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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

CITY AND COUNTY OF SAN FRANCISCO,

Plaintiff,

vs.

ALEX M. AZAR II et al.,

Defendants.

STATE OF CALIFORNIA, *by and through* ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

vs.

ALEX M. AZAR II et al.,

Defendants.

COUNTY OF SANTA CLARA et al.,

Plaintiffs,

vs.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES et al.,

Defendants.

No. C 19-02405 WHA
Related to
No. C 19-02769 WHA
No. C 19-02916 WHA

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

Hon. William Alsup
Hearing: October 30, 2019, 8:00 a.m.

Phillip Burton Federal Building & United States Courthouse, Courtroom 12, 19th Fl., 450 Golden Gate Ave., San Francisco, CA 94102

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INTRODUCTION

Defendants respectfully ask that the Court grant their motion to dismiss or, in the alternative, for summary judgment. Plaintiffs' brief is long on hyperbole, but Plaintiffs at no point articulate how the challenged regulation, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) [hereinafter Rule], meaningfully differs from the statutes that it administers (Federal Conscience Statutes), *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. Remarkably, Plaintiffs do not challenge the underlying Federal Conscience Statutes. Nor do they 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 Plaintiffs' challenge to the Rule.

Plaintiffs' specific arguments fail for other reasons, too. The main thrust of Plaintiffs' Administrative Procedure Act (APA) challenge is that the Rule exceeds Defendants' statutory authority. But Plaintiffs' argument is belied by the delegations of authority in certain of the Federal Conscience Statutes and other statutes identified in the Rule. Plaintiffs' 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 to Plaintiffs' claim, the Rule is also entirely consistent with the provisions scattered throughout the United States Code that Plaintiffs cite. And, in promulgating the Rule, Defendants made reasonable decisions, thoroughly considering the issues raised in the comments and providing thoughtful explanations in response.

Plaintiffs' constitutional claims likewise fail. At the threshold, Plaintiffs' Spending and Establishment Clause claims are not ripe. Plaintiffs insist that the loss of "billions of dollars in federal funding" is imminent, *see* Pls.' Mem. P. & A. & Opp'n Defs.' Mot. Dismiss or Summ. J. 2, ECF No. 113 [hereinafter Pls.' Opp'n], even though several speculative events would need to occur before Plaintiffs could lose federal funding for failure to comply with the Federal Conscience Statutes. Furthermore, Plaintiffs' Spending and Establishment Clause claims fail on the merits. The funding conditions that Plaintiffs challenge flow from the Federal Conscience Statutes, which is fatal to Plaintiffs' Spending

Clause claim because Plaintiffs do not challenge those Statutes. The Rule also does not "establish" religion in any way; it protects religious beliefs only where the Federal Conscience Statutes protect religious beliefs, not to mention that most of the Federal Conscience Statutes address objections regardless of their religious or secular nature. In addition, Plaintiffs lack standing to claim violations of equal protection, due process, or free speech, and those claims are meritless besides. Nor does the Rule create separation of powers concerns.

Last, even if the Court held some aspect of the Rule unlawful—which it should not—the Rule's severability clause instructs the Court to sever the offending portion 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.

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

As Defendants explained in their opening brief, the Federal Conscience Statutes, the housekeeping statutes, and various other statutes support the Rule. *See See* Defs.' Mot. Dismiss or Summ. J. 12–14, ECF No. 54 [hereinafter Defs.' Mem.]; *see also* 84 Fed. Reg. at 23,183–86, 23,263 (describing the various authorities). Plaintiffs respond that certain Federal Conscience Statutes lack an explicit delegation provision and that the housekeeping statutes do not support the Rule. *See* Pls.' Opp'n 27–30. As discussed below, Plaintiffs are wrong on these points. Crucially, however, Plaintiffs *do not respond* to one of Defendants' central arguments: to wit, the Rule is no different than HHS's longstanding regulatory regime of monitoring and enforcing the condition in federal awards that recipients must comply with federal law. *See* Defs.' Mem. 13–14; *see also* 84 Fed. Reg. at 23,183–84 (describing HHS's authority under federal award regulations). Accordingly, Plaintiffs have abandoned argument on this point and the Court should grant Defendants' motion with respect to this claim. *See Ramirez v. City of Buena Park*, 560 F.3d 1012, 1026 (9th Cir. 2009).

Even if the Court considers Defendants' unrebutted statutory authority argument, it should still dismiss Plaintiffs' claim. As Defendants explained in their opening brief, *see* Defs.' Mem. 13–14, 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 grants and contracts regulations that correspond to 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. Furthermore, 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 Amendments] with the Departmental funding component(s) from which the entity, to which a complaint has been filed, receives funding."). The 2019 Rule simply makes explicit that under existing (and 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.[1]

In addition to this longstanding authority, several statutory provisions explicitly grant HHS sufficient regulatory authority to promulgate the Rule. *See* 84 Fed. Reg. 23, 184–85, 23,263 (citing, *inter alia*, 42 U.S.C. §§ 1302, 18023, 18041, 18113, 263a, 1315a). And, as discussed in the definitions section *infra*, the Federal Conscience Statutes implicitly grant HHS the authority to administer them.

Plaintiffs' response—that the presence of explicit rulemaking authority in some contexts indicates the lack of delegation in others, *see* Pls.' Opp'n 29–30—is unsupported and incorrect. Although Congress has explicitly delegated enforcement authority in some contexts, the existence of explicit delegations in other statutes has no bearing on HHS's authority to ensure compliance with the Federal Conscience Statutes and this Rule under the provisions of the HHS UAR or HHSAR or the other statutes cited in the Rule. Plaintiffs have not shown that the statutes that contain explicit delegations, which were enacted in

[1] Plaintiffs incorrectly suggest that the housekeeping statutes cannot support regulations that relate to later-enacted statutes. *See* Pls.' Opp'n 29. First, such a rule would absurdly restrict HHS's ability to enforce all statutes enacted after the housekeeping statutes under the HHS UAR and HHSAR. Second, it is inconsistent with the forward-thinking purpose of the housekeeping statutes to permit an "agency to regulate its own affairs." *Chrystler Corp. v. Brown*, 441 U.S. 281, 309 (1979).

different sessions of Congress and as different public laws, are subject to inter-textual comparison as Plaintiffs would like. *See Erlenbaugh v. United States*, 409 U.S. 239, 243–44 (1972) (describing the standard for comparing different statutes). Furthermore, Plaintiffs' theory cannot be squared with longstanding precedent that "[s]ometimes the legislative delegation to an agency on a particular question is implicit." *Chevron U.S.A. Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837, 844 (1984).

