JOSEPH H. HUNT
Assistant Attorney General
JAMES M. BURNHAM
Deputy Assistant Attorney General
CHRISTOPHER A. BATES
Senior Counsel to the Assistant Attorney General
MICHELLE R. BENNETT
Assistant Branch Director
REBECCA M. KOPPLIN
BRADLEY P. HUMPHREYS
Trial Attorneys
Federal Programs Branch
U.S. Department of Justice, Civil Division
1100 L Street, N.W.
Washington, DC 20005
(202) 514-3953
Rebecca.M.Kopplin@usdoj.gov
Counsel for Defendants

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

No. 2:19-cv-0183-SAB

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS, OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Hearing: November 7, 2019
With Oral Argument: 10:00 AM

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INTRODUCTION

Plaintiff's brief is long on hyperbole (including the erroneous assertion that Defendants "acquiesced in an injunction" of the Rule, Pl.'s MSJ & Opp'n (Pl.'s Opp'n) 1, ECF No. 57), but Plaintiff at no point articulates how the challenged regulation, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (the Rule), 84 Fed. Reg. 23,170 (May 21, 2019), meaningfully differs from the Federal Conscience Statutes that it implements, *see generally id.* at 23,264–69 (to be codified at 45 C.F.R. § 88.3). That is because, far from being a sea change, the Rule merely implements and clarifies important preexisting conscience protections enacted by Congress. Significantly, Plaintiff does not challenge the underlying Federal Conscience Statutes. Nor does it challenge the authority of the Department of Health and Human Services (HHS) to condition federal funds on compliance with federal law, including the Federal Conscience Statues. Together, these omissions are fatal to Plaintiff's challenge to the Rule.

Plaintiff's specific arguments fail for other reasons, too. The main thrust of Plaintiff's Administrative Procedure Act (APA) challenge is that the Rule exceeds Defendants' statutory authority. But Plaintiff's argument is belied by the delegations of authority in certain of the Federal Conscience Statutes and other statutes identified in the Rule. Plaintiff's attack on several of the Rule's definitions fares no better because those definitions are consistent with the plain text of the Statutes and the dictionary meanings of the relevant terms. At the very least, the Rule's definitions are entitled to *Chevron* deference and are reasonable. Contrary

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to Plaintiff's claim, the Rule is also entirely consistent with other law. And, in promulgating the Rule, Defendants acted reasonably, thoroughly considered the issues raised in the comments, and provided thoughtful explanations in response.

Plaintiff's constitutional claims likewise fail. At the threshold, Plaintiff's Spending and Establishment Clause claims are not ripe. Several speculative events must occur before Plaintiff could lose federal funding. Furthermore, the funding conditions that Plaintiff challenges flow from the Federal Conscience Statutes, not the Rule, and the Rule does not "establish" religion in any way—it protects religious beliefs only where the Federal Conscience Statutes do so, and like the Statutes, it addresses objections regardless of their religious or secular nature.

Last, even if the Court were to hold some aspects of the Rule unlawful, the Rule's severability clause instructs the Court to sever the offending portions from the Rule rather than vacate the Rule entirely. Any relief, moreover, should be limited to the parties before the Court and should not extend nationwide.

ARGUMENT

I. The Rule Fits Comfortably Within HHS's Authority.

Plaintiff argues that "HHS's motion ignores the threshold issue of whether it has authority to interpret the Church, Coats-Snowe, and Weldon Amendments." *See* Pl.'s Opp'n 6. But this was not oversight; Plaintiff *conceded* HHS's authority to interpret these statutes by arguing that the Court should "apply the framework established in *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)." *See* Pl.'s Mot. Prelim. Inj. 23, ECF No. 8. Of course, a court applies that

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framework only when it "reviews an agency's construction *of the statute which it administers*." *Chevron*, 467 U.S. at 842 (emphasis added). Nowhere in its complaint does Plaintiff allege that HHS lacks authority to interpret the Church, Coats-Snowe, and Weldon Amendments. *See* Compl. ¶¶ 75–97, 110–14, ECF No. 1. Rather, Plaintiff alleges that the *way* HHS defined certain terms and the *way* HHS established enforcement procedures exceeded HHS's authority. Likewise, in Plaintiff's preliminary injunction motion, Plaintiff argued that certain definitions exceeded HHS's authority, but not that HHS lacked authority to define such terms at all. *See* Pl.'s Mot. Prelim. Inj. 18–23. The Court should reject Plaintiff's eleventh hour attempt to challenge this aspect of HHS's statutory authority.

Should the Court consider Plaintiff's unchallenged and belated argument, it should nevertheless reject it on the merits. HHS has fully explained its statutory authority in the Rule. *See* 84 Fed. Reg. at 23,183–86; *see also id.* at 23,263 (listing statutes). In brief, this authority comes from the Federal Conscience Statutes, various housekeeping statutes, and various other statutes.

First, several statutes explicitly authorize HHS to issue the Rule, which merely provides public notice of HHS's process for implementing the requirements of the Federal Conscience Statutes and the interpretations of those Statutes that HHS will employ in that process. The full list of these statutes is in the Rule. *See* 84 Fed. Reg. at 23,184–85. For example, 42 U.S.C. § 18041 authorizes the Secretary to issue regulations related to the conscience provisions and other provisions in Title I of the Affordable Care Act (ACA). And 42 U.S.C.

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§ 1302 authorizes the Secretary to promulgate regulations that provide for compliance by participants in the Medicare, Medicaid, and Children's Health Insurance Program.

Furthermore, the Rule's enforcement authority section reflects longstanding—and unchallenged—law concerning HHS's authority to monitor and enforce compliance with federal awards that it issues. Pursuant to various housekeeping and other statutes, *see* 5 U.S.C. § 301, 40 U.S.C. § 121(c), 10 U.S.C. ch. 137, and 51 U.S.C. § 20113, HHS has promulgated federal award regulations that correspond to and or supplement the Uniform Administrative Requirements (UAR) and Federal Acquisition Regulation (FAR) (known as the HHS UAR and HHSAR), which among other things govern the enforcement of conditions in federal awards. Under these regulations, recipients of HHS's federal awards are required to comply "with U.S. statutory and public policy requirements," 45 C.F.R. § 75.300(a), which include the Federal Conscience Statutes. HHS may, and in some cases must, audit recipients for compliance with this and other conditions. *See* 45 C.F.R. §§ 75.500–75.520. And if a recipient does not comply with a federal award's requirements, HHS may impose additional conditions or take further action, including to "[w]holly or partly suspend . . . or terminate the Federal award." 45 C.F.R. § 75.371. Further, under the 2011 Rule, HHS explicitly states that it enforces the Church, Coats-Snowe, and Weldon Amendments using these procedures. *See* 45 C.F.R. § 88.2 ("OCR will coordinate the handling of complaints [based on the Church, Coats-Snowe, and Weldon

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Amendments] with the Departmental funding component(s) from which the entity, to which a complaint has been filed, receives funding."). In addition to this longstanding authority, several statutory provisions explicitly grant HHS authority for the Rule. *See* 42 U.S.C. §§ 1302, 18023, 18113, 18041, 263a, and 1315a. The Rule simply makes explicit that, under longstanding, unchallenged HHS UAR and HHSAR procedures, recipients of HHS funds must comply with the Federal Conscience Statutes and may face certain consequences if they do not.

Last, as discussed in the definitions section *infra*, the Federal Conscience Statutes implicitly grant HHS the authority to administer them.

