IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, *Plaintiff*, v. 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-GLR

MOTION TO DISMISS OR, IN THE ALTNERNATIVE, FOR SUMMARY JUDGMENT

Pursuant to Rule 12(b)(1), Rule 12(b)(6), and Rule 56 of the Federal Rules of Civil Procedure, and this Court's July 2, 2019 and July 31, 2019 Marginal Orders, Defendants move to dismiss Plaintiff's complaint or, in the alternative, for summary judgment. Although Defendants do not believe it is necessary for the Court to rule on Plaintiff's pending motion for a preliminary injunction, Defendants also oppose that motion.

Included with this motion are Defendants' memorandum of law, the portions of the administrative record cited therein (excluding citations to the Federal Register), and a proposed order.

Dated: August 22, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of August, 2019, a copy of the foregoing was filed electronically and was thus served on all counsel of record.

/s/ Bradley P. Humphreys
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, *Plaintiff*, v. 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*.	No. 1:19-cv-01672-GLR

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS OR, IN THE ALTNERNATIVE, FOR SUMMARY JUDGMENT AND IN OPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Since the beginning of this nation, the United States has recognized the importance of and protected rights of conscience. This case concerns the numerous conscience and anti-discrimination protections that Congress has enacted in the health care arena. Collectively, these Federal Conscience Statutes protect individuals and entities with religious, moral, or other views associated with providing (or, in some cases, providing coverage for) certain services in government provided or government-funded health care programs. To name one such provision, the Church Amendments bar the recipients of specific federal funds from, for example, firing a nurse because he or she declines to participate in an abortion for religious or moral reasons. 42 U.S.C. § 300a-7(c). Other Federal Conscience Statutes relate to different health care services, such as assisted suicide, and cover additional health care entities, such as insurers.

The Federal Conscience Statutes work by placing conditions on federal funding—those who accept the funds voluntarily accept the conscience protection and anti-discrimination provisions. Plaintiff, the Mayor and City Council of Baltimore, has accepted and plans to continue accepting federal funds subject to the Federal Conscience Statutes. But Plaintiff apparently objects to the accompanying federal conditions. Of course, it is completely routine and unobjectionable for the federal government to encourage favored conduct through conditions on federal funding—indeed, it is so routine and unobjectionable that Plaintiff actually cites several of the Federal Conscience Statutes as examples of appropriate legislation and does not challenge a single one. Instead, Plaintiff brings a collateral challenge to the Federal Conscience Statutes by attacking a recent regulation issued by the Department of Health and Human Services (HHS) that describes the agency's process for enforcing the Federal Conscience Statutes as to federal funds that HHS administers. Protecting Statutory Conscience Rights in Health Care;

Delegations of Authority, 84 Fed. Reg. 23,170–01 (May 21, 2019) (the Rule). The Rule provides clarifying definitions and explains how HHS will take enforcement action, but the Rule is not the source of HHS's enforcement authority. To the contrary, the Federal Conscience Statutes themselves obligate and compel HHS to meet the Statutes' conditions in disbursing HHS funding. Plaintiff's challenge to the Rule is therefore misplaced. It is Congress—not HHS—that has made these policy determinations with respect to conscience protections in the health care arena.

Even if that were not the case, Plaintiff's challenge fails on the merits.

First, Plaintiff's cataclysmic predictions about the potential loss of all of its federal health care funding are not ripe. Before Plaintiff's fears could possibly come to pass, multiple speculative events would have to occur. The Court thus lacks a concrete setting and important factual information to resolve Plaintiff's claims, such as an alleged violation, the amount of federal funding that Plaintiff stands to lose, and the interaction between any applicable state statutes, the Rule, and the Federal Conscience Statutes.

Second, the Rule is entirely consistent with the Administrative Procedure Act (APA). The Rule does not change any of the substantive requirements of the Federal Conscience Statutes, but simply clarifies HHS's enforcement process. HHS is acting squarely within its statutory authority to implement the conditions that Congress placed on federal funding. The definitions provided in the Rule, moreover, are consistent with the Federal Conscience Statutes. The Rule comports with other provisions of law. And the Rule is neither arbitrary nor capricious, because HHS thoroughly considered all of the concerns presented in comments.

Third, the Rule comports with the Constitution. Plaintiff's constitutional claims are facial, and therefore to succeed Plaintiff must show that the Rule is invalid in all applications—a

difficult task given that Plaintiff's claims rely on a series of outlandish hypotheticals about HHS's potential enforcement actions. The Federal Conscience Statutes, which Plaintiff endorses, offer recipients a simple deal: federal funds in exchange for nondiscrimination. This offer is well within the bounds of the Spending Clause. If the Statutes do not violate the Spending Clause, then a rule faithfully implementing them also does not. Moreover, it is beyond dispute that when the government acts to preserve neutrality in the face of religious differences, it does not "establish" or prefer religion.

Plaintiff is welcome to structure its own health care systems in the lawful manner of its choice—the Federal Conscience Statutes and the Rule are not universal requirements binding on the world. But the Statutes and Rule do require that, if Plaintiff accepts federal funds, it must extend conscience protection to individuals and health care entities. These conditions are longstanding. If Plaintiff is unwilling to afford such protection to these parties, or has become unwilling, then it has the straightforward remedy of no longer accepting the conditioned federal funds. What Plaintiff may *not* do is accept the benefit of its bargain and then balk at fulfilling its anti-discrimination obligations.

The Court should dismiss this case or, in the alternative, grant summary judgment to Defendants and deny Plaintiff's motion for a preliminary injunction.

LEGAL AND FACTUAL BACKGROUND

I. Statutory History of Relevant Conscience Protections

Congress has long acted to protect the rights of individuals and entities to exercise their consciences in providing government-funded health care. The Rule gives effect to various conscience protection provisions put in place by Congress—referenced collectively as the Federal Conscience Statutes. The four key laws addressed by the Rule and discussed below are

(1) the Church Amendments (42 U.S.C. § 300a-7); (2) the Coats-Snowe Amendment (42 U.S.C. § 238n(a)); (3) the Weldon Amendment (*see, e.g.*, Departments of Defense and Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Div. B., sec. 507(d), Pub. L. No. 115-245, 132 Stat. 2981, 3118 (Sept. 28, 2018)); and (4) the conscience protection provisions in the Patient Protection and Affordable Care Act (ACA) (*i.e.*, 42 U.S.C. § 18113; 42 U.S.C. § 14406(1); 26 U.S.C. § 5000A; 42 U.S.C. § 18081; 42 U.S.C. § 18023(b)(1)(A) and (b)(4)).[1]

A. The Church Amendments

The Church Amendments, which were enacted beginning in the 1970s, generally apply to entities that receive certain federal funds and to health service programs and research activities funded by HHS. 42 U.S.C. § 300a-7. The Church Amendments prohibit discrimination based on religious beliefs or moral convictions regarding sterilization procedures, abortion, or, more generally, health service or research activities, including based on an individual's performance (or assistance in) such a procedure or activity, the refusal to perform (or assist in) such a

[1] Other statutes implemented by the Rule include conscience protections for Medicare Advantage organizations and Medicaid managed care organizations with moral or religious objections to counseling or referral for certain services (42 U.S.C. §§ 1395w-22(j)(3)(B) and 1396u-2(b)(3)(B)); conscience protections related to the performance of advanced directives (42 U.S.C. §§ 1395cc(f), 1396a(w)(3), and 14406(2)); conscience and nondiscrimination protections for organizations related to Global Health Programs, to the extent such funds are administered by the Secretary of Health and Human Services (22 U.S.C. § 7631(d)); conscience protections attached to federal funding regarding abortion and involuntarily sterilization, to the extent such funding is administered by the Secretary (22 U.S.C. § 2151b(f)), *see, e.g.*, the Consolidated Appropriations Act, 2019, Pub. L. No. 116-6, Div. F, sec. 7018, 133 Stat. 13, 307); conscience protections from compulsory health care or services generally (42 U.S.C.§§ 1396f and 5106i(a)), and under specific programs for hearing screening (42 U.S.C. § 280g-1(d)), occupational illness testing (29 U.S.C. § 669(a)(5)), vaccination (42 U.S.C. § 1396s(c)(2)(B)(ii)), and mental health treatment (42 U.S.C. § 290bb-36(f)); and protections for religious, nonmedical health care providers and their patients from certain requirements under Medicare and Medicaid that may burden their exercise of their religious beliefs regarding medical treatment (*e.g.*, 42 U.S.C. §§ 1320a-1(h), 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j-1(b)).

procedure or activity, and based on an individual's religious beliefs or moral convictions about such procedures more generally. *Id*. The Church Amendments contain provisions explicitly protecting the rights of both individuals and entities. *Id.* Examples of discrimination barred by the Church Amendments include the threat of an individual losing his or her job because of his or her refusal to perform (or assist in the performance of) abortion, and the threat of an entity being forced to provide abortions as a condition of receiving government funding. *See generally id.* Although the statute codifying the Church Amendments does not define its terms, parts of it apply explicitly to both the "performance" of such procedures or activities and "assist[ing] in the performance of" such procedures or activities. 42 U.S.C. § 300a-7(b)(1), (b)(2), (c)(1)(B), (c)(2)(B), (d), (e).

B. The Coats-Snowe Amendment

Section 245 of the Public Health Service Act, known as the Coats-Snowe Amendment, was enacted by Congress with bipartisan support in 1996. A sponsor of the statute, Senator Snowe, described her goal as to "protect those institutions and those individuals who do not want to get involved in the performance or training of abortion," while still maintaining adequate medical training standards for women's gynecological care. Balanced Budget Downpayment Act, II, 142 Cong. Rec. S2268 (Statement of Sen. Snowe) (Mar. 19, 1996).

Specifically, the Coats-Snowe Amendment prohibits the federal government and any State or local government that receives federal financial assistance from discriminating against a health care entity that, among other things, refuses to perform induced abortions; to provide, receive, or require training on performing induced abortions; or to provide referrals or make arrangements for such activities. 42 U.S.C. § 238n(a)(1). The Coats-Snowe Amendment defines the term "health care entity" as *including* (and, therefore, not being limited to) an "individual

physician, a postgraduate physician training program, and a participant in a program of training in the health professions." *Id.* § 238n(c)(2)The Coats-Snowe Amendment also applies to accreditation of postgraduate physician training programs. *Id.* § 238n(b)(1).

C. The Weldon Amendment

Since 2004, Congress has also included nondiscrimination protections, the Weldon Amendment, in every appropriations bill for the Departments of Labor, Health and Human Services, and Education. *See, e.g.*, Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, Title V, sec. 508(d)(1)–(2), 118 Stat. 2809, 3163 (2004); Pub. L. No. 115-245, Div. B., sec. 507(d), 132 Stat. at 3118. The Weldon Amendment provides, in pertinent part, that "[n]one of the funds made available in this Act may be made available to a federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." *Id*. The Weldon Amendment's scope and definitions are broad, defining the term "health care entity" as "includ[ing] an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id*. The Weldon Amendment is a restriction on HHS's use of funds, and thus, HHS must abide by the Weldon Amendment in its use and distribution of funds, through grant programs or otherwise.

D. Conscience Protections in the ACA

Congress separately included several conscience protections in the ACA, including:

Section 1553 of the ACA provides that the federal government, and any State or local government or health care provider that receives federal financial assistance under the ACA, or any health plan created under the ACA

> may not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

42 U.S.C. § 18113. In § 1553, Congress again defined the term "health care entity" broadly to "include [] an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* Section 1553 also specifically designates HHS's Office for Civil Rights (OCR) to receive complaints of discrimination relating to participation in causing the death of an individual, such as by assisted suicide, euthanasia, or mercy killing. *Id*.

Section 1303 declares that the ACA does not require health plans to provide coverage of abortion services as part of "essential health benefits." 42 U.S.C. § 18023(b)(1)(A)(i). Furthermore, no qualified health plan offered through an ACA exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for, abortions. *See id.* § 18023(b)(4). The ACA also clarified that nothing in the Act is to be construed to "have any effect on federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion." *Id.* § 18023(c)(2)(A).

Section 1411 designates HHS as the agency responsible for issuing certifications to individuals who are entitled to an exemption from the individual responsibility requirement

imposed under section 5000A of the Internal Revenue Code, including when such individuals are exempt based on a hardship (such as the inability to secure affordable coverage without abortion), are members of an exempt religious organization or division, or participate in a "health care sharing ministry." 42 U.S.C. § 18081(b)(5)(A); *see also* 26 U.S.C. § 5000A(d)(2).

II. Unchallenged Rules that Require Compliance with the Federal Conscience Statutes

HHS has issued several rules, in addition to the challenged Rule, that require recipients of federal funds to comply with federal law, including the Federal Conscience Statutes. For example, HHS promulgated the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (UAR), which impose consistent and enforceable requirements for grant recipients. *See* Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 79 Fed. Reg. 75,871, 75,889 (Dec. 19, 2014). These requirements are broad-ranging, and include records retention and management, property, and procurement standards; fiscal and program management standards; and importantly for this litigation, statutory and national policy requirements and remedies for noncompliance. The UAR states, "The Federal awarding agency must manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented *in full accordance with U.S. statutory and public policy requirements*: Including, but not limited to, . . . prohibiting discrimination." 45 C.F.R. § 75.300(a) (emphasis added). It also lists remedies for noncompliance:

> If a non–Federal entity fails to comply with *Federal statutes, regulations, or the terms and conditions of a Federal award*, the HHS awarding agency or pass-through entity may impose additional conditions, as described in § 75.207. If the HHS awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the HHS awarding agency

> or pass-through entity may take one or more of the following actions, as appropriate in the circumstances:
>
> > (a) Temporarily withhold cash payments pending correction of the deficiency by the non–Federal entity or more severe enforcement action by the HHS awarding agency or pass-through entity.
> >
> > (b) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.
> >
> > (c) Wholly or partly suspend (suspension of award activities) or terminate the Federal award.
> >
> > (d) Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding agency regulations at 2 CFR part 376 (or in the case of a pass-through entity, recommend such a proceeding be initiated by a HHS awarding agency).
> >
> > (e) Withhold further Federal awards for the project or program.
> >
> > (f) Take other remedies that may be legally available.

45 C.F.R. § 75.371 (emphasis added). The UAR also describes how HHS may terminate a federal award. *See* 45 C.F.R. §§ 75.372–75.375. And last, the UAR sets forth standards for auditing nonfederal entities expending federal awards. *See* 45 C.F.R. §§ 75.501–75.520.

The Federal Acquisition Regulation (FAR), C.F.R. Title 48, allows the government to enforce contractor compliance with federal law. The FAR applies to all acquisitions, which are defined, in part, as the acquiring by contract with appropriated funds of supplies or services by and for the use of the federal government through purchase or lease. 48 C.F.R. § 2.101. The FAR provides for the inclusion of a contract clause, specifically for the purchase of commercial items, that a "Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract." 48 C.F.R. § 52.212-4(q). The FAR also requires inclusion, for example, of a clause in contracts that requires contractors to promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. 48 C.F.R. § 52.203-13. The FAR provides a variety of mechanisms that may be used to enforce such contract provisions. 48 C.F.R. Pt. 49.

HHS has also issued its own acquisition regulation, the HHS Acquisition Regulations (HHSAR), 48 C.F.R. Ch. 3, pursuant to 48 C.F.R. § 1.103. The HHSAR requires contractors to comply with various aspects of federal law. The HHSAR additionally includes a nondiscrimination clause for conscience objections relating to receiving assistance under section 104A of the Foreign Assistance Act of 1961, the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care, 48 C.F.R. § 352.270-9.

III. HHS Conscience Protection Regulations

A. 2008 and 2011 HHS Conscience Protection Regulations

In 2008, HHS issued regulations clarifying the applicability of the Church, Coats-Snowe, and Weldon Amendments and designating OCR to receive complaints and coordinate with applicable HHS funding components to enforce the Federal Conscience Statutes. *See* 45 C.F.R. § 88 *et seq.* (2008 Rule); Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072 (Dec. 19, 2008). The 2008 Rule recognized (1) the lack of consistent awareness of these statutory protections among federally funded recipients and protected persons and entities, and (2) the need for greater enforcement mechanisms to ensure that HHS funds do not support morally coercive or discriminatory policies or practices in violation of the Federal Conscience Statutes. 73 Fed. Reg. at 78,078–81.

In 2011, however, HHS rescinded the 2008 Rule in part and issued a new rule with a more limited scope and enforcement mechanism after noting concerns about whether the 2008

Rule was consistent with the new administration's priorities. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968 (2011 Rule); *see also* Rescission of the Regulation Entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law"; Proposal, 74 Fed. Reg. 10,207 (Mar. 10, 2009). The preamble to the 2011 Rule expressed HHS's support for conscience protections for health care providers and indicated the need for enforcement of the Federal Conscience Statutes. *See, e.g.*, *id.* at 9968–69. Nevertheless, the 2011 Rule created ambiguity regarding OCR's enforcement tools and removed the definitions of key statutory terms. *Id.*

B. Notice of Proposed Rulemaking

On January 26, 2018, HHS published a Notice of Proposed Rulemaking (NPRM) to revise and expand earlier regulations in order to properly implement the Federal Conscience Statutes in programs funded by HHS. *See generally* NPRM, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (Jan. 26, 2018). HHS's stated goals were to (1) "effectively and comprehensively enforce Federal health care conscience and associated anti-discrimination laws," (2) grant OCR overall enforcement responsibility to ensure compliance with these federal laws; and (3) clear up confusion caused by certain OCR sub-regulatory guidance. *Id.* at 3881, 3890. In particular, "there [wa]s a significant need to amend the 2011 Rule to ensure knowledge, compliance, and enforcement of the Federal health care conscience and associated anti-discrimination laws." *Id*. at 3887. For example, the 2011 Rule was inadequate because it covered only three of the Federal Conscience Statutes. Following a sixty-day comment period, HHS analyzed and carefully considered all comments on the NPRM and made appropriate modifications before finalizing the Rule. *See* 84 Fed. Reg. at 23,180.

C. Final Rule

The Rule implements federal nondiscrimination protections for individuals, health care providers, and health care entities with objections—including religious or moral objections—to providing, participating in, paying for, or referring for certain health care services, and also provides procedures for the effective enforcement of those protections. The Rule clarifies the requirements of the Federal Conscience Statutes, addresses the inadequate enforcement of conscience rights under existing federal laws, and educates individuals and entities who presently lack knowledge of their statutory and civil rights or obligations under HHS-funded or administered programs. 84 Fed. Reg. at 23,175–79. The Rule does not change the substantive law of the Federal Conscience Statutes, as established by Congress. *See id.* at 23,256 ("This rule holds States and local governments accountable for compliance with [the Federal Conscience Statutes] by setting forth mechanisms for OCR investigation and HHS enforcement related to those requirements. The Rule does not change the substantive conscience protections or anti-discrimination requirements of these statutes.").

The Rule has five principal provisions.

First, the Rule sets forth, in a single place, the various statutory conscience protections that apply to particular HHS-funded health programs. *See* 45 C.F.R. § 88.

Second, it defines various terms in the Federal Conscience Statutes in a way that implements the plain text and spirit of those Statutes and fully protects religious and moral conscience objections. Among the statutory terms defined in the Rule are "assist in the performance," "discriminate or discrimination," "health care entity," and "referral or refer for." *See* 45 C.F.R. § 88.2. Other than "health care entity," Congress did not define these terms in the

relevant statutes. Accordingly, the Rule defines these statutory terms to clarify their scope and to provide adequate enforcement notice to covered entities.

Third, the Rule requires recipients of federal funds to provide assurances and certifications of compliance with the applicable federal conscience requirements. 45 C.F.R. § 88.4. Written assurances and certifications of compliance with the Federal Conscience Statutes must be submitted during the application and reapplication processes associated with receiving federal financial assistance or federal assistance. *Id.* Entities that are already receiving such assistance as of the effective date of the Rule are not required to submit an assurance or certification until they reapply for such assistance, alter the terms of existing assistance, or apply for new lines of federal assistance. *Id.* OCR may require additional assurances and certifications if OCR or HHS has reason to suspect noncompliance with the Federal Conscience Statutes. *Id.*

Fourth, the Rule establishes enforcement tools to protect conscience rights. 45 C.F.R. § 88.7. OCR will conduct outreach, provide technical assistance, initiate compliance reviews, conduct investigations, and seek voluntary resolutions to more effectively address violations and resolve complaints. *Id.* Where voluntary resolutions are not possible, OCR will supervise and coordinate compliance using existing and longstanding procedures to enforce conditions on grants, contracts, and other funding instruments. *Id*. (citing, *e.g.*, the FAR and 45 C.F.R. Pt. 75).[2]

[2] Involuntary remedies—such as the withholding of funds, termination, suspension, or debarment—will not occur under the Rule itself, but rather, under HHS's separate regulations governing grants and contracts. 84 Fed. Reg. 23,222; *see also* 45 C.F.R. § 75.374 (addressing HHS's process when a non-federal entity fails to comply with conditions on a federal award, and requiring that "[u]pon taking any remedy for non-compliance, the HHS awarding agency must provide the non-Federal entity an opportunity to object and provide information and documentation challenging the suspension or termination action, in accordance with written processes and procedures published by the HHS awarding agency" and "must comply with any requirements for hearings, appeals or other administrative proceedings to which the non-Federal entity is entitled under any statute or regulation applicable to the action involved"); 45 C.F.R. Pt.

To ensure that recipients of HHS funds comply with their legal obligations, as HHS does with other civil rights laws within its purview, HHS will require certain funding recipients (and sub-recipients) to maintain records and cooperate with OCR's investigations, reviews, and enforcement actions. *Id.*; NPRM, 83 Fed. Reg. 3881.

Fifth, the Rule incentivizes, but does not require, recipients and sub-recipients to post a notice summarizing the Federal Conscience Statutes on their website, in employee materials or student handbooks, or in another prominent location in the workplace. *See* 45 C.F.R. § 88.5.

The Rule also includes a severability provision. *See* 45 C.F.R. § 88.10. It states that, if any part of the Rule is held to be invalid or unenforceable, it shall be severable from the remainder of the Rule, which shall remain in full force and effect to the maximum extent permitted by law. *See* 45 C.F.R. § 88.10.

D. This Litigation

Plaintiff filed suit challenging the Rule and moved for a preliminary injunction. *See* Compl., ECF No. 1; Pl.'s Mem. in Supp. of Mot. Prelim. Inj. (PI Mem.), ECF No. 14-1. Subsequently, the Court granted the parties' stipulated request to postpone the effective date of the Rule until November 22, 2019, and held Plaintiff's motion for a preliminary injunction in abeyance. Order, ECF No. 26. The Court also set a briefing schedule for cross-motions for summary judgment. *Id.* Thereafter, the Court ordered Defendants to oppose Plaintiff's previously filed preliminary injunction motion. *See* Order, ECF No. 36. Defendants now move to dismiss or, in the alternative, for summary judgment and oppose Plaintiff's motion for a preliminary injunction.

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16 (describing the procedures of the Departmental Appeals Board, which reviews certain grants disputes as specified in Appendix A to Part 16).

ARGUMENT

I. Legal Standard

Defendants move to dismiss Plaintiff's claims in their entirety under Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiff bears the burden to show subject matter jurisdiction, and the Court must determine whether it has jurisdiction before addressing the merits. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95, 104 (1998). Under Rule 12(b)(6), a court should grant a motion to dismiss if the complaint does not contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). Furthermore, Plaintiff raises only facial challenges to the Rule, which are "the most difficult challenge[s] to mount successfully." *United States v. Salerno,* 481 U.S. 739, 745 (1987). To prevail, Plaintiff must "establish that no set of circumstances exists under which [the Rule] would be valid, or that the [Rule] lacks any plainly legitimate sweep." *United States v. Stevens*, 559 U.S. 460, 472 (2010) (quotations omitted).

