 180-degree policy change. Exhibit 1 cites HHS's own now-discredited assertion of a "rise in the rate of complaint filings." Def. Opp.

Ex. 1 [Dkt. 92-1] ("The preamble [to the NPRM] provides ample documentation of the record of violations of the federal conscience statutes in the United States."); *see also id.* Ex. 4 [Dkt. 92-4] (claiming, without support, a "sharp increase in administrative complaints over the past year"). *Cf. id.* Ex. 2 [Dkt. 92-2] (citing to instances of alleged violation of conscience protections that largely occurred before 2011). Indeed, one of HHS's cited comments *supports* the 2011 Rule's recognition that conscience protections should not facilitate denials of services based on "discomfort" or "animus." *Id.* Ex. 5 [Dkt. 92-5] at 2 ("Every individual seeking health care should always be treated with kindness and respect, and failure to do so because of discomfort with or animus against an individual on any basis is unacceptable."). Yet, as set forth in Section IV.C, *infra*, the Rule ignores this important concern entirely. Because HHS acted arbitrarily and capriciously in "chang[ing] course without any explanation for why [its earlier] analysis was faulty," the Rule must be set aside. *Casa De Maryland,* 924 F.3d at 705.

HHS also has no response to the City's argument that it failed to consider that "its prior policy has engendered serious reliance interests." *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015); Pl. Br. 12. HHS cites to a line-item in the cost-benefit analysis regarding familiarization, Def. Opp. 17, but nowhere (not in the Rule or in its briefs) even acknowledges the numerous comments regarding how healthcare entities have structured their programs to accord with the existing legislative and regulatory framework for conscience protections. *See, e.g.* Pl. Br. 12 n.10.[14] That failure renders the Rule arbitrary and capricious. *Casa De Maryland*, 924 F.3d at

[14] *See also, e.g.*, Ex. 66 (AR32771) (City of Miami opposing rule that "would broadly expand opportunities for healthcare workers to refuse to participate in certain medical procedures on the basis of a moral or religious objection," and noting that Proposed Rule is estimated to "impact somewhere between 364,640 to 571,412 entities including public and private hospitals, specialty hospitals, …youth services, shelters, nursing and hospice facilities, offices of mental health practitioners, and family planning centers[.]").

705 ("Although the government insists that Acting Secretary Duke considered these interests in connection with her decision to rescind DACA, her Memo makes no mention of [the hundreds and thousands of people [who] had structured their lives on the availability of deferred action].").

C. HHS improperly disregarded concrete evidence of harm to patients from discrimination.

When a Court considers an agency's stated reasons for a decision in conducting arbitrary and capricious review, it must satisfy itself that the agency "consider[ed] *and respond[ed]* to significant comments received during the period for public comment." *Mayor & City Council of Baltimore v. Azar*, 392 F. Supp. 3d 602 (D. Md. 2019) (citing *Perez*, 135 S. Ct. at 1203). Conclusory statements that HHS considered all the comments are not enough, where, as here, "when it came to explaining [the changed policy] the Department said almost nothing." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2120 (2016).

HHS's opposition focuses entirely on how the Rule would supposedly encourage more religious healthcare providers to "enter the health care field" (a proposition not supported by serious evidence) and does not even acknowledge comments about how the Rule will increase discriminatory denials of care. Def. Opp. 19-21. If HHS had explained *why* it prioritized religious rights over the rights of patients to uninterrupted, non-discriminatory care, there might have been a genuine question whether that explanation was "satisfactory" under the APA. *Casa de Maryland*, 924 F.3d at 703. But HHS did not provide *any* explanation. It ignored the problem entirely. This is quintessentially arbitrary and capricious.

The 2011 Rule placed the issue of discrimination against patients front and center. *See* 73 Fed. Reg. 9974 (Federal Conscience Statutes were "never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable."). HHS's failure to address this problem is even more arbitrary in

light of the agency's "lack of reasoned explication for a regulation that is inconsistent with the Department's longstanding earlier position." *Encino Motorcars*, 136 S. Ct. at 2120–21.

V. The Rule Violates the Establishment and Spending Clauses.

A. The City's constitutional claims under the APA are justiciable.[15]

HHS wrongly argues that the City's constitutional claims are unripe in the absence of agency enforcement action. With respect to the Spending Clause violation, the injury here is the unlawful coercion inherent in the decision whether to accept federal funds in the first place. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581-82 (2012) (threatened loss is "economic dragooning" that leaves no real option but to acquiesce). The Rule's new, draconian clawback remedy means that accepting funding—under greatly expanded conditions—might result in having to repay monies already spent, thus endangering not just future *federal* funding but also funds from other sources. That HHS might decline to enforce to the fullest extent does not offset the risk associated with the *new* coercive conditions attached to such a significant part of the City's budget.

HHS argues that review of the City's Establishment Clause claim must await enforcement to determine how the definition of discrimination will be applied. But the Rule's expansive definition, *see* Section II.C, *supra*, places unprecedented limits on providers' ability to accommodate employees while ensuring patient health and safety. The Rule forbids almost any employment action toward religious objectors other than absolute obeisance. The City must grapple with this reality now. The constitutional claims are thus ripe for review.

[15] HHS is wrong that the Court cannot consider declarations filed in support of the City's suit. HHS's challenge to the City's standing, while meritless, not only authorizes, but requires the City to "supplement the record to the extent necessary to explain and substantiate its entitlement to judicial review." *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002). The declarations establish standing by showing how the Rule will both harm the City directly and interfere with the City's ability to protect the public health.

B. The Rule Violates the Spending Clause.

In an attempt to rescue the Rule from Spending Clause prohibitions, HHS resorts to its fallback that the Rule merely mirrors what the Statutes already require. As explained in Section I, *supra*, nothing could be further from the truth. As particularly relevant here, the threat of complete loss and clawback of federal funding—even funding unrelated to conscience objections—renders the expanded conditions unconstitutionally coercive. The expanded enforcement is a transformation "in kind, not merely degree." *See NFIB*, 567 U.S. at 582-83 (finding irrelevant that Congress called the program a "modification" when it was in effect a "new program").[16]

C. The Rule violates the Establishment Clause.

i. The Rule imposes the burdens of objecting employees' religious beliefs on third parties, including the City, providers, and patients.