Plaintiffs' other response—that *United States v. Marion County School District*, 625 F.2d 607 (5th Cir. 1980), and *United States v. Mattson*, 600 F.2d 1295 (9th Cir. 1979), do not support the government's inherent authority to impose contractual assurances—is not a response to Defendants' argument at all. Defendants cited those cases for the proposition that when the government issues funds on certain conditions, it has the inherent authority to sue for a breach of those conditions. *See Marion Cty. Sch. Dist.*, 625 F.2d at 609 ("As the Supreme Court has long recognized, the United States may attach conditions to a grant of federal assistance, the recipient of the grant is obligated to perform the conditions, and the United States has an inherent right to sue for enforcement of the recipient's obligation in court."); *Mattson*, 600 F.2d at 1299 (recognizing that the government wielded "the threat of withholding funds should the states not comply with all procedural requirements").[2] The Rule does not establish or seek to establish HHS's authority to impose those conditions in the first place; rather, it explains *how* HHS enforces those conditions using existing authority.[3]

II. The Challenged Definitions Are within HHS's Statutory Authority.

The challenged definitions in the Rule reflect the unambiguous meaning of the terms in the Federal Conscience Statutes. At a minimum, they are reasonable interpretations entitled to *Chevron* deference.

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

Plaintiffs contend that the Rule's definitions are not entitled to *Chevron* deference because

[2] Plaintiffs also overgeneralize *Mattson*'s holding. The court rejected the government's inherent authority to sue for *injunctive* relief, *see* 600 F.2d at 1297, not to withhold federal funds for failure to comply with conditions in federal awards, *see id.* at 1299, which is the dispute in this case.

[3] The Court has asked "what specific denial of abortion or sterilization scenarios are covered by the new rule, but were not covered under the federal conscience statutes." Notice re Briefing, ECF No. 135. The answer is straightforward: there are no such scenarios. As Defendants have explained, the Rule simply employs existing procedures to administer the Federal Conscience Statutes among recipients of HHS's funds; it does not add any conditions to those Statutes. And the Rule certainly does not define the term "sterilization," as the *Santa Clara* Plaintiffs suggest, *see* Santa Clara's Compl. ¶ 101, ECF No. 1.

Congress has not delegated authority to HHS to interpret the Federal Conscience Statutes. *See* Pls.' Opp'n 31. But, as explained in Defendants' opening brief and below, Congress has delegated such authority both explicitly and implicitly. *See* Defs.' Mem. 12–14. The Court thus should review Plaintiffs' challenges to the Rule's definitions under the highly deferential framework set forth in *Chevron*.

To begin with, 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. A number of statutory provisions provide authority for HHS to promulgate the Rule, including 42 U.S.C. §§ 1302, 18023, 18041, 18113, 263a, and 1315a. *See* Defs.' Mem. 14; 84 Fed. Reg. at 23,185 (listing statutes). And other statutes that support HHS's enforcement of federal awards, 5 U.S.C. § 301; 40 U.S.C. § 121(c) (procurement contracts); 42 U.S.C. § 216 (grants), also explicitly delegate such authority. *See* Defs.' Mem. 13–14.

Yet another source of authority is the implicit delegation from the Federal Conscience Statutes themselves. Just as Congress may delegate authority to the agency explicitly, "[s]ometimes the legislative delegation to an agency on a particular question is implicit." *Chevron*, 467 U.S. at 844. Although Plaintiffs focus on whether the Rule is supported by explicit delegation provisions (and it is), implicit delegations are also common: "The power of an administrative agency to administer a congressionally created and funded program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." *Morton v. Ruiz*, 415 U.S. 199, 231 (1974). "[I]t can still be apparent from the agency's generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law, even one about which 'Congress did not actually have an intent' as to a particular result." *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001) (quoting *Chevron*, 467 U.S. at 845). To determine whether Congress has implicitly delegated authority, courts 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 explicitly 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 explicitly detail the mechanisms to ensure that recipients comply with the Statutes' conditions. In view of the lack of private rights of action. *see* Defs.' Mem. 28, surely Congress did not intend to impose significant conditions on federal funds without also authorizing HHS to employ longstanding procedures to enforce those conditions with respect to the funds that HHS disburses and administers and, to the extent a term is ambiguous, to interpret such ambiguity. These are quintessentially interstitial questions; they are important for the administration of the Statutes, but the Statutes themselves do not answer them.

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 that apply in different contexts, is estimated to cover 502,899 entities. *See* 84 Fed. Reg. at 23,235.

Last, HHS has significant expertise developed over years of 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. OCR has also investigated complaints of discrimination, issued notices of violations, and negotiated settlements with entities found to have violated the Federal Conscience Statutes and implementing regulations. Its staff has experience overseeing and ensuring the protection of civil rights, including protection from discrimination, such as religious discrimination. Based on this experience, HHS determined there was a need to provide more concrete and detailed guidance on how the agency intends to enforce conscience protections with respect to recipients of its federal funds.

B. The Rule's Definitions Are Consistent with the Federal Conscience Statutes

1. "Assist in the Performance"

Plaintiffs' only objection to HHS's definition of "assist in the performance" is that it is allegedly inconsistent with the Church Amendments' legislative history. However, this meager objection ignores the plain text of the statute and overstates the legislative history. First, Plaintiffs fail to respond to any of Defendants' points regarding the standard dictionary definition of "assist," *see* Defs.' Mem. 15. Instead, Plaintiffs suggest that a medical dictionary must be consulted rather than a standard dictionary. The Ninth Circuit, however, regularly consults *Merriam-Webster* at *Chevron* step one. *See, e.g.*, *Lagandaon v. Ashcroft*, 383 F.3d 983, 988 (9th Cir. 2004). Plaintiffs offer no statutory basis to deviate from this practice here.[4] Nor do they identify a contradictory definition in a medical dictionary. *See* Pls.' Opp'n 33 n.52. In addition, and as Defendants have also explained, *see* Defs.' Mem. 16, the text of the Church Amendments is not limited to individuals who *perform* certain procedures, but rather extends to individuals who *assist* in the performance: "No individual shall be required to *perform* or *assist in the performance* of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services 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." *See* 42 U.S.C. § 300a-7(d) (emphasis added).

The legislative history that Plaintiffs cite does not contradict the Rule's definition for several reasons. First, 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 above, the text supports the Rule's definition. Second, Plaintiffs cite 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 Central Dist. of Cal.*, 435 F.3d

[4] Plaintiffs' citation to extra-record declarations, *see* Pls.' Opp'n 33 n.52, is inappropriate *See infra* sec. X. In APA cases, courts cannot consult extra-record documents outside of limited circumstances, which are not present here. *See Sw. Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1450–51 (9th Cir. 1996). Furthermore, it is unclear why Plaintiffs seek to use a medical dictionary with respect to only "assist in performance." That this is their only response to the commonsense meaning of "assist in the performance" suggests the weakness of their argument.

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

2. "Discriminate or Discrimination"

Plaintiffs' response to the definition of "discriminate or discrimination" is remarkably bereft of legal citations or response to the *Chevron* arguments in Defendants' opening brief. Instead, Plaintiffs assert—without any acknowledgement of what the Rule actually says—that the Rule "encompasses almost any adverse employment action toward religious objectors without considering what may be legally justifiable." *See* Pls.' Opp'n 34. This is *not* what the Rule says. As explained in Defendants' opening brief, *see* Defs.' Mem. 16–17, 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)).