Plaintiff raises a number of arguments in response, none of which have merit. Plaintiff argues that "UAR remedies focus on the specific 'cost of the activity or action not in compliance.'" Pl.'s Opp'n 10 (quoting 45 C.F.R. § 75.371(b), (c)). This quote is taken entirely out of context. That is *not* the focus of § 75.371, the portion of the HHS UAR related to remedies. Rather, that section permits HHS to impose a number of remedies, up to and including to "[w]holly or partly suspend (suspension of award activities) or terminate the Federal award" and to "[w]ithhold further Federal awards for the project or program." 45 C.F.R. § 75.371(c), (e). Plaintiff cites only *one* of the other five listed remedies.

Plaintiff also argues that the Rule permits HHS to take certain actions without "exhausting attempts to resolve the matter informally." *See* Pl.'s Opp'n 10. Plaintiff appears to refer to the provision of the HHS UAR that states that HHS "may impose additional conditions" if a recipient fails to comply with a federal

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award's conditions and that HHS may pursue certain remedies "[i]f the HHS awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions." *See* 45 C.F.R. § 75.371. However, the Rule does not supplant § 75.371; rather, the Rule follows the HHS UAR *to the letter*. *See* 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. § 88.7(i)(3)) (stating that enforcement actions are to be taken "pursuant to statutes and regulations which govern the administration of contracts (e.g., Federal Acquisition Regulation), grants (e.g., 45 C.F.R. part 75) and CMS funding arrangements (e.g., the Social Security Act)").

II. The Challenged Definitions Are Reasonable.

A. The Highly Deferential Standard Described in *Chevron* Applies.

Plaintiff contends for the first time in its brief that the Rule's definitions are not entitled to *Chevron* deference because Congress has not delegated authority to HHS to interpret the Federal Conscience Statutes. *See* Pl.'s Opp'n 6–9. However, as explained above, Congress has delegated such authority both explicitly and implicitly. The Court thus should review Plaintiff's challenges to the Rule's definitions under the highly deferential framework set forth in *Chevron*.

In addition to the authorities described above, the Federal Conscience Statutes implicitly grant HHS authority to promulgate the Rule. Just as Congress may delegate authority to an agency explicitly, "[s]ometimes the legislative delegation to an agency on a particular question is implicit." *Chevron*, 467 U.S. at 844. To determine whether Congress has implicitly delegated authority, courts

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consider "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time." *See Barnhart v. Walton*, 535 U.S. 212, 222 (2002). All of these factors weigh in HHS's favor.

First, the subject of the Rule is interstitial in nature and necessary to the administration of the Federal Conscience Statutes. In general, the Federal Consciences Statutes direct HHS to issue federal funds contingent on recipients' complying with the Statutes' conditions. *See, e.g.*, 42 U.S.C. § 300a-7(c) (prohibiting recipients of certain federal funds from discriminating on certain bases). But the Statutes do not define the key terms listed in the Rule's definitions section. And even when definitions are provided, they are non-exhaustive. *See, e.g.*, 42 U.S.C. § 238n(c) (defining "health care entity" through a non-exhaustive list of examples). Furthermore, the Statutes do not describe how to ensure that recipients comply with the Statutes' conditions. Particularly because the Federal Conscience Statutes lack a private right of action, *see Cenzon-DeCarlo v. Mount Sinai Hosp.*, 626 F.3d 695, 698–99 (2d Cir. 2010); *see generally* 84 Fed. Reg. at 23,178, the Statutes would be dead letter if HHS could not enforce them. Surely Congress did not intend to impose significant conditions on federal funds without also authorizing HHS to employ longstanding procedures to enforce those conditions and, to the extent a term is ambiguous, to interpret such ambiguity. These are quintessentially interstitial questions.

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In addition, the administration of federal awards connected to the Federal Conscience Statutes is complex. "The HHS Office of the Secretary and its 11 Operating Divisions (OpDivs) administer more than 300 programs covering a wide spectrum of activities." HHS, FY 2018 *Agency Financial Report* 7 (Nov. 14, 2018), https://www.hhs.gov/sites/default/files/fy-2018-hhs-agency-financial-report.pdf. In total, "HHS is responsible for more than a quarter of all federal outlays and administers more grant dollars than all other federal agencies combined." *Id.* And the Rule, which addresses a variety of statutes, is estimated to cover 502,899 entities. *See* 84 Fed. Reg. at 23,235.

Last, HHS has significant expertise enforcing civil rights laws in the health care context, including the Federal Conscience Statutes. HHS has promulgated regulations regarding the Federal Conscience Statutes several times. And the Office for Civil Rights (OCR) in particular has investigated discrimination complaints, issued notices of violations, and negotiated settlements with entities found to have violated the Federal Conscience Statutes. Based on this experience, HHS determined a need to provide more concrete and detailed guidance on how it enforces conscience protections with respect to recipients of its federal funds.

B. The Court Should Uphold the Rule's Definitions.

1. "Assist in the Performance"

Rather than respond to Defendants' *Chevron* arguments, *see* Defs.' Mot. Dismiss or Summ. J. (Defs.' Mem.) 26–28, ECF No. 44, Plaintiff raises three objections to HHS's definition of "assist in the performance." None of these

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objections is correct.

First, the legislative history that Plaintiff cites does not contradict the Rule's definition for several reasons. Courts "cannot ignore clear statutory text because of legislative floor statements," *see United States v. Hall*, 617 F.3d 1161, 1167 (9th Cir. 2010), and for the reasons explained in Defendants' opening brief, the statutory text supports the Rule's definition. In addition, Plaintiff cites only a single comment that the Church Amendments' sponsor made on the floor of the Senate. "Floor statements are not given the same weight as some other types of legislative history, such as committee reports, because they generally represent only the view of the speaker and not necessarily that of the entire body." *See Kenna v. U.S. Dist. Ct. for the Cent. Dist. of Cal.*, 435 F.3d 1011, 1015 (9th Cir. 2006). Although sponsors' floor statements may be given more weight than non-sponsors' floor statements, Senator Church's statement is entitled to little or no weight because the relevant House committee issued a report on the statute that did not endorse his statement. *See* H.R. Rep. No. 93-227, at 11 (1973). At any rate, the substance of Senator Church's statement does not conflict with the Rule. Just as Senator Church did not intend, when voting for the bill, "to permit a frivolous objection from someone unconnected with the procedure," 119 Cong. Rec. 9,597 (Mar. 27, 1973), so too does the Rule exclude such unconnected persons from its definition. Rather, there must be "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." 84

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

Second, Plaintiff offers no support for the proposition that the Church Amendments are limited to "the actual performance of an abortion or sterilization procedure," Pl.'s Opp'n 16. The statute covers both *performance* and *assistance in the performance*. *See e.g.*, 42 U.S.C. § 300a-7(d) ("No individual shall be required to *perform* or *assist in the performance* of [a covered service or activity] if his *performance* or *assistance in the performance* of such part of such program or activity would be contrary to his religious beliefs or moral convictions." (emphasis added)). And as Defendants have explained, the dictionary definitions of these terms support the Rule. *See* Defs.' Mem. 27. Rather than respond to these arguments, Plaintiff conjures highly attenuated examples, *see* Pl.'s Opp'n 17, that have no basis in the Rule.