HHS in effect contends that the Establishment Clause tolerates religious accommodations no matter the material burdens and costs they impose on third parties. Def. Opp. 28. That position is irreconcilable with Supreme Court precedent.[17] *See* Pl. Br. 35–36 & n.25. The question is not

[16] Courts also permit plaintiffs to submit extra-record evidence in support of their constitutional claims under § 706(2)(B). *See, e.g.*, *Tafas v. Dudas*, 530 F. Supp. 2d 786, 802 (E.D. Va. 2008) ("When a court is reviewing the constitutional validity of agency action pursuant to 5 U.S.C. § 706(2)(B), it should make 'an independent assessment of a citizens' claim of constitutional right.") (quoting *Porter v. Califano*, 592 F.2d 770, 780 (5th Cir. 1979)); *Nat'l Med. Enters., Inc. v. Shalala*, 826 F. Supp. 558, 565 n.11 (D.D.C. 1993) (allowing plaintiffs to submit additional declaration not in administrative record); *Rydeen v. Quigg*, 748 F. Supp. 900, 906 (D.D.C. 1990) (same). *Fort Sumter Tours, Inc. v. Babbitt*, 66 F.3d 1324 (4th Cir. 1995), cited by HHS, Def. Opp. 31–32, recognizes but that there may be circumstances to justify expanding the record or allowing discovery. *Babbitt* did not involve a constitutional challenge under Section 706(2)(B) of the APA. The declarations provide highly relevant merits evidence. The declarations here demonstrate a far greater injury to the City than the 20 percent loss of funding in *NFIB*.

[17] The cases on which HHS relies do not support its position. Justice Kennedy's concurrence in *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*—joined by no other Justice—acknowledges that "[t]here is a point … at which an accommodation may impose a burden on nonadherents so great that it becomes an establishment," and explains that the issue did not arise in the case. 512 U.S. 687, 725 (1994) (Kennedy, J., concurring). In *Gillette v. United States*, 401 U.S. 437, 448-54 (1971), the Court held only that the statute did not violate the Establishment Clause by treating similarly situated religious objectors differently. *Gillette* did not present the question whether the

whether courts must "take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries," *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005)—they must. The question is when does an accommodation become an unconstitutional religious preference. This Court need not identify that precise threshold because, as the City has shown, Pl. Br. 38, the burdens in this case are far more severe than those that required invalidation in, for example, *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1 (1989), and *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985).

ii. The Rule impermissibly prefers religion over other beliefs.

The Rule violates the Establishment Clause because its "ostensible object" and primary effect are to advance religion. *McCreary County. v. ACLU of Ky.*, 545 U.S. 844, 860, 863 (2005). That is so whether or not the Rule uses some religiously neutral language or purports to treat religious and nonreligious objectors alike. *See, e.g.*, *id.*; *Kiryas Joel*, 512 U.S. at 699 ("identification here of the [favored] group . . . in terms not expressly religious" "does not end" Court's inquiry into whether challenged statute afforded unconstitutional preference to religious group); *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 531–33 (1993) (Establishment Clause "forbids subtle departures from neutrality"). Here, the "departures from neutrality" are not subtle. HHS boasts of them:

> The rule will promote protection of religious beliefs and moral convictions, which is a societal good based on fundamental rights . . . . 'It is the duty of every man to render to the Creator such homage, and such only, as he believes to be acceptable to him.'"

84 Fed. Reg. 23,246. That the Rule recognizes some "non-religious beliefs" as well as the favored religious ones, Def. Opp. 28, is no defense.

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exemption impermissibly harmed any identifiable nonbeneficiary, which it didn't. *See, e.g.*, Geddicks & Van Tassell, *RFRA Exemptions from the Contraception Mandate: An Unconstitutional Accommodation of Religion*, 49 Harv. C.R.–C.L. L. Rev., 343, 367 & n.114 (2014). Finally, *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 339 (1987), underscores this constitutional rule. Pl. Br. 39 & n.27.

If the government, in prioritizing religion, is not removing a burden on religious exercise of its own making, it impermissibly favors and elevates one person's religious beliefs over others' beliefs and other rights. *Caldor*, 472 U.S. at 709–10. Contrary to HHS's suggestion, Def. Opp. 30, Title VII complies with this principle and highlights why the Rule does not: Title VII's religious-accommodation provision ameliorates burdens on employees' religious exercise imposed by the statute's nondiscrimination provisions. And it avoids materially burdening nonbeneficiaries by not requiring accommodations that impose more than a "*de minimis* cost" to the employer. *Trans World Airlines v. Hardison*, 432 U.S. 63, 81, 84 (1977); *E.E.O.C. v. Firestone Fibers & Textiles Co.*, 515 F.3d 307, 312–14 (4th Cir. 2008). The Rule, in contrast, impermissibly privileges some employees' religious beliefs over others and demands that employers bear the costs of religious accommodation without exception and without regard to burden on the employer.

VI. The Court Should Vacate the Rule in Its Entirety.

The deficiencies in the Rule pervade the entire Rule and require vacating it in its entirety. As a general matter, Courts "do not attempt, even with the assistance of agency counsel, to fashion a valid regulation from the remnants of the old rule." *Nat'l Treasury Employees Union v. Chertoff*, 452 F.3d 839, 867 (D.C. Cir. 2006). HHS asserts that "portions of the Rule can clearly operate independently from each other," Def. Opp. 33, but does not explain how severing any portion of the Rule would "leave a sensible regulation in place." *MD/DC/DE Broadcasters Ass'n v. F.C.C.*, 253 F.3d 732, 735 (D.C. Cir. 2001). Maintaining only part of the Rule would be particularly ill-advised in light of the threat of "confusion" about the Federal Conscience Statutes. Def. Opp. 16.

CONCLUSION

The City requests that the Court vacate and set aside the Rule before November 22, 2019 or, if necessary, preliminarily enjoin the Rule pending resolution of the merits.

DATED: October 4, 2019

Respectfully submitted,

By: */s/ Suzanne Sangree*

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CERTIFICATE OF SERVICE

I hereby certify that on October 4, 2019 the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system and all counsel of record will receive an electronic copy via the Court's CM/ECF system.

/s/ Elisha B. Barron
Elisha B. Barron

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE,

Plaintiff,

vs.

ALEX M. AZAR, II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

Case No. 1:19-cv-01672

DECLARATION OF SUZANNE SANGREE IN SUPPORT OF PLAINTIFF'S REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

I, Suzanne Sangree, declare that, if called upon, I would testify to the following:

1. I am a member of the Maryland State Bar, admitted to practice before this Court, employed by the Baltimore City Department of Law as Senior Public Safety Counsel and Director of Affirmative Litigation, and am counsel to Plaintiff in this action. I submit this Declaration in support of Plaintiffs' motion for summary judgment.