Plaintiffs also suggest that the Rule should permit additional rationales to justify adverse employment actions, pointing to Title VII. *See* Pls.' Opp'n 34. However, Plaintiffs do not identify a statutory basis to import their desired provisions of Title VII into the Federal Conscience Statutes. And again, to the extent such provisions are incorporated in the Federal Conscience Statutes, HHS recognizes them. *See* 84 Fed. Reg. at 23,263 (stating that the Rule applies the Federal Conscience Statutes).

3. "Health Care Entity"

Plaintiffs' 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 and Weldon

Amendments as well as § 1553 identify examples of health care entities in non-exhaustive lists. *See* Defs.' Mem. 17–18. Plaintiffs suggest that these lists are exhaustive, arguing that the term "include," which proceeds each statutory list, is limiting. Although the term "include" *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"). Plaintiffs offer no reason why the usual definition of "includes" should not apply other than their own preference.

Furthermore, Plaintiffs have yet to explain why any of the examples of a health care entity in the definition are not, in fact, health care entities. Instead, they hyperbolically assert that the Rule's definition includes "all members of the workforce of a healthcare entity." Pls.' Opp'n 32. This assertion is not supported by the text of the Rule, which identifies specific positions covered by the Coats-Snowe and Weldon Amendments. *See* 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2). In fact, each item in the Rule's definition is a dictionary example of a healthcare entity.

4. "Referral or Refer For"

Finally, Plaintiffs argue 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 consequences. *See* Pls.' Opp'n 33–34. Both points can be dismissed out of hand. Plaintiffs' statutory argument is circular; they quote the Coats-Snowe and Weldon Amendments and state—without explanation—that the definition "strains the plain language of both statutes." *See* Pls.' Opp'n 33. Such a perfunctory argument leaves the Court and Defendants guessing. At a minimum, this is no response to Defendants' argument that the dictionary definition of "refer" and an intra-textual analysis of the statutes supports the Rule's definition. *See* Defs.' Mem. 19.

Plaintiffs' other argument—that the definition would deprive patients of information—is not only incorrect, it also is untethered from any statutory analysis. First, 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 have a medical, legal, ethical, or other duty to do so." 84 Fed. Reg. at 23,200.

Rather, the Rule protects certain individuals from "being coerced by entities receiving Federal funds to violate their moral or religious convictions." *Id.* And at any rate, the meaning of the term "referral or refer for" is *legal* in nature. To the extent that Plaintiffs would like to require a health care entity to issue referrals or refer for procedures in violation of that entity's moral or religious convictions, Plaintiffs' objection is to the Federal Conscience Statutes themselves (the source of such protections), not the Rule.

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

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

Plaintiffs press on with their extraordinary claim that § 1554 of the ACA 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* Pls.' Opp'n at 35. It is worth pausing to consider the incredible breadth of Plaintiffs' argument: if they were correct, § 1554 would render meaningless (if not completely abrogate) many Federal Conscience Statutes that touch on health care because—by respecting the conscience rights of health care entities—the Statutes allegedly "impede access" to care. And § 1554 would do this without mentioning any of the Federal Conscience Statutes and without otherwise indicating that Congress intended to limit in some cases decades-old conditions. Plaintiffs' reading of § 1554 would also mean that HHS could not condition Medicare or Medicaid funding through regulations. To suggest that Congress intended any of this is absurd.

As Defendants explained in their opening brief, there is no plausible reason to accept Plaintiffs' sweeping interpretation of § 1554. *See* Defs.' Mem. 21–22. 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 Plaintiffs' argument that § 1554 somehow interferes with implementation of the Federal Conscience Statutes through the Rule. Plaintiffs' rebuttal—that § 1303(c)(2) "works together" with § 1554 because § 1303(c)(2) "does not 'create[],' 'impede[],' 'interfere[] with,' 'restrict,' or 'violate[],' healthcare rights or access," Pls.' Opp'n 36 (alterations in original)—misses the point. Congress was clear that the ACA,

including § 1554, should not have "any effect" on federal conscience protections. *See* 42 U.S.C. § 18023(c)(2).

B. Section 1557 of the ACA

Plaintiffs' § 1557 argument should also be rejected out of hand. Plaintiffs barely attempt to defend it in their brief. *See* Pls.' Opp'n 37. Putting aside that Plaintiffs can point to no actual conflict between the Rule and § 1557 in their facial challenge, Congress stated explicitly in § 1303(c)(2) of the ACA that nothing in that act (e.g., § 1557) should have "any effect" on federal conscience protections. *See* 42 U.S.C. § 18023(c)(2). Plaintiffs offer no reason to ignore Congress's clear instruction.

C. Emergency Medical Treatment and Active Labor Act

Plaintiffs claim 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. Pls.' Opp'n 36–37. The case that Plaintiffs cite for that proposition, however, offers no such support. In *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, (N.D. Cal. Mar. 18, 2008), the district court *rejected* the plaintiff's challenge to the Weldon Amendment. Much like Plaintiffs here, the plaintiff claimed that there was a conflict between EMTALA and the Weldon Amendment. But the district court held that there was no clear indication of a conflict, relying on the Ninth Circuit's instruction that "to the extent that statutes can be harmonized, they should be." *Id.* at *4 (citing *United States v. Trident Seafoods Corp.*, 92 F.3d 855, 862 (9th Cir. 1996)). The Court should hold no differently here.

As Defendants explained in the preamble to the Rule and in their opening brief, HHS believes the Rule can be read harmoniously with EMTALA and does not foresee any circumstance in which fulfilling the requirements of EMTALA would violate the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,183; Defs.' Mem. 23–24. 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. Plaintiffs may continue to abide by EMTALA's requirements without any reasonable fear that doing so would run afoul of the Federal Conscience Statutes.

D. Title X

Plaintiffs also continue to press their argument that the Rule somehow conflicts with Title X. Pls,' Opp'n 37–38. This claim fails for multiple reasons. First, Plaintiffs do not identify any portion of Title X with which the Rule allegedly conflicts. And, indeed, there is nothing in Title X that could plausibly prevent HHS from implementing the Federal Conscience Statutes. *See* Pub. L. No. 91-572, 84 Stat. 1504 (1970). Plaintiffs' argument appears to be that, because Title X grantees *may* (though are not required to) counsel women regarding pregnancy options, including abortion, those grantees will somehow violate Title X when one of their individual employees declines to provide such counseling. *See* Pls.' Opp'n 37. But that is not correct. Title X does not *require* pregnancy counseling at all, much less that every single one of a Title X grantee's employees do so, even against their conscience. There is no conflict between the Rule and Title X, and the Court should reject Plaintiffs' attempt to manufacture one.

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 5 U.S.C. § 706(1) because HHS provided "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); *see also* Defs.' Mem. 25–30. Plaintiffs' arguments to the contrary are meritless. HHS supported each challenged aspect of the Rule with sound and detailed reasoning, and Plaintiffs' attempt to couch their 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. Here, 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." 83 Fed. Reg. at 3,887. 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,[5] (4) a survey conducted in 2009, (5) comments received in the 2008 and 2011 rulemakings, and (6) various studies and articles. *See* 84 Fed. Reg. 23175–79; *see also* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3,880, 3,887–891 (proposed Jan. 26, 2018).