Last, Plaintiff argues that the use of the term "counseling" in other provisions in the Church Amendments, "training" in the Coats-Snowe Amendment, and "referral" in the Weldon Amendment precludes the use of those terms in the definition of "assist in the performance." *See* Pl.'s Opp'n 16–17. Plaintiff cites no authority for this proposition, instead suggesting that Congress knew "how to draft legislation that would cover these activities when it wanted to." *See id.* at 17. But Plaintiff has not shown that the statutes on which it relies, which were enacted in different sessions of Congress and as different public laws, *see* 84 Fed. Reg. at 23,188, are subject to inter-textual comparison. *See Erlenbaugh v. United States*, 409 U.S. 239, 243–44 (1972) (describing the

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standard for comparing different statutes). On the contrary, as HHS explained in the Rule, "Counseling and referral are common and well understood forms of assistance that materially help people reach desired medical ends." *See* 84 Fed. Reg. at 23,188 (describing examples).

2. "Discriminate" or "Discrimination"

The Court should reject Plaintiff's response to the definition of "discriminate" or "discrimination" for two reasons. First, as with the definition of "assist in the performance," Plaintiff ignores Defendants' *Chevron* arguments, *see* Defs.' Mem. 29–30. And second, Plaintiff misreads the Rule, mistaking a list of what *may* constitute discrimination for a list of what *constitutes* discrimination.

Plaintiff asserts—without any acknowledgement of what the Rule actually says—that the Rule "makes almost any adverse employment action towards objectors actionable regardless of whether the action might be legally justifiable." *See* Pl.'s Opp'n 20. This is *not* what the Rule says. As explained in Defendants' opening brief, *see* Defs.' Mem. 29, the definition is quite clear that it provides a non-exhaustive list of what *may* constitute discrimination "as applicable to, and to the extent permitted by, the applicable statute," *see* 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). Furthermore, the Rule identifies certain actions that definitively do not constitute discrimination. *See id.* (subsections (4)–(6)). HHS chose to define "discriminate" or "discrimination" in this open-ended way precisely because of the concerns that Plaintiff raises. As HHS explained, "The definition . . . does not trigger violations based on any adverse action whatsoever,

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but 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.

3. "Health Care Entity"

Plaintiff's threadbare arguments regarding HHS's definition of "health care entity" likewise do not pass muster. As Defendants explained in their opening brief, the Coats-Snowe Amendment, and Weldon Amendment, and § 1553 identify examples of health care entities in non-exhaustive lists. *See* Defs.' Mem. 32–33. Plaintiff suggests that these lists are exhaustive, arguing that the term "includes," which precedes each statutory list, is limiting. Although the term "includes" *can* be limiting, the Supreme Court has quoted approvingly that "the word 'includes' is *usually* a term of enlargement, and not of limitation." *Samatar v. Yousuf*, 560 U.S. 305, 317 n.10 (2010) (emphasis added) (quoting 2A N. Singer & J. Singer, Sutherland on Statutory Construction § 47.7, p. 305 (7th ed.2007)); *see also Include*, Merriam-Webster, https://www.merriam-webster.com/dictionary/include (defining "include" as "to take in or comprise as a part of a whole or group"). Plaintiff offers no reason why the usual definition of "includes" should not apply other than its own preference.

Furthermore, Plaintiff has yet to explain why any of the examples of a health care entity in the definition are not, in fact, health care entities. Instead, it hyperbolically asserts that the Rule's definition includes "entities that are entirely outside of the health profession," citing health plan sponsors, plan issuers, and third-party administrators. Pl.'s Opp'n 14. However, HHS has explained why each

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of these groups are, under the applicable provisions, "health care entities":

> Because the focus of both laws includes protection of health plans, it is consistent with their language and scope to include "a plan sponsor" as a protected "heath care entity." In the action of sponsoring a health plan or health coverage, the plan sponsor engages in an important function with respect to health care. Although the sponsor, the plan, and the issuer are all distinct entities, sponsoring a plan and paying for coverage (by an issuer, in the case of a fully insured plan) or for health care services (in the case of a self-insured plan) are part and parcel of the provision of health coverage under a group health plan. The Weldon Amendment is written to prohibit discrimination against, among others, entities that do not provide abortion in health coverage; ACA section 1553 is similarly written to protect entities from being required to provide certain health care items or services in connection with health plans and the ACA. Both laws define health care entity to include the catch-all phrase "any other kind of health care facility, organization, or plan," in order to protect a broad range of entities that might be engaged in providing coverage or services and subject to discrimination for not providing or covering abortion or assisted suicide, respectively. Therefore, treating a plan sponsor as a protected health care entity is consistent with the text of the Weldon Amendment and ACA section 1553.

84 Fed. Reg. at 21,195.

4. "Referral or Refer for"

Finally, Plaintiff argues that the Rule's definition of "referral" or "refer for" is inconsistent with the Federal Conscience Statutes because it is contrary to the text of the Coats-Snowe and Weldon Amendments and could have negative effects. *See* Pl.'s Opp'n 17–20. Both points can be readily dismissed. The Rule "do[es] not prohibit any doctor or health care entity from providing information to their patients—or referring for a medical service or treatment—if they feel they

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have a medical, legal, ethical, or other duty to do so." 84 Fed. Reg. at 23,200. Rather, the Rule protects certain providers from "being coerced by entities receiving Federal funds to violate their moral or religious convictions." *Id.*

In any event, Plaintiff's statutory argument is circular; they quote the Coats-Snowe and Weldon Amendments and state—without explanation—that the definition "goes well beyond the plain language of the underlying statutes." *See* Pl.'s Opp'n 17–18. Plaintiff also argues that the Rule's definition is inconsistent with the medical meaning of the term. Ordinarily, however, the Ninth Circuit consults *Merriam-Webster* at *Chevron* step one. *See, e.g.*, *Lagandaon v. Ashcroft*, 383 F.3d 983, 988 (9th Cir. 2004). And Defendants have explained why the dictionary definition supports the Rule. *See* Defs.' Mem. 35–37. Plaintiff does not explain why Congress would intend to employ a specialized definition of the term, such as the medical definition.

Plaintiff's other argument—that the definition would lead to unreasonable results—is irrelevant because the Court's review at *Chevron* step one is limited to the strict meaning of the statute. The meaning of the term "referral or refer for" is a *legal* question, not a medical ethics question. In addition, far from being established ethical principles, the principles to which Plaintiff points are a matter of debate within the medical community. *See* AR 538,670, Ex. 15 (finding that only "57% of physicians agreed that doctors must refer patients regardless of whether or not the doctor believes the referral itself is immoral").

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

A. Emergency Medical Treatment and Active Labor Act

Plaintiff claims that the Rule violates the Emergency Medical Treatment and Active Labor Act (EMTALA) because it "fails to provide for any balancing" in cases of emergency care. Pl.'s Opp'n 23. Plaintiff's case, however, offers no support. In *California v. United States*, No. 05-00328, 2008 WL 744840, (N.D. Cal. Mar. 18, 2008), the district court *rejected* the plaintiff's challenge to the Weldon Amendment. Much like Plaintiff here, the plaintiff in *California* alleged a conflict between EMTALA and the Weldon Amendment. But the district court found no clear indication of a conflict, in part because "to the extent that statutes can be harmonized, they should be." *Id.* at *4 (citation omitted). The same principle applies here.