2. Attached to this Declaration are true and correct copies of the following numbered exhibits, all of which are part of the administrative record produced by Defendants in this action (AR):

3. Attached hereto as Exhibit 51 is a is a true and correct copy of AR140635-140648.

4. Attached hereto as Exhibit 52 is a is a true and correct copy of AR138013-AR138014.

5. Attached hereto as Exhibit 53 is a is a true and correct copy of AR59389-59393.

6. Attached hereto as Exhibit 54 is a is a true and correct copy of AR106.

7. Attached hereto as Exhibit 55 is a is a true and correct copy of AR6649.

8. Attached hereto as Exhibit 56 is a is a true and correct copy of AR7577.

9. Attached hereto as Exhibit 57 is a is a true and correct copy of AR8890.

10. Attached hereto as Exhibit 58 is a is a true and correct copy of AR9247.

11. Attached hereto as Exhibit 59 is a is a true and correct copy of AR9506.

12. Attached hereto as Exhibit 60 is a is a true and correct copy of AR10053.

13. Attached hereto as Exhibit 61 is a is a true and correct copy of AR135903.

14. Attached hereto as Exhibit 62 is a is a true and correct copy of AR134884.

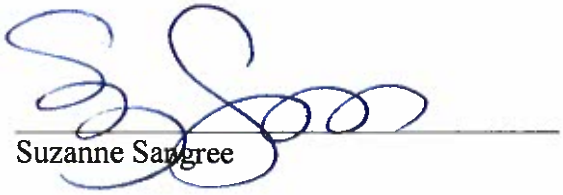
15. Attached hereto as Exhibit 63 is a is a true and correct copy of AR134797.

16. Attached hereto as Exhibit 64 is a is a true and correct copy of AR136181.

17. Attached hereto as Exhibit 65 is a is a true and correct copy of AR147879-147881.

18. Attached hereto as Exhibit 66 is a is a true and correct copy of AR32771-32772.

I declare under penalty of perjury that the foregoing is true and correct and that this Declaration was executed on October 4, 2019, in the State of Maryland.



Suzanne Sangree

EXHIBIT 51

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March 27, 2018

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

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 A Better Balance: The Work & Family Legal Center in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.

A Better Balance is a national legal advocacy organization dedicated to promoting fairness in the workplace and helping employees meet the conflicting demands of work and family through policy advocacy, outreach, and direct legal services. We are leading advocates for policies that help working families such as paid sick leave, paid family and medical leave, and policies that combat discrimination based on pregnancy and family status. We are also working to combat LGBT employment nondiscrimination through our national LGBT Work-Family project. We believe that when all working parents and caregivers have a fair shot in the workplace, our families, our communities, and our nation are healthier and stronger.

A Better Balance believes a health care provider's personal beliefs should never determine the care a patient receives. That is why we strongly oppose the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.[1]

The Proposed Rule seeks to unlawfully expand refusals to provide care by attempting to allow individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program. In addition, the Proposed Rule unlawfully attempts to create new refusals. Such expansions exceed the Department's authority; violate the Constitution;

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

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undermine the ability of states to protect their citizens; undermine critical HHS programs like Title X; interfere with the provider-patient relationship; and threaten the health and well-being of people across the country and around the world.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR")—the new "Conscience and Religious Freedom Division"—the Department seeks to inappropriately use OCR's limited resources 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. For these reasons A Better Balance calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

I. The Proposed Rule Unlawfully Exceeds the Department's Authority by Impermissibly Expanding Religious Refusals to Provide Care

The Proposed Rule attempts to expand the reach not only of existing harmful refusal of care laws but also to create new refusals of care where none were intended.

A. The Proposed Rule Seeks to Allow the Refusal of any Health Service Based on Personal Belief

The Proposed Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and transition-related care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[2] Read in conjunction with the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

B. The Proposed Rule Unlawfully Expands Already Harmful Abortion/Sterilization Refusal of Care Laws

Already existing refusal of care laws are used across the country to deny patients the care they need.[3] The Proposed Rule attempts to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church

[2] *See id.* at 12.

[3] *See, e.g.*, *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

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Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.[4] But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on.[5] Such an attempted expansion goes beyond what the statute enacted by Congress allows. Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things, individuals working under global health programs funded by the Department thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.[6] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.[7]

Furthermore, the Proposed Rule's new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the Proposed Rule seeks to enforce. Specifically, under the Coats and Weldon Amendments "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[8] The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[9] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly

[4] The Church Amendments, 42 U.S.C. § 300a-7 (2018).
[5] *See* Rule *supra* note 1, at 185.
[6] *Id.* at 180.
[7] *Id.* at 183.
[8] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[9] *See* Rule *supra* note 1, at 182.

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defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert.[10]

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination."[11] In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."[12] In a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is vague and inappropriate. Further, it provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

II. The Proposed Rule Carries Severe Consequences for Patients and Will Exacerbate Already Existing Inequities

A. Refusals of Care Make it Difficult for Many Individuals to Access the Care They Need

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need.[13] Accessing quality, culturally competent care and overcoming outright discrimination is an even greater challenge for those living in areas with already limited access to health providers. The Proposed Regulation threatens to make access even harder and, for some, nearly impossible.

Patients living in less densely populated areas already face a myriad of barriers to care including less access to health insurance coverage, lower incomes, and lower rates of paid sick leave. This is in addition to the universal costs of transportation, taking time from work, and other incidentals that go along with obtaining care in the first place. For many, the sheer distance to a

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[10] The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.

[11] *See* Rule *supra* note 1, at 180.

[12] *Id.*

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

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healthcare facility can be a significant barrier to getting care. For example, more than half of rural women live more than 30 minutes away from a hospital that provides basic obstetric care.[14] Patients seeking more specialized care like that required for fertility treatments, endocrinology, or HIV treatment or prevention are often hours away from the closest facility offering these services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria as for other kinds of care.[15]

This means that if these patients are turned away or refused treatment, it will be much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[16] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[17] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[18] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[19] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[20] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give

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[14] American College of Obstetrics and Gynecologists, *Health Disparities in Rural Women* (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

[15] Sandy E. James et al., *The Report of the U.S. Transgender Survey* 99 (2016), www.ustranssurvey.org/report

[16] 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.