Plaintiffs assail HHS's reliance on recent complaints that OCR received to argue that the agency failed to acknowledge record evidence allegedly contradicting its assertions. *See* Pls.' Opp'n 24–25. 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.

Furthermore, although Defendants have acknowledged that many of the complaints that OCR received related to matters that are outside the scope of the Federal Conscience Statutes, a sizeable number of complaints *did* implicate the relevant Statutes and underscore the need to both clarify the scope of, and more robustly safeguard, the conscience rights protected by the Statutes.[6] While the complaints in the

[5] *See, e.g.*, Administrative Record (AR) 135,736–746, Ex. 4 (comment from a "diverse group of faith-based ministries" stating that "[f]or the wellbeing of patients and the integrity of the [health care] profession, . . . healthcare professionals must 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 Ascension, a faith-based healthcare organization, applauding HHS "for taking steps to protect the religious freedoms of all Americans, 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 from Catholic Health Association noting 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 from Alliance Defending Freedom 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 organizations stating that the proposed Rule would "help guarantee that health care institutions and professionals are not pushed into [a] Hobson's choice"). Although the AR has been filed with the Court, Defendants have attached citations to the AR to this brief for the Court's convenience.

[6] Defendants cited some complaints in their opening brief as examples, *see* Defs.' Mem. 53, and

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

HHS's recent investigations into complaints alleging conscience discrimination, meanwhile, do not undercut HHS's reasons for promulgating the Rule, as Plaintiffs argue, *see* Pls.' Opp'n 25 (claiming that HHS is "engaging in 'robust' enforcement of the federal conscience statutes" under its current authority (citation omitted)). 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 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 Plaintiffs' 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.

Plaintiffs also complain that HHS failed to consider the Rule's purported impact on a host of matters such as patients, providers, and the Title VII reasonable-accommodation framework, Pls.' Opp'n 16–24, 25–27. For the following reasons, these arguments fail.[7]

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–

include others here, *see, e.g.*, AR 542,017–26, Ex. 6 (complaint that California's health insurance abortion coverage mandate violates 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 healthcare 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 contraception mandate litigation); AR 545,932, Ex. 12 (nurse alleges that university hospital refused to hire her for full-time faculty position 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 the University of Vermont 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).

[7] Plaintiffs improperly rely on declarations in support of their argument that the Rule violates the APA. *See infra* sec. X.

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 could 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.*

Plaintiffs speculate about a series of far-fetched harms and claim that the agency "brushed those concerns aside." *See* Pls.' Opp'n 16–17. But they conflate 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 Plaintiffs nor the comments on which they rely 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 to the children of LGBT individuals or "curtail or eliminate reproductive healthcare and training," Pls.' Opp'n 17. *See* 84 Fed. Reg. at 23,252. Plaintiffs' objections boil down 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.[8] *See Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety*

[8] Plaintiffs claim that "none of the purported authorizing [Federal Conscience] statutes require" or allow HHS to conclude that certain conscience rights are "'worth protecting even if they impact [overall or individual] access to a particular service, such as abortion.'" Pls.' Opp'n 18–19 (quoting 84 Fed. Reg. at 23,182). But none of the Statutes make protection of the applicable conscience rights conditional. *See,*

Admin., 494 F.3d 188, 210–11 (D.C. Cir. 2007).

Contrary to Plaintiffs' assertions, HHS's conclusion that the benefits of the Rule outweigh its burdens is not "pure conjecture," Pls.' Opp'n 22. The agency thoroughly analyzed the Rule's benefits by considering the available evidence and identified several benefits beyond the probable increase in overall access to medical care, including 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* Defs.' Mem. It stands to reason 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, and it is 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. F.C.C.*, 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 Plaintiffs offer no contrary studies, in the record or elsewhere. 84

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e.g., 42 U.S.C. § 300a-7 (Church Amendments); 42 U.S.C. § 238n(a) (Coats-Snowe Amendment); Pub. L. No. 115-245, 132 Stat. 2981, 3118 (most recent iteration of the Weldon Amendment); 42 U.S.C. §§ 18081, 18023(b)(1)(A). (b)(4), 18113, 14406(1) (certain conscience protection provisions in the Patient Protection and Affordable Care Act). And while Plaintiffs point to the emergency treatment requirements in EMTALA, the Rule makes clear that HHS believes that EMTALA does not conflict with the Federal Conscience Statutes or the Rule. 84 Fed. Reg. at 23,183; *see also* 73 Fed. Reg. at 78087–88.

Fed. Reg. 23,810. Plaintiffs fail to explain why the agency should be required to perform an unworkable study in these circumstances on the specific effects of the Rule before it went into effect. *See BellSouth Corp. v. FCC*, 162 F.3d 1215, 1221 (D.C. Cir. 1999).

Impact on Providers. HHS also extensively considered the Rule's impact on providers and other affected entities. 84 Fed. Reg. 23,239–46. The agency identified several categories of potential burdens, attempted to quantify them with the available data, and considered comments suggesting that the proposed rule's notice, assurance, and certification requirements were too burdensome. *Id.*; *see also id.* at 23,217, 23241. In response to comments, the agency modified its notice provision "from a requirement to a voluntary action and to accept self-drafting of notices to provide greater tailoring to individual circumstances." *Id.* at 23,217. HHS also "exempted certain classes of recipients from" the assurance and certification requirements in § 88.4 of the Rule. *Id.* at 23,241. "The impact of the exemption means that . . . approximately 70 percent of recipients do not have to comply with the assurance and certification requirement." *Id.* As to the recipients that remain subject to the assurance and certification requirements, HHS explained that the requirements provide "important protections to persons and entities under these laws and would be consistent with requirements under other civil rights laws" because entities would be more likely to understand their obligations upon application for federal funding and be more vigilant about complying with the Federal Conscience Statutes. *Id.* at 23,213–14. HHS therefore acknowledged and factored in the reasonable burdens associated with the Rule and ultimately concluded that "the benefits . . . justify the burdens of the regulatory action." *Id.* at 23,277. Contrary to Plaintiffs' assertions, *see* Pls.' Opp'n 21–22, HHS did not disregard commenters' concerns when data was unavailable; rather, while it noted that certain burdens "cannot be fully monetized," 84 Fed. Reg. at 23,239, it considered them to the extent it could, *see id.* at 23,239–46. Plaintiffs' attacks on HHS's burden analysis attempt to elevate Plaintiffs' judgment over that of the agency and, accordingly, must fail.

Title VII. Plaintiffs also claim that HHS "substitutes Title VII's established religious-accommodation process with a process that would be fundamentally unworkable," Pls.' Opp'n 25–26, and failed to explain why it departed from Title VII's framework, *id.* at 27. Plaintiffs' complaint, however, is nothing more than a policy disagreement with the path HHS took in promulgating the Rule. 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 American 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. Plaintiffs would simply prefer that HHS had made a different choice.