As Defendants explained in the preamble to the Rule and in their opening brief, HHS does not foresee any circumstance in which complying with EMTALA would conflict with the requirements of the Federal Conscience Statutes or thereby the Rule. *See* 84 Fed. Reg. at 23,183; Defs.' Mem. 43–44. OCR, moreover, "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. Plaintiff may continue to follow EMTALA's requirements without any reasonable fear it will violate the Statutes as implemented by the Rule.

B. Section 1554 of the Affordable Care Act (ACA)

Plaintiff presses on with its extraordinary claim that § 1554 of the ACA

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prohibits HHS from promulgating any regulation that, *inter alia*, "creates [a] barrier," "impedes [] access," or "limits the availability of health care treatment," including by allowing a health care entity with an objection to providing, for instance, an abortion, to abstain from doing so. *See* Pl.'s Opp'n 24–25. If Plaintiff's incredibly broad argument were correct, § 1554 would render meaningless (if not completely abrogate) any regulatory attempt to implement the Federal Conscience Statutes in the context of health care because those regulations would allegedly "impede access" to care. Plaintiff's reading of § 1554 would also extend far beyond federal conscience protections—it would mean, for example, that HHS could not implement even statutory conditions on Medicare or Medicaid funding through regulations. To suggest that Congress intended that is absurd.

As Defendants explained in their opening brief, there is no plausible reason to accept Plaintiff's sweeping interpretation of § 1554. *See* Defs.' Mem. 38–43. In § 1303(c)(2) of the ACA, Congress was absolutely clear that nothing in the ACA (including § 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 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). That provision is fatal to Plaintiff's argument.

C. The ACA's Preventive Care Coverage Requirement

For reasons Defendants have already explained, *see* Defs.' Mem. 43, Plaintiff cannot succeed on its claim that the Rule conflicts with the ACA's

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preventive care requirement. *See* 42 U.S.C. § 300gg-13(a)(4). With respect to Plaintiff's argument under § 1554, the ACA contains an explicit instruction in § 1303(c)(2) that *nothing* in the ACA should have "*any effect*" on federal conscience protection. *See* 42 U.S.C. § 18023(c)(2) (emphasis added).

Plaintiff attempts to skirt § 1303(c)(2), claiming that Defendants' "overlook[] that the conflict with the contraceptive coverage requirement is created by the Rule, not the refusal statutes." Pl.'s Opp'n 29. Although Plaintiff's point is unclear, and the Rule merely implements the Federal Conscience Statutes, it appears that Plaintiff is obliquely referencing an argument put forth by the plaintiffs challenging the Rule in another district that the Rule is not a "law" within the meaning of § 1303(c)(2) because it is a regulation rather than a statute. *See Mayor and City Council of Baltimore v. Azar*, No. 1:19-cv-01672-GLR, ECF No. 50-1 at 19 (D. Md.). Assuming that is Plaintiff's argument, it fails. Of course the Rule is "law"—otherwise, Plaintiff would have no reason to challenge it. And had Congress intended § 1303(c)(2) to apply only to federal *statutes*, it could have said so. Unsurprisingly, Plaintiff cites no case holding that the term "law" does not include lawfully promulgated agency regulations, and therefore the Court can reject this claim out of hand. *See United States v. Mitchell*, 39 F.3d 465, 468 (4th Cir. 1994) ("'Law' is commonly defined to include administrative regulations.").

D. Title X

Plaintiff also continues to argue that the Rule somehow conflicts with Title X. Pl.'s Opp'n 29–30. This claim fails for multiple reasons. First, Plaintiff does

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not identify any portion of Title X with which the Rule allegedly conflicts. Indeed, nothing in Title X could plausibly prevent HHS from implementing the Federal Conscience Statutes. *See* Pub. L. No. 91-572, 84 Stat. 1504 (1970). Plaintiff appears to think that, because Title X grantees *may* (but are not required to) counsel women regarding pregnancy options, including abortion, those grantees will somehow violate Title X if an individual employee declines to provide such counseling. *See* Pl.'s Opp'n 29–30. But that is not correct. Title X does not *require* pregnancy counseling at all, much less counseling by every single one of a Title X grantee's employees, even against their conscience. The Court should reject Plaintiff's attempt to manufacture a conflict between the Rule and Title X.[1]

IV. The Rule Is the Product of Reasoned Decision-Making.

As Defendants explained in their opening brief, the Rule is neither arbitrary nor capricious under the APA because HHS provided "a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted); *see also* Defs.' Mem. 47–54. Plaintiff's arguments to the contrary are meritless. HHS supported each challenged aspect of the Rule with sound and detailed reasoning,

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[1] Plaintiff also claims that the Rule conflicts with Title VII of the Civil Rights Act of 1964. *See* Compl. ¶ 122. Defendants explained in their opening brief why that claim is meritless, *see* Defs.' Mem. 46–47, and Plaintiff has abandoned that claim by not responding to Defendants' arguments.

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and Plaintiff's attempt to couch its policy disagreements as an APA challenge must fail. *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 374 F.3d 1251, 1263 (D.C. Cir. 2004) (rejecting an "arbitrary-and-capricious challenge [that] boils down to a policy disagreement").

A. HHS Adequately Explained Its Reasons for the Rule.

First, HHS offered a reasoned explanation for changing course from the 2011 Rule. The agency proposed a new rule because, "[a]fter reviewing the previous rulemakings, comments from the public, and OCR's enforcement activities," it concluded that the 2011 Rule "created confusion over what is and is not required under Federal health care conscience laws and narrowed OCR's enforcement authority." Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3,880-01, 3,887 (Jan. 26, 2018). In promulgating the Rule, HHS considered (1) recent, documented instances of alleged and demonstrated conscience discrimination, such as litigation regarding new, potentially discriminatory laws passed by various States, (2) complaints that OCR has received in recent years, (3) comments received during the 2018–19 rulemaking,[2] (4) a survey conducted in 2009, (5) comments received in the 2008

[2] *See, e.g.*, Administrative Record (AR) 135,736–746, Ex. 4 (comment from a "diverse group of faith-based ministries" that "[f]or the wellbeing of patients and the integrity of the [health care] profession, . . . healthcare professionals must

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and 2011 rulemakings, and (6) various studies and articles. *See* 84 Fed. Reg. 23175–79; *see also* 83 Fed. Reg. at 3,887–891.

Plaintiff assails HHS's reliance on recent complaints that OCR received to argue that the agency failed to acknowledge record evidence allegedly

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be free to practice medicine in accordance with their professional judgment and ethical beliefs" and noting "examples of violations against conscience rights in healthcare, indicating that the threat to conscience rights is rising"); AR 134,132–136, Ex. 3 (comment from a faith-based healthcare organization, applauding HHS for protecting religious freedom "especially when it comes to healthcare workers and organizations that are called by their faith to serve *all* persons, especially those who are poor and vulnerable"); AR 139,527–529, Ex. 5 (comment that "[t]he lack of implementing regulations and of clarity concerning enforcement mechanisms for [the Federal Conscience Statues] has stymied their effectiveness"); AR 133,746–758, Ex. 2 (comment supporting the proposed Rule because it seeks "to not only raise awareness of conscience rights but to put . . . teeth into federal protections for those rights"); AR 28,049–053, Ex. 1 (comment from various religious groups stating that the proposed Rule would "help guarantee that health care institutions and professionals are not pushed into [a] Hobson's choice").