[17] *See, e.g.*, *supra* note 3.

[18] *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.

[19] *See* Julia Kaye, et al., *Health Care* Denied, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[20] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

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her the procedure.[21] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[22]

B. Refusals of Care are Especially Dangerous for Those Already Facing Barriers to Care

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[23] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[24] In rural areas there may be no other sources of health and life preserving medical care.[25] In developing countries where many health systems are weak, health care options and supplies are often unavailable.[26] When these individuals encounter refusals of care, they may have nowhere else to go.

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

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

[22] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

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

[24] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[25] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[26] *See* Nurith Aizenman, *Health Care Costs Push a Staggering Number of People into Extreme Poverty*, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggering-number-of-people-into-extreme-poverty; *Tracking Universal Health Coverage: 2017 Global Monitoring Report*, WORLD HEALTH ORG. & THE WORLD BANK (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.

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Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[27] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care.[28] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[29] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[30]

In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.[31]

C. In Proposing this Rule, the Agency has Abandoned its Legal Obligations to Adequately Account for Harm to Patients

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. Under Executive Order 13563, an agency may propose regulations only where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[32] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[33]

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[27] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[28] *See id.* at 10-13.
[29] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[30] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.
[31] *See The Mexico City Policy: An Explainer*, KAISER FAMILY FOUND. (June 1, 2017), https://www.kff.org/global-health-policy/fact-sheet/mexico-city-policy-explainer/.
[32] Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.
[33] *See* Rule *supra* note 1, at 94-177.

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Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[34] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[35]

III. The Proposed Rule Will Undermine Critical Federal Health Programs, Including Title X

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.[36] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[37] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[38] 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.[39] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. 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.[40] 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,

[34] U.S. Const. amend. I; *Cutter v. Wilkinson*, 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
[35] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.
[36] *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 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.
[37] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[38] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[39] *See, e.g.*, Rule *supra* note 1, at 180-185.
[40] *See* NFPRHA *supra* note 34.

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including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[41]

IV. The Proposed Rule Will Carry Severe Consequences for Providers and Undermine the Provider-Patient Relationship

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, or moral convictions of these providers.[42] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.[43] Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[44] By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.[45]

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral, and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease,

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[41] *See id.*
[42] *See* Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[43] *See* TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).
[44] *See id.*
[45] *See* Rule *supra* note 1, at 150-151.

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diabetes, epilepsy, lupus, obesity, and cancer.[46] Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[47] No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

V. The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[48] Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is both illogical and affirmatively harmful. For example, the notice and certification of compliance and assurance requirements do not make sense when applied to the laws the Proposed Rule seeks to enforce.[49] They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

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[46] For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

[47] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

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

[49] *See* Rule *supra* note 1, at 203-214.

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The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[50] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[51]

Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. 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.[52] And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth.[53] Further, the disparity in maternal mortality is growing rather than decreasing,[54] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.[55] And due to gender biases and disparities in

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[50] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

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

[52] *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.

[53] *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.

[54] *See id.*

[55] *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).

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research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[56] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[57] 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 their actual or perceived sexual orientation or gender identity in the year before the survey.[58]

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[59]

VI. The Proposed Rule Conflicts with Other Existing Federal Law

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals to care it would create.

For example, the Proposed Rule makes no mention of Title VII,[60] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[61] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[62] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public

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[56] *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).
[57] *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. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.
[58] *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.
[59] *See supra* note 46.
[60] 42 U.S.C. § 2000e-2 (1964).
[61] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.
[62] *See id.*

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safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[63]

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling even though the employer would not be required to do so under Title VII.[64] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[65] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[66] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

VII. The Proposed Rule Will Make It Harder for States to Protect their Residents

[63] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.
[64] *See* Rule *supra* note 1, at 180-181.
[65] 42 U.S.C. § 1295dd(a)-(c) (2003).
[66] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

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The Proposed Rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[67] Moreover, the Proposed Rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[68]

Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons A Better Balance calls on the Department to withdraw the Proposed Rule in its entirety.

Sincerely,

Marcella Kocolatos
Staff Attorney

[67] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[68] *See id.*

EXHIBIT 52

NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

March 27, 2018

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

Dear Secretary Azar:

On behalf of the National Association of County and City Health Officials (NACCHO) and nearly 3,000 local health departments, thank you for the opportunity to provide comments on the proposed Department of Health and Human Services (HHS) regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority."

Local public health departments are the governmental agencies that work every day in their communities to prevent disease, promote wellness, and protect health. They organize community partnerships and facilitate important conversations with a number of stakeholders about how to create the conditions in which all people can be healthy.

NACCHO has several concerns about the proposed rule and its effect on access to necessary primary care services. **The rule's emphasis on accommodating religious beliefs could interfere with delivery of appropriate care and services.** As proposed, the rule will give health care providers a license based on religious beliefs 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.

NACCHO calls on HHS to include explicit language making clear that religious beliefs will not be used to deny access to health services or to discriminate against people based on reproductive health decisions, gender identity or sexual orientation. In addition, NACCHO calls on HHS to continue activities to identify and address health disparities with the ultimate goal of eliminating them. In activities spanning the Office for Civil Rights, Office of Minority Health, Office of Women's Health as well as the Centers for Medicare & Medicaid Services, all of HHS' endeavors must ensure that disparities are not heightened but are prevented.

Teen births are decreasing and abortion rates are the lowest they have been since the Roe v Wade Supreme Court decision, in large part because of increased access to evidence-based health education and health services. We cannot afford to turn back the clock on this progress. The proposed rule may open the door to discrimination by health care providers based on individually held beliefs. To protect the public's health, the patient's needs must come first. Furthermore, these new priorities are worrisome as they reflect an ideology that aims to dictate the decisions people can make about their bodies and health care.

1201 Eye Street NW, Fourth Floor, Washington, DC 20005 P (202) 783 5550 F (202) 783 1583 www.naccho.org

Public Health
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Lesbian, gay, bisexual and transgender (LGBT) people are considered a vulnerable population as it concerns their health. LGBT people face higher rates of HIV/AIDS, depression, an increased risk of some cancers, and are twice as likely as their heterosexual peers to have a substance use disorder. Transgender people in particular are at higher risk for a range of poor health outcomes. For example, the 2015 U.S. Transgender Survey, a national study of nearly 28,000 transgender adults, found that respondents were nearly five times more likely to be living with HIV than the general population, with even higher rates for some populations: for example, nearly one in five (19%) Black transgender women living with HIV, more than 63 times the rate in the general population. Transgender respondents were nearly eight times more like than the general population to be living with serious psychological distress based on the Kessler 6 scale, with higher rates correlating with experiences of discrimination, violence, and rejection.