V. Plaintiffs' Spending Clause and Establishment Clause Claims Are Not Ripe.

Plaintiffs' 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 applying the Rule before assessing the merits of Plaintiffs' constitutional claims and whether there would be any harm to Plaintiffs in the interim. Plaintiffs cannot dispute that they have not been the subject of any enforcement action, or that multiple steps would have to occur before any loss of federal funds could come to pass. And of course if Plaintiffs did violate the Rule, and the agency's informal resolution attempts failed, and the agency took enforcement action against Plaintiffs, and all other applicable procedures were exhausted, Plaintiffs offer no reason why they could not seek judicial relief *then*.

Plaintiffs are also unsuccessful in distinguishing *NFPRHA v. Gonzales*, 468 F.3d 826, 827 (D.C. Cir. 2006), and *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, at *3 (N.D. Cal. Mar. 18, 2008). Plaintiffs argue that the definition of "discrimination" and other terms in the Rule present an "immediate regulatory burden[]" that was lacking in *NFPRHA*, Pls.' Opp'n 14, but *NFPRHA* involved a challenge to the entire Weldon Amendment, which originated various conscience-based restrictions on federal funds in the first place. To distinguish *California*, Plaintiffs suggest that there is an ongoing enforcement action against them, but the letter they cite discusses an investigation occurring directly under

the Statutes, not under the Rule. Pls.' Opp'n 5 & n.3, 15. Plaintiffs argue that they must decide now on their future course of action, but that was equally true when the Weldon Amendment was enacted prior to *NFPRHA* and *California*. And, to the extent that Defendants do not challenge the ripeness of Plaintiffs' non-constitutional claims, those claims will still be adjudicated.

VI. The Rule Does Not Violate the Spending Clause.

In their Spending Clause arguments, Pls.' Opp'n 38–42, Plaintiffs reaffirm that they do not object to the Federal Conscience Statutes and double-down on their insistence that the Rule is an unconstitutional departure from the Statutes. But Plaintiffs do not even attempt to identify an unconstitutional difference between the two. For example, Plaintiffs argue the Rule is coercive because it potentially affects a large pot of money, *id.* at 38–39, but precisely the same is true of the Federal Conscience Statutes. The Rule does not expand the Statutes—for example, it does not "bootstrap[]" the consequences of a violation of the Weldon Amendment into a violation of other provisions, *contra id.* at 39. As Defendants have explained elsewhere, the Rule is a clarifying regulation that does not alter the Statutes' substantive requirements. 84 Fed. Reg. at 23,256.

HHS's previous comments concerning the interaction of the Spending Clause and the Weldon Amendment are not relevant here, where Plaintiffs do not challenge the constitutionality of the Weldon Amendment. *Cf.* Pls.' Opp'n 39 (citing App'x 396). Indeed, HHS's sensitivity to the Spending Clause provides no reason to rush to judgment on the Rule given that it is not yet in effect and thus has never been applied in a specific factual circumstance.

The Rule, like the Federal Conscience Statutes, is unambiguous, and Plaintiffs had ample notice of the conditions attached to federal funds. As Defendants have previously explained, Defs.' Mem. 32, the standard for conditions on federal funds is not perfect clarity or perfect notice. When a condition is present but "largely indeterminate," the Spending Clause is satisfied if a state nonetheless chooses to accept the federal funds. *Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002); *see also id.* ("Congress is not required to list every factual instance in which a state will fail to comply with a condition."). The question is whether the state knew the funds were conditioned. Plaintiffs do not substantively dispute this contention or assert that they did not understand that the Federal Conscience Statutes included non-discrimination requirements. It is thus irrelevant if Plaintiffs believe there is some

uncertainty concerning specific definitions or subrecipients.[9] Indeed, it is ironic that Plaintiffs object to the lack of clarity and specificity in the Rule, when the Rule provides additional clarity for funding recipients as compared to the Statutes.

Likewise, Plaintiffs argue that the funds at issue are allegedly unrelated to the conscience protections' purpose of alleviating potential conscience burdens on individual and institutional health care entities. Pls.' Opp'n at 42. If any such nexus problem existed, however, it would apply equally to the Statutes, since it is the Statutes that determine which sources of federal funds are subject to conditions. Plaintiffs do not explain how the Rule, which applies only to HHS administered, conducted, or funded programs, would somehow affect Plaintiffs' funds from the Departments of Labor and Education. *See* 84 Fed. Reg. at 23,170 (stating that the rule addresses enforcement of "Federal conscience and anti-discrimination laws applicable to the Department, its programs, and recipients of HHS funds"). To the extent that remedies under other regulations, such as the UAR, may affect other funds, those other regulations are not altered by the Rule or challenged by Plaintiffs.

Nor are the conditions on federal funds retroactive—Plaintiffs admit that they have long been aware of the funding conditions set by the Federal Conscience Statutes. This is not a case where, as in *NFIB*, the programs are being changed so dramatically that they constitute entirely new programs. *Cf. Nat'l Fed'n of Indep. Bus.* (*NFIB*) *v. Sebelius*, 567 U.S. 519, 582–83 (2012) (holding that the Medicaid statute authorized Congress to modify the statute's terms without creating Spending Clause problems, so long as the modifications did not rise to the level of creating a new program). Instead, as discussed previously, the Rule merely implements the Statutes, and Plaintiffs are incorrect that this is a shift in kind rather than degree, for the reasons previously discussed.

And of course, the Spending Clause does not bar *all* adjustments to the terms on which the federal government offers funds—if that were the case, 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 engaging in multiple pages of Spending Clause analysis to determine the extent of the changes).

[9] Plaintiffs do not rebut that the Rule addresses concerns about liability for sub-recipients' actions. *Compare* Defs.' Mem. at 32 (citing 84 Fed. Reg. at 23,220), *with* Pls.' Opp'n at 40 n.61.

VII. The Rule Does Not Violate the Establishment Clause.

Plaintiffs fail to reconcile the essential tension of their Establishment Clause argument: their insistence that the Rule somehow violates the Establishment Clause and their apparent concession that the Federal Conscience Statutes do not. Other than Plaintiffs' unsupported assertion that the Rule "wildly expands" the Statutes, Pls.' Opp'n 42, (which is incorrect, for the reasons stated *supra*), Plaintiffs fail to explain why the Statutes do not likewise burden third parties, elevate religion over non-religion, or entangle the government with religion.

Plaintiffs boldly argue that the Rule improperly advances certain religious beliefs, even though the Rule (and Statutes) do not endorse any religion, much less a specific religion. Both the Rule and Statutes are generally neutral between religion and non-religion.[10] *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). The fact that the government accommodates both religious and non-religious objections has long been a factor indicating that there is no Establishment Clause violation, *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 704 (1994) (collecting cases), and Plaintiffs cite no contrary case finding an Establishment Clause violation as to a statute or regulation that accommodates objections whether based on religion or not.

Plaintiffs misstate the law by asserting that the government can protect religious liberty through religious accommodations "only to alleviate substantial government-imposed burdens on religious practice." Pls.' Opp'n 45. Title VII, which Plaintiffs cite with approval elsewhere in their brief, is a clear counterexample where the government has required private entities not to discriminate based on their employee's religious beliefs. *See* Cal. Gov. Code § 12940 (likewise prohibiting employers from discriminating against employees based on religious creed). Plaintiffs cite cases discussing RFRA, Pls.' Opp'n 46, but RFRA is not a ceiling on the government's power to accommodate religious freedom.