In the alternative, Defendants ask that the Court enter summary judgment in their favor. Summary judgment is appropriate if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). For claims brought under the APA, a motion for summary judgment is the appropriate vehicle for summary disposition of the case with one significant caveat: "the district judge sits as an appellate tribunal" to resolve issues at summary judgment. *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001).

Under the APA, an agency's decision must be upheld unless arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). Under this deferential standard, the agency's decision is presumed valid, and the Court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). An agency's decision may be deemed arbitrary and capricious only in circumstances where the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or where its decision "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n, Inc., v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). The Court may not "substitute its judgment for that of the agency." *Id*.

Because cross-dispositive motions will be before the Court, there should be no need to address Plaintiff's motion for a preliminary injunction. A preliminary injunction is "an extraordinary and drastic remedy" that should not be granted unless the movant carries the burden of persuasion by a clear showing. *Munaf v. Green*, 553 U.S. 674, 689–90 (2008). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. NRDC*, 555 U.S. 7, 20 (2008). Plaintiff fails to satisfy any of these requirements.

II. Plaintiff's Constitutional Claims Are Unripe.

As an initial matter, Plaintiff's Spending Clause and Establishment Clause claims are not ripe for review, because Plaintiff has identified no specific enforcement action taken against it

under the Rule—as indeed, it cannot, given that Defendants have postponed the effective date of the Rule. Both claims rely on hypotheses about HHS's enforcement of the Rule that are not yet clearly factually defined. At least two courts have declined to decide similarly premature challenges to the underlying Federal Conscience Statutes on standing and ripeness grounds. *See, e.g.*, *Nat'l Family Planning & Reprod. Health Ass'n, Inc. (NFPRHA) v. Gonzales*, 468 F.3d 826, 827 (D.C. Cir. 2006); *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, at *3 (N.D. Cal. Mar. 18, 2008).

In particular, Plaintiff's constitutional claims are not ripe because they rest on "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (citation omitted). For example, Plaintiff is concerned that, hypothetically, an EMT would decline to transport a person for emergency care for a reason covered by the Rule. PI Mem. at 40. Even assuming this speculative scenario would be covered by the Rule, it would require several steps in order to come to fruition. First, an EMT would have to refuse to transport a patient for reasons covered by the Rule and Federal Conscience Statutes. Next, Plaintiff would have to decide to take action against that EMT in violation of the Federal Conscience Statutes. Then, the episode would have to come to the attention of HHS, HHS would have to find Plaintiff's actions to be discriminatory under one of the Federal Conscience Statutes, and HHS would have to take enforcement action under the Rule that would endanger Plaintiff's funding. Finally, that enforcement action would have to be upheld after exhaustion of all available administrative remedies. *See supra* n.2. The occurrence of any of these steps is far from certain, much less all of them. Thus, judicial resolution of Plaintiff's constitutional claims "may turn out to [be] unnecessary." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 736 (1998).

In addition, this case presents no concrete factual situation in which to evaluate Plaintiff's constitutional claims. Courts "should not be forced to decide . . . constitutional questions in a vacuum." *W. E. B. DuBois Clubs of Am. v. Clark*, 389 U.S. 309, 312 (1967). Because the Rule has never been enforced, and indeed, no funding has ever been withheld under the Federal Conscience Statutes, the contours of any such enforcement action and the scope of funding that may be at risk is unknown. To exercise jurisdiction in advance of any such enforcement action would be "premature" when "there had been no final decision on the nature and impact of the [government's] actions." *Washlefske v. Winston*, 234 F.3d 179, 182 (4th Cir. 2000).

These claims are also unripe because Plaintiff would suffer no hardship whatsoever as to its constitutional claims if judicial review were postponed. A party suffers no hardship warranting review unless governmental action "now inflicts significant practical harm upon the interests that the [plaintiff] advances." *Ohio Forestry Ass'n*, 523 U.S. at 733; *see also Nat'l Park Hosp. Ass'n v. U.S. Dep't of the Interior*, 538 U.S. 803, 810 (2003) (noting that a case is not ripe unless "the impact" of the challenged law is "'felt immediately by those subject to it in conducting their day-to-day affairs'" (citation omitted)).

Plaintiff cannot claim hardship based on the mere existence of the Rule. *See Miller v. Brown*, 462 F.3d 312, 319 (4th Cir. 2006). Nor is Plaintiff in any immediate danger. Plaintiff's supposed dilemma—between abandoning state health care policy or losing billions of dollars in federal funds—is not an "immediate" one justifying review of Plaintiff's premature claims. Should Plaintiff discriminate in a fashion barred by the Federal Conscience Statutes, and should HHS take enforcement action under the Rule, and should Plaintiff decide not to comply through informal means, Plaintiff will then have the opportunity, if necessary, to present its constitutional challenges to the Rule to a court. Because no "irremediable adverse consequences [will] flow

from requiring [Plaintiff to bring] a later challenge," *Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 164 (1967), there is no need to decide Plaintiff's Spending Clause and Establishment Clause claims at this time. *See Poe v. Ullman*, 367 U.S. 497, 503 (1961).

As noted above, these considerations have caused two courts to decline—on ripeness and standing grounds—to adjudicate similar challenges to the underlying Federal Conscience Statutes. In *NFPRHA*, 468 F.3d 826, the plaintiff brought Spending Clause and vagueness challenges to the Weldon Amendment. The D.C. Circuit dismissed, holding that the plaintiff lacked standing, given that it had not been injured by the Amendment and could not show that it was likely to be. *Id.* Similarly, in *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840 (N.D. Cal. Mar. 18, 2008), California challenged the Weldon Amendment on Spending Clause and other grounds. The court dismissed the case for lack of ripeness and standing because "whether California will risk losing federal funds pursuant to the Weldon Amendment if it seeks to enforce [a particular state law provision] is contingent upon a series of future events that may not ever occur." *Id.* at *5. This Court should likewise dismiss Plaintiff's constitutional claims as unripe.

III. Plaintiff's Claims Lack Merit.

A. HHS Has Statutory Authority to Issue the Rule.

Plaintiff's statutory authority claims fail because HHS acted within its authority when promulgating the Rule. Much of the error in Plaintiff's argument stems from its misidentification of the statutes that provide HHS with authority to issue the Rule. As HHS explained, *see* 84 Fed. Reg. at 23,183–86, the enforcement portion of the Rule, which Plaintiff alleges poses the most imminent threat to its funding, merely sets forth existing HHS processes: OCR will investigate complaints and seek voluntary resolutions, and any involuntary remedies will occur through

HHS funding components in coordination with OCR, with those components using pre-existing grants and contracts regulations processes. *See* 84 Fed. Reg. at 23,271 (to be codified at 45 C.F.R. § 88.7(i)). Overall, these are housekeeping matters, enacted pursuant to 5 U.S.C. § 301, concerning how HHS is governed and how it administers federal statutes. Despite Plaintiff's assertion to the contrary, the Rule is also supported by each of the Federal Conscience Statutes themselves. When Congress required HHS, its programs, and recipients of its Federal funds to comply, that implicitly included a grant of authority to HHS to take measures to ensure HHS administers its programs in compliance with federal law. Moreover, the procedures set forth in the Rule that Plaintiff most takes issue with—the involuntary remedies outlined at § 88.7(i)(3) if voluntary resolutions cannot be reached—state they are to be pursued under the authority of HHS's other, preexisting grants and contracts regulations—regulations whose authority Plaintiff does not challenge. *See, e.g.*, 45 C.F.R. §§ 75.300, 75.371, 75.503, 75.507; 2 C.F.R Pt. 376; 48 C.F.R. Pt. 9.4; 48 C.F.R. §§ 9.406-2, 9.406-3.

The assurance and certification requirement of the Rule simply implements other unchallenged requirements in those grants and contracts regulations that require entities receiving federal funds to comply "with U.S. statutory and public policy requirements." *See* 45 C.F.R. § 75.300(a). The substantive requirements of the Rule regarding covered entities, 84 Fed. Reg. at 23,264–69 (to be codified at 45 C.F.R. § 88.3), do nothing more than reiterate the text of the Federal Conscience Statutes themselves and specify, according to that text, which entities the statutes affect. And the definitions in the Rule are another housekeeping matter concerning how HHS interprets the Federal Conscience Statutes when it ensures compliance with the statutes.

Therefore, as HHS explained, the agency's authority does not derive solely from the Federal Conscience Statutes, but rather from the interaction of those statutes with HHS's

authority to impose terms and conditions in its grants, contracts, and other funding instruments, and in its programs. *See* 84 Fed. Reg. at 23,183–85. In brief, when Congress instructs HHS to withhold federal funds from entities that do not comply with conscience laws, HHS has the authority, enshrined in 5 U.S.C. § 301, 40 U.S.C. § 121(c), their implementing regulations, and various other statutes, to ensure that Congress's instructions are carried out. Standard measures for ensuring compliance with Congress's directives, such as complaint investigation or defining relevant terms, do not conflict with that authority.

Pursuant to 5 U.S.C. § 301, which permits "[t]he head of an Executive department [to] prescribe regulations for the government of his department," HHS has issued several regulations regarding the administration of funding instruments, such as grants or contracts. Chief among these for purposes of this litigation are UAR and the HHSAR, which were promulgated pursuant to 40 U.S.C. § 121(c), in addition to § 301. The UAR requires "that Federal funding is expended and associated programs are implemented *in full accordance with U.S. statutory* and public policy *requirements*: Including, but not limited to, those protecting public welfare, the environment, and *prohibiting discrimination*." 45 C.F.R. § 75.300(a) (emphasis added). Similarly, the HHSAR permits HHS to include "requirements of law" and "HHS-wide policies" in its contracts. *See* 48 C.F.R. § 301.101(b)(1)(i).

Of course, some of the federal statutes with which recipients of federal funds must comply are the Federal Conscience Statutes, which prohibit the government and recipients of federal funds from discriminating against entities that decline to engage in certain activities. The Rule does not alter or amend the obligations of the respective statutes, 84 Fed. Reg. at 23,185, but rather ensures, through the ordinary grant and contract issuing process, that recipients of

federal funds do not violate those statutes through the ordinary grant and contract issuing process.

The authority to ensure compliance with grant conditions is consistent with the well-established power of the United States "to fix the terms and conditions upon which its money allotments to state and other governmental entities should be disbursed." *See United States v. Marion Cty. Sch. Dist.*, 625 F.2d 607, 609 (5th Cir. 1980) (collecting Supreme Court cases). Inherent in the authority to fix such terms and conditions is the authority to sue for specific performance of the recipient's obligations under the grants that it accepts. *See id.* Nowhere is this authority exercised with greater prominence than to enforce civil rights. *See id.* In light of this inherent authority to sue for specific performance, it must be the case that HHS can rely on § 301, the UAR, and the HHSAR to take more modest steps to assure compliance, such as investigating a complaint.

In addition to HHS's authority to enforce the conditions of the grants and contracts that it awards, certain statutes explicitly authorize HHS to promulgate regulations implementing conscience protections. For instance, the ACA authorizes the Secretary to issue regulations setting standards for meeting certain of the statute's requirements, including the prohibition against discrimination on the basis of provision of abortion, 42 U.S.C. § 18023(b)(4), and the prohibition against discrimination regarding assisted suicide, *id.* § 18113. *See id.* § 18041(a)(1). The latter statutory provision explicitly authorizes OCR to receive complaints of discrimination regarding assisted suicide. *Id.* § 18113(d). The Secretary is also authorized to promulgate such regulations "as may be necessary to the efficient administration of the functions with which" he is charged under Medicare, Medicaid, and the Children's Health Insurance Program. *See* 42 U.S.C. § 1302; *see also id.* § 1302 (granting rulemaking authority regarding small rural

hospitals); 42 U.S.C. § 263a(f)(1)(E) (granting rulemaking authority regarding certification of laboratories). And, the Secretary has authority to promulgate regulations related to certain Centers for Medicare & Medicaid Services funding instruments. *See, e.g.*, 42 U.S.C. § 1315a; *see generally* 84 Fed. Reg. at 23,185 (listing statutes).

B. The Challenged Definitions Are Reasonable Exercises of HHS's Statutory Authority.

Plaintiff's attack on four definitions in the Rule—(1) *assist in the performance*, (2) *discriminate* or *discrimination*, (3) *health care entity*, and (4) *referral* or *refer for*—is without merit. Because Congress has delegated rulemaking authority to HHS by means of the authorities discussed in the proceeding section, review of these claims is governed by *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). Under this standard, a court first asks "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If the answer is yes, the court must give effect to Congress's intent. If the answer is no—that is, if the statute is ambiguous—"the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. For the reasons set forth below, Plaintiff's challenge to each definition fails at step one or, in the alternative, at step two of *Chevron*.

1. "Assist in the Performance"

HHS's definition of "assist in the performance" is entirely consistent with the Church Amendments, 42 U.S.C. § 300a-7(d), the only conscience statute that contains the term. Although the term is used in the Church Amendments, it is not explicitly defined. The Rule defines the term "assist in the performance" as follows:

> to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity. This may include counseling, referral, training, or otherwise making arrangements for the procedure or a part of a health service program or research activity, depending on whether aid is provided by such actions.

84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

1. Plaintiff's challenge fails at *Chevron* step one because Congress has directly spoken to the precise question at issue. *Chevron*, 467 U.S. at 842–43. The Court need only open the dictionary, *see Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 52 (2011) (applying a dictionary definition at step one), which contains the same common-sense definition as the Rule: *Merriam-Webster* defines *assist* as "to give usually supplementary support or aid to," https://www.merriam-webster.com/dictionary/assist (last visited Aug. 18, 2019), and *performance* as "the execution of an action," https://www.merriam-webster.com/dictionary/performance (last visited Aug. 18, 2019). The Rule's definition is as close to the dictionary definition of these terms as can be without repeating them verbatim: *assist in the performance* is limited to "specific, reasonable, and articulable" connections between the conscientious objector's action and the medical procedure. 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). "If the connection between an action and a procedure is irrational, there is no actual connection by which the action specifically furthers the procedure." *Id.* at 23,187.

2. Even if the Court determines that the term "assist in the performance" is ambiguous, the Court should still uphold HHS's definition because it is eminently reasonable. At step two, "*Chevron* requires a federal court to accept the agency's construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation." *Nat'l Cable & Telecomms. Ass'n v. Brand-X Internet Servs.*, 545 U.S. 967, 980 (2005).

HHS's definition is reasonable in light of the dictionary definitions of "assist" and "performance" and the Rule's requirement that "a specific, reasonable, and articulable connection" exist between the conscientious objector's action and the medical procedure. 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2); *see also id.* at 23,187 (excluding irrational or

excessively attenuated connections). In addition, the Rule furthers the statute's purpose of protecting individuals and health care entities from discrimination on the basis of their religious beliefs or moral convictions by recipients of federal funds; for example, under the Rule, individuals who schedule a patient's abortion are not outside the scope of the Church Amendments merely because they do not perform the abortion themselves. The Rule recognizes that such individuals too are protected because they provide necessary assistance in the performance of an abortion. *See id.* at 23,188.

2. "Discriminate or Discrimination"

Plaintiff's challenge to HHS's definition of "discriminate or discrimination" is also meritless. The definition, which consists of a three-point list of examples that apply *only to the extent permitted by the Federal Conscience Statutes*, is by definition reasonable. Virtually all of the Statutes covered by the Rule employ the term "discriminate" and, as with "assist in the performance," do not define it. For example, the Coats-Snowe Amendment provides that government recipients of federal funds "may not subject any health care entity to discrimination" on certain bases, such as the "refus[al] to undergo training in the performance of induced abortions." 42 U.S.C. § 238n(a)(1). But the Coats-Snowe Amendment does not explicitly define "discrimination." Consistent with the varying types of discrimination that the Federal Conscience Statutes prohibit, the Rule provides a non-exhaustive list of actions that may constitute discrimination. *See* 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). This list applies "to the extent permitted by the applicable statute." *See id.* The definition then provides several safe harbors, consisting of actions that, if taken by a regulated entity, would not constitute discrimination. *See id.*

1. Plaintiff's challenge to this definition fails at *Chevron* step one. By its terms, the definition does not extend beyond the Statutes to which it applies. *See* 45 C.F.R. § 88.2 (defining the term to include actions "as applicable to, and to the extent permitted by, the applicable statute"). Therefore, the definition does not exceed Congress's intent because it explicitly *cannot* exceed Congress's intent. Moreover, the common definition of "discrimination" is "to make a difference in treatment or favor on a basis other than individual merit," *Discriminate*, Merriam-Webster, https://www.merriam-webster.com/dictionary/discriminate (last visited Aug. 18, 2019), and the Rule merely makes explicit the various manifestations of that broad definition.

2. Even if the term is ambiguous, the Court should uphold HHS's definition at *Chevron* step two. As discussed above, the definition by its terms does not extend beyond the meaning of the Statutes, but rather "must be read in the context of each underlying statute at issue, any other related provisions of the Rule, and the facts and circumstances." 84 Fed. Reg. at 23,192. To provide guidance on the meaning of discrimination without being under-inclusive, HHS used the word "includes" to establish a non-exhaustive list of examples that could, in the context of the particular underlying Federal Conscience Statute, constitute discrimination. *See id.* at 23,190. And, to ensure that the Rule was not over-inclusive, HHS included three provisions to protect entities that seek to accommodate those with religious or moral objections. *See id.* at 23,263 (to be codified at 45 C.F.R. § 88.2).

3. "Health Care Entity"

Plaintiff's challenge to HHS's definition of "health care entity," which appears in the Weldon Amendment, the Coats-Snowe Amendment, and the ACA, also fails. The Rule defines "health care entity" in two parts:

> (1) For purposes of the Coats-Snowe Amendment (42 U.S.C. 238n) and the subsections of this part implementing that law (§ 88.3(b)), an individual physician

> or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; or any other health care provider or health care facility. As applicable, components of State or local governments may be health care entities under the Coats-Snowe Amendment; and
>
> (2) For purposes of the Weldon Amendment (e.g., Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Pub. L. 115-245, Div. B., sec. 507(d), 132 Stat. 2981, 3118 (Sept. 28, 2018)), Patient Protection and Affordable Care Act section 1553 (42 U.S.C. 18113), and to sections of this part implementing those laws (§ 88.3(c) and (e)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; a provider-sponsored organization; a health maintenance organization; a health insurance issuer; a health insurance plan (including group or individual plans); a plan sponsor or third-party administrator; or any other kind of health care organization, facility, or plan. As applicable, components of State or local governments may be health care entities under the Weldon Amendment and Patient Protection and Affordable Care Act section 1553.

84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2).

1. Beginning with the text, each of these statutes defines the term through a non-exhaustive list of constituent entities. The Coats-Snowe Amendment provides that a health care entity "*includes* an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." 42 U.S.C. § 238n(c)(2) (emphasis added). The Weldon Amendment and the ACA provide that the term "*includes* an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." 42 U.S.C. § 18113(b) (emphasis added); Pub. L. No. 115-245, § 507(d)(2), 132 Stat. at 3118. The term "'include' can signal that the list that follows is meant to be illustrative rather than exhaustive." *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010).

Furthermore, both statutes contain catch-all phrases: "a participant in a program of training in the health professions" in the Coats-Snowe Amendment, and "other health care professional" and "any other kind of health care facility, organization, or plan" in the Weldon Amendment and ACA. 42 U.S.C. § 238n(c)(2); *id*. § 18113(b). Given these features, the statutes plainly contemplate a broader group of health care entities than those explicitly listed.

2. Even if the term "health care entity" in the Federal Conscience Statutes were ambiguous, the Rule's definition is reasonable for the reasons stated above: the statutes explicitly contemplate the inclusion of entities beyond those explicitly listed in the statutes, and Plaintiff has not identified any entity in the Rule's definition that would not meet the ordinary dictionary definition of "health care entity" or the statutes' catch-all provisions. Furthermore, the Rule recognizes that the definition of "health care entity" is a flexible one that depends on "the context of the factual and legal issues applicable to the situation." 84 Fed. Reg. at 23,196. None of the Rule's definitions apply in all circumstances. *See id.*

4. "Referral or Refer For"

Last, Plaintiff's challenge to "referral or refer for" is misplaced. As with many of the other definitions in the Rule, "referral or refer for" is not defined in the Weldon Amendment, the Coats-Snowe Amendment, or the ACA, the only statutes in which they appear. The Rule defines "referral or refer for" through a list of activities that qualify as "referral or refer for": the term

> includes the provision of information in oral, written, or electronic form (including names, addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure.

84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2).

1. The Rule's definition is consistent with Congress's intent. Although the statutes do not include a definition of "referral or refer for" and the legislative history is silent on the matter, the ordinary dictionary definition of the term indicates Congress's intent. *See Mayo Found. for Med. Educ. & Research*, 562 U.S. at 52. As HHS explained, "The rule's definition of 'referral' or 'refer for' . . . comports with dictionary definitions of the word 'refer,' such as the Merriam-Webster's definition of 'to send or direct for treatment, aid, information, or decision.'" 84 Fed. Reg. at 23,200 (quoting *Refer*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/refer). The statutes' structure also makes Congress's intent clear. The addition of the term "for" following "refer" indicates that Congress did not intend the statutes to be limited to a referral document, but rather to include any referral for abortion (or other health services) in a more general sense. For example, the Coats-Snowe Amendment protects not only a health care entity that declines to refer a patient to an abortion provider, but also a health care entity that declines to refer "for" abortions generally. *See, e.g.*, 42 U.S.C. § 238n(a)(1).

2. In the alternative, the Rule's definition should be upheld at *Chevron* step two. In addition to being consistent with dictionary definitions and the statutes' structure, the Rule's definition is faithful to the statutes' remedial purposes. As HHS explained, defining the term "referral or refer for" more narrowly would exclude forms of coercion that the Federal Conscience Statutes protect against. For example, the Supreme Court recently held that a law requiring health care providers to post notices regarding the availability of state-subsidized abortion likely violated the First Amendment. *See Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2378–79 (2018). A narrower definition would not include referrals of this sort, even though they constitute unconstitutional coercion of a health care entity that has a conscientious objection to abortion. The Weldon Amendment, Coats-Snowe Amendments, and

the ACA are not this narrow, and HHS acted reasonably when it interpreted the term accordingly.

The Rule is reasonable for another reason as well: it uses a non-exhaustive list that "guide[s] the scope of the definition," recognizing that the terms "take many forms and occur in many contexts." 84 Fed. Reg. at 23,201. This flexibility means that "the applicability of the rule would turn on the individual facts and circumstances of each case" (*i.e.*, "the relationship between the treatment subject to a referral request and the underlying service or procedure giving rise to the request"). *Id.*

C. The Rule Is Consistent with Other Provisions of Law.

Plaintiff also claims that the Rule conflicts with certain provisions of the United States Code. No such conflict exists.

1. Section 1554 of the ACA

Plaintiff claims that the Rule conflicts with Section 1554 of the ACA. *See* Compl. ¶ 174–18; PI Mem. at 17–19. That provision states that, "[n]otwithstanding any other provision of [the ACA], the Secretary of Health and Human Services shall not promulgate any regulation that" (1) "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care"; (2) "impedes timely access to health care services"; (3) "interferes with communications regarding a full range of treatment options between the patient and the provider"; (4) "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions"; (5) "violates the principles of informed consent and the ethical standards of health care professionals"; or (6) "limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114.