The medical community and scientific research has repeatedly demonstrated that the poor health outcomes that LGBT people face are not associated with any inherent pathology, but rather high rates of poverty, discrimination in the workplace, schools, and other areas, and barriers to nondiscriminatory health care that meets their needs. Refusals to treat individuals according to medical standards of care put patients' health at risk, particularly for women and LGBT individuals. Expanding religious refusals will further put needed care, including reproductive health care, out of reach for many. Given the broadly-written and unclear language of the proposed rule, if implemented, some providers may misuse this rule to deny services to LGBT individuals on the basis of perceived or actual sexual orientation and gender identity. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care impairs the ability of patients to make a health decision that expresses their self-determination.

Thank you again for the opportunity to comment on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority." NACCHO and local health departments look forward to continued opportunities to partner with the federal government to protect the public and ensure optimal health. Please contact me at lhanen@naccho.org/202-507-4255 for any further information.

Sincerely,

Laura A. Hanen

Laura A. Hanen, MPP
Interim Executive Director & Chief of Government Affairs

EXHIBIT 53

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 One Colorado Education Fund (OCEF) in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. OCEF is Colorado's leading advocacy organization dedicated to advancing equality for lesbian, gay, bisexual, transgender, and queer (LGBTQ) Coloradans and their families. Since its inception in early 2010, OCEF has made significant progress mobilizing the LGBTQ community in the state, including building a list of more than 60,000 supporters statewide. OCEF also built a coalition of 200 organizations representing two million Coloradans and 200 faith leaders in support of civil unions and full marriage equality, which came to Colorado in October 2014. In addition to relationship recognition, OCEF led a coalition of 30 organizations to successfully advocate for a comprehensive anti-bullying law, helped create 230 new gay-straight alliances (GSA's) in Colorado high schools, and trained over 10,000 educators. OCEF also led the development of the Colorado LGBTQ Health Coalition in collaboration with leading health equity experts and released three comprehensive health reports to nearly 3,000 policy makers, healthcare professionals, and LGBTQ people throughout Colorado.

Every day, too many LGBTQ people experience discrimination and other barriers to accessing the care they need. These barriers are especially pronounced for transgender individuals. The proposed regulation ignores the prevalence of discrimination and damage it causes, and it will undoubtedly lead to increased discrimination and denials of care for some of the most vulnerable members of our community. We all deeply value freedom of religion, but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle. Americans deserve better.

1. **Expanding religious refusals can exacerbate the barriers to care that LGBTQ individuals already face.**

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need.[1] Accessing quality, culturally competent care and overcoming outright discrimination is even a greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder and for some people nearly impossible.

Patients living in less densely populated areas already face a myriad of barriers to care including less access to health insurance coverage, lower incomes, and lower rates of paid sick leave. This is in addition to the universal costs of transportation, taking time from work, and other incidentals that go along with obtaining care in the first place. For many, the sheer distance to a healthcare facility can be a significant barrier to getting care. For example, more than half of rural women live more than 30 minutes away from a hospital that provides basic obstetric care.[2] Patients seeking more specialized care like that required for fertility treatments, endocrinology, or HIV treatment or prevention are often hours away from the closest facility offering these services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria as for other kinds of care.[3]

This means if these patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[4] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

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

[2] American College of Obstetrics and Gynecologists, *Health Disparities in Rural Women* (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

[3] Sandy E. James et al., *The Report of the U.S. Transgender Survey* 99 (2016), www.ustranssurvey.org/report

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

2. The regulation attempts to inappropriately broaden religious exemptions in a way that can lead to dangerous denials of medically necessary treatments.

The regulation purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three federal statutes. Each of these statutes refers to specific, limited circumstances in which health care providers or health care entities may not be required to participate in abortion and sterilization procedures. The regulation, however, creates ambiguity about these limited circumstances and encourages an overly broad misinterpretation that goes far beyond what the statutes permit.

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason—potentially including not just sterilization and abortion procedures, but also Pre-Exposure Prophylaxis (PrEP), infertility care, treatments related to gender dysphoria, and even HIV treatment. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.[5]

Doctors may be misled into believing they may refuse on religious grounds to administer an HIV test or prescribe PrEP to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man.[6] In fact, medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the patient where they would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. The regulation could lead a physician to refuse to provide fertility treatments to a same-sex couple, or a pharmacist to refuse to fill a prescription for hormone replacement therapy for a transgender customer. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBTQ patients' access to care services if interpreted—as the proposed rule

[5] https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

[6] https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

We are particularly concerned that the proposed rule will be used to refuse medically necessary care to transgender patients. We are concerned that the rule's sweeping terms and HHS's troubling discussions of a case involving a transgender patient will encourage the mistaken belief that treatments that have an incidental impact on fertility, such as some procedures used to treat gender dysphoria, are sterilization procedures. Treatments for serious medical conditions may have the incidental effect of causing or contributing to infertility: for example, a hysterectomy to treat gender dysphoria, chemotherapy to treat cancer, and a wide range of medications can have the incidental effect of temporarily or permanently causing infertility. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. If religious or moral exemptions related to sterilization are misinterpreted to include treatments that have simply an incidental effect on fertility—as the vague and sweeping language of this rule encourages—it can lead to refusals that go even further beyond what federal law allows and unlawfully encourages individuals and institutions to refuse a dangerously broad range of medically needed treatments.

3. The proposed rule tramples on states' and local governments' efforts to protect patients' health and safety, including their nondiscrimination laws.

The Department claims that its unwarranted new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. It therefore is disingenuous for the Department to claim that the proposed rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.

4. The regulation lacks safeguards to protect patients from harmful refusals of care.

The proposed regulation is dangerously silent in regards to the needs of patients and the impact that expanding religious refusals can have on their health. The proposed regulation includes no limitations to its sweeping exemptions that would protect patients' rights under the law and ensures that they receive 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.

Indeed, the Establishment Clause of the First Amendment requires the government to adequately account for burdens a religious accommodation may impose on others, including patients, and

prohibits granting accommodations when they would materially harm any third party. As detailed at length above, the proposed regulation would cause significant harm by interfering with patients' access to healthcare and thus, conflicts with this constitutional bar.