Plaintiffs assert—without support—that the Rule "protects certain denominations' religious

[10] And the handful of Federal Conscience Statutes that are limited to religious objectors, *see, e.g.*, 42 U.S.C. §§ 1320a-1(h) (referring to religious nonmedical health care institutions), are not challenged by Plaintiffs. In any event, the Establishment Clause does not prevent the government from accommodating religion. *See, e.g., Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 335 (1987).

beliefs in opposition to religious freedom and LGBT rights," Pls.' Opp'n 46, and suggest—again, baselessly—that the Rule is HHS's attempt to "favor[]" the Jewish faith over other traditions, Pls.' Opp'n 46. This is an astonishingly wrong argument. On its face, the Rule explains its purpose to protect the conscience rights, both religious and non-religious, of entities covered by the Federal Conscience Statutes. Under Plaintiffs' flawed logic, a federal requirement that school lunch include fruits and vegetables would violate the Establishment Clause by "favoring" Seventh-day Adventism, Jainism, or other faith groups that encourage vegetarianism. Finally, 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, as Plaintiffs suggest, favor particular religious beliefs.

And of course if any of these contentions were correct (and they are not), they would apply equally to the Statutes, which originate the conditions on federal funds and control which services are affected. For the same reasons, the Rule does not coerce anyone to adhere to purportedly favored religious practices, or entangle the government with religion. Pls.' Opp'n 46–47.

Plaintiffs continue to argue that the Establishment Clause bars *any* burdens on a third party, but Supreme Court precedent forecloses this extreme view. "[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. Instead, potential burden is one factor that the court may consider to determine if an accommodation strays into the unlawful fostering of religion. *See Amos*, 483 U.S. at 334–35. Here, as previously discussed, the Rule does not improperly foster religion because it also protects 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 provision of the Church Amendments satisfied the Establishment Clause without analyzing the burden on third parties).

Contrary to Plaintiffs' view, the problem that the Supreme Court identified in *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985), was not the burden on third parties, but rather that the statute offered a

benefit only to the religiously inclined. In *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1 (1989), the Supreme Court discussed tax exemptions for religious and nonreligious organizations that had been upheld 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, s*ee also Hobbie v. Unemployment 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 an award of unemployment benefits to a religious objector when the benefits were available to the religious and non-religious alike 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. Nor does the Rule "require[] Plaintiffs to accede to all religious objections." Pls.' Opp'n 43. Many conceivable religious objections would not be covered by any of the Federal Conscience Statutes, and, thus, would not be covered by the Rule.

VIII. The Rule Does Not Violate Equal Protection or Due Process.

Plaintiffs lack third-party standing to bring facial equal protection and due process challenges to the Rule, and in any event fail to state a claim.

Plaintiffs now assert that they bring their Equal Protection, Due Process, and Free Speech claims through the Santa Clara physician-plaintiffs, and claim an unequivocal right to do so. Pls.' Opp'n 11. Plaintiffs rely on *Singleton v. Wulff*, 428 U.S. 106, 117 (1976), which concerned the rights of "physicians who perform nonmedically indicated abortions," *id.* at 108, to assert rights on behalf of pregnant "women patients as against governmental interference with the abortion decision," *id.* at 106. But Plaintiffs attempt to extend that case to circumstances well beyond its ken.[11] None of the Santa Clara physician-plaintiffs appear to be "physicians who perform nonmedically indicated abortions," *id.* at 108; *Santa Clara v. HHS*, 19-cv-2916, Compl. ("Santa Clara Mem.") ¶¶ 29–46, ECF No. 1; *see also Santa Clara v. HHS*, 19-cv-

[11] As the *Singleton* court emphasized, "[u]nless the 'provider of services' that he has in mind enjoys with his 'client' a confidential relationship such as that of the doctor and patient, unless the 'client's' claim is imminently moot, as the pregnant woman's technically is, the standing issue in such a future case will not be definitively controlled by this one." *Singleton*, 428 U.S. at 118 n.6 (plurality op.).

2916; *see also* Decl. of Colleen McNicholas ¶ 6, ECF No. 36-14 at 3–4, and none of them plead that their specific patients' claims may be "imminently moot" in the way that pregnant, abortion-seeking women's claims can be, thus potentially necessitating the physicians' assertion of their patients' rights.[12] *Singleton*, 428 U.S. at 115–16; *see also* Santa Clara Compl. ¶¶ 29–46. Thus, *Singleton* and its progeny do not control, nor do Plaintiffs identify any other binding precedent that would allow them to raise claims on behalf of third-party patients in this case. *See* Pls.' Opp'n 11–12.

Even if the Santa Clara Plaintiffs had standing, their claims, which would essentially require this Court to treat the Federal Conscience Statutes themselves as invalid, fail. Plaintiffs narrow their previously sweeping Equal Protection claim to challenge only the Rule's purported "targeting [of] transgender patients' transition-related health care needs for religious and moral objection," Pls.' Opp'n 47; *compare with* Santa Clara Compl. ¶ 245. But the Rule's provisions apply regardless of whether a patient is transgender, and thus, they do not treat individuals unequally. Indeed, in their opening brief, Defendants explained that Plaintiffs' Equal Protection claim fails because the Rule does not create suspect classes, facially infringe on any fundamental right, or evince purposeful discrimination. Defs.' Mem. 37–38. Plaintiffs offer no response to these arguments in their opposition.

Plaintiffs do suggest that the Rule targets transgender patients by characterizing "medically-necessary healthcare procedures sought by transgender patients to treat gender dysphoria as 'sterilization,'" Pls.' Opp'n 47, but the Rule does no such thing. The Rule does not define the term "sterilization"—for purposes of the Church Amendments or otherwise. *See generally* 45 C.F.R. § 88.1–88.10. Instead, the agency explained that it would consider the issue of whether the Federal Conscience Statutes "apply to sterilizations performed in the context of gender dysphoria," if necessary, "on a case-

[12] Regarding transgender patients, on whose behalf Plaintiffs appear to raise their Equal Protection and Free Speech claims, Plaintiffs attempt to extend the imminent-mootness prong described in *Singleton* to cases in which transgender patients seek gender-transition treatments. They do so by improperly relying on facts asserted in a declaration submitted by a putative expert attached to their opposition brief. *See infra* sec. X. The declaration, moreover, generally predicts that some "[g]ender dysmorphic patients who are assigned a male sex at birth but identify as female and lack access to appropriate care are often so desperate for relief that they may resort to life-threatening attempts at auto-castration . . . ." Decl. of Randi Ettner ¶ 22, ECF No. 75. This generalized statement about decisions that *some* gender dysmorphic patients *may* take is insufficient to show that any claims that the Santa Clara physician-plaintiffs' specific patients have are "imminently moot,.L." *Cf. Kowalski v. Tesmer*, 543 U.S. 125, 131 (2004).

by-case basis." 84 Fed. Reg. 23,205. Plaintiffs' claim based on a non-existent definition is meritless.[13]

Finally, contrary to Plaintiffs' assertions, Pls.' Opp'n 47–48, the Rule clearly bears a rational relationship to the government's interest in preventing conscience discrimination as set forth in the Federal Conscience Statutes. *See* 84 Fed. Reg. 23,175; *see also Erotic Serv. Provider Legal Educ. & Research Project v. Gascon*, 880 F.3d 450, 457 (9th Cir. 2018), *amended*, 881 F.3d 792 (9th Cir. 2018) ("Rational basis review is highly deferential to the government, allowing any conceivable rational basis to suffice.").