Plaintiff's claim is meritless. All six subjects of Section 1554's sub-sections involve the *denial* of information or services to patients. The Rule, however, denies nothing. It merely revises the 2011 Rule to ensure knowledge of, compliance with, and enforcement of, the longstanding Federal Conscience Statutes. At bottom, Plaintiff's objection is not so much to the Rule as to the Federal Conscience Statutes that the Rule implements. Under Plaintiff's theory, any time a health care entity that receives federal funds exercises its right under the Federal Conscience Statutes to decline to provide a service to which it objects, HHS would violate Section 1554. Plaintiff's argument, then, is that Congress essentially abrogated the Federal Conscience Statutes through Section 1554. Plaintiff takes this position even as to the Weldon Amendment, which Congress has readopted every year since the ACA's passage.

The Court should reject Plaintiff's untenable position. First, Section 1554 expressly applies "[n]otwithstanding any other provision *of this Act*," 42 U.S.C. § 18114 (emphasis added)—that is, the ACA. The great majority of the Federal Conscience Statutes that the Rule implements, of course, are not part of the ACA. Nor are the statutes that give the Secretary authority to award funding grants part of the ACA. Had Congress intended Section 1554 to extend beyond the ACA, it could have simply specified that it applies "[n]otwithstanding any other provision of law." 42 U.S.C. § 18032(d)(3)(D)(i). By its own terms, Section 1554 does not apply to conscience protection provisions outside of the ACA, and therefore does not undermine the Rule's validity. Another reason that Section 1554 is of no moment is that the Rule does not create, impede, interfere with, restrict, or violate anything. Instead, it simply limits what the government chooses to fund—*i.e.*, providers that do not engage in discrimination.

Putting that threshold point aside, Congress went out of its way in the ACA to make clear that nothing in that statute undermines the Federal Conscience Statutes on which the Rule is based. Specifically, Section 1303(c)(2) of the ACA states that

> Nothing in this Act [*i.e.*, the ACA, including Section 1554] shall be construed to have *any effect* on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

42 U.S.C. § 18023(c)(2) (emphasis added). This clear expression of congressional intent fatally undercuts Plaintiff's argument that Section 1554 somehow prevents HHS from giving effect to the Federal Conscience Statutes.

It is a basic principle of statutory interpretation, moreover, that Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Plaintiff would have this Court believe that Congress effectively gutted the Federal Conscience Statutes, without any meaningful legislative history so indicating, when it passed Section 1554. That proposition is implausible on its face.[3]

Defendants' interpretation of Section 1554 also comports with common sense. Section 1554's subsections are open-ended. Nothing in the statute specifies, for example, what constitutes an "unreasonable barrier[]," "appropriate medical care," "all relevant information," or "the ethical standards of health care professionals." 42 U.S.C. § 18114. And there is nothing in the ACA's legislative history that sheds light on this provision. Under these circumstances, it is a

[3] Congress also went on to add *additional* conscience protections in the ACA. *See, e.g.*, 42 U.S.C. § 18113. The ACA, thus, actually adds to and underscores the importance of the Federal Conscience Statutes, contrary to Plaintiff's claim.

substantial question whether Section 1554 claims are reviewable under the APA at all. *See Citizens to Pres. Overton Park*, 401 U.S. at 410 (explaining that the APA does not authorize judicial review of agency decision where "statutes are drawn in such broad terms that in a given case there is no law to apply" (citation omitted)).[4] But even if Section 1554 claims are reviewable, it is inconceivable that Congress intended to subject the entire U.S. Code to these general and wholly undefined concepts—and that it did so without leaving any meaningful legislative history.

Other principles point in the same direction. "[I]t is a commonplace of statutory construction that the specific governs the general," *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384–85 (1992). "[T]he specific provision is construed as an exception to the general one." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (citation omitted). Thus, even if Section 1554 applied to regulations implementing the Federal Conscience Statutes (it does not), and even if Section 1554 and those Statutes were in conflict (they are not), the Federal Conscience Statutes would prevail over Section 1554. Section 1554 is at best a general prohibition of certain types of regulations (very broadly described) and does not speak to conscience objections at all. The Federal Conscience Statutes, by contrast, contain specific protections with respect to specific activities in the context of federally funded health programs and research activities. Section 1554, therefore, must give way to the more specific Federal Conscience Statutes and the Rule interpreting them.

[4] Even within the ACA, HHS routinely issues regulations placing criteria and limits on what the government will fund, and on what will be covered in ACA programs. Under Plaintiff's standardless interpretation of Section 1554, it is far from clear that the government could ever impose *any* limit on *any* parameter of a health program—even if the program's own statute requires it. Nor is it evident how a court could possibly evaluate challenges brought under Section 1554 if that provision sweeps as broadly as Plaintiff claims.

2. Section 1557 of the ACA

Plaintiff further claims that the Rule conflicts with Section 1557 of the ACA, 42 U.S.C. § 18116. PI Mem. at 20; *see also* Compl. ¶ 73. This claim is meritless. Section 1557 provides that, subject to certain exceptions, "an individual shall not," on the grounds of race, color, national origin, sex, disability, or age, "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). Nothing in the Rule runs afoul of this prohibition.

As an initial matter, as explained in the preamble to the Rule, OCR intends "to read every law passed by Congress in harmony to the fullest extent possible so that there is maximum compliance with the terms of each law," including both the Federal Conscience Statutes and Section 1557. 84 Fed. Reg. at 23,183. Plaintiff's speculation that there could be some situation in which the Rule conflicts with Section 1557 is therefore just that—speculation—and has no place in a facial challenge. Even assuming there could be some conflict, however, Congress expressly stated that nothing in the ACA should be construed to have "*any effect*" on federal conscience protection. 42 U.S.C. § 18023(c)(2) (emphasis added). Plaintiff's claim under Section 1557—*i.e.*, that the Rule, which implements the Federal Conscience Statutes, is inconsistent with Section 1557—cannot survive such clear contrary instruction from Congress.

3. Emergency Medical Treatment and Active Labor Act (EMTALA)

Plaintiff also argues that the Rule conflicts with EMTALA, which requires hospitals with emergency departments to either (1) provide emergency care "within the staff and facilities available at the hospital," or (2) transfer the patient to another medical facility in circumstances permitted by the statute. 42 U.S.C. § 1395dd(b)(1)(A). *See* Compl. ¶ 175; PI Mem. at 19–20.

There is no conflict, however. As previously noted, HHS explained in the preamble to the Rule, that OCR "intends to read every law passed by Congress in harmony to the fullest extent possible so that there is maximum compliance with the terms of each law." 84 Fed. Reg. at 23,183. With respect to EMTALA specifically, HHS indicated that it generally agrees with the explanation in the preamble to the 2008 Rule that fulfilling the requirements of EMTALA would *not* conflict with the Federal Conscience Statutes that the Rule interprets. *See id.*

Plaintiff points to (alleged) potential uncertainty created by the Rule, with the "possibility" of sanctions for non-compliance. *See* PI Mem. at 19. But in considering Plaintiff's facial challenge to the Rule, the Court should not assume that some future, hypothetical conflict between EMTALA and the Rule will come to pass. *See Reno v. Flores*, 507 U.S. 292, 309 (1993). HHS has explained that it is "not aware of any instance where a facility required to provide emergency care under EMTALA was unable to do so because its entire staff objected to the service on religious or moral grounds." 73 Fed. Reg. 78,087. And in any event, HHS has stated that "where EMTALA might apply in a particular case, the Department would apply both EMTALA and the relevant law under this rule harmoniously to the extent possible." 84 Fed. Reg. 23,188.

4. Medicaid and Medicare Informed Consent Requirements

Plaintiff further contends that the Rule violates a provision of the Medicaid statute, 42 U.S.C. § 1396u-2(b)(3)(B), and a similar provision of the Medicare statute, *id.* § 1395w-22(j)(3)(C). *See* Compl. ¶ 176. Those provisions provide a rule of construction with respect to the specific conscience protections contained in 42 U.S.C. § 1396u-2(b)(3)(B) and 42 U.S.C. § 1395w-22(j)(3)(B), instructing that they should not be construed to interfere with state disclosure requirements. Plaintiff reasons that (1) because 42 U.S.C. § 1396u-2(b)(3)(B) and 42

U.S.C. § 1395w-22(j)(3)(B) should not be construed to affect State disclosure laws, and (2) because the Rule would preempt state disclosure laws if those laws required health care entities to engage in activities to which they object, then (3) the Rule is unlawful.

Plaintiff's conclusion does not follow from its premises. The Rule merely implements the construction of the provisions of the Medicaid and Medicare statutes required by § 1396u-2(b)(3)(B) and § 1395w-22(j)(3)(C), respectively. Those rules of construction, moreover, would apply only to state disclosure requirements that rely on § 1396u-2(b)(3)(B) or § 1395w-22(j)(3)(B) for authority. They are simply not implicated as to the disclosure requirements Plaintiff points to in its complaint. *See* Compl. ¶¶ 80, 176.

5. Title VII of the Civil Rights Act of 1964

Plaintiff also argues that, because the Rule does not include the same "undue hardship" exception that Congress included in Title VII, there is a conflict between that statute and the Rule. Compl. ¶ 177 (citing 42 U.S.C. § 2000e(j)). Not so. The Rule implements the substantive requirements of the Federal Conscience Statutes, which, unlike Title VII, contain no such exception. Indeed, that Congress included an "undue hardship" exception in Title VII but declined to do so in the Federal Conscience Statutes is strong evidence that Congress did not intend for such an exception to apply. *Cf., e.g.*, *Franklin Nat'l Bank of Franklin Square v. New York*, 347 U.S. 373, 378 (1954) (finding "no indication that Congress intended to make [a particular issue] subject to local restrictions, as it has done by express language in several other instances"). In addition, the Federal Conscience Statutes apply in more specific contexts than does Title VII, and therefore it is reasonable to infer—given the absence of the "undue hardship" exception in the Federal Conscience Statutes—that Congress did not intend for that exception to

apply to these statutes. *See* 84 Fed. Reg. at 23,191; *see also Morales*, 504 U.S. at 384–85 ("[I]t is a commonplace of statutory construction that the specific governs the general.").

D. The Rule Is Neither Arbitrary Nor Capricious.

Agency action must be upheld in the face of an APA claim if the agency "examine[s] the relevant data and articulate[s] a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n, of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted); *Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009). Under this deferential standard of review, "a court is not to substitute its judgment for that of the agency . . . and should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citations omitted). The Rule easily satisfies this deferential review.

Plaintiff makes several general arguments in support of its claim that the Rule is "arbitrary" and "capricious." None is persuasive, and none can overcome the presumption of validity to which the agency rulemaking is entitled.

1. HHS Adequately Explained Why It Issued the Rule.

The Rule undeniably revises HHS's approach to enforcing the Federal Conscience Statutes. But HHS is permitted to "consider varying interpretations and the wisdom of its policy on a continuing basis, for example, in response to changed factual circumstances, or a change in administrations." *Nat'l Cable & Telecomm. Ass'n v. Brand-X Internet Servs.*, 545 U.S. 967, 981 (2005) (internal citation omitted). As the Supreme Court has explained, there is no heightened standard when an agency changes its policy so long as the agency shows that "the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to

be better, which the conscious change of course adequately indicates." *Fox Television*, 556 U.S. at 515. HHS has met that standard here.

Contrary to Plaintiff's claim, Compl. ¶ 191, HHS's decision to promulgate the Rule was well-grounded in the evidence before the agency. As HHS explained in the preamble to the Rule, it determined that the preexisting regulatory structure was insufficient to protect the statutory rights and liberty interests of health care entities. *See* 84 Fed. Reg. at 23,228. HHS reasonably judged that the 2011 Rule lacked adequate measures to ensure compliance with the Federal Conscience Statutes and promoted confusion, not clarity, about the scope of those statutory protections. The 2011 Rule related to just three of the many Federal Conscience Statutes and did not provide adequate incentives for covered entities to "institute proactive measures to protect conscience, prohibit coercion, and promote nondiscrimination." *Id.* at 23,228. Moreover, the 2011 Rule failed to provide sufficient information concerning the scope of the various Federal Conscience Statutes, especially regarding their interaction with state laws, including state laws adopted since the promulgation of the 2011 Rule. *Id.*; *see also* NPRM, 83 Fed. Reg. at 3889. HHS also relied, in part, on complaints it received of alleged violations of the Federal Conscience Statutes. *See* NPRM, 83 Fed. Reg. at 3886; 84 Fed. Reg. at 23,229. The increase in complaints is, of course, just "one of the many metrics used to demonstrate the importance of this rule." 84 Fed. Reg. at 23,229. The increase in complaints was both real and significant. Many of these complaints allege violations of religious and conscience-based beliefs in the medical setting, and while a large subset of them complain of conduct that is outside the scope of the Federal Conscience Statutes and the Rule,[5] some do implicate the relevant statutes, *see*, *e.g.*,

[5] For example, many complaints were from patients and/or parents who criticized the vaccination policies at schools and medical offices, *see, e.g.*, AR 542458 (Ex. D).

Admin. Record (AR) 544,188–207 (Ex. A); 544516 (Ex. B); 544612–23 (Ex. C). Further, the complaints overall illustrate the need for HHS to clarify the scope and effect of the Federal Conscience Statutes.

2. HHS's Definitions Were the Product of Reasoned Decisionmaking.

As discussed above, HHS crafted each definition in the Rule in a reasonable exercise of its statutory authority. The defined terms are also neither arbitrary nor capricious. Plaintiff claims that the definitions of "assist in the performance," "discrimination," "health care entity," and "referral" "create an unworkable situation." Compl ¶¶ 192–93. In support of this argument, Plaintiff offers various uncertainties and hypothetical examples of potential outcomes of the Rule. *See* PI Mem. at 32–33; Compl. ¶¶ 192–93. But again, Plaintiff's challenge is facial, and the fact that it can "point to a hypothetical case in which the rule might lead to an arbitrary result does not render the rule 'arbitrary or capricious." *Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 619 (1991).

HHS weighed comments that argued that the proposed definitions did not go far enough and others that complained that the definitions were overbroad, and provided thoughtful, detailed explanations for why each of the challenged definitions correctly interpreted the relevant statutes. *See generally* 84 Fed. Reg. at 23,186–203; *e.g., id.* at 23,194 (declining to explicitly incorporate "social workers and schools of social work" into the definition of "health care entity" because "[i]t is unclear in many circumstances [whether] such entities deliver health care"); *id.* at 23,191 (explaining that HHS would not incorporate into the rule the "undue hardship" exception for reasonable accommodations under Title VII because Congress did not adopt such an exception in the Federal Conscience Statutes). The agency also modified each challenged definition in response to the comments it received, including narrowing and clarifying each

definition in significant respects. *See id.* at 23,181–203; *e.g.*, *id.* at 23,186–89 (reviewing several categories of comments asserting that the proposed definition of "assist in the performance of" was overbroad, agreeing in part, and narrowing the definition from "to participate in any activity" with an "articulable connection[,]" to "to take an action that has a specific, reasonable, and articulable connection," among other changes and clarifications). HHS thus satisfied its APA obligations.

3. HHS Reasonably Weighed the Rule's Costs and Benefits.

In addition to HHS's purpose of improving knowledge about and enforcement of the Federal Conscience Statutes, HHS identified four primary benefits of the Rule in its cost-benefit analysis: (1) increasing the number of health care providers; (2) improving the doctor-patient relationship; (3) eliminating the harm from requiring health care entities to violate their consciences; and (4) reducing unlawful discrimination in the health care industry and promoting personal freedom. 84 Fed. Reg. at 23,246. To the extent that HHS relied on a limited 2009 poll to reach this conclusion, the agency did not act unreasonably in considering it. *Cf. San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 995 (9th Cir. 2014) (Even "if the only available data is "'weak,' and thus not dispositive," an agency's reliance on such data 'does not render the agency's determination 'arbitrary and capricious'" (citation omitted)). HHS's policy determination relied on its own analysis, the comments it received in response to the NPRM, anecdotal evidence, and, yes, the 2009 poll. 84 Fed. Reg. at 23,247. There was nothing unreasonable, arbitrary, or capricious in HHS considering the poll as one of the relevant data points among other non-empirical evidence. *See Fox Television*, 556 U.S. at 521 ("[E]ven in the absence of evidence, the agency's predictive judgment (which merits deference) makes entire sense. To predict that complete immunity for fleeting expletives, ardently desired by

broadcasters, will lead to a substantial increase in fleeting expletives seems to us an exercise in logic rather than clairvoyance."). Moreover, HHS scarcely assigned controlling weight to either the 2009 survey or the ramifications of that survey: HHS ultimately concluded that it lacked sufficient data to quantify the theoretical effect but that the available data was adequate "to conclude that the rule will increase, or at least not decrease, access to health care providers and services." 84 Fed. Reg. at 23,247.

HHS also considered other potential benefits of the Rule for health care entities, such as the reduction in "harm that providers suffer when they are forced to violate their consciences." 84 Fed. Reg. at 23,246 (citing, among other sources, Kevin Theriot & Ken Connelly, *Free to Do No Harm: Conscience Protections for Healthcare Professionals*, 49 Ariz. Stat. L.J. 549, 565 (2017)).

Whether the Rule would increase or decrease the number of providers is a difficult policy assessment that should be left to the entity with responsibility for making those assessments—HHS. Indeed, "[w]hether [the Court] would have done what the agency did is immaterial," so long as the agency engages in an appropriate decisionmaking process. *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 718 (D.C. Cir. 2016). The court asks only whether the decision "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park*, 401 U.S. at 416. Here, HHS assessed the available evidence and reasonably concluded that the Rule would "increase, or at least not decrease," the number of providers. 84 Fed. Reg. at 23,247.

Plaintiff separately argues that HHS inadequately considered the effect of the Rule on health care access. *See also* Compl. ¶ 194. But HHS received no data that would "enable[] a reliable quantification of the effect of the rule on access to providers and to care," 84 Fed. Reg.

at 23,250. Absent reliable data from which to quantify the effects, HHS was scarcely arbitrary in relying on the data it did have—and that data indicated that, if anything, the Rule would increase the number of available providers, which can reasonably be predicted to improve patient care. *See id.* at 23,180; *see also Fox Television*, 556 U.S. at 521.

Furthermore, HHS explicitly sought comments on "whether this final rule would result in unjustified limitations on access to health care." 84 Fed. Reg. at 23,250; NPRM, 83 Fed. Reg. at 3900 (request for comment). Ultimately, and as HHS explained, the majority of the comments it received in response to that request focused on preexisting discrimination in health care and did not attempt to answer the question of how the Rule itself would affect access to health care. 84 Fed. Reg. at 23,250. HHS studied academic literature relating to preexisting statutes, but found "insufficient evidence to conclude that conscience protections have negative effects on access to health care." *See id.* at 23,251 & n.345. HHS also considered a report with anecdotal data on discrimination against LGBT patients in states with religious freedom laws. 84. Fed. Reg. at 23,252. But, as HHS explained, that report contained only anecdotal accounts—thus making it unfit for extrapolation—and made no attempt to establish a causal mechanism between religious freedom laws and the discrimination it reported. *Id.*

Many of these questions—the precise effect of the Rule on patient care, the effort that will be required to comply with a new policy—are difficult to answer. Plaintiff's view seems to be that an agency cannot take an action until it has commissioned or executed studies on every potential repercussion of that action. While that might be a technocrat's dream, it is not what the APA requires. Instead, the APA commits these decisions to the agency's expertise. "Whether [the Court] would have done what the agency did is immaterial," so long as the agency engages in an appropriate decisionmaking process. *Mingo Logan Coal Co.*, 829 F.3d at 718. Where, as

here, HHS assessed the available evidence on a subject, and reached a reasonable conclusion, this Court should not accept Plaintiff's invitation to second-guess the agency's policy conclusions.

Finally, Plaintiff argues that the Rule "fail[s] to provide any exception for medical emergencies," as provided in EMTALA "or where refusal to provide services would cause 'undue hardship,'" as set forth in Title VII. Compl. ¶ 195. But HHS clearly considered the Rule's effect on the administration of EMTALA's medical-emergency provisions and reiterated its 2008 conclusion that "the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and antidiscrimination laws," 84 Fed. Reg. at 23,183, and further stated that "where EMTALA might apply in a particular case, the Department would apply both EMTALA and the relevant law under this rule harmoniously to the extent possible." *Id.* at 23,188.

And as for Title VII's "undue hardship" exception, Plaintiff casts the exception as a universal requirement in the implementation of all anti-discrimination statutes. But Title VII's protections are distinct from the Federal Conscience Statutes that Congress separately enacted. What is more, HHS reasonably concluded that the status quo was not adequately protecting at least some health care providers who object to participating in certain care, in part due to the increasing number of complaints it was receiving. *See* 84 Fed. Reg. at 23,254 (rejecting the option of maintaining the status quo because that would "perpetuate the current circumstances necessitating Federal regulation, which include (1) inadequate to non-existent Federal government frameworks to enforce Federal conscience and anti-discrimination laws and (2) inadequate information and understanding about the obligations of regulated persons and entities and the rights of persons, entities, and health care entities under the Federal conscience and

antidiscrimination laws"). While the Rule adopts the Title VII reasonable-accommodation-of-religion framework in part by recognizing that "when appropriate accommodations are made for objections protected by Federal conscience and antidiscrimination laws, those accommodations do not themselves constitute discrimination," HHS sensibly declined to adopt Title VII's "undue hardship" exception because "Congress chose not to place that limitation on the protections set forth in the [later-in-time] Federal conscience and antidiscrimination laws." 84 Fed. Reg. at 23,191.

E. The Rule Comports with the Establishment Clause.

Plaintiff argues that the Rule violates the Establishment Clause, Compl. ¶¶ 199–203; PI Mem. at 30–33, but under its theory, it would be the *preexisting* Federal Conscience Statutes that violate the Establishment Clause by creating supposed "favoritism toward religious beliefs." Yet Plaintiff does not challenge the Federal Conscience Statutes themselves. And as explained above, the Rule does not change the substantive law that Congress established in the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,256.

Plaintiff does not challenge the Federal Conscience Statutes, because those statutes do not violate the Establishment Clause. For example, the Ninth Circuit concluded decades ago in *Chrisman v. Sisters of St. Joseph of Peace* that a provision of the Church Amendments was proper under the Establishment Clause because Congress was seeking to "preserve the government's neutrality in the face of religious differences" rather than to "affirmatively prefer[] one religion over another."[6] 506 F.2d 308, 311 (9th Cir. 1974). The Ninth Circuit analogized the situation to

[6] As explained above, the Church Amendments are a series of conscience-protection provisions enacted in the 1970s and now codified at 42 U.S.C. § 300a-7. 84 Fed. Reg. at 23,171. *Chrisman* addresses one of these provisions, Pub. L. No. 93-45, 87 Stat. 95 § 401 (1973). *Chrisman*, 506 F.2d at 310 & n.6.

Sherbert v. Verner, 374 U.S. 398 (1963), which recognized that a religious adherent's receipt of a government benefit did not establish religion, but rather, "reflects nothing more than the governmental obligation of neutrality in the face of religious differences." *Id.* at 409. Likewise, the Ninth Circuit upheld against an Establishment Clause challenge another of the Federal Conscience Statutes that permitted Medicare and Medicaid payments for the nonmedical care of persons who object to conventional medical care. *See Kong v. Scully*, 341 F.3d 1132 (9th Cir. 2003), *opinion amended on denial of reh'g*, 357 F.3d 895 (9th Cir. 2004) (upholding amendments to 42 U.S.C. § 1320 and 42 U.S.C. § 1395). In passing the remaining Federal Conscience Statutes, the government has similarly done nothing more than preserve its neutrality toward religion. If Plaintiff accepts the constitutionality of the Federal Conscience Statutes (as it appears to), it is nonsensical to claim that the Rule, which merely implements those statutes, violates the Establishment Clause.

