

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

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

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

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INTRODUCTION

Defendants respectfully ask that the Court enter summary judgment in their favor. Plaintiff's brief is long on hyperbole, but Plaintiff at no point articulates how it believes the challenged Rule meaningfully differs from the Federal Conscience Statutes. That is because—far from being a sea change, as Plaintiff argues—the Rule merely implements and clarifies those important preexisting conscience protections enacted by Congress. Remarkably, 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 Statutes. Taken together, these concessions are fatal to Plaintiff's claims against the Rule. At bottom, because the Federal Conscience Statutes are lawful conditions on the receipt of federal funding, and because the Rule faithfully and reasonably implements those longstanding conditions as to funds HHS administers, Plaintiff's suit fails.

Plaintiff's specific arguments fail for other reasons, too. The main thrust of Plaintiff's Administrative Procedure Act (APA) challenge is the claim that the Rule exceeds Defendants' statutory authority. But Plaintiff's argument is belied by the explicit delegations of authority in certain of the Federal Conscience Statutes and other statutes identified in the preamble to the Rule. Plaintiff's attack on several of the Rule's definitions fares no better because the 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 Plaintiff's claim, the Rule is also entirely consistent with the provisions scattered throughout the U.S. Code that Plaintiff cites. And, in promulgating the Rule, Defendants engaged in reasoned decisionmaking, thoroughly considering the issues raised in the comments and providing reasoned explanations in response.

Plaintiff’s constitutional claims likewise fail. As an initial matter, they are not ripe. Several speculative events would need to take place before Plaintiff could potentially lose federal funding for failure to comply with the Rule. There is simply no immediate risk of withdrawal of funds that would make Plaintiff’s Spending Clause and Establishment Clause claims ripe. In any event, those claims fail on the merits. The funding conditions Plaintiff challenges flow from the Federal Conscience Statutes themselves, which—because Plaintiff does not challenge those Statutes—is fatal to Plaintiff’s Spending Clause claim. The Rule also does not “establish” religion in any way. It protects religious beliefs only where the underlying statutes protect religious beliefs. Moreover, most of the protections provided by the Rule (and the underlying Federal Conscience Statutes) address objections to certain services regardless of whether those objections are based on religious or non-religious beliefs.

For all these reasons, the Court should enter judgment in favor of Defendants. However, even if the Court were to find some aspect of the Rule unlawful—which it should not—the Court would be obligated by the Rule’s severability clause to sever that portion from the remainder of the Rule rather than vacate the Rule in its entirety. Any relief, moreover, should be limited to the parties before the Court and not extend nationwide.

ARGUMENT

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

As Defendants explained in their opening brief, a variety of authorities support the Rule, including the Federal Conscience Statutes and various housekeeping statutes. *See* Defs.’ Mem. 18–23; *see also* 84 Fed. Reg. at 23,183–86, 23,263 (describing the various authorities). Plaintiff argues in response that certain Federal Conscience Statutes lack an explicit delegation provision and that the housekeeping statutes do not support the Rule. *See* Pl.’s Opp’n 27–30. As discussed below, Plaintiff is wrong on both points. Crucially, however, Plaintiff *does even not respond* to

one of Defendants' central statutory authority arguments: namely, that 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, Plaintiff has abandoned argument on this point, and the Court should award summary judgment in Defendants' favor. *See Kairgadam v. Bell Atl. Corp.*, 46 F. App'x 194, 195 (4th Cir. 2002); *Johnson v. United States*, 861 F. Supp. 2d 629, 634 (D. Md. 2012).

Even if the Court considers Defendants' unrebutted statutory authority argument, it should still award summary judgment in Defendants' favor. As Defendants explained in their opening brief, 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. *See* Defs.' Mem. 18–23. 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 grant and contract 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 Amendments] with the Departmental funding component(s) from which the entity, to which a complaint has been filed, receives funding.”). The 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.

In addition to this longstanding and unrebutted authority, several statutory provisions explicitly grant HHS sufficient regulatory authority here. *See* Defs.’ Mem. 22–23; 84 Fed. Reg. at 23,184–85 (identifying, *inter alia*, 42 U.S.C. §§ 1302, 18023, 18041, 18113, 263a, 1315a).¹ And, as discussed in the definitions section *infra*, the Federal Conscience Statutes implicitly grant HHS the authority to administer them.