As for their Due Process challenge, Plaintiffs attempt to escape the Supreme Court's decision in *Rust v. Sullivan*, 500 U.S. 173, 193 (1991), with no more than a cursory sentence claiming that they have made a "specific showing" of undue burden and a level of harm "failing any level of scrutiny." Pls.' Opp'n 50–51. But contrary to Plaintiffs' assertions, they have not shown that the Rule facially violates any fundamental right,[14] *see* Pls.' Opp'n 49–50; even if the Court could consider Plaintiffs' declarations (and it cannot, *see infra* sec. X), those declarations at most speculate about the Rule's potential downstream effects.[15] That is not enough to sustain a facial, substantive due process challenge. *Lopez-Valenzuela v. Arpaio*, 770 F.3d 772, 780 (9th Cir. 2014) ("To succeed on their facial challenge, the plaintiffs must show that the [challenged rule is] unconstitutional in all . . . applications."); *United States v. Salerno*, 481 U.S. 739, 745 (1987). And *Rust* makes cleal#ed00 U.S. at 201, let alone a duty to fund health care entities that discriminate against those who object to abortion or other similar services or procedures on conscience grounds. That such regulations "do not impermissibly burden a woman's Fifth Amendment rights is

[13] The Court has asked "whether the word 'sterilization' as used in the Church Amendments was intended to cover transgender medical operations and/or gender reassignment surgery." ECF No. 135. As noted above, HHS did not address that question in the Rule and has not otherwise taken a position on whether the Church Amendments intended to cover such procedures. The Court thus need not resolve the issue here, on this facial challenge, since Plaintiffs challenge only the Rule itself.

[14] Nor do Plaintiffs establish that "gender identity[] and self-definition" are fundamental rights for the purposes of Due Process analysis. *But see Karnoski v. Trump*, 926 F.3d 1180, 1201 (9th Cir. 2019) (applying intermediate scrutiny to a government policy that excluded transgender individuals).

[15] *See, e.g.*, Second Decl. of Colleen McNicholas ¶ 27, ECF No. 87 ("To the extent that [the Rule] discourages entities like Trust Women from offering any services to which our employees, volunteers, or contractors may possibly object and threatens to remove or even claw back funding from entities that do not comply with such broad requirements, it is unworkable and could force Trust Women and other providers across the country to drastically alter the care we offer to patient or close entirely."); Decl. of Elizabeth Barnes ¶ 20, ECF No. 60 ("The Rule creates an opening for anti-wwwws to infiltrate and incapacitate our clinic by . . . creating threats to security as well as the basic right of the patient to non-judgmental supportive care . . . .").

evident" from a whole line of cases predating *Rust*, and Plaintiffs offer no meaningful reason to stray from this established jurisprudence. *Id.*

I. The Rule Does Not Violate the Free Speech Clause.

Even assuming that the Santa Clara physician-plaintiffs have standing to raise a Free Speech challenge to the Rule on behalf of their patients—which they do not—the Rule does not unconstitutionally burden their patients' speech. As Defendants explained in their opening brief, the Rule imposes *no* burdens or other restrictions on patients' speech and merely ensures health care entities' compliance with the funding restrictions in the Federal Conscience Statutes.[16] Defs.' Mem. 35–36. Here again, Plaintiffs fail to grapple with the Supreme Court's decision in *Rust*, dismissing the case because it purportedly did not involve patient rights and instead weaving together inapposite case law to make their point. Pls.' Opp'n 51–52. But the plaintiffs in *Rust* did claim that the regulations at issue "violate[d] the 'free speech rights of private health care organizations that receive Title X funds, of their staff, *and of their patients*' by impermissibly imposing 'viewpoint-discriminatory conditions on government subsidies,'" *Rust*, 500 U.S. at 192 (emphasis added), and the Court in turn explained that there was "no question" that the regulations were constitutional, *id.* "To hold that the Government unconstitutionally discriminates on the basis of viewpoint when it chooses to fund a program dedicated to advance certain permissible goals, because the program in advancing those goals necessarily discourages alternative goals, would render numerous Government programs constitutionally suspect." *Id.* at 194.

IX. The Rule Creates No Separation of Powers Concerns.

Plaintiffs' arguments concerning the separation of powers, Pls.' Mem. at 52–54, continue to misapprehend the Rule by suggesting that the Rule changes the amount of money or funding sources that the Federal Conscience Statutes could affect. As previously explained, 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*.

[16] Nor do Plaintiffs plead that "deterrence [of protected speech] was a substantial or motivating factor in the [agency's] conduct." *Mendocino Envtl. Ctr. v. Mendocino Cnty.*, 192 F.3d 1283, 1300 (9th Cir. 1999).

X. The Court May Not Consider Plaintiffs' Extra-Record Materials.

The Court should reject Plaintiffs' improper attempt to create a new record for the purposes of this litigation by submitting declarations and other materials to bolster their merits arguments. The APA provides that, "[i]n making the [] determinations [regarding the lawfulness of agency action], the court shall review the whole record," 5 U.S.C. § 706, and the Supreme Court has long held that the whole record is limited to "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) (holding that "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court"); *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985) ("The task of the reviewing court is to apply the appropriate APA standard . . . to the agency decision based on the record the agency presents to the reviewing court.").

Ninth Circuit decisions reflect these same principles that the court should ordinarily not consider extra-record evidence when evaluating the merits of claims brought under the APA. *See, e.g.*, *Jet Inv., Inc. v. Dep't of Army*, 84 F.3d 1137, 1139 (9th Cir. 1996). The Ninth Circuit "allows for a court to review material outside of the administrative record" in only "four narrow circumstances." *Cachil Dehe Band of Wintun Indians of Colusa Indian Cmty. v. Zinke*, 889 F.3d 584, 600 (9th Cir. 2018). Those narrow exceptions are as follows: (1) where the extra record-evidence is necessary to determine whether the agency has considered all relevant factors and has explained its decision; (2) where the agency has relied on documents not in the record; (3) where supplementing the record is necessary to explain technical terms or complex subject matter; or (4) where plaintiffs make a showing of agency bad faith. *Id.* The scope of these exceptions is "constrained, so that the exception does not undermine the general rule." *Lands Council v. Powell*, 395 F.3d 1019, 1039 (9th Cir. 2005). Otherwise, "[w]ere the federal courts routinely or liberally to admit new evidence when reviewing agency decisions, it would be obvious that the federal courts would be proceeding, in effect, *de novo* rather than with the proper deference to agency processes, expertise, and decisionmaking." *Id.* Plaintiffs bear the burden of demonstrating that the administrative record is inadequate. *Animal Def. Council v. Hodel*, 840 F.2d 1432, 1437 (9th Cir. 1988).