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contradicting its assertions.[3] *See* Pl.'s Opp'n 31–35, 38–40. But again, HHS considered the complaints in conjunction with all of the factors discussed above and noted that the complaints *alleged* violations of the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,245. The presence or absence of complaints does not, by itself, paint a full picture of whether individuals and entities understand their rights and obligations under the Federal Conscience Statutes; as HHS indicated elsewhere, the agency is concerned that "segments of the public have been dissuaded from complaining about religious discrimination in the health care setting to OCR as the result, at least in part, of [the agency's previous,] unduly narrow interpretations of the Weldon Amendment." 84 Fed. Reg. at 23,179.

Further, although Defendants have acknowledged that many of the complaints that OCR received related to matters outside the scope of the Federal Conscience Statutes, a sizeable number of complaints *did* implicate the relevant Statutes and underscored the need to both clarify the scope of, and more robustly safeguard, the conscience rights protected by the Statutes.[4] While the complaints

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[3] In support of this argument, Plaintiff improperly relies upon extra-record evidence in the form of a declaration. *See infra* Part IX.

[4] Defendants cited some complaints in their opening brief as examples, *see* Defs.' Mem. 49, and include others here, *see, e.g.*, AR 542,017–26, Ex. 6 (complaint that California's health insurance abortion coverage mandate violates

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in the record are not the sole reason for HHS's decision to promulgate the Rule, they represent one factor that HHS considered in determining that "there is a significant need to amend the 2011 Rule to ensure knowledge of, compliance with,

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the Weldon Amendment); AR 542,151, Ex. 7 (nursing student alleges discrimination due to request for an exemption from assisting in abortions); AR 542,229–60, Ex. 13 (complaint against Illinois statute mandating that health care providers exercising conscience rights to engage in compelled speech and referrals); AR 542,285, Ex. 8 (complaint against Hawaii's statutory mandate that religious-based alternative pregnancy centers must advertise for state-funded abortions); AR 542,316–24, Ex. 9 (complaint against Pennsylvania's involvement in contraceptive mandate litigation); AR 545,932, Ex. 12 (nurse alleges that university hospital refused to hire her because of her views regarding abortion); AR 542,337, Ex. 10 (pediatric nurse complains that hospital informed her that she could no longer work in the health department clinics if she was unwilling to participate in the provision of abortion-related services) AR 544,612–23, Ex. 11 (complaint against a university medical center for deceptively coercing nurse to participate in elective abortion); AR 544,945–52, Ex. 14 (complaint by pharmacist who objects to filling birth control prescriptions).

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and enforcement of" the Federal Conscience Statutes.[5] 84 Fed. Reg. at 23,175.

HHS's past investigations into complaints alleging conscience discrimination, likewise, do not undercut the agency's reasons for promulgating the Rule, as Plaintiff argues. *See* Pl.'s Opp'n 35. A central objective of the Rule is to dispel "confusion" created in part by the 2011 Rule "over what is and is not required" under the Federal Conscience Statutes. 84 Fed. Reg. at 23,175. The Rule

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[5] Plaintiff attacks the relevance of two of the complaints highlighted in Defendants' opening brief. Pl.'s Opp'n 38–40. But the complaints indicate both general and specific concerns about the conscience rights of individuals in the health care field. The letter from the American Association of Pro-Life Obstetricians and Gynecologists highlights the "continuing chilling effects on [the] conscientious performance of ob-gyn services" by pro-life obstetricians. Defs.' Mem. Ex. B at 12, ECF No. 44-2. And the complaint by a Department of Corrections employee based on the employee's objection to providing hormone therapy could potentially relate to the Federal Conscience Statutes that protect objections to sterilization or the Church Amendments that more broadly protect conscience rights, if applicable. *See id.* at 44. These complaints, and others, support HHS's conclusion that the public needs more information about what is and is not protected under the Federal Conscience Statutes and that OCR needs more tools to better ensure compliance with the Statutes' conditions on HHS's funding.

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also clarifies for recipients of HHS funds the procedures that HHS uses to enforce the Federal Conscience Statutes. *See id.* The fact that HHS can also enforce the Statutes under the 2011 Rule does not undermine these purposes; indeed, it reveals as unfounded Plaintiff's objections to HHS's authority to promulgate the Rule, which is based in part on the same authority as the 2011 Rule.

B. HHS Considered All Important Aspects of the Problem.

Plaintiff also complains that HHS failed to consider the Rule's purported impact on a host of matters such as patients, providers, the Title VII framework, medical ethics, and emergency care. Pl.'s Opp'n 40–57. These arguments all fail.

Impact on Patient Populations. As Defendants explained in their opening brief, HHS considered whether the Rule would harm access to care and reasonably concluded that it would not. Defs.' Mem. 27–28. HHS reached this conclusion for several reasons. First, implementation and enforcement of the Federal Conscience Statutes "would help alleviate the country's shortage of health care providers," 84 Fed. Reg. at 23,180, as the Statutes make it easier for health care professionals to perform their jobs while staying true to their religious beliefs or moral convictions. Second, the agency was unaware of any data or persuasive reasoning, presented by commenters or otherwise, demonstrating that the Rule would negatively impact access to care. *See id.* at 23,180–82. As noted in the Rule, "[a]ccess to care is a critical concern" of HHS, 84 Fed. Reg. at 23,180, and HHS examined the commenters' concerns closely, *id.* at 23,180–82, 23,253–55. The agency probed commenters' illogical assumption that "there are health care providers in

underserved communities who are protected by these laws but are offering services to which they object anyway," *id.* at 23,181, and explained why it believed that the Rule would improve access to care by (1) encouraging individuals who had previously "anticipated they would be pressured to violate their consciences" to enter the health care field, *id.*; (2) preventing some health care entities from leaving the field in light of data indicating that some entities currently felt pressure to do so, *id.*; and (3) allowing an increase in the provision of health care by religious institutions, *id.*

Plaintiff speculates about a series of far-fetched harms stemming from potential conscience objections that may not even come within the ambit of the Statutes implemented by the Rule and claim that the agency "fundamentally failed to address" these issues. Pl.'s Opp'n 43; *see also id.* 41–43. But Plaintiff conflates the receipt of certain federal funds conditioned on protecting the conscience rights of individual and institutional health care entities with the absolute denial of care for entire swaths of the patient population. Further, neither Plaintiff nor the comments on which it relies explain why the Rule, which does not require any entity to refuse to care for patients and which for the most part protects conscience objections to specified services such as abortion, sterilization, and assisted suicide, *see* 84 Fed. Reg. at 23,170–74, would deny treatment for depression or would protect the refusal of assistance to "a person with a disability in performing parenting tasks because the person was married to someone of the same gender." Pl.'s Opp'n 42; *see also* 84 Fed. Reg. at 23,252. Plaintiff's objections boil down

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to a policy disagreement with Congress over its decision to protect health care entities that have conscience objections to performing certain services and do not warrant invalidation of the Rule. *See Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 210–11 (D.C. Cir. 2007).