Indeed, for all of the same reasons that the Federal Conscience Statutes are in harmony with the Establishment Clause, the Rule is, too. "[T]here is ample room for accommodation of religion under the Establishment Clause." *Corp. of Presiding Bishop of Church v. Amos*, 483 U.S. 327, 338 (1987). The Rule serves the legitimate secular purpose of alleviating potential burdens of conscience on individual and institutional health care entities, just as the Federal Conscience Statutes do. Additionally, the Rule neither promotes nor subsidizes any religious message or belief; rather, it explains the enforcement processes for existing federal statutes. Finally, the Rule, like many of the Federal Conscience Statutes, is generally neutral between various religions and between religion and non-religion. *Cf., e.g.*, 42 U.S.C. § 238n (Coats-Snowe Amendment, the applicability of which does not turn on a religious belief); Pub. L. No. 115-245, Div. B., § 507(d) (Weldon Amendment, the applicability of which does not turn on

religious belief); 42 U.S.C. § 300a-7 (Church Amendments, which equally protect health care providers from discrimination based on religious beliefs or moral convictions).[7]

Burden on third parties – Plaintiff's argument that the Rule impermissibly burdens third parties, PI Mem. at 30–32, fails because the Establishment Clause does not bar religious accommodations that could have an adverse effect on others. For example, in *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327 (1987), the Supreme Court held that Title VII's religious exemption to the prohibition against religious discrimination in employment was consistent with the Establishment Clause even though it allowed an employer to terminate the plaintiff's employment. While the plaintiff was "[u]ndoubtedly" adversely affected, "it was the Church[,] . . . not the Government" that caused that effect. 483 U.S. at 337 n.15. Similarly, in *Doe v. Bolton*, the Supreme Court characterized a state statute that allowed hospitals, physicians, and other employees to refrain from participating in abortions as "appropriate protection [for] the individual and [ ] the denominational hospital." 410 U.S. 179, 197–98 (1973).

Here, the Federal Conscience Statutes (and, therefore, the Rule) do not directly burden anyone; instead, they simply encourage entities not to discriminate by placing conditions on federal funds. If any adverse effects occur, they result from the conscience decisions of health care entities, not the government. *See Amos*, 483 U.S. at 337 n.15 (noting that plaintiff "was not legally obligated" to take the steps necessary to save his job, and that his discharge "was not required by statute"). Finally, to the extent it is appropriate to consider the burdens on third parties in the Establishment Clause context and determine if they "override other significant

[7] Plaintiff unpersuasively refers to a "strict scrutiny" test, PI Mem. at 30 (citing *Larson v. Valente*, 456 U.S. 228 (1982)), which applies only to *denominational* preferences. *Larson*, 456 U.S. at 246. But the Rule contains no sectarian preference.

interests," *Cutter v. Wilkinson*, 544 U.S. 709, 720, 722 (2005), Congress has already struck this balance by conditioning federal health care funds on compliance with the Federal Conscience Statutes. Plaintiff further demonstrates the illogic of its position by arguing that the precise balance struck by its current laws (and its interpretation of the Statutes) to "respect[] employees' religious beliefs" while providing care is acceptable, but that any deviation would cause a parade of horribles. PI Mem. at 31–32.

Coercion – Plaintiff's argument that the Rule coerces religious exercise, PI Mem. at 32–33, is nonsensical. The Rule (and the Federal Conscience Statutes) protects health care entities in determining whether to participate in providing (or covering) certain care. The Federal Conscience Statutes and the Rule do not "dictate" to anyone, PI Mem. at 32; rather they offer conditioned federal funds for recipients to accept or not. If Plaintiff wishes to engage in the discrimination prohibited by the Federal Conscience Statutes, then it is free to decline HHS funds and make its own unfettered decisions. And, in any event, protecting the conscience rights of a health care provider does not "coerce" the patient into "participating" in the provider's conscientious beliefs.

F. The Rule Complies with the Spending Clause.

Plaintiff alleges that the Rule violates the Spending Clause. Compl. ¶¶ 204–06; PI Mem. at 33–36. More specifically, Plaintiff alleges that the Rule is coercive, that the Rule is ambiguous, that the Rule is retroactive, and that the Rule's requirements are insufficiently related to the purpose of the Federal Conscience Statutes. All of these contentions are wrong.

As an initial matter, although Plaintiff purports to object to the *Rule*, its true objection is to the Federal Conscience Statutes, which originated the conditions on the government's offer of funds. The Rule does not alter the Statutes' substantive conscience requirements. *See* 84 Fed.

Reg. at 23,256. Nor can Plaintiff show that the Rule deviates from the Statutes in an unconstitutional way, because many of its arguments—for example, that the amount of funding at stake is coercively large—apply equally to the Rule *and* the Statutes. In other instances, the Rule is clearly *less* susceptible to attack than the Statutes—for example, Plaintiff argues that the conditions on federal grants are ambiguous, but the Rule provides greater clarity than the Statutes themselves.

Furthermore, Plaintiff's specific objections under the Spending Clause fail on their merits. Congress's Article I authority to "set the terms on which it disburses federal money to the States" is "broad," and these conditions fall within that authority. *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006); *see also, e.g.*, *South Dakota v. Dole*, 483 U.S. 203, 206 (1987) (noting that Congress has "repeatedly employed the [spending] power to further broad policy objectives by conditioning receipt of federal moneys upon compliance by the recipient with federal statutory and administrative directives" (citations omitted)).

Coercion – A conditional offer of federal funds will be found to be unduly coercive only in the unusual case—"[i]n the typical case we look to the States to defend their prerogatives by adopting 'the simple expedient of not yielding' to federal blandishments." *NFIB v. Sebelius*, 567 U.S. 519, 579 (2012) (Roberts, C.J.) (quoting *Massachusetts v. Mellon*, 262 U. S. 447, 482 (1923)). Comparing this case to *NFIB* shows that no unconstitutional coercion has occurred. In *NFIB*, the Supreme Court concluded that an ACA provision that conditioned all Medicaid funds on a state's agreement to expand its Medicaid program violated the Spending Clause by "transform[ing]" Medicaid into a new program. 567 U.S. at 583. The Federal Conscience Statutes and the Rule are quite different.

First, unlike in *NFIB*, where states were provided with a binary choice—either expand their Medicaid programs, or lose all of their Medicaid funding—it is far from clear that noncompliance with the Federal Conscience Statutes and the Rule would impact *all* of the funding sources identified by Plaintiff. HHS has a variety of enforcement options when the conditions for its grants are not met, and the Rule clarifies that HHS will always begin by trying to resolve a potential violation through informal means. 84 Fed. Reg. at 23,271 ("If an investigation or compliance review indicates a failure to comply with Federal conscience and antidiscrimination laws or this part, OCR will so inform the relevant parties and *the matter will be resolved by informal means whenever possible*." (emphasis added)); *see also supra* n.2 (discussing HHS's enforcement procedures). Far from the "gun to the head" at issue in *NFIB*, 567 U.S. at 581, this series of informal enforcement proceedings is not unduly coercive. Plaintiff's apocalyptic (and hypothetical) scenarios of complete funding loss—scenarios that have not remotely come to pass in the decades that many of the Federal Conscience Statutes have been in effect—are of no help. Plaintiff cannot succeed on its facial challenge by identifying a handful of implausible and speculative circumstances in which the operation of the Federal Conscience Statutes and the Rule *might* have a coercive effect; instead, it must show that the Rule has *no* constitutional applications. *Sineneng-Smith*, 910 F.3d at 470. And, the further factual context that would be available if such a scenario did occur would be helpful to the Court in evaluating Plaintiff's Spending Clause claims, thus highlighting the lack of ripeness at this time.

Second, unlike in *NFIB*, Plaintiff cannot plead surprise because the Federal Conscience Statutes and their conditions have existed for decades. *See, e.g.*, 42 U.S.C. § 300a-7 (first Church Amendments enacted in 1973); 42 U.S.C. § 238n (Coats-Snowe Amendment, enacted in 1996). The ACA provisions at issue in *NFIB* required the states to adopt an entirely new Medicaid

expansion. *Cf. NFIB*, 567 U.S. at 584 (Roberts, C.J.) (criticizing the Medicaid expansion as an attempt to "enlist[] the States in a new health care program" and "surpris[e] participating States with postacceptance or 'retroactive' conditions" (citation omitted)). If anything, the Rule should be an improvement from Plaintiff's perspective because the Rule provides additional clarity, transparency, notice, and insight into HHS's enforcement processes.

Plaintiff also misunderstands the Rule, suggesting that the Rule "expands" the Weldon Amendment, in effect applying the requirements of other Federal Conscience Statutes to the funds affected by the Weldon Amendment. PI Mem. at 33–34. This is not the case. As discussed, the Rule does *not* change the substantive law, and therefore does *not* amalgamate all of the Statutes together and apply all the requirements of this result to all of the funding sources affected by each Federal Conscience Statute. Plaintiff is at a loss, therefore, to explain why the Rule would violate the Spending Clause if the Weldon Amendment does not.

Ambiguity – Plaintiff makes no attempt to argue that the terms of the *Federal Conscience Statutes* are ambiguous, likely because each clearly provides unambiguous notice to funding recipients of the Statutes' anti-discrimination provisions. The Rule—which adds additional clarification and interpretation on top of that are already provided in the Statutes—is necessarily clearer and less ambiguous than the Statutes. Both are more than adequate to pass the ambiguity analysis, which focuses on whether or not potential recipients are aware that the federal government has placed conditions on federal funds, rather than on whether every detail of such conditions has been set forth. *See W. Virginia Dep't of Health & Human Res. v. Sebelius*, 649 F.3d 217, 223–24 (4th Cir. 2011) ("[G]iven the ever-increasing complexity of modern legislation, Congress need not spell out every condition with flawless precision for a provision to be enforceable."); *id.* (noting that "states must bear some responsibility for any harm to them

allegedly caused by an ambiguous provision, as they had an opportunity to seek clarification of the program requirements" (quotation marks and citation omitted); *see also Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 24–25 (1981) (holding that when Congress has "express[ed] clearly its intent to condition the grant of federal funds" such a grant may be proper even if the state's obligations are "largely indeterminate"); *Va. Dep't of Educ. v. Riley*, 106 F.3d 559, 562 (4th Cir. 1997) (holding that Congress must "clearly and unambiguously" impose conditions on federal funds).

Plaintiff's argument about sub-recipients is also misplaced. PI Mem. at 34–35. The Federal Conscience Statutes, of course, do not permit funding recipients to outsource discrimination to sub-recipients—that Plaintiff may not like this condition does not make it *ambiguous*. But to the extent that Plaintiff expresses the concern that it will be penalized for misconduct by sub-recipients when it has no knowledge of any such violations, this concern delves deep into the type of speculation about hypothetical enforcement actions that renders Plaintiff's Spending Clause claim unripe for resolution, and was addressed by HHS in its changes to the Rule after the NPRM. 84 Fed. Reg. at 23,220.

Retroactivity – Plaintiff argues that the Rule is such a "surprise" that it renders the Federal Conscience Statutes a retroactive condition on federal funding. PI Mem. at 35. But this is merely a retread of Plaintiff's statutory authority arguments, which fail for the reasons described above. In any event, as *NFIB* illustrates, there is no Spending Clause barrier to clarifying the terms on which an entity may receive federal funding. *Cf. NFIB*, 567 U.S. at 582–83 (holding that the Medicaid statute authorized Congress to modify its terms without creating Spending Clause problems, so long as the modifications did not rise to the level of creating a new program). Here, the Rule's explanation and clarification of the Federal Conscience Statutes

certainly does not rise to the level of creating a new program. Plaintiff has been on notice of the existence of the Statutes for many years, and there is nothing retroactive about HHS deciding to improve its enforcement of them.

Nexus – Plaintiff's allegation that the Rule is not adequately related to the purpose of the targeted funding, PI Mem. at 36, fails because it is the Federal Conscience Statutes—not the Rule—that establish the linkage between conscience protections and federal funding. Further, the governmental purpose of the statutes is to ensure that federal funds do not subsidize discrimination against individual and institutional health care entities on the basis of their moral, religious, or other beliefs about certain care (or coverage), in service of the government's interests in protecting the free exercise of religion and in encouraging and overseeing a robust health care system. *See Mayweathers*, 314 F.3d at 1066–67 (upholding the Religious Land Use and Institutionalized Persons Act (RLUIPA) against a Spending Clause challenge because "by fostering non-discrimination, RLUIPA follows a long tradition of federal legislation designed to guard against unfair bias and infringement on fundamental freedoms"). Plaintiff objects that the funding for its "labor and educational programs," PI Mem. at 36, might also be at risk, but offers no evidence to support this claim. The Rule applies only to funds administered, conducted, or funded by HHS. Plaintiff should not succeed on its *facial* challenge on the speculative theory that the Rule could somehow affect funds provided other departments.

IV. Plaintiff Will Suffer No Imminent Irreparable Harm.

Showing irreparable harm in the absence of a preliminary injunction is necessary for Plaintiff to obtain such relief. *See Winter*, 555 U.S. at 19. And not just any showing will suffice. A party "seeking preliminary relief [must] demonstrate that irreparable injury is likely in the absence of an injunction." *Id.* at 22. Plaintiff cannot carry that burden.

Putting aside its allegations of constitutional injury, which fail for the reasons described above, Plaintiff contends that the ability of its health department to provide quality care will be harmed if it accommodates the conscience rights of health care entities that Congress has recognized through the Federal Conscience Statutes. *See, e.g.*, Compl. ¶ 4; PI Mem. at 37–41. Plaintiff argues, for instance, that medical departments will be unable to make staffing decisions because they will not know which providers are willing to perform which services. PI Mem. at 40. These alleged harms are purely speculative and based on a misunderstanding of what the Federal Conscience Statutes and the Rule actually require. Contrary to Plaintiff's characterization, the Rule does, in fact, allow hospitals and other medical departments to make staffing decisions—including those for emergency personnel—based on the conscience objections of individual providers. *See* 45 C.F.R. § 88.2(4); 84 Fed. Reg. at 23,191–92. Entities may make accommodations, such as moving an individual to a different position, if the individual is willing to do so. *See* 84 Fed. Reg. at 23,191. Only in the limited circumstance where the individual cannot be accommodated without discrimination would a hospital need to consider additional staffing. Moreover, entities subject to the Rule may require employees to inform them about potential objections to providing certain services, in order to facilitate such staffing decisions, so long as there is a reasonable likelihood the provider would be asked in good faith to perform those services. *See* 45 C.F.R. § 88.2(5); 84 Fed. Reg. at 23,191. There is, therefore, no basis to accept the parade of horribles that Plaintiff alleges, and no reason to believe that Plaintiff's medical department will be unable to provide adequate health care while still respecting conscience rights. Accordingly, Plaintiff cannot show any non-speculative, irreparable harm on that basis.

Plaintiff also claims irreparable injury based on administrative changes it will need to

make, and new policies it will need to adopt, in light of the Rule's clarification of the Federal Conscience Statutes. *See* PI Mem. at 38–40. But "ordinary compliance costs are typically insufficient to constitute irreparable harm," *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005) (collecting cases), and Plaintiff offers no reason why this case should be treated any differently.

Plaintiff's allegation that it will be harmed by a loss of HHS funding, PI Mem. at 43–46, also does not establish irreparable injury, because it is too speculative. As explained above, a long chain of events would have to occur before Plaintiff would actually lose any HHS funding. HHS would first need to investigate a complaint of a violation, and, if HHS determined that a violation had occurred, and then it would work with the grantee to try to accomplish compliance. The process for enforcement set out in the Rule is designed to encourage voluntary compliance by recipients and sub-recipients informal means. 45 C.F.R. § 88.7(i)(2). If recipients are unwilling to comply voluntarily, OCR would first take intermediate steps to attempt to achieve compliance, such as imposing additional conditions. There is no reason to believe, therefore, that Plaintiff faces any imminent loss of funding—much less the drastic consequences Plaintiff describes—as soon as the Rule goes into effect.

The remainder of Plaintiff's arguments address the Rule's purported impact on third parties not before the Court.[8] Plaintiff lacks standing to raise these alleged harms, *see Warth v. Seldin*, 422 U.S. 490, 499 (1975) and, *a fortiori*, Plaintiff cannot obtain a preliminary injunction based on allegations of third-party harm.

[8] *See, e.g.*, PI Mem. at 42 (hypothesizing that patients will feel stigmatized if refused care by a provider); *id.* at 43 (alleging that patients will forgo care).

V. The Balance of Equities and the Public Interest Weigh in Favor of Denying Plaintiff's Preliminary Injunction Motion.

On the other side of the ledger, the government "suffers a form of irreparable injury" if it "is enjoined by a court from effectuating statutes enacted by representatives of its people." *Maryland v. King*, 133 S. Ct. 1, 3 (2012) (Roberts, J., in chambers) (citation omitted).[9] That is particularly true here, as the government has a compelling interest in ensuring knowledge of, compliance with, and enforcement of, federal conscience and anti-discrimination laws, and in protecting religious liberty and conscience, which the Rule seeks to accomplish. *See Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996). The need to avoid that harm significantly outweighs any of Plaintiff's asserted injuries, particularly in light of Defendants' delay of the effective date of the Rule so that this case can be decided on cross-motions for summary judgment.

VI. Any Relief Should Be Limited.

For the reasons discussed above, the Court should dismiss this case or, in the alternative, grant summary judgment to Defendants and deny Plaintiff's forthcoming motion for summary judgment. The Court should also deny Plaintiff's motion for a preliminary injunction. But even if the Court were to disagree, under the Court's constitutionally prescribed role, any relief should be limited to redressing the injuries of the parties before this Court. *See Gill v. Whitford*, 138 S. Ct. 1916, 1921, 1933–34 (2018). Equitable principles likewise require that any relief "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted).

Here, Plaintiff fails to show that nationwide relief is necessary to redress its alleged injuries. To start, Plaintiff's choice to bring a facial challenge does not justify nationwide relief.

[9] When the federal government is the opposing party, the balance of equities and public interest merge. *See Nken v. Holder*, 556 U.S. 418, 435 (2009).

See City & Cty. of San Francisco v. Trump, 897 F.3d 1225, 1244–45 (9th Cir. 2018) (vacating nationwide scope of injunction in facial constitutional challenge to executive order). Nor does Plaintiff's decision to bring APA claims necessitate a nationwide remedy. *See, e.g.*, *California v. Azar*, 911 F.3d 558, 582–84 (9th Cir. 2018). A court "do[es] not lightly assume that Congress has intended to depart from established principles" regarding equitable discretion, *Weinberger v. Romero-Barcelo,* 456 U.S. 305, 313 (1982), and the APA's general instruction that unlawful agency action "shall" be "set aside," 5 U.S.C. § 706(2), is insufficient to mandate such a departure. The Supreme Court therefore has confirmed that, even in an APA case, "equitable defenses may be interposed." *Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967). Accordingly, the Court should construe the "set aside" language in Section 706(2) as applying only to the named Plaintiff, especially given that no federal court had issued a nationwide injunction before Congress's enactment of the APA in 1946, nor would do so for more than fifteen years thereafter, *Trump v. Hawaii*, 138 S. Ct. 2392, 2426 (2018) (Thomas, J., concurring).

Nationwide relief would be particularly harmful here given that three other district courts in California, New York, and Washington are currently considering similar challenges. If the government prevails in all three other jurisdictions, nationwide relief here would render those victories meaningless as a practical matter. It would also preclude appellate courts from testing Plaintiff's factual assertions against the Rule's operation in other jurisdictions.

Similarly, should the Court decide to set aside or enjoin any portion of the Rule, the Court should allow the remainder to go into effect. In determining whether severance is appropriate, courts look to both the agency's intent and whether the regulation can function sensibly without the excised provision(s). *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001). Here, the intent of the agency is clear: Section 88.10 of the Rule provides

that, if a provision of the Rule is held to be invalid or unenforceable, "such provision shall be severable," and "[a] severed provision shall not affect the remainder of this part." 84 Fed. Reg. at 23,272; *see also id.* at 23,226. Nor is there any functional reason why the entire Rule must fall if the Court agrees with Plaintiff's attacks on particular provisions. The Rule implements a variety of statutory provisions protecting conscience, but Plaintiff has not alleged harms stemming from compliance with the Rule with respect to each and every one of those statutes. Moreover, the various definitions in Section 88.2 that Plaintiff challenges can operate independently of one another, as can the other provisions in the Rule. And there is certainly no logical basis for setting aside or enjoining the entire Rule if the Court agrees with only some of Plaintiff's challenges.

Finally, if the Court does set aside the Rule or enter an injunction, the Court should make clear that this relief does not prevent HHS from continuing to investigate violations of, and to enforce, federal conscience and anti-discrimination laws under the prior 2011 Rule or the Federal Conscience Statutes themselves. Such investigations are independent of the Rule that is the subject of this lawsuit and require the investment of significant resources, and therefore HHS should not be prevented from continuing to pursue them, or from acting under its existing statutory or regulatory enforcement authority, even if the Court were to otherwise set aside or enjoin the Rule.

CONCLUSION

For the reasons stated above, Defendants respectfully ask that the Court dismiss this case or, in the alternative, enter judgment in Defendants' favor. Defendants also ask the Court to deny Plaintiff's motion for a preliminary injunction.

Dated: August 22, 2019 Respectfully submitted,

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EXHIBIT A

Form Approved: OMB No. 0990-0269.
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

CIVIL RIGHTS DISCRIMINATION COMPLAINT

YOUR FIRST NAME	YOUR LAST NAME
[redacted]	[redacted]
HOME / CELL PHONE (Please include area code)	WORK PHONE (Please include area code)
[redacted]	
STREET ADDRESS	CITY
[redacted]	[redacted]
STATE	ZIP	E-MAIL ADDRESS (If available)
[redacted]	[redacted]	[redacted]

Are you filing this complaint for someone else? ☐ Yes ☒ No

If Yes, whose civil rights do you believe were violated?

FIRST NAME	LAST NAME

I believe that I have been (or someone else has been) discriminated against on the basis of:

☐ Race / Color / National Origin ☐ Age ☒ Religion / Conscience ☐ Sex

☐ Disability ☐ Other (specify): _____

Who or what agency or organization do you believe discriminated against you (or someone else)?

PERSON/AGENCY/ORGANIZATION

Washington State Department of Corrections

STREET ADDRESS	CITY
7345 Linderson Way SW	Tumwater
STATE	ZIP	PHONE (Please include area code)
Washington	98501	(360) 725-8213

When do you believe that the discrimination occurred?

LIST DATE(S)

10/02/2017

Describe briefly what happened. How and why do you believe that you have been discriminated against? Please be as specific as possible.
(Attach additional pages as needed)

No reasonable accommodation provided for my religious objection to prescribing hormones to men wanting to transition into women. When other providers offered to prescribe hormones to these patients under my care they were told by DOC leadership that they could not see my patients and no accommodation has been provided. Attached is a more detailed account as well as emails from my Facility Medical director, Chief medical officer, and the health care authority.

Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

SIGNATURE	DATE *(mm/dd/yyyy)*
[redacted]	03/06/2018

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of Sections 1553 and 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, and other civil rights statutes. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible discrimination, for internal systems operations, or for routine uses, which include disclosure of information outside the Department of Health and Human Services (HHS) for purposes associated with civil rights compliance and as permitted by law. It is illegal for a recipient of Federal financial assistance from HHS to intimidate, threaten, coerce, or discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under Federal civil rights laws. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's web site at: **www.hhs.gov/ocr/civilrights/complaints/index.html**. To submit a complaint using alternative methods, see reverse page (page 2 of the complaint form).