None of the Ninth Circuit's recognized exceptions applies here, nor have Plaintiffs claimed that any exception applies. Defendants provided the administrative record to Plaintiffs on July 22, 2019, and

then supplemented it—mostly with materials that were already publicly available—on August 19, 2019. Plaintiffs therefore had ample opportunity to seek to supplement the administrative record or to identify any deficiencies if they believed it to be incomplete. But Plaintiffs have not done so.

Instead, Plaintiffs baldly flout the longstanding rule limiting review to the administrative record. For example, Plaintiffs rely in several instances on declarations to attempt to support their arguments that the Rule is arbitrary and capricious. *See* Pls.' Opp'n 17; *id.*at 19 & n.36. Plaintiffs cite to the declarations of Darrel Cummings and Sarah Henn to describe certain emergency experiences among their patients. *See* Pls.' Opp'n 17. Dr. Cummings or Dr. Henn could have described those circumstances by submitting comments during the rulemaking, but because they did not, the Court cannot consider their statements now. Plaintiffs also submit the declaration of Randie Chance for his description of complaints contained in the administrative record. *See* Pls.' Opp'n 24. But the complaints in the record speak for themselves, and Dr. Chance's analysis was not before the Secretary when he made his decision. It is therefore not properly part of the Court's merits analysis. Plaintiff also include a declaration from Dr. Wendy Chavkin for her perspective on HHS's citation in the Rule to an article she authored. *Id.* 13, 19, 24. But Dr. Chavkin's article also speaks for itself, and to the extent Dr. Chavkin identifies other potentially relevant articles to consider, she or other commenters could have identified the same articles in comments submitted to the agency during the rulemaking process.

The Court should also limit its review to the administrative record on Plaintiffs' constitutional claims. As Plaintiffs acknowledge, the APA provides the private right of action necessary for Plaintiffs to assert constitutional claims for equitable relief with respect to final agency action. *See* Pls.' Opp'n 13 n.21 ("[T]he APA provides a single cause of action challenging final agency action."); *see also* 5 U.S.C. § 706(2)(B) (permitting judicial review of agency action "contrary to constitutional right, power, privilege, or immunity"). Section 706 of the APA, by its plain language, restricts the review of constitutional claims to the administrative record. A contrary rule—one of admitting exception for constitutional claims—would "incentivize every unsuccessful party to agency action to allege . . . constitutional violations to trade in the APA's restrictive procedures" for the Federal Rules of Civil Procedure. *Jarita Mesa Livestock Grazing Ass'n v. U.S. Forest Serv.*, 58 F. Supp. 3d 1191, 1238 (D.N.M. 2014). Defendants, moreover, are aware of no Ninth Circuit decision recognizing an exception to the

record review rule for constitutional claims. And many district courts have rejected requests to create any such exception. *See, e.g.*, *Jiahao Kuang v. U.S. Dep't of Defense*, 2019 WL 293379, at *2-3 (N.D. Cal. Jan 23, 2019); *Moralez v. Perdue*, 2017 WL 2265855, at *3 (E.D. Cal. May 24, 2017). The Court should therefore reject Plaintiffs' improper attempt to support their constitutional claims with extra-record material. *See, e.g.*, Pls.' Opp'n 41 & nn. 63–65 (citing declarations for Plaintiffs' Spending Clause claim); *id.* at 43 (citing declarations for Plaintiffs' Establishment Clause claim).

The Ninth Circuit confirmed this principle in *Fence Creek Cattle Co. v. U.S. Forest Service*, in which it affirmed the judgment of the district court to limit review to the administrative record even though the plaintiff had alleged violations of "constitutional due process guarantees." 602 F.3d 1125, 1131 (9th Cir. 2010). The court of appeals reiterated that "expansion of the administrative record" is permitted only in "four narrowly construed circumstances," discussed above. *See id*. Accordingly, and as a district court helpfully summarized, "when a constitutional challenge to agency action requires evaluating the substance of an agency's decision made on an administrative record, that challenge must be judged on the record before the agency." *Bellion Spirits, LLC v. United States*, 335 F. Supp. 3d 32, 43 (D.D.C. 2018). No matter how Plaintiffs frame this case, this Court will ultimately "evaluat[e] the substance of an agency's decision," *id.* That evaluation should rest on the administrative record alone, as the APA requires.

Because none of the Ninth Circuit's exceptions applies, the Court should not consider extra-record material when evaluating the merits of Plaintiffs' claims. Defendants acknowledge, of course, that Plaintiffs have flooded the docket with declarations purporting 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 Plaintiffs to comment on the alleged impact of HHS's proposals was during the rulemaking process, Defendants do not address the factual allegations in Plaintiffs' declarations. Nor is it necessary for the Court to address those allegations in order to resolve the legal questions at issue in the parties' cross motions for summary judgment. *See, e.g.*, *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) ("As we have repeatedly recognized [ ], when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal. The entire case on review is a question of law." (internal quotation omitted)).

XI. Any Relief Accorded to Plaintiffs Should Be Limited.

For all the reasons described above, and in Defendants' opening brief, the Rule is lawful and therefore should not be vacated. Plaintiffs insist, however, that, if the Court finds that any part of the Rule is invalid, it must strike down the Rule in its entirety, rather than respect the agency's clear intent that portions of the Rule found to be invalid should be severed from the remainder. *See* Pl.'s Opp'n 40; *see also* 84 Fed. Reg. at 23,272. Plaintiffs fault Defendants for providing only a "conclusory severance argument." Pl.'s Opp'n 40. But Plaintiffs ignore that it is *Plaintiffs'* burden—not Defendants'—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 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."). It is therefore Plaintiffs whose severability analysis is lacking. In any event, portions of the Rule can clearly operate independently from each other. For example, if the Court were to strike down any particular definition in the Rule (which it should not, for the reasons explained above), the remaining definitions and other provisions of the Rule could continue to operate independently.

Finally, although the Rule is lawful for the reasons Defendants have explained, if the Court were to disagree, any relief must be limited to the specific Plaintiffs before the Court. Plaintiffs insist that nationwide relief is the "usual" remedy under the APA. But Plaintiffs ignore the Supreme Court's recent instruction to the contrary. In *Gill v. Whitford*, 138 S. Ct. 1916 (2018), the Court explained that any remedy "must be tailored to redress the plaintiff's particular injury." *Id.* at 1934. Vacating the Rule on a nationwide basis would go far beyond what is necessary to address Plaintiffs' particular alleged injury, and nationwide relief would effectively stop courts in other jurisdictions assessing similar challenges from evaluating those separate claims. *See* Defs.' Mem. 38–39.[17]

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion and deny Plaintiffs' motion.

Dated: September 26, 2019 Respectfully Submitted,

[17] Defendants previously explained that, even if the Court were to set aside 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. *See* Defs.' Mem. 40. Plaintiffs did not respond and therefore have conceded the point.

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