Plaintiff also erroneously argues that HHS ignored commenters' concerns that the Rule might "make it impossible for service providers to anticipate" objections, absent a provision for advance notice of conscience objections. Pl.'s Opp'n 42. HHS in fact responded to those concerns, including by modifying the definition to "discriminate" or "discrimination" to clarify that "employers may require a protected employee to inform them" of protected conscience objections "to the extent there is a reasonable likelihood that the protected entity or individual may be asked in good faith" to undertake an objected-to activity. 84 Fed. Reg. at 23,189–93. HHS further specified "that the employer may use alternate staff or methods to provide or further any objected-to conduct, subject to certain limitations designed to protect the objecting person." *Id.*

Contrary to Plaintiff's assertions, HHS's conclusion that the benefits of the Rule outweigh its burdens is not "entirely speculative." Pl.'s Opp'n 55. The agency thoroughly analyzed the Rule's benefits by considering the available evidence and identified several benefits including the probable increase in overall access to medical care, an increase in the quality of care that patients receive, and a decrease in unlawful discrimination. *See* 84 Fed. Reg. at 23,246–54. Regarding access to care, HHS explained that it expects the Rule "to remove barriers to the

entry of certain health professionals, and to delay the exit [of others] from the field, by reducing discrimination or coercion that health professionals anticipate or experience," and supported that conclusion by relying on public comments received, academic literature, and historical support for conscience protections. *Id.* Defendants have already explained why the agency's reliance on 2009 and 2011 polls in conjunction with other evidence was not unreasonable, especially in light of a lack of "data that allows for an estimate of the effect of this rule on access to services," 84 Fed. Reg. at 23,247; *see also* Defs.' Mem. 50-52. It is entirely reasonable that the Rule's clarification of the protections in the Federal Conscience Statutes would allow more health care entities with conscience objections to certain medical procedures or services to enter, or stay, in the field, thereby allowing them to provide more care to patients overall. It is likewise logical that "[t]he burden of not being able to receive any health care clearly outweighs the burden of not being able to receive a particular treatment" from a particular provider. 84 Fed. Reg. at 23,252.

Nor was it arbitrary or capricious for HHS to reach this conclusion in the absence of empirical data (one way or the other) on the Rule's potential impact on access to care. "[P]redictive calculations are a murky science in the best of circumstances, and the [agency] naturally has no access to infallible data." *Cablevision Sys. Corp. v. FCC*, 597 F.3d 1306, 1314 (D.C. Cir. 2010). Here, HHS considered studies that "specifically found that there is insufficient evidence to conclude that conscience protections have negative effects on access to care," and

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Plaintiff offers no contrary studies, in the record or elsewhere. 84 Fed. Reg. at 23,810. Plaintiff fails to explain why the agency should be required to perform an unworkable study in these circumstances before the Rule goes into effect. *See BellSouth Corp. v. FCC*, 162 F.3d 1215, 1221 (D.C. Cir. 1999).

Title VII. Next, Plaintiff claims that HHS failed to explain why it did not follow Title VII's framework in the Rule. Pl.'s Opp'n 53–55. Plaintiff's complaint, however, is nothing more than a policy disagreement with HHS. As is evident from the preamble to the Rule, HHS clearly explained why it did not adopt the Title VII framework to implement the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,190–91. For one, Title VII contains distinct protections from the Federal Conscience Statutes, and therefore HHS was not required to incorporate standards from that separate statute. HHS explained that Congress's decision to

> take a different approach in Title VII as compared to [the Federal Conscience Statutes] is consistent with the fact that Title VII's comprehensive regulation of . . . employers applies in far more contexts, and is more vast, variable, and potentially burdensome (and, therefore, warranting of greater exceptions) than the more targeted conscience statutes that are the subject of this rule, which are health care specific, and often procedure specific, and which are specific to the exercise of Congress's Spending Clause authority.

Id. at 23,191. HHS did, however, consider the reasonable-accommodation standard set forth under Title VII and adopted components of that standard when modifying the definition of "discrimination" in response to comments on the proposed Rule. *See id.* Thus, it can hardly be said that HHS failed to adequately

consider or explain its choices *vis-a-vis* Title VII. Plaintiff would simply prefer that HHS had made a different choice.

Medical Ethics. Meanwhile, Plaintiff's assertion that the Rule is unlawful because it failed to consider "basic medical ethics," Pl.'s Opp'n 50, is unsupported by law or logic. The Rule, and the Federal Conscience Statutes that undergird it, do not require any medical professional to act unethically. Plaintiff highlights comments raising concerns that the Rule (1) "will allow discrimination against patients, exacerbate health inequities, and undermine patients' access to care" and (2) "threatens principles of informed consent." Pl.'s Opp'n 52. But Defendants have already explained why the Rule is unlikely to further discrimination or decrease access to care. *See supra*. And HHS's response to commenters' concerns about informed consent was not "conclusory," *see* Pl.'s Opp'n 53; rather, HHS explained that "medical ethics have long protected rights of conscience alongside the principles of informed consent" and that while the Federal Conscience Statutes protect "entities from being required to provide referrals for abortion," and the Rule ensures compliance with the Statutes, the Rule "will not change existing laws requiring doctors to secure informed consent from patients before performing medical procedures." 84 Fed. Reg. at 23,201. Plaintiff fails to explain why these explanations are arbitrary and capricious.

Indeed, the Rule does not compel anyone to refuse to provide medical care in any given circumstance and thus does not run afoul of the medical industries' suggested limitations on an individual's right to object to performing certain

services and procedures. *See* 84 Fed. Reg. at 23,200–1. While Plaintiff may prefer that HHS codify internal standards developed by certain medical associations, "this final rule provides for the enforcement of protections established by the people's representatives in Congress; the Department has no authority to override Congress's balancing of the protections." *Id.* at 23,182.

Emergency care. Finally, Plaintiff claims that the Rule will have "devastating effects" on emergency medicine. Pl.'s Opp'n 43. But the Rule does not infringe on physicians' duties to provide medically indicated care in an emergency and, indeed, recognizes that emergency treatment and stabilization of patients "who present in an emergency does not conflict with Federal conscience and antidiscrimination laws." 84 Fed. Reg. at 23,283. The Rule also makes clear that EMTALA does not conflict with the Federal Conscience Statutes or the Rule. *Id.*; *see also* 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. 78,087–88 (Dec. 19, 2008). Plaintiff does not identify a situation where the Rule compels a physician to violate his or her ethical duties to provide medically required care in an emergency situation, and even if it could, the Rule should not be found facially invalid on that basis. *See Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 619 (1991) ("The fact that petitioner can point to a hypothetical case in which the rule might lead to an arbitrary result does not render the rule 'arbitrary or capricious.'"). Indeed, by complaining that HHS's general conclusions in this regard are insufficient, Plaintiff essentially claims confusion

about when and how the Rule might apply in certain hypothetical scenarios. *See id.* But again, Plaintiff's uncertainty does not render the entire Rule arbitrary and capricious in all applications. *See id.* Further, a health care entity can easily request HHS's assistance to resolve specific questions. *See* 84 Fed. Reg. at 23,180.

V. Plaintiff's Spending and Establishment Clause Claims Are Not Ripe.

Plaintiff's Spending Clause and Establishment Clause claims are not ripe. The ripeness analysis turns on whether the Court would benefit from awaiting a concrete enforcement action under the Rule before assessing Plaintiff's constitutional claims and whether there would be any harm to Plaintiff in the interim. Plaintiff cannot dispute that it has not been the subject of any enforcement action under the Rule, or that multiple steps would have to occur before any loss of federal funds could come to pass. (Plaintiff attempts to draw support from the fact that a complaint involving Washington was cited in this lawsuit, Pl.'s Opp'n 5, but even assuming any enforcement action were occurring, it would be under the Federal Conscience Statutes, not the Rule, which is not yet in effect.) And of course if Plaintiff did violate the Rule, and the agency's informal resolution attempts failed, and the agency took enforcement action against Plaintiff, and all other applicable procedures were exhausted, Plaintiff offers no reason it could not seek judicial relief *then*. Although Plaintiff suggests that HHS might not begin with informal efforts at enforcement, Pl.'s Opp'n 60, such unsupported speculation is insufficient to establish ripeness for Plaintiff's facial challenge.