The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.

Do you need special accommodations for us to communicate with you about this complaint? (Check all that apply)

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter (specify language): _____

☐ Foreign language interpreter (specify language): _____ ☐ Other: _____

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME
HOME PHONE (Please include area code)	WORK PHONE (Please include area code)

STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS (If available)

Have you filed your complaint anywhere else? If so, please provide the following. (Attach additional pages as needed)

PERSON/AGENCY/ORGANIZATION/ COURT NAME(S)

EEOC, DOC internal discrimination complaint

DATE(S) FILED	CASE NUMBER(S) (If known)
02/06/2018, 11/16/2017	null, null

To help us better serve the public, please provide the following information for the person you believe was discriminated against (you or the person on whose behalf you are filing).

ETHNICITY (select one)

☐ Hispanic or Latino

☒ Not Hispanic or Latino

RACE (select one or more)

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American ☒ White ☐ Other (specify): _____

PRIMARY LANGUAGE SPOKEN (if other then English) _____

How did you learn about the Office for Civil Rights?

☒ HHS Website/Internet Search ☐ Family/Friend/Associate ☐ Religious/Community Org ☐ Lawyer/Legal Org ☐ Phone Directory ☐ Employer

☐ Fed/State/Local Gov ☐ Healthcare Provider/Health Plan ☐ Conference/OCR Brochure ☐ Other (specify): _____

To submit a complaint, please type or print, sign, and return completed complaint form package (including consent form) to the OCR Headquarters address below.

U.S. Department of Health and Human Services
Office for Civil Rights
Centralized Case Management Operations
200 Independence Ave., S.W.
Suite 515F, HHH Building
Washington, D.C. 20201
Customer Response Center: (800) 368-1019
Fax: (202) 619-3818
TDD: (800) 537-7697
Email: ocrmail@hhs.gov

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail complaint form to this address.**

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, which are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

Please read and review the documents entitled, *Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights* and *Protecting Personal Information in Complaint Investigations* for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.

- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose information, including personally identifying information, which it has gathered as part of its investigation of my complaint.

- In addition, I understand that as a complainant I am covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS' investigation, conciliation, or enforcement process.

After reading the above information, please check ONLY ONE of the following boxes:

[X] **CONSENT:** I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me in my case file to persons at the entity or agency under investigation or to other relevant persons, agencies, or entities during any part of HHS' investigation, conciliation, or enforcement process.

[ ] **CONSENT DENIED:** I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of my complaint and may result in closure of the investigation.

Signature: [redacted] Date: 03/06/2018

**Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.*

Name (Please print): [redacted]

Address: [redacted]

Telephone Number: [redacted]

NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 U.S.C. § 552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion, and conscience under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d *et seq.*), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794), the Age Discrimination Act of 1975 (42 U.S.C. § 6101 *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et seq.), Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§ 295m and 296g), Section 1553 of the Affordable Care Act (42 U.S.C. § 18113), the Church Amendments (42 U.S.C. § 300a-7), the Coats-Snowe Amendment (42 U.S.C. § 238n) and the Weldon Amendment (*e.g.*, Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, Tit. V, § 507);
(ii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§ 291 *et seq.* and 300s *et seq.*) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill- Burton facilities);
(iii) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(iv) Title II of the Americans with Disabilities Act (42 U.S.C. § 12131 et seq.) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.
(v) The Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule) at 45 C.F.R. Part 160 and Subparts A and E of Part 164, which enforce the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. § 1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of Federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of Federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.

OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. § 552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. § 5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act
A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. § 552) (FOIA) and HHS regulations at 45 C.F.R. Part 5.

Fraud and False Statements
Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry".

PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Because of the Privacy Act, OCR will use your name or other personal information with a signed consent and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

Access to OCR's files and records is controlled by the Freedom of Information Act (FOIA). Under FOIA, OCR may be required to release information about this case upon public request. In the event that OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals, or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If OCR receives protected health information about you in connection with a HIPAA Privacy Rule investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under the Freedom of Information Act and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages; please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed $100.00.

If you have any questions about this complaint and consent package, Please contact OCR at http://www.hhs.gov/ocr/office/about/contactus/index.html

OR

Contact the Customer Response Center at (800) 368-1019

(see contact information on page 2 of the Complaint Form)

-April 2017 - Offender Approved by gender dysphoria Care Review Committee (CRC) for hormone therapy. My religious conviction will not allow me to prescribe hormones for this indication. [redacted] provided a reasonable accommodation at that time by taking over the management of this element of the patient's healthcare request.
-September 28th forwarded KITE from NEW offender requesting renewal of hormones for GD to [redacted]
-September 29th 2017 - Annual DOC health care provider meeting. Three hours of education on Gender dysphoria (GD).
-October 2nd - Noticed KITE response from [redacted] to offender saying "follow up with PCP." [redacted] volunteered to manage this issue for the patient.
-October 4th - Medical provider meeting: [redacted] read a series of scenarios asking the providers about religious ethics in the medical field. She gave an example of a Muslim working as a hospitalist who morally objected to hospice care because he viewed it as similar to euthanasia. She gave another example of a Jehovah's Witness working in an ER who morally objected to blood transfusions. (Both of these scenarios are extreme situations that would never happen. You would never encounter a hospitalist who wouldn't be ok with hospice and you would never find an ER provider who was not ok with blood transfusions.) In both of these scenarios she emphasized the "undue hardship" that would be placed on the conscientious objector's colleagues. These were directed at me in front of my colleagues.
-October 9th - Had in person conversation with [redacted] regarding treatment of GD. She stated that it would be the expectation of the provider on site to prescribe hormones and if I decided to stay working for the DOC than I would be expected to prescribe. I expressed that it is not an option for me to prescribe for this due to my conscience and religious beliefs. I expanded that other providers have already offered to do this. (See email chain started on October 9th titled "conversation with [redacted]")
-October 12th - Email from [redacted] forwarding an email to [redacted] and myself stating "forwarding to his primary care providers." [redacted] replied to the email.
-October 18th - Forwarded KITE from offender regarding GD to [redacted] and [redacted]. Phone call with [redacted] (CMO) (@10:44 on state phone) and [redacted] (@13:02pm on work phone [redacted] Told them individually that this is a personal religious conviction that causes me to not be able to prescribe hormones for this indication but that I have found ways to mitigate this through other providers. Both of them stated that if I were to stay with the department I would be expected to prescribe this medication. If they were to allow this then it would be a slippery slope for anyone with religious convictions to not follow department policy.
-October 24th - Email from [redacted] to [redacted] stating "this is [redacted] patient and he needs to see the patient."
-October 26th around 1500 - [redacted] called [redacted] and ordered her not to prescribe any hormone therapy for inmates at IMU and to call her if I asked her to do so. Email from [redacted] with a KITE to the offender stating "Per [redacted], [redacted] is your provider while you are in the IMU"…
-October 31st - Received call from [redacted] who told me that [redacted] called her and told her she was "forbidden" from seeing my patients.
-December 11th - Email from [redacted] stating that the department cannot accommodate to my religious conviction.

-January 4th – Phone call from internal discrimination stating that there will not be an investigation as this is clearly under the rules of discrimination for Washington State.
March 6th – Received call from [redacted] (Program Manager - Diversity & Recruitment) and he states that [redacted] did not believe that my accommodation was reasonable. He did not really address my questions as to why beyond referencing policy 100.500 as their rational. That in some way I was being discriminatory. Did not feel like they addressed the fact that they are refusing to let me refer patients based on a religious belief.

I have never been discriminatory to any patient. In fact, I saw this particular patient regarding other medical issues. I told him that his hormone management would be managed by [redacted] and [redacted]. He was fine with this. I am unable to prescribe or order laboratory tests for this indication because of my conscience and religious objections and it is getting to the point where I am feeling discriminated against for my beliefs. Telling all the other providers that they cannot see any of my patients is discriminatory because this has not been done to any other providers and the reason is because of my religious belief. I am providing access to care and there are willing prescribers to manage this low acuity issue in a small subset of inmates and clearly does not pose undue hardship on anyone. There had been reasonable accommodation for this in the past but is now being taken away. I feel like [redacted] and DOC health services leadership is placing undue burden on me and is being irresponsible by knowing what I have said yet continuing to pass the issue to me as if I am going to change my mind on my deeply held convictions. Attempting to force my hand is creating a hostile work environment for me.

[redacted]

From: [redacted]
Sent: Monday, December 11, 2017 4:51 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Conscientious objection.

Hi [redacted]

My apologies. [redacted] and I have been playing "phone tag" due to our busy schedules.

After consultation with DOC Leadership, it will continue to be an expectation that you provide all health care to your patient panel. Passing patient care to another clinician due to personal beliefs is not something that the Department cannot support.

While I do respect your personal beliefs, this is something that we cannot accommodate.

[redacted]

From: [redacted]
Sent: Friday, December 08, 2017 2:03 PM
To: [redacted]
Subject: Conscientious objection.

[redacted]

I wanted to hear from you what your understanding is of my consciences objection to prescribing hormone therapy for transgender individuals. I know that [redacted] was supposed to reach out to you but I have not heard back yet. Is it still leadership's stance that if I stay employed with the DOC I will be expected to prescribe hormones for this indication and that no reasonable accommodation will be provided?

Thanks,

[redacted]

[redacted]

Monroe Correction Complex

Phone: [redacted]

[redacted]

From: [redacted]
Sent: Thursday, October 26, 2017 8:26 AM
To: [redacted]
Cc: [redacted]
Subject: RE: [redacted]

Hello,
I want to remind us all that every medical practitioner is expected to uphold the mission of the DOC and provide care to their patients as consistent with Department policies. No one practitioner is allowed to pick and choose those conditions within appropriate scope of practice that they will and will not treat. It is the responsibility of each provider to fully manage each patient's medical needs within their capabilities, escalating or referring care to specialists as appropriate. Intentionally failing or refusing to fully manage each patient's medical needs impedes the care of the patient and may lead to corrective or disciplinary action. Please note that referrals to other providers to manage these patients creates extra work burden for one's colleagues and can create a sense that the patient is being treated differently than others.

[redacted]
Chief Medical Officer
Health Services Division
Department of Corrections
Tumwater, WA 98504-1123

From: [redacted]
Sent: Wednesday, October 25, 2017 12:24 PM
To: [redacted]
Cc: [redacted]
K. [redacted]
Subject: RE: [redacted]

As discussed, you've received training on how to manage these patients, and it is expected of the midlevel providers to provide their direct care. It is not appropriate to wash your hands of this issue, which is what you are seeking to do by sending all these kites to me.

From [redacted]
Sent: Wednesday, October 25, 2017 12:21 PM
To: [redacted]
Cc:
Subject: [redacted]

[redacted]

From: [redacted]
Sent: Tuesday, October 10, 2017 7:42 PM
To: [redacted]
Subject: [redacted]

I will be at MCC again this week both Wednesday 10/11 and Thursday 10/12. I will attempt to stop by and see you then.

[redacted] Union Representative
Teamsters Local Union No. 117

[redacted]
We build unity and power for all working people to improve lives and lift up our communities. This is our Union.

Teamsters Local Union No. 117 Confidentiality Statement

This message and any attached files might contain confidential information protected by federal and state law. The information is intended only for the use of the individual(s) or entities originally named as addressees. The improper disclosure of such information may be subject to civil or criminal penalties. If this message reached you in error, please contact the sender and destroy this message. Disclosing, copying, forwarding, or distributing the information by unauthorized individuals or entities is strictly prohibited by law.

-----Original Message-----
From: [redacted]
Sent: Tuesday, October 10, 2017 8:28 AM
To: [redacted]
Subject: FW: Conversation with [redacted]

[redacted]
I am not sure what your role is but I am seeking some legal counsel as I am a teamsters member. Below is a conversation that has started surrounding the gender dysphoria issue in our state. I am a medical provider at Monroe Correctional Complex. I am a blue badge employee and have been for 2 years. The issue is this: I am ethically opposed to prescribing hormone therapy to men for the purpose of "treating" their gender dysphoria but it is the DOCs mission to do this. I am essential being told that I will need to prescribe these medications or find another Job. Do you have any suggestions on a route I should take

[redacted]
I included you because you are my union representative. Feel free to stop by the IMU to discuss further

-----Original Message-----
From: [redacted]
Sent: Tuesday, October 10, 2017 8:04 AM
To: [redacted]
Cc: [redacted]
Subject: Re: Conversation with [redacted]

Hi [redacted]

That's not quite what I said, but if it's what you took away from that conversation, please let me clarify.

You are not being asked to leave. What I said was that as an employee acting on behalf of the state, you are expected to carry out the mission of DOC, which includes providing hormone treatment for gender dysphoria. If you are unwilling to do this, then you need to examine whether DOC is the right place for you.

But as long as you continue in your role as a medical provider for DOC, you will be expected to provide this care.

Your personal beliefs do not enter into the issue, though I do recognize that your decision will be determined by them. And no one is happy that you may choose to leave.

However, if you determine that you cannot support DOC's mission in this regard, we will support you in seeking other employment, and provide an excellent recommendation.

I hope this clarifies things.

Thanks,
[redacted]

Sent from my iPhone

> On Oct 9, 2017, at 9:25 PM, [redacted]
>
> I had a conversation with [redacted] today and I wanted to make sure that I am understanding what you all decided.
>
> Essentially, it is now part of the DOCs mission to treat transgender individuals with hormone therapy and this therapy will be issued by the provider onsite once approved by the gender dysphasia CRC. And if i, the prescriber, cannot align myself with this mission due to my strong conviction that this is harmful to my patients in a medical, social, biblical, and biologic way, I will be asked to find a job elsewhere.
>
> Is this accurate?
>
> Anyone feel free to answer.
>
> Sent from my iPhone

[redacted]

From: [redacted]
Sent: Thursday, October 19, 2017 12:04 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Conversation with [redacted]

Sorry- this was stuck in my outbox from yesterday.

From: [redacted]
Sent: Thursday, October 19, 2017 12:03 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Conversation with [redacted]

[redacted]
Good speaking with you today. I understand your position and I hope I have been able to clearly articulate the importance of DOC practitioners adhering to the Department policy in treating pat6ients. As we discussed, the next step is for you to speak with [redacted]. I copy both of them as well as their assistants here.
best,
[redacted]

From: [redacted]
Sent: Monday, October 16, 2017 10:40 PM
To: [redacted]
Subject: Re: Conversation with [redacted]

[redacted] I initially told you that tomorrow might work for me but I actually will not be in tomorrow. I should be in on Wednesday however if you want to talk. Let me know. We could also just do a phone call sometime
Thanks,
[redacted]

Sent from my iPhone

On Oct 11, 2017, at 10:44 AM, [redacted] wrote:

> Hi [redacted]
> [redacted] is out of the office so I will respond.
> Thank you for reaching out and sharing your understanding of the conversation you had with [redacted] regarding the treatment of Gender Dysphoria within the Department of Corrections. It is true that it is DOC policy to provide medically appropriate treatment to individuals with Gender Dysphoria as approved by the Gender Dysphoria Care Review Committee. This includes hormonal treatment according to guidelines consistent with community practice.
> I am happy to meet and discuss your concerns with you. I could come out to Monroe next week on a mutually agreeable date.
> best,
>
> [redacted]
> Chief Medical Officer
> Health Services, Department of Corrections

From: [redacted]
Sent: Monday, October 09, 2017 9:25 PM
To: [redacted]
(DOC)
Subject: Conversation with [redacted]

I had a conversation with [redacted] today and I wanted to make sure that I am understanding what you all decided.

Essentially, it is now part of the DOCs mission to treat transgender individuals with hormone therapy and this therapy will be issued by the provider onsite once approved by the gender dysphasia CRC. And if i, the prescriber, cannot align myself with this mission due to my strong conviction that this is harmful to my patients in a medical, social, biblical, and biologic way, I will be asked to find a job elsewhere.

Is this accurate?

Anyone feel free to answer.

Sent from my iPhone

I understand. I will manage these patient by continuing to refer them to either you or one of the other providers in a timely manner just like is done with the hepatitis C patients.

From: [redacted]
Sent: Wednesday, October 25, 2017 12:03 PM
To: [redacted]
Cc: [redacted]
Subject: RE: [redacted]

[redacted]

As you've been told separately by me, [redacted] you are expected to manage patients' transgender issues while they reside on your unit, as is expected of all providers.

Thanks,

[redacted]
Facility Medical Director, MCC
[redacted]

From [redacted]
Sent: Wednesday, October 25, 2017 9:50 AM
To: [redacted]
Cc: [redacted]
Subject: RE: [redacted]

I did see the patient in regard to his Ensure request and ear pain. I told him that [redacted] would be managing his transgender issue. He had no issue with another provider seeing him for this. He was quite frustrated that he only received 2 responses from the 12 kites he has sent. Please see this patient at your convenience.
Thanks.
[redacted]

From: [redacted]
Sent: Wednesday, October 25, 2017 8:30 AM
To [redacted]
Subject: FW: [redacted]

Hey [redacted]
FYI
Thanks,

[redacted]

From: [redacted]
Sent: Tuesday, October 24, 2017 4:10 PM
To: [redacted]
Subject: RE: [redacted]

This is [redacted]atient and he needs to see the patient.

From: [redacted]
Sent: Tuesday, October 24, 2017 3:00 PM
To: [redacted]
Cc [redacted]
Subject: FW: [redacted]

Hi [redacted],
Would you like me to see [redacted] in the IMU or would you like to?
Thanks,
[redacted]

From [redacted]
Sent: Tuesday, October 24, 2017 11:32 AM
To: [redacted]
Subject: RE: [redacted]

Not sure. I asked this morning but they don't know. Could be for a few more weeks.

From: [redacted]
Sent: Tuesday, October 24, 2017 11:32 AM
To [redacted]
Subject: RE: [redacted]

Any idea on how long she will be in the IMU?

From [redacted]
Sent: Tuesday, October 24, 2017 11:19 AM
To: [redacted]
Subject: [redacted]

[redacted]
Is wanting some follow up regarding his hormones. He is not happy that his testosterone is so high. Ill defer to you.

[redacted]

No reasonable accommodation provided for my religious objection to prescribing hormones to men wanting to transition into women. When other providers offered to prescribe hormones to these patients under my care they were told by DOC leadership that they could not see my patients and no accommodation has been provided. Attached is a more detailed account as well as emails from my Facility Medical director, Chief medical officer, and the health care authority.

EXHIBIT B

Form Approved: OMB No. 0945-0002
Expiration Date: 04/30/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

Civil Rights Discrimination Complaint

YOUR FIRST NAME	YOUR LAST NAME
[redacted]	N/A
HOME PHONE (*Please include area code*)	WORK PHONE (*Please include area code*)
	[redacted]
STREET ADDRESS	CITY
[redacted]	
STATE / ZIP	E-MAIL ADDRESS (*If available*)
[redacted]	

Are you filing this complaint for someone else? ☑ Yes ☐ No

If Yes, whose civil rights do you believe were violated?

FIRST NAME	LAST NAME
American Association of ProLife Ob-Gyn	

I believe that I have been (or someone else has been) discriminated against on the basis of:

☐ Race / Color / National Origin ☐ Age ■ Religion / Conscience ☐ Sex
☐ Disability ☐ Other (specify):

Who or what agency or organization do you believe discriminated ag

PERSON / AGENCY / ORGANIZATION [redacted]

STREET ADDRESS	
409 12th Street SW	Washington
STATE / ZIP	PHONE (*Please include area code*)
D.C. 20024	(202) 638-5277

When do you believe that the occurred?

LIST DATE(S)

Starting November 2007 to present

Describe briefly what happened. How and why do you believe you have been discriminated against? Please be as specific as possible.

(Attach additional pages as needed)

Please see letter attached stating specifics

Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

SIGNATURE DATE 3/23/2018

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of Sections 1553 and 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, and other civil rights statutes. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible discrimination, for internal systems operations, or for routine uses, which include disclosure of information outside the Department of Health and Human Services (HHS) for purposes associated with civil rights compliance and as permitted by law. It is illegal for a recipient of Federal financial assistance from HHS to intimidate, threaten, coerce, or discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under Federal civil rights laws. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's web site at: **www.hhs.gov/ocr/civilrights/complaints/index.html**. To submit a complaint using alternative methods, see reverse page (page 2 of the complaint form).

The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.

Do you need special accommodations for OCR to communicate with you about this complaint? (*Check all that apply*)

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter (specify language): _____

☐ Foreign language interpreter (specify language): _____ ☐ Other: _____

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME
HOME PHONE (*Please include area code*)	WORK PHONE (*Please include area code*)

STREET ADDRESS		CITY
STATE	ZIP	E-MAIL ADDRESS (If available)

Have you filed your complaint anywhere else? If so, please provide the following. (*Attach additional pages as needed*)

PERSON / AGENCY / ORGANIZATION / COURT NAME(S)

DATE(S) FILED	CASE NUMBER(S) (If known)

To help us better serve the public; please provide the following information for the person you believe was discriminated against (you or the person on whose behalf you are filing).

ETHNICITY (*select one*)

☐ Hispanic or Latino ☐ Not Hispanic or Latino

RACE (*select one or more*)

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American ☐ White ☐ Other (specify): _____

PRIMARY LANGUAGE SPOKEN (if other than English):

How did you learn about the Office for Civil Rights?

■ HHS Website /Internet Search ☐ Family / Friend /Associate ☐ Religious /Community Org ☐ Lawyer /Legal Org ☐ Phone Directory ☐ Employer

☐ Fed /State/Local Gov ☐ Healthcare Provider /Health Plan ☐ Conference /OCR Brochure ☐ Other(*specify*):

To submit a complaint, please type or print, sign, and return completed complaint form package (including consent form) to the OCR Headquarters address below.

U.S. Department of Health and Human Services

Office for Civil Rights
Centralized Case Management Operations
200 Independence Ave., S.W.
Suite 515F, HHH Building
Washington, D.C. 20201
Customer Response Center: (800) 368-1019
Fax: (202) 619-3818
TDD: (800) 537-7697
Email: ocrmail@hhs.gov

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail this complaint form to this address.**

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, which are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

Please read and review the documents entitled, Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights and Protecting Personal Information in Complaint Investigations for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.

- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose information, including personally identifying information, which it has gathered as part of its investigation of my complaint.

- In addition, I understand that as a complainant I am covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS' investigation, conciliation, or enforcement process.

After reading the above information, please check ONLY ONE of the following boxes:

☒ **CONSENT**: I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me in my case file to persons at the entity or agency under investigation or to other relevant persons, agencies, or entities during any part of HHS' investigation, conciliation, or enforcement process.

☐ **CONSENT DENIED**: I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of my complaint and may result in closure of the investigation.

Signature: Date: 3/23/2018

**Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.*

Name (Pl[redacted]

Address:

Telephon

NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 U.S.C. § 552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion, and conscience under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d *et seq.*), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794), the Age Discrimination Act of 1975 (42 U.S.C. § 6101 *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et seq.), Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§ 295m and 296g), Section 1553 of the Affordable Care Act (42 U.S.C. § 18113), the Church Amendments (42 U.S.C. § 300a-7), the Coats-Snowe Amendment (42 U.S.C. § 238n) and the Weldon Amendment (*e.g.*, Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, Tit. V, § 507);
(ii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§ 291 *et seq.* and 300s *et seq.*) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill- Burton facilities);
(iii) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(iv) Title II of the Americans with Disabilities Act (42 U.S.C. § 12131 et seq.) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.
(v) The Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule) at 45 C.F.R. Part 160 and Subparts A and E of Part 164, which enforce the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. § 1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of Federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of Federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.

OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. § 552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. § 5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act
A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. § 552) (FOIA) and HHS regulations at 45 C.F.R. Part 5.

Fraud and False Statements
Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry".

PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Because of the Privacy Act, OCR will use your name or other personal information with a signed consent and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

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THOMAS MORE SOCIETY
A National Public Interest Law Firm

March 23, 2018

Via US Mail & email: ocrmail@hhs.gov

U.S. Department of Health and Human Services
Office of Civil Rights
Centralized Case Management Operations
200 Independence Ave., S.W.
Suite 515F, HHH Building
Washington, D.C. 20201

Re: Violations of Conscience Rights of Physicians

Dear members of the Office of Civil Rights for the Department:

We write on behalf of our client, American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG") and its Executive Director, [redacted] M.D., seeking the assistance of the Office of Civil Rights to investigate ongoing efforts by the American College of Obstetricians and Gynecologists ("ACOG") and its lobbying sister organization American Congress of Obstetrics and Gynecology ("The Congress") to stifle and countermand conscience rights of pro-life physicians to decline to perform, participate in, or assist in the performance of abortion practices because of their conscience and/or religious opposition to such practices.

AAPLOG is a nonprofit professional medical organization consisting of approximately 4,000 obstetrician-gynecologist members and associates practicing medicine in the United States and in several foreign countries. Its mission is to encourage the practice of medicine consistent with scientific truth and the Hippocratic oath, both of which it views as orienting medicine, as a healing art, toward the well-being and flourishing of all human life. ACOG is another membership organization of obstetricians and gynecologists. It purports to represent 58,000 physicians and partners. The Congress, ACOG's sister organization, a 501(c)(4) organization under the Internal Revenue Code, exists "to promote policy positions" of ACOG, in other words, to lobby. All members of ACOG are automatically members of The Congress regardless of the desire of the member to abstain from the Congress's pro-abortion lobbying.

In November 2007 ACOG issued Ethics Statement #385. **Exhibit One.** ACOG in this statement declares to be "unethical" any physician refusing to perform or refer for elective abortions. This statement was promptly and vigorously called into

question by AAPLOG, other medical associations, and speakers before the President's Council on Bioethics. See, e.g., **Exhibit Two** (AAPLOG Response of Feb. 6, 2008); **Exhibit Three** (Letter from Catholic Medical Association, February 28, 2008); **Exhibit Four** (Joint Letter of Protest by various medical organizations, Dec. 7, 2007); **Exhibit Five** (Letter by 16 Members of Congress, March 14, 2008). These and other objectors requested that ACOG retract the Ethics Statement #385 as being unsupported and discriminatory. At the same time, the Department of Health and Human Services ("HHS") sent a letter to the American Board of Obstetrics and Gynecology ("ABOG"), which is the certifying body for obstetricians and gynecologists in the U.S., objecting to the ACOG policy and questioning its influence on ob-gyn certification procedures. See **Exhibit Six** (March 14, 2008 Letter to [redacted], M.D., Executive Director ABOG). ABOG responded with a letter protesting its innocence. See **Exhibit Seven** (March 19, 2008 Letter of [redacted], M.D. to [redacted], Secretary HHS). ACOG itself responded to the criticism by promising its members to revisit Ethics Statement #385, see **Exhibit Eight** (Letter to [redacted] March 26, 2008), but it never changed the policy, instead reconfirming it, most recently in 2016.[1]

ABOG's letter (Exhibit Seven) as a disclaimer carries no legal weight, since it is not an affirmative policy statement of ABOG itself. It thus gives no assurance to a pro-life ob-gyn against accusation of unethical conduct under Ethics Statement #385 upon a conscience-based refusal to perform or refer for abortion. What is needed is an affirmative statement from ABOG declaring that a conscience-based refusal to perform or refer for abortion does *not* constitute an ethical violation. But that has not been forthcoming. Without it an ob-gyn remains vulnerable to the possibility that his or her conscience-based refusal to participate in abortion could be considered unethical, prompting a loss of board certification, loss of employment, and other professional and personal adverse consequences. In that respect, the threat posed by Ethics Statement #385 is neither imaginary nor inflated. Under ABOG's current rules, an accusation of unethical professional behavior can lead to rescission of board certification, loss of licensure, and loss of hospital privileges.[2] Indeed, the very existence of Ethics Statement #385 is a

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[1] See https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine (last visited, March 21, 2018).

[2] See 2018 Bulletin for the Certifying Examination in Obstetrics and Gynecology, accessible at https://www.abog.org/bulletins/2018%20Certifying%20Examination%20in%20Obstetrics%20and%20Gynecology.pdf (last visited March 21, 2018). The Bulletin states, at p.7: "If a candidate is involved in an investigation by a health care organization regarding practice

sword of Damocles hanging over Hippocratic oath physicians, and exerts a continuing chilling effect on their conscientious performance of ob-gyn services.

This ongoing state of affairs -- in which a licensed and board certified obstetrician-gynecologist can potentially be denied certification solely on the basis of refusal to perform or refer for abortions -- is also undesirable and counterproductive from the standpoint of public policy. As is well known, the United States suffers from a critical shortage of physicians, particularly in rural and other underserved areas of the country. To qualify and certify a single ob-gyn takes eight years of training, including four years of medical school and four years in an approved ob-gyn residency program. Qualified, dedicated ob-gyns provide desperately needed obstetric and gynecological services throughout the United States, including in rural and underserved areas of our country where their professional services often constitute the primary care for women of reproductive age. To deny certification to a fully trained ob-gyn solely because of ideological disagreement with a conscience-based objection to perform or refer for abortion would disserve all women who depend on such physicians, and exacerbate the already critical shortage of health care professionals in rural and other underserved communities, which desperately require such services. This makes no sense as sound public policy.

The 4,000 members of AAPLOG and countless other physicians consider ACOG Ethics Statement #385 to pose an intentional and systematic threat to the right of Hippocratic physicians in this country to follow, on the basis of conscience, time-honored Hippocratic principles of medicine. The very existence of this policy violates the conscience rights of all AAPLOG members, whom Dr. Harrison represents as Executive Director of AAPLOG, and the conscience rights of all pro-life physicians in this country.

For these reasons, AAPLOG hereby petitions the OCR for an investigation into:

1. The systematic and continued violation of conscience rights of Hippocratic physicians authorized by ACOG's adoption and continued advancement of Ethics Statement #385.

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activities or for ethical or moral issues, the individual will not be scheduled for examination, and a decision to approve or disapprove the application will be deferred until either the candidate has been cleared or until ABOG has received sufficient information to make a final decision." See also, at p. 8: "This means that each such medical license must not be restricted, suspended, on probation, revoked, nor include conditions of practice. The terms 'restricted' and 'conditions' include any and all limitations, terms or requirements imposed on a physician's license regardless of whether they deal directly with patient care."

2. The relationship between ABOG with ACOG, an abortion advocacy organization, and the use by ABOG of ACOG Ethics Statement #385 as a criteria for board certification.

3. The unlawful use by covered entities of ABOG board certification or ACOG Ethics Statement #385 to intimidate and discriminate against individuals in violation of federal laws protecting conscience rights.

We respectfully request your office, after investigating these issues, to take appropriate action to prevent -- both now and for the future -- ACOG's political views favoring abortion, and its policy statements arising from those views, from interfering with, curtailing, or punishing the rights of conscience of pro-life physicians and service providers. In this regard, we respectfully request that HHS issue regulations that: (1) Require covered entities to provide a clear statement that covered entities cannot discriminate against individuals or healthcare entities because they refuse to perform, refer for, or train to perform, elective abortions; and (2) Require covered entities to post notices informing all healthcare providers of their conscience rights as well as that government offices individuals or healthcare entities can contact to request assistance in the event their rights are violated.

AAPLOG believes that HHS should take these and other steps necessary to prevent ABOG and ACOG from the current cat-and-mouse strategy that is being used to intimidate and harass pro-life physicians and service providers in a manner wholly inconsistent with the letter and spirit of the federal laws protecting conscience.

Thank you for considering this complaint. Please contact the undersigned in the event additional information is needed to bring your investigation to conclusion.

Respectfully,

[redacted]

Counsel, Thomas More Society

[redacted]

Enclosures

EXHIBIT ONE

The Limits of Conscientious Refusal in Reproductive Medicine

ACOG COMMITTEE OPINION

Number 385, November 2007 *Reaffirmed 2016*

Committee on Ethics

PDF Format

The Limits of Conscientious Refusal in Reproductive Medicine

ABSTRACT: Health care providers occasionally may find that providing indicated, even standard, care would present for them a personal moral problem—a conflict of conscience—particularly in the field of reproductive medicine. Although respect for conscience is important, conscientious refusals should be limited if they constitute an imposition of religious or moral beliefs on patients, negatively affect a patient's health, are based on scientific misinformation, or create or reinforce racial or socioeconomic inequalities. Conscientious refusals that conflict with patient well-being should be accommodated only if the primary duty to the patient can be fulfilled. All health care providers must provide accurate and unbiased information so that patients can make informed decisions. Where conscience implores physicians to deviate from standard practices, they must provide potential patients with accurate and prior notice of their personal moral commitments. Physicians and other health care providers have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that patients request. In resource-poor areas, access to safe and legal reproductive services should be maintained. Providers with moral or religious objections should either practice in proximity to individuals who do not share their views or ensure that referral processes are in place. In an emergency in which referral is not possible or might negatively have an impact on a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care.

Physicians and other providers may not always agree with the decisions patients make about their own health and health care. Such differences are expected—and, indeed, underlie the American model of informed consent and respect for patient autonomy. Occasionally, however, providers anticipate that providing indicated, even standard, care would present for them a personal moral problem—a conflict of conscience. In such cases, some providers claim a right to refuse to provide certain services, refuse to refer patients to another provider for these services, or even decline to inform patients of their existing options (1).

Conscientious refusals have been particularly widespread in the arena of reproductive medicine, in which there are deep divisions regarding the moral acceptability of pregnancy termination and contraception. In Texas, for example, a pharmacist rejected a rape victim's prescription for emergency contraception, arguing that dispensing the medication was a "violation of morals" (2). In Virginia, a 42-year-old mother of two was refused a prescription for emergency contraception, became pregnant, and ultimately underwent an abortion she tried to prevent by requesting emergency contraception (3). In California, a physician refused to perform intrauterine insemination for a lesbian couple, prompted by religious beliefs and disapproval of lesbians having children (4). In Nebraska, a 19-year-old woman with a life-threatening pulmonary embolism at 10 weeks of gestation was refused a first-trimester pregnancy termination when admitted to a religiously affiliated hospital and was ultimately transferred by ambulance to another facility to undergo the procedure (5). At the heart of each of these examples of refusal is a claim of conscience—a claim that to provide certain services would compromise the moral integrity of a provider or institution.

In this opinion, the American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics considers the issues raised by conscientious refusals in reproductive medicine and outlines a framework for defining the ethically appropriate limits of conscientious refusal in reproductive health contexts. The committee begins by offering a definition of conscience and describing what might constitute an authentic claim of conscience. Next, it discusses the limits of conscientious refusals, describing how claims of conscience should be weighed in the context of other values critical to the ethical provision of health care. It then outlines options for public policy regarding conscientious refusals in reproductive medicine. Finally, the committee proposes a series of recommendations that maximize accommodation of an individual's religious or moral beliefs while avoiding imposition of these beliefs on others or interfering with the safe, timely, and financially feasible access to reproductive health care that all women deserve.

Defining Conscience

In this effort to reconcile the sometimes competing demands of religious or moral freedom and reproductive rights, it is important to characterize what is meant by conscience. Conscience has been defined as the private, constant, ethically

attuned part of the human character. It operates as an internal sanction that comes into play through critical reflection about a certain action or inaction (6). An appeal to conscience would express a sentiment such as "If I were to do 'x,' I could not live with myself/I would hate myself/I wouldn't be able to sleep at night." According to this definition, not to act in accordance with one's conscience is to betray oneself—to risk personal wholeness or identity. Thus, what is taken seriously and is the specific focus of this document is not simply a broad claim to provider autonomy (7), but rather the particular claim to a provider's right to protect his or her moral integrity—to uphold the "soundness, reliability, wholeness and integration of [one's] moral character" (8).

Personal conscience, so conceived, is not merely a source of potential conflict. Rather, it has a critical and useful place in the practice of medicine. In many cases, it can foster thoughtful, effective, and humane care. Ethical decision making in medicine often touches on individuals' deepest identity–conferring beliefs about the nature and meaning of creating and sustaining life (9). Yet, conscience also may conflict with professional and ethical standards and result in inefficiency, adverse outcomes, violation of patients' rights, and erosion of trust if, for example, one's conscience limits the information or care provided to a patient. Finding a balance between respect for conscience and other important values is critical to the ethical practice of medicine.

In some circumstances, respect for conscience must be weighed against respect for particular social values. Challenges to a health care professional's integrity may occur when a practitioner feels that actions required by an external authority violate the goals of medicine and his or her fiduciary obligations to the patient. Established clinical norms may come into conflict with guidelines imposed by law, regulation, or public policy. For example, policies that mandate physician reporting of undocumented patients to immigration authorities conflict with norms such as privacy and confidentiality and the primary principle of nonmaleficence that govern the provider–patient relationship (10). Such challenges to integrity can result in considerable moral distress for providers and are best met through organized advocacy on the part of professional organizations (11, 12). When threats to patient well-being and the health care professional's integrity are at issue, some individual providers find a conscience-based refusal to comply with policies and acceptance of any associated professional and personal consequences to be the only morally tenable course of action (10).

Claims of conscience are not always genuine. They may mask distaste for certain procedures, discriminatory attitudes, or other self-interested motives (13). Providers who decide not to perform abortions primarily because they find the procedure unpleasant or because they fear criticism from those in society who advocate against it do not have a genuine claim of conscience. Nor do providers who refuse to provide care for individuals because of fear of disease transmission to themselves or other patients. Positions that are merely self-protective do not constitute the basis for a genuine claim of conscience. Furthermore, the logic of conscience, as a form of self-reflection on and judgment about whether one's own acts are obligatory or prohibited, means that it would be odd or absurd to say "I would have a guilty conscience if she did 'x.'" Although some have raised concerns about complicity in the context of referral to another provider for requested medical care, the logic of conscience entails that to act in accordance with conscience, the provider need not rebuke other providers or obstruct them from performing an act (8). Finally, referral to another provider need not be conceptualized as a repudiation or compromise of one's own values, but instead can be seen as an acknowledgment of both the widespread and thoughtful disagreement among physicians and society at large and the moral sincerity of others with whom one disagrees (14).

The authenticity of conscience can be assessed through inquiry into 1) the extent to which the underlying values asserted constitute a core component of a provider's identity, 2) the depth of the provider's reflection on the issue at hand, and 3) the likelihood that the provider will experience guilt, shame, or loss of self-respect by performing the act in question (9). It is the genuine claim of conscience that is considered next, in the context of the values that guide ethical health care.

Defining Limits for Conscientious Refusal

Even when appeals to conscience are genuine, when a provider's moral integrity is truly at stake, there are clearly limits to the degree to which appeals to conscience may justifiably guide decision making. Although respect for conscience is a value, it is only a prima facie value, which means it can and should be overridden in the interest of other moral obligations that outweigh it in a given circumstance. Professional ethics requires that health be delivered in a way that is respectful of patient autonomy, timely and effective, evidence based, and nondiscriminatory. By virtue of entering the profession of medicine, physicians accept a set of moral values—and duties—that are central to medical practice (15). Thus, with professional privileges come professional responsibilities to patients, which must precede a provider's personal interests (16). When conscientious refusals conflict with moral obligations that are central to the ethical practice of medicine, ethical care requires either that the physician provide care despite reservations or that there be resources in place to allow the patient to gain access to care in the presence of conscientious refusal. In the following sections, four criteria are highlighted as important in determining appropriate limits for conscientious refusal in reproductive health contexts.

1. Potential for Imposition

The first important consideration in defining limits for conscientious refusal is the degree to which a refusal constitutes an imposition on patients who do not share the objector's beliefs. One of the guiding principles in the practice of medicine is respect for patient autonomy, a principle that holds that persons should be free to choose and act without controlling constraints imposed by others. To respect a patient's autonomy is to respect her capacities and perspectives, including her right to hold certain views, make certain choices, and take certain actions based on personal values and beliefs (17). Respect involves acknowledging decision-making rights and acting in a way that enables patients to make choices for themselves. Respect for autonomy has particular importance in reproductive decision making, which involves private, personal, often pivotal decisions about sexuality and childbearing.

It is not uncommon for conscientious refusals to result in imposition of religious or moral beliefs on a patient who may not share these beliefs, which may undermine respect for patient autonomy. Women's informed requests for contraception or sterilization, for example, are an important expression of autonomous choice regarding reproductive decision making. Refusals to dispense contraception may constitute a failure to respect women's capacity to decide for themselves whether and under what circumstances to become pregnant.

Similar issues arise when patients are unable to obtain medication that has been prescribed by a physician. Although pharmacist conduct is beyond the scope of this document, refusals by other professionals can have an important impact on a physician's efforts to provide appropriate reproductive health care. Providing complete, scientifically accurate information about options for reproductive health, including contraception, sterilization, and abortion, is fundamental to respect for patient autonomy and forms the basis of informed decision making in reproductive medicine. Providers refusing to provide such information on the grounds of moral or religious objection fail in their fundamental duty to enable patients to make decisions for themselves. When the potential for imposition and breach of autonomy is high due either to controlling constraints on medication or procedures or to the provider's withholding of information critical to reproductive decision making, conscientious refusal cannot be justified.

2. Effect on Patient Health

A second important consideration in evaluating conscientious refusal is the impact such a refusal might have on well-being as the patient perceives it—in particular, the potential for harm. For the purpose of this discussion, harm refers to significant bodily harm, such as pain, disability, or death or a patient's conception of well-being. Those who choose the profession of medicine (like those who choose the profession of law or who are trustees) are bound by special fiduciary duties, which oblige physicians to act in good faith to protect patients' health—particularly to the extent that patients' health interests conflict with physicians' personal or self-interest (16). Although conscientious refusals stem in part from the commitment to "first, do no harm," their result can be just the opposite. For example, religiously based refusals to perform tubal sterilization at the time of cesarean delivery can place a woman in harm's way—either by putting her at risk for an undesired or unsafe pregnancy or by necessitating an additional, separate sterilization procedure with its attendant and additional risks.

Some experts have argued that in the context of pregnancy, a moral obligation to promote fetal well-being also should justifiably guide care. But even though views about the moral status of the fetus and the obligations that status confers differ widely, support of such moral pluralism does not justify an erosion of clinicians' basic obligations to protect the safety of women who are, primarily and unarguably, their patients. Indeed, in the vast majority of cases, the interests of the pregnant woman and fetus converge. For situations in which their interests diverge, the pregnant woman's autonomous decisions should be respected (18). Furthermore, in situations "in which maternal competence for medical decision making is impaired, health care providers should act in the best interests of the woman first and her fetus second" (19).

3. Scientific Integrity

The third criterion for evaluating authentic conscientious refusal is the scientific integrity of the facts supporting the objector's claim. Core to the practice of medicine is a commitment to science and evidence-based practice. Patients rightly expect care guided by best evidence as well as information based on rigorous science. When conscientious refusals reflect a misunderstanding or mistrust of science, limits to conscientious refusal should be defined, in part, by the strength or weakness of the science on which refusals are based. In other words, claims of conscientious refusal should be considered invalid when the rationale for a refusal contradicts the body of scientific evidence.

The broad debate about refusals to dispense emergency contraception, for example, has been complicated by misinformation and a prevalent belief that emergency contraception acts primarily by preventing implantation (20). However, a large body of published evidence supports a different primary mechanism of action, namely the prevention of fertilization. A review of the literature indicates that Plan B can interfere with sperm migration and that preovulatory use of Plan B suppresses the luteinizing hormone surge, which prevents ovulation or leads to the release of ova that are resistant to fertilization. Studies do not support a major postfertilization mechanism of action (21). Although even a slight possibility of postfertilization events may be relevant to some women's decisions about whether to use contraception, provider refusals to dispense emergency contraception based on unsupported beliefs about its primary mechanism of action should not be justified.

In the context of the morally difficult and highly contentious debate about pregnancy termination, scientific integrity is one of several important considerations. For example, some have argued against providing access to abortion based on claims that induced abortion is associated with an increase in breast cancer risk; however, a 2003 U.S. National Cancer Institute panel concluded that there is well-established epidemiologic evidence that induced abortion and breast cancer are not associated (22). Refusals to provide abortion should not be justified on the basis of unsubstantiated health risks to women.

Scientific integrity is particularly important at the level of public policy, where unsound appeals to science may have masked an agenda based on religious beliefs. Delays in granting over-the-counter status for emergency contraception are one such example. Critics of the U.S. Food and Drug Administration's delay cited deep flaws in the science and evidence used to justify the delay, flaws these critics argued were indicative of unspoken and misplaced value judgments (23). Thus, the scientific integrity of a claim of refusal is an important metric in determining the acceptability of conscience-based practices or policies.

4. Potential for Discrimination

Finally, conscientious refusals should be evaluated on the basis of their potential for discrimination. Justice is a complex and important concept that requires medical professionals and policy makers to treat individuals fairly and to provide medical services in a nondiscriminatory manner. One conception of justice, sometimes referred to as the distributive paradigm, calls for fair allocation of society's benefits and burdens. Persons intending conscientious refusal should consider the degree to which they create or reinforce an unfair distribution of the benefits of reproductive technology. For instance, refusal to dispense contraception may place a disproportionate burden on disenfranchised women in resource-poor areas. Whereas a single, affluent professional might experience such a refusal as inconvenient and seek out another physician, a young mother of three depending on public transportation might find such a refusal to be an insurmountable barrier to medication because other options are not realistically available to her. She thus may experience loss of control of her reproductive fate and quality of life for herself and her children. Refusals that unduly burden the most vulnerable of society violate the core commitment to justice in the distribution of health resources.

Another conception of justice is concerned with matters of oppression as well as distribution (24). Thus, the impact of conscientious refusals on oppression of certain groups of people should guide limits for claims of conscience as well. Consider, for instance, refusals to provide infertility services to same-sex couples. It is likely that such couples would be able to obtain infertility services from another provider and would not have their health jeopardized, per se. Nevertheless, allowing physicians to discriminate on the basis of sexual orientation would constitute a deeper insult, namely reinforcing the scientifically unfounded idea that fitness to parent is based on sexual orientation, and, thus, reinforcing the oppressed status of same-sex couples. The concept of oppression raises the implications of all conscientious refusals for gender justice in general. Legitimizing refusals in reproductive contexts may reinforce the tendency to value women primarily with regard to their capacity for reproduction while ignoring their interests and rights as people more generally. As the place of conscience in reproductive medicine is considered, the impact of permissive policies toward conscientious refusals on the status of women must be considered seriously as well.

Some might say that it is not the job of a physician to "fix" social inequities. However, it is the responsibility, whenever possible, of physicians as advocates for patients' needs and rights not to create or reinforce racial or socioeconomic inequalities in society. Thus, refusals that create or reinforce such inequalities should raise significant caution.