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—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, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A standard that appears to allow for none of these considerations, and instead appears to require broad, automatic exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

5. The Department's rushed rulemaking process failed to follow required procedures.

The Department rushed to publish this rule without first publishing any notice regarding in its Unified Regulatory Agenda, as is normally required. The failure to follow proper procedure reflects an inadequate consideration of the rule's impact on patients' health.

The timing of the proposed rule also illustrates a lack of sufficient consideration. The proposed rule was published just two months after the close of a public comment period for a Request for Information closely related to this rule. The 12,000-plus public comments were not all posted until mid-December, a month before this proposed rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the proposed rule—namely, the refusal of care by federally funded health care institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the Request for Information and whether the proposed rule was developed in an arbitrary and capricious manner.

Conclusion

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

Sincerely,

Daniel Ramos, Executive Director

EXHIBIT 54

PUBLIC SUBMISSION

As of: June 22, 2019
Received: February 06, 2018
Status: Posted
Posted: March 28, 2018
Tracking No.1k2-91cj-1cmr
Comments Due: March 27, 2018
Submission Type:API

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-0088
Comment on FR Doc # 2018-01226

Submitter Information

Name: Chauna Brocht
Address:21218
Email: chaunabrocht@gmail.com

General Comment

I am deeply concerned about this new rule. I am a lesbian and am a parent of two children. I am concerned that someone could deny them basic medical care because they have two mothers. This rule will embolden medical providers to deny basic health care to lesbian, gay, transgender and bisexual people and their families. Any religious freedom needs to be balanced by the freedom to obtain quality health care. This rule needs to be more specific so that it can't be mis-interpreted to include denying health care based on sexual orientation or gender identity. These protections need to be written explicitly into the rule.

EXHIBIT 55

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 05, 2018
Status: Posted
Posted: March 28, 2018
Tracking No.1k2-91uj-kj6n
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-6578
Comment on FR Doc # 2018-01226

Submitter Information

Name: Terry Mays

General Comment

I am a Transwoman living in the state of Indiana. It has been very plain over the years in speeches and in actions from Mike Pence of his hatred towards not only the LGBT community but a particular hatred toward the trans community. He has always had very close ties both as governor of Indiana and now in his current office to the Family Research Council and he is the main force driving this fundamentalist program nationally that he did in Indiana which resulted in the disastrous religious freedom restoration act. How will this effect me. Well I constant live in fear anyway living in a small town in rural Indiana. The fear of getting beaten, discriminated against in employment, housing, etc or flat out murdered. But one of the fears I did not have was in dealing with my health care providers because there were protections in place for me against being discriminated against. With this there will no longer be a safe place anywhere for me. For me The guarantee of Life, Liberty and the Pursuit of Happiness was stripped from me the moment I transitioned and it is the same for anyone like me in this country. One of the most basic tenants that citizens enjoy in this country is not a guarantee for myself. I can be killed in my State and someone can use the Trans panic defense and go completely free. I can be discriminated against in employment, education, housing or just simply walking into a store, because of their "fundamental christian values" thus robbing me of the Pursuit of Happiness and in some cases my Liberty. I live in constant fear of being beaten by the public at large and there is no guarantee that there will be anyone in the police department that will aide me or if they do I may be the one arrested instead robbing me of my Liberty. This is the reality of living as a transwoman in rural America this will only make things worse for us. Those of us who already know we are second class citizens not afforded the basic tenants guaranteed other citizens.

EXHIBIT 56

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 01, 2018
Status: Posted
Posted: March 28, 2018
Tracking No.1k2-91rq-qiwo
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-7506
Comment on FR Doc # 2018-01226

Submitter Information

Name: Mary De Ridder

General Comment

For women and LGBTQ people this proposal needs to be shut down. My daughter has a right to healthcare just like any daughter should.

The right to believe is absolutely fundamental. The right to discriminate is not. Please reconsider this regulation -- and make clear that discrimination has no place in this country, especially in healthcare.

EXHIBIT 57

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 13, 2018
Status: Posted
Posted: March 28, 2018
Tracking No.1k2-91zx-2vvs
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-8817
Comment on FR Doc # 2018-01226

Submitter Information

Name: Lorraine Flaherty
Address:98133
Email: Lmf7b@yahoo.com

General Comment

As the mother of a transgender man and as a health care provider I strongly object to these changes. It is often difficult and frightening for our LGBT brothers and sisters and for women to access certain types of legal, medically necessary care. Our country has an obligation to protect and serve our most vulnerable.

EXHIBIT 58

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 01, 2018
Status: Posted
Posted: March 28, 2018
Tracking No.1k2-91rr-hvgp
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-9173
Comment on FR Doc # 2018-01226

Submitter Information

Name: Christopher Clough

General Comment

I am transgender and I have been blessed with access to health professionals who have supported me. It's been easier for me in a major metropolitan area. But many of my brothers are in small, rural communities with very few health care providers. They are dependent on doctors putting people first, not subjective beliefs. This bill undercuts the basic humanity and violates human rights.

EXHIBIT 59

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 21, 2018
Status: Posted
Posted: March 28, 2018
Tracking No.1k2-925a-9f0y
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-9431
Comment on FR Doc # 2018-01226

Submitter Information

Name: Jay Melzer

General Comment

I deserve as much right to healthcare as any cisgender citizen of this nation, as do all of my transgender and LGB brothers and sisters. One cannot choose to "disbelieve" or "disagree" with a person's identity - your opinion does not change who they are. Our right to exist is not a matter of conscience. The right to believe is absolutely fundamental. The right to discriminate is not. Please reconsider this regulation -- and make clear that discrimination has no place in this country, especially in healthcare.

EXHIBIT 60

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 22, 2018
Status: Posted
Posted: March 28, 2018
Tracking No.1k2-925q-5a4q
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-9977
Comment on FR Doc # 2018-01226

Submitter Information

Name: Caitlin Gaffin

General Comment

As a queer woman, I have had experiences where I have been uncomfortable sharing my sexual history with my healthcare provider, which is not ideal considering patients should be encouraged to be as truthful as possible with their doctors and healthcare providers. Also, as a woman, I worry of being denied birth control options due to religious or moral exemptions should healthcare discrimination be allowed to exist. No one should be afraid of not receiving the care that they need and desire - we must do better.