Plaintiff is also unsuccessful in distinguishing *NFPRHA v. Gonzales*, 468

F.3d 826, 827 (D.C. Cir. 2006), and *California v. United States*, 2008 WL 744840, at *3. Plaintiff argues that *NFPRHA* involved standing rather than ripeness, Pl.'s Opp'n 4, but "[r]ipeness and standing are closely related" and may "boil down to the same question." *Montana Envtl. Info. Ctr. v. Stone-Manning*, 766 F.3d 1184, 1188–89 (9th Cir. 2014) (citation omitted). To distinguish *California*, Plaintiff suggests that it is somehow in a more difficult position than the plaintiff in that case because it must decide on a future course of action now, but that was equally true when the Weldon Amendment was enacted prior to *NFPRHA* and *California*.

VI. The Rule Complies with the Spending Clause.

In discussing the Spending Clause, Plaintiff notably limits itself to arguing that the Rule is coercive, and not that the conditions placed on federal funds are ambiguous or lack a nexus to the government's interests. Pl.'s Opp'n 58-60. Plaintiff's coerciveness argument boils down to the assertion that the Rule has so dramatically changed the Statute's regime as to constitute a new program. This argument repeats Plaintiff's APA arguments, and fails for the same reasons.

Plaintiff points to the amount of funding affected by the Rule, Pl.'s Opp'n 59, but it is the *Federal Conscience Statutes* that determine which funds are covered by the conditions, and Plaintiff does not challenge the Statutes. And, unlike in *NFIB v. Sebelius*, 567 U.S. 519 (2012), Plaintiff is not faced with a binary choice to either accept a new program or sacrifice all of its funding under an existing program. As Defendants previously explained, Defs.' Mem. 64–65, the Rule's enforcement procedures will remain individualized and will begin with

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informal means. *See* 84 Fed. Reg. at 23,271, 23,222.

Nor does the Rule threaten to "withdraw[] existing funds . . . as a penalty for not complying with new conditions." Pl.'s Opp'n 59-60. Plaintiff admits that it has long been aware of the Federal Conscience Statutes' funding conditions, and nothing about the Rule changes those conditions so dramatically that they constitute entirely new programs. *Cf. NFIB*, 567 U.S. at 582–83 (holding that modification of the Medicaid statute did not violate the Spending Clause so long as the modifications did not rise to the level of creating a new program). Instead the Rule merely implements the Statutes. 84 Fed. Reg. at 23,256. And of course, the Spending Clause does not bar *all* adjustments to the terms on which the federal government offers funds—if that were so, the Supreme Court's opinion in *NFIB* would likely have been much shorter. *See NFIB*, 567 U.S. at 575, 583, 585 (noting that "[t]here is no doubt that the Act dramatically increases state obligations under Medicaid" before taking multiple pages to analyze the extent of the changes).

VII. The Rule Comports with the Establishment Clause.

Plaintiff does not even attempt to reconcile the essential tension of its Establishment Clause argument: its insistence that the Rule somehow violates the Establishment Clause and its apparent concession that the Federal Conscience Statutes do not. Each of Plaintiff's theories for why the Rule violates the Establishment Clause (which fail on the merits, as described below) would apply equally to the Statutes.

Although Plaintiff concedes that the "touchstone" of the Establishment

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Clause is "governmental neutrality between religion and religion, and between religion and nonreligion," Pl.'s Opp'n 60 (citation omitted), Plaintiff overlooks the fact that the Rule (like the Statutes) is generally neutral between religion and non-religion.[6] *See, e.g.*, 42 U.S.C. § 238n (Coats-Snowe Amendment); Pub. L. No. 115-245, Div. B., sec. 507(d), 132 Stat. 2981 (Weldon Amendment); 42 U.S.C. § 300a-7 (Church Amendments); 84 Fed. Reg. 23,170. This is strong evidence that neither violates the Establishment Clause, *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 704 (1994) (collecting cases), and Plaintiff cites no contrary case finding an Establishment Clause violation in a statute accommodating both religious and nonreligious objections.

Plaintiff argues that the Rule violates the Establishment Clause by giving employees an absolute right not to perform certain procedures. Pl.'s Opp'n 61-63. As noted above, however, any such "right" derives from the Statutes, which generally do not require that the employee have a *religious* objection. Plaintiff also does not explain why, for example, the Church Amendment's requirement that entities receiving certain federal funds not compel providers to perform

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[6] Plaintiff does not challenge the handful of Federal Conscience Statutes that are limited to religious objectors. *See, e.g.*, 42 U.S.C. § 1320a-1(h) (religious nonmedical health care institutions). In any event, the Establishment Clause does not bar government accommodation of religion. *See, e.g.*, *Corp. of Pres. Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 335 (1987).

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abortions would be any less "absolute and unqualified" than the operation of the Rule. *Cf. Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308, 311 (9th Cir. 1974) (concluding that a Church Amendment provision satisfied the Establishment Clause without considering whether it created an "absolute" duty to accommodate religious objections).

Contrary to Plaintiff's view, the problem that the Supreme Court identified in *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985), was not the provision of an "absolute and unqualified" right, but rather that the statute benefited only the religious. Indeed, there is no suggestion that it would have violated the Establishment Clause if Connecticut had offered all employees an "absolute and unqualified" day off work. In *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1 (1989), the Supreme Court discussed lawful tax exemptions for religious and nonreligious organizations and explained, citing *Thornton*, that "were [the] benefits confined to religious organizations . . . we would not have hesitated to strike them down for lacking a secular purpose and effect." *Id*. at 11, *see also Hobbie v. Unemp. Appeals Comm'n of Fla.*, 480 U.S. 136, 144–46 & n.11 (1987) (citing *Thornton* as an example of an impermissible religious preference and upholding a benefit to a religious objector because "the provision of unemployment benefits generally available within the State to religious observers . . . neutrally accommodate[s] religious beliefs and practices, without endorsement"). Here, the Establishment Clause is not violated because the Statutes and Rule address both religious and non-religious objections and do not "coerce" anyone to participate in any

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particular religious practice. *Contra* Pl.'s Opp'n 66-67. Indeed, the Church Amendments (and thus the Rule in implementing them) equally protect entities from discrimination based on choosing to *perform* abortions and choosing *not* to perform abortions, *see, e.g.*, 42 U.S.C. § 300a-7(c)(1), further demonstrating that the Rule does not favor particular religious beliefs.