Institutional and Organizational Responsibilities

Given these limits, individual practitioners may face difficult decisions about adherence to conscience in the context of professional responsibilities. Some have offered, however, that "accepting a collective obligation does not mean that all members of the profession are forced to violate their own consciences" (1). Rather, institutions and professional organizations should work to create and maintain organizational structures that ensure nondiscriminatory access to all professional services and minimize the need for individual practitioners to act in opposition to their deeply held beliefs. This requires at the very least that systems be in place for counseling and referral, particularly in resource-poor areas where conscientious refusals have significant potential to limit patient choice, and that individuals and institutions "act affirmatively to protect patients from unexpected and disruptive denials of service" (13). Individuals and institutions should support staffing that does not place practitioners or facilities in situations in which the harms and thus conflicts from conscientious refusals are likely to arise. For example, those who feel it improper to prescribe emergency contraception should not staff sites, such as emergency rooms, in which such requests are likely to arise, and prompt disposition of emergency contraception is required and often integral to professional practice. Similarly, institutions that uphold doctrinal objections should not position themselves as primary providers of emergency care for victims of sexual assault; when such patients do present for care, they should be given prophylaxis. Institutions should work toward structures that reduce the impact on patients of professionals' refusals to provide standard reproductive services.

Recommendations

Respect for conscience is one of many values important to the ethical practice of reproductive medicine. Given this framework for analysis, the ACOG Committee on Ethics proposes the following recommendations, which it believes maximize respect for health care professionals' consciences without compromising the health and well-being of the women they serve.

1. In the provision of reproductive services, the patient's well-being must be paramount. Any conscientious refusal that conflicts with a patient's well-being should be accommodated only if the primary duty to the patient can be fulfilled.
2. Health care providers must impart accurate and unbiased information so that patients can make informed decisions about their health care. They must disclose scientifically accurate and professionally accepted characterizations of reproductive health services.
3. Where conscience implores physicians to deviate from standard practices, including abortion, sterilization, and provision of contraceptives, they must provide potential patients with accurate and prior notice of their personal moral commitments. In the process of providing prior notice, physicians should not use their professional authority to argue or advocate these positions.
4. Physicians and other health care professionals have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that their patients request.
5. In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections.
6. In resource-poor areas, access to safe and legal reproductive services should be maintained. Conscientious refusals that undermine access should raise significant caution. Providers with moral or religious objections should either practice in proximity to individuals who do not share their views or ensure that referral processes are in place so that patients have access to the service that the physician does not wish to provide. Rights to withdraw from caring for an individual should not be a pretext for interfering with patients' rights to health care services.
7. Lawmakers should advance policies that balance protection of providers' consciences with the critical goal of ensuring timely, effective, evidence-based, and safe access to all women seeking reproductive services.

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ISSN 1074-861X

EXHIBIT TWO

AAPLOG - AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS
EXECUTIVE OFFICE: AAPLOG 339 River Ave, Holland, MI 49423 Website: www.aaplog.org
Telephone: (616) 546-2639 E-Mail: prolifeob@aol.com
February 6, 2008

AAPLOG RESPONSE TO THE ACOG ETHICS COMMITTEE OPINION #385, TITLED "THE LIMITS OFCONSCIENTIOUS REFUSAL IN REPRODUCTIVE MEDICINE"

The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), one of the largest Special Interest Groups of the American College of Obstetricians and Gynecologists (ACOG), strongly objects to the November 2007 release of ACOG Committee Opinion, Number 385, titled "The Limits of Conscientious Refusal in Reproductive Medicine."

We find it unethical and unacceptable that a small committee of ACOG members would pretend to provide the moral compass for 49,000 other members on one of the most ethically controversial issues in our society and within our medical specialty—and that without ever consulting the full membership.

ACOG Committee Opinion #385 is in opposition to 2500 years of accepted Hippocratic ethical medical tradition. Legal elective abortion made a unique arrival in the late 1960s in the United States as part of a legal-societal initiative, rather than as the culmination of a scientific process in biomedicine. The acceptance of elective abortion in American medical practice was contrary to the historic ethical position of Western medicine with regard to abortion.

Therefore it is of great concern that this committee opinion repeatedly describes elective abortion, and other controversial reproductive medical procedures and services as "standard." The term "standard," as used in the document, is never defined. Ideally, a care "standard" would involve a balanced and thorough consideration of the existing medical literature for the effect on the patient's health and well being, both in the short term and in the long term. There is scant evidence regarding the outcomes of elective abortion, other than its decided effectiveness at ending a pregnancy. In general, the long term safety of abortion, and its "benefit" for women, has been either assumed, or accepted on the basis of inadequate follow-up studies.

On the contrary, there are poor reproductive and other health outcomes associated with elective abortion in methodologically sound scientific studies. The data from nations with extensive computer based health registries, where linkage with subsequent health outcomes is a practical reality, show that elective

abortion has significant adverse association with subsequent preterm birth,[1] depression,[2] suicide,[3] placenta previa.[4] and breast cancer.[5] ("Although it remains uncertain whether elective abortion increases subsequent breast cancer, it is clear that a decision to abort and delay pregnancy culminates in a loss of protection with the net effect being an increased risk.")[4]

While there may be conflicting data with regard to these issues, ACOG documents have summarily denied the significance of any literature demonstrating an association. We are aware of no current ACOG educational materials providing balance to this extreme position.

In this regard, we also find the Opinion statement, "Health care providers must impart accurate and unbiased information so that patients can make informed decisions about their health care," to be at odds with the actual practice of informed consent in elective abortion. The College has allowed the development of a procedure (elective abortion) in its specialty area for which record keeping is inadequate and meaningful tracking of complications is virtually impossible. There is a relative absence of data collected on abortion and subsequent health status in the United States. ACOG has colluded in this state of affairs by not insisting on adequate record keeping and reporting for this procedure. Since accurate risk and complication rates are unavailable, it is vacuous to make reference to "accurate and unbiased information" for making "informed" decisions.

Further, in most instances, the abortion practitioner is not responsible to care for "complications" of his or her work, and often may not even be aware that a complication has occurred. Rather, the emergency room physician, or the obstetrician/gynecologist on call for the emergency department, inherits untoward fallout of abortion. Therefore the physician performing the procedure cannot even accurately reference his or her own experience with regard to complications in informed consent conversations. This is the only instance in American medicine where the operating physician is not the primary physician responsible for the initial oversight of complications of their surgical procedure. Perhaps the ACOG

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[1] National Academy of Science's Institute of Medicine report " Preterm Birth: Causes, Consequences, and Prevention." July 2006, Appendix, page 518-19; Calhoun, B, Rooney, B; "Induced Abortion and Risk of Later Premature Birth," Journal of American Physicians and Surgeons, Volt 8, #2, 2003.

[2] David M. Fergusson, et al; "Abortion In Young Women And Subsequent Mental Health," J. of Child Psychology and Psychiatry, Vol 47:1 2006.

[3] Gissler, M, et.al., "Pregnancy associated deaths in Finland 1987-1994, Acta Obsetricia et Gynecologica Scandinavica 76:651-657, 1997.

[4] Thorp, et al, "Long Term Physical and Psychological Health Consequences of Induced Abortion: Review of the Evidence," OB GYN Survey, Vol 58, No. 1, 2002.

[5] MacMahon, et al, Bull. "Age at First Birth and Breast Cancer Risk", WHO 43:209-221, 1970; Trichopolous D, Hsieh C, MacMahon B, Lin T, et al, Age at any Birth and Breast Cancer Risk, International J Cancer, 31:70l-704, 1983.

Committee on Ethics should address the strange ethics of this "prevailing standard" of reproductive health service.

Dr. Allan Sawyer, who is an AAPLOG member and current Chairman of the ACOG Committee on Coding and Nomenclature, as well as chairman of a hospital ethics committee, has stated in a prior letter to ACOG, "It is a foundational principle of ethics that autonomy must be balanced by the other principles of ethics. Any one principle of ethics cannot trump all of the others, otherwise there is distortion of truth and the dominant principle ends up skewing the analysis. The end result often is anything but ethical. ACOG's Committee Opinion #385 is an excellent example of the collapse of ethical decision-making when patient autonomy is allowed to dominate over every other principle of ethics. This is not so much an ethics committee opinion as it is a document that promotes the right-to-abortion-on-demand stance of ACOG."[6] Dr. Sawyer's comments accurately reflect AAPLOG's position on this issue.

The idea that physicians are obligated to provide or refer for elective abortion services simply on the basis of "patient request" is antithetical to the practice of modern medicine. It is to make patient autonomy rule over physician conscience. It is to make the physician the corner vendor. A more balanced approach would be to accept that where opinions vary, the patient is free to seek a second opinion, but not to impose her will on the attending physician.

The Ethics Committee directive that those who oppose elective abortion on conscience grounds should locate their practice in proximity to an abortionist for patient convenience is patently absurd. Quite apart from our conscience convictions, this is a completely unrealistic idea. Conformity with this recommendation would result in large swathes of the United States being without any obstetric or gynecologic care (the large majority of abortion clinics are located in the inner city).

The Committee Opinion informs us that conscience based refusals should be evaluated on the basis of their potential for discrimination. For years a glaring example of systematic discrimination has been implicitly accepted within the current provision of abortion services nationwide. Year after year, African-American women have their unborn children aborted at a per capita rate three times that of Caucasian women. There has never been a protest from ACOG against this extreme disproportion in the actual distribution of abortion services. What would the Ethics Committee advise to rectify this inequity? Should the abortion rate be increased for Caucasian women, or should the abortion rate be decreased for African-American women, in order to meet the standards of justice and equitable distribution of reproductive health services?

[6] Used with Dr. Sawyer's permission

Finally, it seems that the Ethics Committee does not understand the strength and depth of a conscience conviction against the elective, deliberate taking of an unborn human life. This is not a negotiable issue for those who hold this conviction. The United States Supreme Court allowed elective abortion to be a legal right. The U.S. Supreme Court is not an infallible moral guide for a person's conscience, as evidenced by a previous similar egregious ruling.[7]

For these reasons, we, the AAPLOG board of directors, find this Committee Opinion to be neither scientifically nor ethically sound. We strongly urge that Committee Opinion #385 be rescinded at the earliest opportunity.

Sincerely,

Joseph L. DeCook, MD, FACOG, Vice-President, AAPLOG, for the Executive Committee and the Board of AAPLOG

[7] We reference the infamous Dred Scott vs Sanford case of 1857, in which the Supreme Court of the United States found, by a 7-2 majority, that no person of African descent could claim U.S. Citizenship. (Africans, according to the Court, were "beings of an inferior order, and altogether unfit to associate with the white race,… so far inferior that they had no rights which the white man was bound to respect.") Since slaves had no claim to citizenship, they could not bring suit in court. We find the status of the unborn under Roe to be strikingly similar to the plight of the African slaves under Dred Scott: Both are human beings, but neither had/has basic human rights: neither had/has the legal right to appeal to the courts for justice or protection when they were/are victims of inhumane treatment or purposeful killing.

EXHIBIT THREE

[redacted]D.
Board President
American College of Obstetricians and Gynecologists
409 12th St., S.W.
Washington, D.C. 20090-6920
February 28, 2008

Dear[redacted]:

On November 7, 2007, the American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics released an Opinion, "The Limits of Conscientious Refusal in Reproductive Medicine" (the "Opinion"), which attempts to resolve the issue of ethically appropriate limits of conscientious judgments in reproductive medicine. This is an issue that demands serious attention and sustained dialogue. Unfortunately, however, the Opinion not only fails to provide helpful guidance, but is so flawed that it threatens the reputation of ACOG itself. The Catholic Medical Association urges ACOG to rescind this opinion immediately.

The Committee on Ethics' Opinion exhibits three fatal flaws: (1) it is woefully inadequate in basic ethical theory and analysis; (2) the "considerations" advanced to limit conscientious judgments are so vague and contentious that they cannot meaningfully function as ethical or professional guidelines; and (3) the solutions proposed are unjust, unworkable, and harmful to the profession of medicine. We elaborate on these points briefly below.

1. Flaws in Ethical Analysis. The Opinion contains a seriously flawed and gratuitously condescending approach to conscience. The Opinion describes conscience in limited, negative, emotional terms, emphasizing such terms as "private," "sanction," "sentiment," and emotions such as self-hatred. At best, the Opinion notes, "Personal conscience, so conceived, is not merely a source of potential conflict." In fact, however, while conscience is a personal, subjective judgment, it is not merely "private" or relativistic. Conscientious judgments provide guidance both for good actions that should be done and unethical actions that should be refused. It is true that conscientious judgments are at times accompanied by emotion, particularly in conflict cases. Still, conscience is not a matter of feeling, as the Opinion suggests, but a judgment about moral truth.

In addition to providing an inadequate description of the nature and role of conscience, the Opinion fails to do justice to the ethical issue of cooperation in evil raised by providing referrals for abortion and, indeed, dismisses concerns about complicity in gravely immoral actions.

This disregard for the harm caused by complicity in moral evil is particularly hard to understand given the painful lessons the medical profession learned from physicians' silent tolerance of, or complicity in, the crimes against humanity in Nazi Germany. Here in the United States, in the infamous Tuskegee Syphilis Study, U.S. Public Health Service physicians denied treatment to patients with syphilis so they could study the late stages of the disease. Moreover, physicians participated or acquiesced in involuntary sterilizations under color of law in more than 30 more states between 1907 and the early 1970s. All agree now that these practices were unethical and a violation of patients' rights and that physicians were wrong to cooperate, even tacitly, or to remain silent, even when they were not direct participants.

The Opinion mentions, but fails to describe, what it means by the "set of moral values – and duties – that are central to medical practice." Since the Opinion goes on to list four "criteria" that ostensibly trump physicians' ethical convictions, it appears that these are the moral values and duties the Ethics Committee has in mind. Inexplicably missing in this section of the Opinion is any mention of respect for human life, which *has* been recognized by most physicians across centuries and cultures as a fundamental value and duty that *is* central to the practice of medicine.

Finally, the Opinion attempts, in several ways, to legitimize a moral duty to provide any requested "reproductive service." The Opinion appeals to terminology such as "standard care," "standard reproductive services," and "standard practices" without ever defining who or what has established these standards. The Opinion attempts to conflate the duty to provide treatment in an emergency with a new obligation – to provide "medically indicated and requested care" where failure to do so "might" negatively affect a patient's "mental health." This so-called obligation is unnecessary and completely unfounded. Our position is that elective abortion is not healthcare, nor does it qualify as an emergency. In a true emergency, where a pregnant woman's life is in danger, physicians can and should strive to save the lives of the mother and her unborn child.

2. Considerations Limiting Conscientious Refusal. The "considerations" that the Opinion claims limit conscientious judgments are so vague and contentious that they cannot meaningfully function as ethical guidelines. For example, the Opinion cites the "degree of imposition" as a criterion for overriding the ethical and professional judgment of physicians. It is

not clear at all what kinds or degrees of "imposition" will trump ethical judgment, much less why they should. In appealing to the criterion of "effect on patient health," the Opinion unfairly assumes that all requested reproductive interventions (including abortion or egg harvesting) are in fact good for the patient's health. Moreover, it unfairly implies that physicians with ethical objections to such practices are not motivated precisely by concern for the patient's short and long term health. In appealing to the category of scientific integrity, the Opinion overstates the certainty that current science can provide about the mechanism of drugs (such as those used in Plan B). And it fails to recognize that the real "possibility of postfertilization events" inherent in the use of such drugs *is* a valid matter for a professional's clinical and ethical judgment. Finally, in appealing to "matters of oppression," the Opinion injects a dubious political criterion into the heart of medical decision-making.

3. Solutions Proposed. The Opinion proposes solutions that are unjust, unworkable, and harmful to the profession of medicine. The Opinion unfairly dictates that only physicians who oppose a specific set of medical "services" should be required to provide patients with "prior notice of their personal moral commitments." We think that *all* physicians should be ready to explain, whenever appropriate, their ethical convictions with regard to medical practice and care. To suggest that providers with pro-life ethical convictions "practice in proximity to individuals who do not share their views" is unworkable.

The solutions proposed in the Opinion are not only unjust and unworkable, but harmful to the profession of medicine. First, by negatively and narrowly defining conscience and by suggesting that judgments of conscience are best left to "organized advocacy" groups, the Opinion tacitly discourages physicians from thinking and acting in accordance with their judgment of what is ethical or unethical. The demand that physicians provide "professionally accepted characterizations of reproductive health services" shows distrust of professionals and of the quality of the medical profession as a whole. Second, in appealing to the vague criterion of past discrimination allegedly suffered by some people, the Opinion allows values and considerations extraneous to the practice and profession of medicine to dictate treatment modalities.

Third, the Opinion invites lawmakers to enforce compliance with these vague and contentious notions. This would run counter to AMA Code of Ethics Opinion E-10.05: "[I]t may be ethically permissible for physicians to decline a potential patient when . . . [a] specific treatment sought by an individual is incompatible with the physician's personal, religious, or moral beliefs." Moreover, this expressly contradicts ACOG's own Statement of Policy on Abortion: "The intervention of legislative bodies into medical decision making is inappropriate, ill-advised and dangerous."

Such legislation could not help but undermine the freedom and integrity of the profession of medicine and invite additional litigation and legislation that have nothing to do with promoting the health of women. Indeed, ACOG should be aware that legislation attempting to enforce this Opinion would violate constitutional and statutory protections of physicians' freedom of religion and conscience rights at federal and state levels. Finally, driving out physicians who respect the value of every human life – born and unborn – from the profession of obstetrics and gynecology would harm the profession and the health of many women and children.

There is a great deal of work to be done in assisting members of ACOG to practice medicine conscientiously, and to educate patients on what this means and why it is important. We stand ready to assist in this task. However, to be valid, any effort will have to be based on sound ethical analysis, undertaken in a spirit of dialogue, with respect for diversity in beliefs. The Committee on Ethics Opinion No. 385 falls significantly short in all these respects. Therefore, it should be rescinded immediately.

Respectfully,

[redacted]

President, Catholic Medical Association

[redacted]

Executive Director, Catholic Medical Association

cc.:

[redacted]

Chair, ACOG Committee on Ethics

[redacted]

c/o ACOG Ethics Committee

[redacted]

c/o ACOG Ethics Committee

EXHIBIT FOUR

Project Logo **Protection of Conscience Project**
www.consciencelaws.org
Service, not Servitude

Joint Letter of Protest

Christian Medical Association *et al*

Reproduced with permission

December 7, 2007

American College of Obstetricians and Gynecology
Douglas W. Laube, MD, President
PO Box 96920
Washington, D.C. 20090-6920

Dear [redacted]:

The undersigned individuals and organizations urge the repudiation and withdrawal of the recently published position statement of The Committee on Ethics of the American College of Obstetricians and Gynecologists (ACOG), "The Limits of Conscientious Refusal in Reproductive Medicine."

The ACOG statement suggests a profound misunderstanding of the nature and exercise of conscience, an underlying bias against persons of faith and an apparent attempt to disenfranchise physicians who oppose ACOG's political activism on abortion.

The paper indicates that ACOG views the exercise of conscience and faith not so much as a cornerstone right in a democracy or as a historic hallmark of medicine, but rather as an inconvenient obstacle to abortion access.

A few excerpts from ACOG's paper illustrate these concerns:

> 1. "An appeal to conscience would express a sentiment such as 'If I were to do 'x,' I could not live with myself / I would hate myself, I wouldn't be able to sleep at night."

By caricaturing conscience as a pitifully self-centered, subjective feeling, ACOG denigrates the objective sources of conviction. Physicians of faith base decisions of conscience not on personal whims and feelings but on the objective teachings of Scripture--the same Scriptures that have provided the foundation for the laws of much of civilization. A physician's conscience may also be informed by time-honored ethical standards such as the Hippocratic Oath, which for centuries provided a foundation for medical ethics until abortion advocacy censored its teachings.

> 2. Physicians may not exercise their right of conscience if that might "constitute an imposition of religious or moral beliefs on patients."

is tantamount to "imposing religious or moral beliefs on patients."

> 3. "Physiciansâ€¦have the duty to refer patients in a timely manner to other providers if they do not feel they can in conscience provide the standard reproductive service that patients request."

This assertion contradicts a basic corollary of conscience. The same life-honoring, objective principles- "Thou shalt not kill," and "first, do no harm"--that persuade many conscientious physicians not to perform abortions also persuade them not to recommend someone else to do the deed.

> 4. "All healthcare providers must provide accurate and unbiased information so that patients can make informed decisions."

Normally no one would question this principle, but in this case, context is everything. Since ACOG has gone to court to fight laws requiring abortion doctors to offer informed consent information to patients on the risks and alternatives to abortion,[1] clearly ACOG intends to selectively apply this requirement only to pro-life physicians to force them to offer abortion as an option.

> 5. "Providers with moral or religious objections should â€¦ practice in proximity to individuals who do not share their viewsâ€¦"

It is incredible that ACOG would actually require a pro-life physician to relocate his or her practice to be close to an abortion facility. Besides the fact that this drastic requirement is selectively invoked only against pro-life doctors, it would also have the negative practical impact of removing desperately needed doctors from underserved areas.

ACOG's misguided and uninformed public statement on conscience limits is bound to have the effect, whether unintended or actually intended, of discouraging persons of faith from practicing or choosing obstetrics and gynecology as a profession. At a time when many communities are already suffering the loss of obstetricians and gynecologists forced out of their practices for economic reasons, it seems especially unwise to send such a message of ideological intolerance and religious discrimination.

ACOG's aggressive political advocacy for abortion has significantly impaired its ability to speak for all physicians and to judge matters of medical ethics without bias. We urge ACOG to reconsider and withdraw this statement as a step toward remedying that lamentable loss of respectability and credibility.

Sincerely,

[redacted]

Notes

1. American College of Obstetricians v. Thornburgh, 737 F.2d 283, 297-98 (3d Cir.1984).

cc: ACOG Executive Board Affairs
ACOG Government Relations
ACOG Clinical Practice

EXHIBIT FIVE

Congress of the United States
Washington, DC 20515

March 14, 2008

[redacted] MD, MS, President
The American College of Obstetricians and Gynecology
409 12th Street, SW
Washington, DC 20090-6920

Dear [redacted],

We are deeply concerned to learn of The American College of Obstetricians and Gynecology (ACOG) Committee Opinion #385 which could destroy the rights of conscience for pro-life obstetricians and gynecologists across our nation. Conforming to this guideline would force pro-life OB-GYNs to violate their moral and ethical beliefs regarding controversial issues like abortion. Furthermore, when paired with newly revised certification policies of the American Board of Obstetrics and Gynecology that condition board certification on compliance with ACOG ethics guidelines, we are concerned that the views represented in Opinion #385 can be used to force valuable pro-life OB-GYNs out of the practice of medicine for exercising their rights of conscience. *If used as a basis for decertifying physicians, these physicians* would most likely lose hospital privileges and effectively be put out of business, denying the physician's right to practice his or her profession. Moreover, pro-life women would lose the right to choose OB-GYNs who share their moral convictions.

As you know, Opinion #385 entitled "The Limits of Conscientious Refusal in Reproductive Medicine," contains seven recommendations that we believe jeopardize the rights of conscience of OB/GYNs. This report calls on OB-GYNs to disregard their moral, ethical or religious objections to abortion and instructs them to perform or refer for abortion. Opinion #385 also obligates the protection of the liberty interests of the pregnant women over the life and health of the unborn child, regardless of what the provider believes is in the best interests of both patients. This is a worrisome departure from professional standards set by state legislatures and other professional medical organizations such as the American Medical Association (AMA). The AMA House of Delegates policy on abortion states: "Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally held moral principles." Currently, nearly all states recognize the right of physicians to refuse to provide abortions.