EXHIBIT 61

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 27, 2018
Status: Posted
Posted: March 29, 2018
Tracking No.1k2-9292-q6lw
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-69948
Comment on FR Doc # 2018-01226

Submitter Information

Name: Joseph Freund
Address:50321
Email: drjosephfreund@ucsdsm.org

General Comment

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

As a family doctor who provides care to lesbian, gay, bisexual, transgender and queer patients I strongly object to this proposed regulation, which I see as simply a way to discriminate against LGBTQ patients, and refused service and the medical care they need and deserve. One's religious beliefs should not be a license to discriminate and deny care because they have a moral or religious belief that is contrary to someone living in integrity.

As a gay man it is frightening to consider that I could be denied care because I am gay which conflicts with a provider's religious belief.

This proposed regulation goes way too far and should not be adopted.

EXHIBIT 62

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 26, 2018
Status: Posted
Posted: March 29, 2018
Tracking No.1k2-928r-bpq3
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-69197
Comment on FR Doc # 2018-01226

Submitter Information

Name: Kate Bishop

General Comment

I'm a 44-year-old queer woman living with uncontrolled diabetes, depression that significantly impacts my functioning, and an IUD to treat a uterine fibroid. If I don't have access to an LGBTQ-affirming, knowledgeable provider, my daily well-being suffers and my lifespan gets shorter. I've been seen by providers who don't ask questions about my relationships and sexual health. Like most people, if they don't ask, I don't feel comfortable bringing it up. When I can't be my whole self in the exam room, it's really hard to answer the questions with full honesty, which means the provider can't give me the most appropriate treatment and coaching to help me be well. We all deserve better than this, we deserve health care that acknowledges our full humanity. Please shut down this proposed regulation.

EXHIBIT 63

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 26, 2018
Status: Posted
Posted: March 29, 2018
Tracking No.1k2-928q-7s4g
Comments Due: March 27, 2018
Submission Type: Web

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

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-69113
Comment on FR Doc # 2018-01226

Submitter Information

Name: John Otto

General Comment

As a transgender person, I have sometimes been treated differently--and not as well--as I would have been treated otherwise. I have had to pressure physicians to do routine tests and treatments that anyone else would have been able obtain easily. This is not right. I am not someone who is easy to deter, which is the only reason I was successful in getting the treatment I needed. The average person would not have been able to do this.

EXHIBIT 64

Health and Human Services Office of Civil Rights

In health care, patients must always come first. This new proposal from HHS encourages health care providers to abandon the principle of “first, do no harm” in favor of their personal beliefs. This puts transgender patients, people who need reproductive health care, and many others at risk of being denied necessary and even life-saving care. Transgender people already face high levels of discrimination by health care providers: for example, just in the past year, out of respondents to the 2015 U.S. Transgender Survey who saw a health care provider, one-third were denied treatment, turned away, or mistreated.

As a #transgender person I have already experienced discrimination firsthand with the medical system...this proposal makes these issues a hundred times worse & increases the chance of transgender folk receiving poor treatment.

Along with medical experts and many people of faith, I oppose the proposed regulation. Promoting discrimination is wrong, it is unnecessary, and can harm millions of people who need access to basic care.

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

Moxie Fox
1922 D Street
South Lake Tahoe, CA 96150

EXHIBIT 65

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION
www.ncpanet.org

By Electronic Submission

March 27, 2018

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

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

Dear Director Severino:

The National Community Pharmacists Association ("NCPA") appreciates the opportunity to provide comments on the Department of Health and Human Service's Office for Civil Rights' ("OCR") proposed rule, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority* (the "Proposed Rule"). NCPA represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an $80 billion health care marketplace and employ more than 250,000 individuals on a full and part-time basis.

NCPA Urges OCR to Rescind the Proposed Rule

NCPA urges OCR to rescind the Proposed Rule because the Proposed Rule exceeds statutory authority. The laws referenced as the authority for the Proposed Rule only include health care providers that are involved in settings other than hospitals, clinics, and the medical profession. Thus, pharmacists not in these settings fall outside of scope of the statutory authority for this Proposed Rule. If OCR does not rescind this Proposed Rule, we urge OCR to exempt pharmacies, including licensed pharmacists and non-licensed pharmacy employees, given the potential for negative impact on patients' health and pharmacy operations.

THE VOICE OF THE COMMUNITY PHARMACIST
[redacted]

Issues Specific to Community Pharmacists and Pharmacies that OCR Should Consider if OCR does not Rescind the Proposed Rule

NCPA would like to highlight certain issues for community pharmacists and pharmacies that may present themselves with finalization of this Proposed Rule. First, state legislatures, state licensing boards, and provider accreditation bodies currently have robust requirements surrounding discrimination policies that are individual to each state. For example, many states have mandatory dispensing laws that require pharmacists and/or pharmacies to fill all prescriptions presented at the counter subject to certain enumerated exceptions. NCPA supports the rights of each individual state to ensure that the pharmacy profession is regulated in conformity with the differences in policies in each state. Further, NCPA continues to support state boards of pharmacy as the appropriate regulatory bodies to balance the difference between the public's access to care and the rights of licensed pharmacists to exercise their conscience. Thus, NCPA encourages OCR to consider bolstering communications between the federal and state governments to further inform health care professionals and patients of their rights.

As mentioned above, NCPA urges OCR to rescind the Proposed Rule because pharmacists are not the intended provider under the statutory definition of health care professional. However, if pharmacists are considered health care professionals under the statutory authority cited for the Proposed Rule, NCPA would like to highlight that the profession of pharmacy is not a monolith as there are various types of pharmacists and pharmacies, including community, specialty, long term care, and compounding pharmacists and pharmacies. Further, sometimes there is little distinction between the community pharmacist and the community pharmacy as the small-business community pharmacist may be the only pharmacist at the community pharmacy.

Thus, it is important to focus on the potential burdens on small-business community pharmacies and acknowledge that certain requirements under the Proposed Rule may be difficult for community pharmacists and pharmacies to comply with, even if they may not be an issue for chain pharmacists and pharmacies. For example, small-business community pharmacists and pharmacies may have more limited resources and may need more time to comply with the various notice requirements under the Proposed Rule. While the cost to comply may not be prohibitive, it may be difficult to find appropriately formatted language from vendors who supply employee and public notice material for pharmacies. Thus, NCPA requests OCR provide a grace period in which community pharmacies will have adequate time to update their current employee and public notices.