Plaintiff concedes that the Establishment Clause does not flatly prohibit accommodations that may burden third parties, Pl.'s Opp'n 64-66—instead, potential burden is one factor a court considers to determine if an accommodation unlawfully fosters religion. This is in keeping with Supreme Court precedent: "[In *Gillette*,] the Court upheld a military draft exemption, even though the burden on those without religious objection to war (the increased chance of being drafted . . .) was substantial. And in *Corporation of Presiding Bishop*, the Court upheld the Title VII exemption even though it permitted employment discrimination against nonpractitioners of the religious organization's faith." *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist.*, 512 U.S. at 725. Here, as previously discussed, the Rule does not improperly foster religion because it also protects both religious and non-religious objections, and because it merely encourages entities not to *discriminate* against health care providers based on the providers' conscience decisions. *Cf. Chrisman*, 506 F.2d at 311 (concluding that a Church Amendment provision satisfied the Establishment Clause without analyzing the burden on third parties). And it is entirely permissible for the Rule to acknowledge that *one* of its objectives is the protection of religious freedom. *See, e.g.*, 84 Fed. Reg. at 23,170

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("The United States has a long history of providing protections in health care for individuals and entities on the basis of religious beliefs or moral convictions."). This language mirrors various Federal Conscience Statutes. *See, e.g.*, 42 U.S.C. § 300a-7 (Church Amendments, hinging on a person's "religious beliefs or moral convictions"). That Plaintiff objects to this phrasing in the Rule—but not in the Statutes—underscores the incoherence of Plaintiff's attempts to separate the two.

VIII. The Rule Does Not Violate the Separation of Powers.

Plaintiff's separation of powers arguments, Pl.'s Opp'n 57-58, mistakenly suggest that the Rule changes the amount of money or funding sources affected by the Federal Conscience Statutes. But the Rule does not change the Statutes' substantive requirements and thus does not newly link funds tied by statute to the Church Amendments (for example) to violations of the Weldon Amendment (for example) or *vice versa*. To the extent that remedies under other regulations, such as the HHS UAR, may affect other funds, those other regulations are not altered by the Rule or challenged by Plaintiff.

IX. The Court May Not Consider Plaintiff's Extra-Record Materials.

The Court should reject Plaintiff's improper attempt to create a new record by relying on declarations and other materials outside the administrative record. The APA provides that, "the court shall review the whole record," 5 U.S.C. § 706, or "the full administrative record that was before the Secretary at the time he made his decision," *Citizens to Pres. Overton Park Inc. v. Volpe*, 401 U.S. 402, 420 (1971); *see also Camp v. Pitts*, 411 U.S. 138, 142 (1973) ("[T]he focal point for

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judicial review should be the administrative record . . . , not some new record made initially in the reviewing court."). Ninth Circuit decisions agree that the court should not consider extra-record evidence when evaluating APA claims. *See, e.g.*, *Jet Inv., Inc. v. Dep't of Army*, 84 F.3d 1137, 1139 (9th Cir. 1996). Four "narrow" exceptions exist, *Cachil Dehe Band of Wintun Indians v. Zinke*, 889 F.3d 584, 600 (9th Cir. 2018), but none applies here (which Plaintiff has not disputed).

Instead, Plaintiff flouts the longstanding rule limiting review to the administrative record. *See, e.g.*, Pl.'s Opp'n 24-25 (citing declarations in an attempt to establish that the Rule conflicts with § 1554 of the ACA). Plaintiff also submits the declaration of Alexa Kolbi-Molinas to describe complaints contained in the administrative record, *see* Pl.'s Opp'n 33-34, but this analysis is not properly part of the Court's merits analysis because it was not before the Secretary when he made his decision and the complaints speak for themselves.

The Court should also limit its review to the administrative record on Plaintiff's constitutional claims, which rely on the APA for their private right of action. *See* 5 U.S.C. § 706(2)(B) (permitting judicial review of agency action "contrary to constitutional right, power, privilege, or immunity"). Section 706, by its plain language, restricts the review of constitutional claims to the administrative record. A contrary rule would "incentivize" plaintiffs to allege constitutional violations in order to "trade in the APA's restrictive procedures" for the Federal Rules of Civil Procedure. *Jarita Mesa Live. Grazing Ass'n v. Forest Serv.*, 58 F. Supp. 3d 1191, 1238 (D.N.M. 2014); *cf. Fence Creek Cattle Co. v.*

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202) 305-0878

Forest Serv., 602 F.3d 1125, 1131 (9th Cir. 2010) (affirming the limitation of review to the administrative record even though the plaintiff had alleged violations of "constitutional due process guarantees"); *see also, e.g.*, *Jiahao Kuang v. Dep't of Defense*, 2019 WL 293379, at *2-3 (N.D. Cal. Jan 23, 2019); *Moralez v. Perdue*, 2017 WL 2264855, at *3 (E.D. Cal. May 24, 2017). The Court should reject Plaintiff's improper attempt to support its constitutional claims with extra-record material. *See, e.g.*, Pl.'s Opp'n 59 (citing declarations for Spending Clause claim); *id.* at 63, 67 (citing declarations for Establishment Clause claim).

Defendants note that Plaintiff's declarations purport to establish alleged harm that will result from the Rule. Defendants disagree fervently with those allegations for the reasons explained in the preamble to the Rule, among others. However, because review in this case is properly limited to the administrative record, and because the appropriate time for Plaintiff to comment was during the rulemaking process, Defendants do not address the factual allegations in Plaintiff's declarations. Nor is it necessary for the Court to address those allegations to resolve the parties' cross motions for summary judgment.

X. Any Relief Should Be Limited.

The Rule is lawful and should not be vacated. However, if the Court were to find any part of the Rule invalid, it should respect the agency's clear intent and sever those portions from the remainder. *See* 84 Fed. Reg. at 23,272. It is *Plaintiff's* burden to explain why any portion of a lawfully promulgated regulation should not be allowed to go into effect. *Cf. Alaska Airlines v. Donovan*, 766 F.2d

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202) 305-0878

1550, 1560 (D.C. Cir. 1985) ("[T]he burden is placed squarely on the party arguing against severability to demonstrate that Congress would not have enacted the provision without the severed portion."). Portions of the Rule can clearly operate independently. For example, the remaining definitions and provisions of the Rule could continue to operate independently, absent any particular definition.

Furthermore, any relief must be limited to Plaintiff. Plaintiff insists that nationwide relief is the "usual" remedy under the APA, but ignores the Supreme Court's recent contrary instruction that any remedy "must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018). Vacating the Rule nationwide would go far beyond what is necessary to address Plaintiff's particular alleged injury, and would effectively stop courts in other jurisdictions from evaluating similar claims. *See* Defs.' Mem. 64–65.

Finally, in their opening brief, Defendants explained that even if the Court were to strike down any or all of the Rule, the Court should make clear in its order that the relief does not prevent HHS from continuing to investigate violations of, and to enforce, federal conscience and anti-discrimination laws under the existing 2011 Rule or the Federal Conscience Statutes themselves. Plaintiff does not challenge the underlying Statutes and therefore apparently concedes that any relief should not limit HHS's existing statutory or regulatory enforcement authority.

CONCLUSION

For these reasons, the Court should grant Defendants' motion and deny Plaintiff's motion.

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1100 L Street, N.W.
Washington, DC 20005
202) 305-0878

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Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

JOSEPH H. HARRINGTON
United States Attorney

JAMES M. BURNHAM
Deputy Assistant Attorney General

CHRISTOPHER A. BATES
Senior Counsel to the Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Rebecca Kopplin
REBECCA KOPPLIN
(California Bar No. 313970)
BRADLEY P. HUMPHREYS
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005
Tel: (202) 514-3953
Fax: (202) 616-8470
Email: Rebecca.M.Kopplin@usdoj.gov

Counsel for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on October 4, 2019, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification to all counsel of record.

/s/ Rebecca Kopplin
REBECCA KOPPLIN
Trial Attorney
U.S. Department of Justice

U.S. DEPARTMENT OF JUSTICE
1100 L Street, N.W.
Washington, DC 20005
(202) 305-0878