We are aware that member physicians and civil rights organizations have requested for clarification on Opinion #385. We, as Members of the House of Representative are asking the same and want assurance that OB-GYNs will not face severe consequences, including decertification, for refusing to perform or refer for an abortion on grounds of conscience. In light of these concerns, we request a clear explanation of whether Opinion #385 represents the official position of ACOG and what outcomes were intended by those who crafted Opinion #385. Furthermore, as the largest American association of OBGYNs, we ask that you provide further clarification by

explaining the general intent, import and force of ACOG Ethics Opinions as applied under ABOG's 2008 MOC Bulletin. Finally, please clarify the impact of ACOG Ethics Committee reports on board certification and ACOG membership. We request the courtesy of your response to these concerns by March 29th, 2008.

Sincerely,

Phil Gingrey, M.D. (GA-11)

Trent Franks (AZ-2)

Dave Weldon, M.D. (FL-15)

Ron Paul, M.D. (TX-14)

Paul Broun, M.D. (GA-10)

Tom Price, M.D. (GA-6)

James L. Oberstar (MN-8)

Joseph R. Pitts (PA-16)

Christopher H. Smith (NJ-4)

W. Todd Akin (MO-2)

Mike Ferguson (NJ-7)

Scott Garrett (NJ-5)

J. Gresham Barrett (SC-3)

Barbara Cubin (WY)

Jeff Fortenberry (NE-1)

Jean Schmidt (OH-2)

Cc: Anne D. Lyerly, MD, Chair of Ethics Committee
The American College of Obstetricians and Gynecology

Lucia DiVenere, Director of the Department of Government Affairs
American College of Obstetricians and Gynecologists

EXHIBIT SIX

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 14 2008

[redacted]
Executive Director
The American Board of Obstetrics and Gynecology
2915 Vine Street
Dallas, TX 75204

Dear [redacted]:

I am writing to express my strong concern over recent actions that undermine the conscience and other individual rights of health care providers. Specifically, I bring to your attention the potential interaction of the American Board of Obstetrics and Gynecology's (ABOG) Bulletin for 2008 Maintenance of Certification (Bulletin) with a recent report (Opinion Number 385) issued by the American College of Obstetricians and Gynecologists (ACOG) Ethics Committee on November 7, 2007 entitled "The Limits of Conscience Refusal in Reproductive Medicine".

The ACOG Ethics Committee report recommends that in the context of providing abortions, "Physicians and other health care professionals have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive service that patients request." It appears that the interaction of the ABOG Bulletin with the ACOG ethics report would force physicians to violate their conscience by referring patients for abortions or taking other objectionable actions, or risk losing their board certification.

As you know, Congress has protected the rights of physicians and other health care professionals by passing two non-discrimination laws and annually renewing an appropriations rider that protect the rights, including conscience rights, of health care professionals in programs or facilities conducted or supported by federal funds. (See 42 U.S.C. § 238n, 42 U.S.C. § 300a-7, and the Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, 121 Stat. 1844, § 508). Additionally, threats to withhold or revoke board certification can cause serious economic harm to good practitioners.

I am concerned that the actions taken by ACOG and ABOG could result in the denial or revocation of Board certification of a physician who -- but for his or her refusal, for example, to refer a patient for an abortion -- would be certified. These actions, in turn, could result in certain HHS-funded State and local governments, institutions, or other entities that require Board certification taking action against the physician based just on the Board's denial or revocation of certification. In particular, I am concerned that such actions by these entities would violate federal laws against discrimination.

In the hope that compliance of entities with the obligations that accompany certain federal funds will not be jeopardized, it would be helpful if you could clarify that ABOG will not rely on the ACOG Ethics Committee Report, "The Limits of Conscience Refusal in Reproductive Medicine" when making determinations of whether to grant or revoke board certifications.

Thank you very much for your assistance in this matter.

Sincerely,

Michael O. Leavitt

cc:

[redacted]

The American College of Obstetricians and Gynecologists

EXHIBIT SEVEN

ABO+G

American Board of Obstetrics + Gynecology

First in Women's Health

March 19, 2008

Michael O. Leavitt
Secretary
The US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Norman F. Gant, M.D.
Executive Director

Alvin L. Brekken, M.D.
Assistant to the Executive Director

Larry C. Gilstrap, III, M.D.
Director of Evaluation

The Vineyard Centre
2915 Vine Street
Dallas, TX 75204
Phone (214) 871-1619
Fax (214) 871-1943

Dear Secretary Leavitt:

I am responding to your letter addressed to me asking about the American Board of Obstetrics and Gynecology's stand with respect to a physician's choice "to violate their conscience by referring patients for abortions or taking other objectionable actions, or risk losing their board certification." I can only say that I do not know where you came up with any suggestion, much less documentation, that the American Board of Obstetrics and Gynecology has ever asked anyone to violate their own ethical or moral standards.

Please be assured that the American Board of Obstetrics and Gynecology has taken no stand, pro or con, against individual physicians who choose to or choose not to perform abortions or to refer patients to abortion providers. Moreover, such an issue is not a consideration in the applications or in the examinations administered by the American Board of Obstetrics and Gynecology in any of its certification or in its Maintenance of Certification requirements or examinations.

Best Wishes,

[redacted]

Executive Director

NFG/kd

EXHIBIT EIGHT

March 26, 2008

Dear Fellows:

Thank you for your comments on Committee Opinion #385, "The Limits of Conscientious Refusal in Reproductive Medicine." The Committee on Ethics is grateful for the thoughtful and considered input of Fellows regarding this document. We received many letters reflecting the importance of this issue to Fellows, as well as a breadth of opinion regarding the role of conscience in professional life.

The Committee on Ethics met on March 17-18, 2008, and discussed the correspondence received since the Opinion's publication. The letters and a summary of the concerns raised were carefully reviewed. Also the Executive Committee of ACOG's Executive Board met and discussed the Opinion and the response to the Opinion on March 24, 2008.

We want to be clear the Opinion does not compel any Fellow to perform any procedure which he or she finds to be in conflict with his or her conscience and affirms the importance of conscience in shaping ethical professional conduct. For example, while this is not a document focused on abortion, ACOG recognizes that support for or opposition to abortion is a matter of profound moral conviction, and ACOG respects the need and responsibility of its members to determine their individual positions on this issue based on their personal values and beliefs. We want to assure members with a diversity of views on this issue that they have a place in our organization.

Ethics Committee Opinions provide guidance regarding ethical issues. This Committee Opinion is not part of the "Code of Professional Ethics of the American College of Obstetricians and Gynecologists." This Committee Opinion was not intended to be used as a rule of ethical conduct which could be used to affect an individual's initial or continuing Fellowship in ACOG. Similarly, it is not cited in the American Board of Obstetrics and Gynecology's "Bulletin for 2008" and "Bulletin for 2008 Maintenance of Certification," and an obstetrician-gynecologist's board certification is not determined or jeopardized by his or her adherence to this Opinion.

Conscience has an important role in the ethical practice of medicine. While this Opinion attempted to provide guidance for balancing the critical role of conscience with a woman's right to access reproductive medicine, the Executive Committee has noted the uncertain and mixed interpretation of this Opinion. Thus, the Executive Committee has instructed the Committee on Ethics to hold a special meeting as soon as possible to reevaluate ACOG Committee Opinion #385.

Thank you again for your thoughtful comments.

Sincerely yours,

President

EXHIBIT C

ACLJ
American Center
for Law & Justice

May 9, 2018

RECEIVED
MAY 11 2018
HHS/OCR HQ

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

Attn: Conscience and Religious Freedom Division

Re: Complaint for Discrimination in Violation of 42 U.S.C. § 300a-7(c)(1) ("Church Amendment")

Contact attorney for complainant:

Francis J. Manion, Esq.
Geoffrey R. Surtees, Esq.
American Center for Law and Justice
6375 New Hope Rd.
P.O. Box 60
New Hope, KY 40052
502-549-7020
fmanion@aclj.org

Complaint filed on behalf of:

[redacted]

Person/Agency/Organization committing discrimination:

The University of Vermont Medical Center
111 Colchester Avenue
Burlington, Vermont 05401
802-847-0000

Date and nature of discriminatory acts:

In 2017, the complainant, [redacted] RN, was coerced by her employer, University of Vermont Medical Center, Inc. ("UVMMC") into participating in an abortion. Ms [redacted] a Catholic, had previously informed her employer that she

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New Hope, Kentucky 40052
(502) 549-7020
(502) 549-5252 (Facsimile)

could not participate in such procedures as a matter of religious belief. Her employer deliberately misled [redacted] about the nature of the procedure, and then, after [redacted] confirmed that she was, in fact, being assigned to an abortion, refused her request that other equally qualified and available personnel take her place. Fearing a charge of patient abandonment which could bring with it loss of employment and revocation of her nursing license, [redacted] participated in the procedure under duress. She suffered immediate emotional distress, attempted to suppress the event psychologically, and has been haunted by nightmares ever since. In addition, her employer has created a hostile environment targeting [redacted] and other employees who conscientiously object to participating in abortion procedures.

The coerced-participation event described above appears to have been related to a change in UVMMC policy regarding the hospital's performance of abortions. Under the leadership, since 2013, of a hospital board President with decades-long experience in senior leadership of Planned Parenthood facilities in Vermont, Portland, Oregon, and New York City, UVMMC reversed a longstanding policy which limited abortions in its facilities to those considered "medically necessary." While the policy appears to have been changed *sub silentio* at some point even before 2017, hospital staff, including [redacted] and other nurses, were only formally informed of the change in October of 2017. Thus, it is highly possible that other staff and, perhaps, [redacted] herself, have been deceived into participating in other abortion procedures which were misleadingly labeled as "miscarriages" or "medically necessary" but which were, in fact, purely elective abortions.

In addition, following public controversy which arose after the formal disclosure to staff of the hospital's new policy in the Fall of 2017, UVMMC, in February 2018, adopted a revised "Conflict of Care" policy. (Copy attached hereto). This policy is sharply inconsistent with existing federal conscience laws and inappropriately continues to leave the conscience rights of hospital employees to the virtually unbridled discretion of supervisors who, as [redacted] and others will attest, have a history of demeaning, belittling, and failing to respect the views of conscientious objectors.

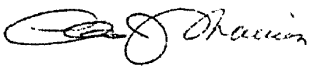
The Church Amendment protects the conscience rights of individuals and entities that object to performing or assisting in the performance of abortion or sterilization procedures if doing so would be contrary to the provider's religious beliefs or moral convictions, and prohibits discrimination in employment of "any physician or other health care personnel . . . because of his religious beliefs or moral convictions respecting sterilization procedures or abortions." 42 U.S.C. §300a-7 *et seq.*

It is clear that [redacted] (and perhaps others employed at UVMMC) has suffered and continues to suffer discrimination and violations of her conscience rights under federal law. We urge your office to immediately initiate an

investigation of these charges and order appropriate remedial and corrective actions as soon as possible.

Our investigation has disclosed identities and contact information of individuals in addition to our client who have information pertinent to this matter. That information, to the extent said individuals have already spoken publicly about it or authorize us to disclose it, will be provided upon request.

Respectfully submitted,



Francis J. Manion
Senior Counsel
American Center for Law & Justice

Date: May 9, 2018

Documents Status: **Approved**

IDENT	HR-F-09
Type of Document	Policy
Applicability Type	Corporate
Title of Owner	Dir Human Resources
Title of Approving Official	VP Human Resources
Date Effective	2/5/2018
Date of Next Review	2/5/2021

THE University of Vermont MEDICAL CENTER

TITLE: Conflict of Care: Staff Conscientious Objection

PURPOSE: UVM Medical Center respects workforce diversity and the cultural values, ethics and religious beliefs of our staff. In situations where a conflict may exist between the employee's cultural values, ethics, and religious beliefs and their participation in any aspect of patient care, UVMMC supports a process by which an employee may request to be excused from performing specific duties.

Patients and their families' perspectives and choices are valued and honored in all phases of care. Accordingly, all patients are entitled to comprehensive, quality care, without regard to their diagnosis, race, color, sex, sexual orientation, gender identity or expression, ancestry, place of birth, HIV status, national origin, religion, marital status, age, language, socioeconomic status, physical or mental disability, protected veteran status.

UVMMC encourages open dialogue between the employee and their leader.

POLICY STATEMENT: Employees may request to be excused from participating in a type of care/treatment in situations where that care/treatment conflicts with the employee's cultural values, ethics, or religious beliefs. Procedures/treatments which may present conflict may include but are ***not limited*** to the following:

- Blood and blood component administration
- Elective termination of pregnancy
- Initiation and cessation of life support
- DNR/Life support issues for critically ill/terminally ill populations
- Assisting with the harvesting of human organs
- Sterilization procedures
- Reproductive technologies

Alternative staffing arrangements will be considered, and if appropriate, arranged. At no time will staff be allowed to act in a manner that negatively impacts the patient's care or treatment.

PROCEDURE:

I. When the need to provide care or treatment of a patient is in conflict with an employee's cultural values, ethics or religious beliefs, the employee may request to be reassigned to other duties and not participate in the specific type of care or treatment. In the event a conflict of care arises, care of the patient will be maintained until alternate staffing arrangements can be provided.

II. UVMMC supports open dialogue between the employee and their leader when a conflict exists for the employee. We recognize that not all conflicts can be predicted. When possible we encourage employees to proactively raise concerns about potential conflicts in order to minimize impact to patient care.

III. During the hiring process, the hiring manager shall discuss the typical scope of practice and service within the department in which the candidate has applied to work. Employees are expected to perform all the duties of their positions as set forth in their job descriptions, given to them at the time of hire or whenever revised.

IV. All new employees are informed about this Conflict of Care policy during new employee orientation.

Printed on: 4/12/2018 11:00 AM By: [redacted]
DISCLAIMER: Only the online policy is considered official. Please compare with on-line document for accuracy.

V. The direct Supervisor/designee shall be responsible for administering and monitoring a process to accommodate an employee's cultural values, ethics, and religious beliefs regarding treatment of patients.

a) An employee who desires to be reassigned from a specific type of care or treatment shall submit the request in writing to the Supervisor/designee. Written request may be received on the form provided in this policy OR via an email addressed to the Supervisor/designee containing the details as requested/outlined on the form.

b) The written request will be acknowledged by the Supervisor/designee and maintained in the appropriate unit resource binder for scheduling purposes within the unit. The Supervisor/designee will assign staff as necessary for appropriate patient coverage. The written request will be placed in the employee's electronic personnel file by the Supervisor/designee.

c) Any conflict which may occur in an emergent situation for which staff may not have previously submitted a written request, may be brought to the Supervisor/designee. Alternative coverage may be sought at the discretion of the Supervisor/designee. The written request shall be submitted by the employee directly following the event and the request will be placed in the employee's electronic personnel file by the Supervisor/designee.

d) Any employee who is excused from an aspect of care will be re-assigned to other responsibilities.

e) In any scenario where circumstances prevent arrangements for alternate coverage, the staff member will be expected to provide the assigned care to ensure patient care is not negatively impacted.

f) Refusal to perform assigned job functions will be addressed in accordance with established corrective action procedures by the supervisor, in consultation with leadership and/or Human Resources.

VI. All employees have access to the Ethics Consultation through UVMMC's Director of Clinical Ethics and can request input on ethical issues by contacting Provider Access Services (847-2700), ask who the ethics consultant on call is and should then contact that consultant by phone or in person.

VII. An employee experiencing ongoing conflict of care issues should seek a transfer to a department or position where conflict of care issues are less likely to occur.

MONITORING PLAN: N/A

DEFINITIONS: N/A

RELATED POLICIES: Code of Conduct B1N; Clinical Ethics Consultations ETH15; Compliance & Privacy Plan B31

REFERENCES: 2017, Hospital Accreditation Standards, The Joint Commission LD.04.02

REVIEWERS: [redacted]

OWNER: [redacted], Dir Human Resources

APPROVING OFFICIAL: [redacted] Human Resources

Documents Status: **Approved**

Conflict of Care Disclosure Form

To be completed by the employee making the request: *Make a copy of this form for your records and then give this form to your leader.*

Your Name: _____ (Please Print)

Your Signature: _____ Date: _____

Please identify the clinical circumstances where you experience personal conflict. Please provide specific details regarding which procedure/treatment you are requesting to be excused from.

Please briefly provide your reasons for requesting removal from the patient's care team.

Received by:_____ (Please Print)

Leader Signature _____ Date Received _____

Printed on: 4/12/2018 11:00 AM By: [redacted]
DISCLAIMER: Only the online policy is considered official. Please compare with on-line document for accuracy.

EXHIBIT D

Form Approved: OMB No. 0990-0269
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

CIVIL RIGHTS DISCRIMINATION COMPLAINT

YOUR FIRST NAME [redacted]

YOUR LAST NAME [redacted]

YOUR CELL PHONE (Please include area code) [redacted]

YOUR HOME PHONE (Please include area code)

STREET ADDRESS [redacted]

CITY [redacted]

STATE [redacted]

ZIP 77379

[redacted] else? ☐ Yes ☒ No

If Yes, whose civil rights do you believe were violated?

FIRST NAME

LAST NAME

I believe that I have been (or someone else has been) discriminated against on the basis of:

☐ Race / Color / National Origin ☐ Age ☒ Religion / Conscience ☐ Sex

☐ Disability ☐ Other (specify):

Who or what agency or organization do you believe discriminated against you (or someone else)?

PERSON/AGENCY/ORGANIZATION

Champions pediatric

STREET ADDRESS

10607 Kuykendahl

CITY

Spring

STATE

Texas

ZIP

77379

PHONE (Please include area code)

When do you believe that the discrimination occurred?

LIST DATE(S)

09/11/2017, 10/20/2017

Describe briefly what happened. How and why do you believe that you have been discriminated against? Please be as specific as possible.
(Attach additional pages as needed)

At my daughters 2 mo checkup when I declined vaccination, I was told she could no longer be a patient there. This also happened the following month at my other childs 18 mo old checkup. My daughter had a severe reaction to a vaccine she recieved there prior, and has an autoimmune issue so they are fully aware of why she cannot be vaccinated any further. I even obtained a medical exemption stating she cannot receive further vaccines on top of already having a conscience exemption. We were kicked out and told by [redacted] the office manager they are a "vaccine only clinic"

Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

SIGNATURE [redacted]

DATE *(mm/dd/yyyy)*

01/20/2018

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of Sections 1553 and 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, and other civil rights statutes. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible discrimination, for internal systems operations, or for routine uses, which include disclosure of information outside the Department of Health and Human Services (HHS) for purposes associated with civil rights compliance and as permitted by law. It is illegal for a recipient of Federal financial assistance from HHS to intimidate, threaten, coerce, or discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under Federal civil rights laws. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's web site at: **www.hhs.gov/ocr/civilrights/complaints/index.html**. To submit a complaint using alternative methods, see reverse page (page 2 of the complaint form)

The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.

Do you need special accommodations for us to communicate with you about this complaint? (Check all that apply)

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter (specify language): _____

☐ Foreign language interpreter (specify language): _____ ☐ Other: _____

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME
HOME PHONE (Please include area code)	WORK PHONE (Please include area code)

STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS (If available)

Have you filed your complaint anywhere else? If so, please provide the following. (Attach additional pages as needed)

PERSON/AGENCY/ORGANIZATION/ COURT NAME(S)

DATE(S) FILED	CASE NUMBER(S) (If known)

To help us better serve the public, please provide the following information for the person you believe was discriminated against (you or the person on whose behalf you are filing).

ETHNICITY (select one)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

RACE (select one or more)

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American ☒ White ☐ Other (specify): _____

PRIMARY LANGUAGE SPOKEN (if other then English) _____

How did you learn about the Office for Civil Rights?

☐ HHS Website/Internet Search ☒ Family/Friend/Associate ☐ Religious/Community Org ☐ Lawyer/Legal Org ☐ Phone Directory ☐ Employer

☐ Fed/State/Local Gov ☐ Healthcare Provider/Health Plan ☐ Conference/OCR Brochure ☐ Other (specify): _____

To submit a complaint, please type or print, sign, and return completed complaint form package (including consent form) to the OCR Headquarters address below.

U.S. Department of Health and Human Services
Office for Civil Rights
Centralized Case Management Operations
200 Independence Ave., S.W.
Suite 515F, HHH Building
Washington, D.C. 20201
Customer Response Center: (800) 368-1019
Fax: (202) 619-3818
TDD: (800) 537-7697
Email: ocrmail@hhs.gov

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including he time for reviewing instruc ions, gathering the data needed and entering and reviewing the information on he completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail complaint form to this address.**

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, which are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

Please read and review the documents entitled, *Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights* and *Protecting Personal Information in Complaint Investigations* for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.

- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose information, including personally identifying information, which it has gathered as part of its investigation of my complaint.

- In addition, I understand that as a complainant I am covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS' investigation, conciliation, or enforcement process.

After reading the above information, please check ONLY ONE of the following boxes:

[X] **CONSENT:** I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me in my case file to persons at the entity or agency under investigation or to other relevant persons, agencies, or entities during any part of HHS' investigation, conciliation, or enforcement process.

[ ] **CONSENT DENIED:** I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of my complaint and may result in closure of the investigation.

Signature: [redacted] Date: 01/20/2018

**Please sign and date to sign if submitting this form by email because submission by email represents your signature.*

Name (Please print): [redacted]

Address: [redacted]

Telephone Number: [redacted]

NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 U.S.C. § 552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion, and conscience under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d *et seq.*), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794), the Age Discrimination Act of 1975 (42 U.S.C. § 6101 *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et seq.), Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§ 295m and 296g), Section 1553 of the Affordable Care Act (42 U.S.C. § 18113), the Church Amendments (42 U.S.C. § 300a-7), the Coats-Snowe Amendment (42 U.S.C. § 238n) and the Weldon Amendment (*e.g.*, Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, Tit. V, § 507);
(ii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§ 291 *et seq.* and 300s *et seq.*) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill- Burton facilities);
(iii) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(iv) Title II of the Americans with Disabilities Act (42 U.S.C. § 12131 et seq.) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.
(v) The Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule) at 45 C.F.R. Part 160 and Subparts A and E of Part 164, which enforce the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. § 1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of Federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of Federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.

OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. § 552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. § 5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act
A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. § 552) (FOIA) and HHS regulations at 45 C.F.R. Part 5.

Fraud and False Statements
Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry".

PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Because of the Privacy Act, OCR will use your name or other personal information with a signed consent and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

Access to OCR's files and records is controlled by the Freedom of Information Act (FOIA). Under FOIA, OCR may be required to release information about this case upon public request. In the event that OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals, or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If OCR receives protected health information about you in connection with a HIPAA Privacy Rule investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under the Freedom of Information Act and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages; please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed $100.00.

If you have any questions about this complaint and consent package, Please contact OCR at http://www.hhs.gov/ocr/office/about/contactus/index.html

OR

Contact the Customer Response Center at (800) 368-1019

(see contact information on page 2 of the Complaint Form)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, *Plaintiff*, v. 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*.	No. 1:19-cv-01672-GLR

[PROPOSED] ORDER

The Court, having considered Defendants' motion to dismiss or, in the alternative, for summary judgment, Plaintiff's opposition, and the entire record herein, orders as follows:

IT IS HEREBY ORDERED that Defendants' motion is GRANTED, and [Plaintiff's complaint is dismissed with prejudice / summary judgment is entered in Defendants' favor].

IT IS FURTHER ORDERED that Plaintiff's motion for a preliminary injunction is DENIED.

IT IS SO ORDERED.

Dated: _____

_____
Hon. George L. Russell III
United States District Judge