In addition, community pharmacists and pharmacies will continue to comply with assurance and certification requirements under federal law. NCPA encourages OCR to ensure community pharmacists and pharmacies will not be financially burdened by the additional reporting requirements under this Proposed Rule. NCPA urges OCR to exempt community pharmacists and pharmacies if OCR finds a financial burden on community pharmacists and pharmacies. At the very least, NCPA urges OCR to provide appropriate time for community pharmacists and pharmacies to put in place mechanisms to comply with the reporting requirements under the Proposed Rule.

Finally, NCPA requests that OCR clarify its definition of support staff covered under the statutory conscience protections. NCPA questions whether the broad definition of "assist in the performance" would include any employee within or agent of a company. For example, a cashier, stock person, or even distributor refuse to carry out their job functions unrelated to dispensing such as refusing to stock the pharmacy shelf or execute a sale for any legal drug. Thus, to ensure predictable flow of medications in the supply chain, including at the pharmacy counter, NCPA encourages OCR to consider narrowing the scope of the Proposed Rule to only health care professionals defined in federal statute cited as statutory authority in the Proposed Rule.

Conclusion

In conclusion, NCPA appreciates the opportunity to comment on the Proposed Rule. NCPA urges OCR to rescind the Proposed Rule because the Proposed Rule exceeds statutory authority. If OCR does not rescind the Proposed Rule, NCPA encourages OCR to consider NCPA's issues highlighted above to ensure community pharmacists/pharmacies and patients are appropriately served by the Proposed Rule. Thank you.

EXHIBIT 66

RESOLUTION 2018-30233

A RESOLUTION OF THE MAYOR AND CITY COMMISSION OF THE CITY OF MIAMI BEACH FLORIDA, OPPOSING A RULE PROPOSED BY THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ENTITLED "PROTECTING STATUTORY CONSCIENCE RIGHTS IN HEALTH CARE; DELEGATIONS OF AUTHORITY" WHICH, AMONG OTHER THINGS, WOULD BROADLY EXPAND OPPORTUNITIES FOR HEALTH CARE WORKERS TO REFUSE TO PARTICIPATE IN CERTAIN MEDICAL PROCEDURES ON THE BASIS OF A MORAL OR RELIGIOUS OBJECTION; AND DIRECTING THE CITY ATTORNEY TO TRANSMIT THIS RESOLUTION AND THE COMMENTS SET FORTH HEREIN TO THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

WHEREAS, the City of Miami Beach ("City") Human Rights Ordinance, codified in Chapter 62 of the City Code, declares that "there is no greater danger to the health, morals safety and welfare of the city and its inhabitants than the existence of prejudice against one another and antagonistic to each other because of actual or perceived differences of race, color, national origin, religion, sex, intersexuality, gender identity, sexual orientation, marital and familial status, age, disability, ancestry, height, weight, domestic partner status, labor organization membership, familial situation, or political affiliation"; and

WHEREAS, the Human Rights Ordinance also declares that "prejudice, intolerance, bigotry and discrimination and disorder occasioned thereby threaten the rights and proper privileges of its inhabitants and menace the very institutions, foundations and bedrock of a free, democratic society"; and

WHEREAS, in view of this policy, the City's Human Rights Ordinance prohibits discrimination in employment, public accommodations, housing, and public services, on the basis of the classification categories identified above; and

WHEREAS, the City is a longstanding municipal leader in ensuring the civil rights of its diverse and cosmopolitan population; and

WHEREAS, on January 28, 2018, the Office of Civil Rights ("OCR"), Office of Secretary of Health and Human Services ("HHS") published a notice of proposed rule, entitled "Protecting Statutory Conscience Rights in Health Care; Delegation of Authority" ("Proposed Rule"); and

WHEREAS, the Proposed Rule creates a new "Conscience and Religious Freedom Division" in the HHS OCR; and

WHEREAS, the stated purpose of the Proposed Rule is to "protect the rights of persons, entities, and health care entities to refuse to perform . . . health care services or research activities to which they may object for religious, moral, ethical, or other reasons"; and

WHEREAS, the Proposed Rule authorizes HHS and, specifically, the OCR to protect workers and penalize organizations that do not allow workers to express their religious and moral objections; and

WHEREAS, the Proposed Rule will also allow providers and facilities to opt out of providing counselling services, referring services in Medicaid and Medicare Advantage programs, advance directives, Global Health Programs, and compulsory health programs, such as immunization, hearing screening, occupational illness testing, and mental illness testing; and

WHEREAS, the Proposed Rule is estimated to impact somewhere between 364,640 to 571,412 entities, including public and private hospitals, specialty hospitals (substance abuse, maternity, cancer), youth services, shelters, nursing and hospice facilities, offices of mental health practitioners, and family planning centers; and

WHEREAS, the Proposed Rule may have far-reaching consequences and be used to justify discrimination against the City's constituents, including women, members of the LGBTQ+ community, and persons living with HIV; as well as individuals seeking birth control prescriptions, emergency contraception, lifesaving abortion, in-vitro fertilization (including for unmarried patients, same-sex couples, and interracial couples), hormone therapy for transgender or intersex patients, gender confirmation surgery, human papillomavirus ("HPV") vaccines, counseling, mental health care or a reference for mental health services; and

WHEREAS, the City Commission of the City of Miami Beach respects the right of individuals to freely practice their religion but opposes any measure that permits the use of religion to perpetuate prejudice and authorize discrimination against others.

NOW, THEREFORE, BE IT DULY RESOLVED BY THE MAYOR AND CITY COMMISSION OF THE CITY OF MIAMI BEACH, FLORIDA, that the Mayor and the City Commission hereby oppose the rule proposed by the U.S. Department of Health and Human Services, entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" which, among other things, would broadly expand opportunities for health care workers to refuse to participate in certain medical procedures on the basis of a moral or religious objection; and direct the City Attorney to transmit this Resolution and the comments set forth herein to the U.S. Department of Health and Human Services.

PASSED and **ADOPTED** this 7 day of March, 2018.

ATTEST:

3/16/18

Rafael Granado
City Clerk

Dan Gelber
Mayor

MIAMI BEACH INCORPORATED MARCH 26TH 1915

(Sponsored by Commissioner Michael Gongora)

APPROVED AS TO
FORM & LANGUAGE
& FOR EXECUTION

3-5-18

City Attorney Date

NK

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