Plaintiff responds that HHS cannot derive authority from “compiling separate general delegations of authority.” *See* Pl.’s Opp’n 23. However, this is not what HHS has done. As described in its opening brief, HHS is required under the Federal Conscience Statutes to apply certain conditions to federal awards, 84 Fed. Reg. at 23,264–69 (to be codified at 45 C.F.R. § 88.3) (describing the conditions). *See* Defs.’ Mem. 20–21. In the Rule, HHS describes the procedures it

¹ Plaintiff claims that only one statute explicitly delegates authority. *See* Pl.’s Opp’n 24 (citing 42 U.S.C. § 18113(d)); *see also id.* at 26 n.19 (arguing that “HHS concedes there is no express delegation). However, as Defendants’ opening brief, the Rule, and the above statutes make clear, there are several express delegations of authority. For example, HHS has authority to issue regulations governing (among other programs) Medicare and Medicaid, which expressly authorizes the Rule with respect to the Federal Conscience Statutes that apply to Medicare or Medicaid and, with respect to their application in such programs, the Federal Conscience Statutes that require HHS to distribute funds under certain conditions. *See, e.g.*, 42 U.S.C. § 1302 (stating that “the Secretary of Health and Human Services . . . shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [the Secretary] is charged under this chapter”); *see also* 42 U.S.C. § 18041 (authorizing regulations under the ACA).

will follow to implement these statutorily required conditions. *See* 84 Fed. Reg. at 23,269–72 (to be codified at 45 C.F.R. §§ 88.4–88.7) (describing the procedures). The interaction of these authorities is patently different from the cases that Plaintiff cites, in which the agencies lacked statutory authority under any of the statutes to which they pointed. *See, e.g., Pharm. Research and Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 39 (D.D.C. 2014) (holding that the five cited statutes did not support the agency’s rulemaking authority).

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.

Plaintiff contends 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 26 n.19. But, as explained in Defendants’ opening brief and below, 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 U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

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 issue the Rule. *See* Defs.’ Mem. 22–23; 84 Fed. Reg. at 23,184–85 (identifying, *inter alia*, 42 U.S.C. §§ 1302, 18023, 18041, 18113, 263a, 1315a). 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. 21–22.

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 Plaintiff focuses 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.” *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 Conscience Statutes direct HHS to issue federal funds contingent on recipients’ compliance with the Statutes’ conditions. *See, e.g.*, 42 U.S.C. § 300a-7(c) (prohibiting recipients of certain federal funds from discriminating on certain

conscience-related 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" as including a non-exhaustive list). Furthermore, the Statutes do not explicitly detail how HHS is to ensure that recipients comply with the Statutes' conditions. And as the Rule discusses, the Statutes do not create private rights of action. *See* 84 Fed. Reg. at 23,178. Surely Congress did not intend to impose such 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 clarify 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 since 2008. The Office for Civil Rights (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.

Plaintiff contends that statutory authority cannot be inferred from the Federal Conscience Statutes for several reasons. All are wrong. First, Plaintiff suggests that explicit delegations of authority in some statutes imply that there is no implicit authority in others. *See* Pl.’s Opp’n 24. However, the existence of explicit delegations in other parts of the United States Code has no bearing on HHS’s authority to ensure compliance with the Federal Conscience Statutes and this Rule under the enforcement provisions of the HHS UAR or HHSAR. Plaintiff has not shown that statutes on which it relies, which were enacted in different sessions of Congress and as different public laws, are subject to inter-textual comparison as they would like. *See Erlenbaugh v. United States*, 409 U.S. 239, 243–44 (1972) (describing the standard for comparing different statutes). Furthermore, Plaintiff’s 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 Defense Council, Inc.*, 467 U.S. 837, 844 (1984). Plaintiff suggests that the Court should hesitate to recognize an implicit delegation because of the Rule’s breadth. *See* Pl.’s Opp’n 25. However, as discussed *supra*, the Rule does not expand HHS’s authority, but rather applies existing procedures for administering federal awards. And at any rate, the breadth of a Rule is not one of the factors the Supreme Court has identified to determine whether there is an implied delegation. *See Barnhart v. Walton*, 535 U.S. 212, 222 (2002).

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

Plaintiff raises a number of counterarguments to each challenged definition, which may be dismissed in turn.

1. “Assist in the Performance”

Plaintiff raises three objections to HHS's definition of this phrase: that the definition is unclear, that it is overly broad, and that it is inconsistent with the Church Amendments' legislative history. *See* Pl.'s Opp'n 26–27. None of these objections is correct. First, Plaintiff bizarrely characterizes as “self-serving” HHS's position that the Rule offers a clear definition without addressing Defendants' central argument that the Rule's definition is consistent with the dictionary definitions. *See id.*

Plaintiff also asserts—without any reference to the text of the Church Amendments—that the Rule is overbroad. Any fair reading of the Church Amendments, however, indicates that they cover a broad range of activity. The text of the Church Amendments is not limited to individuals who *perform* certain procedures, as Plaintiff appears to suggest, but rather includes individuals who *assist in the performance* of such procedures: “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).

And last, the legislative history that Plaintiff identifies, *see* Pl.'s Opp'n 27, is entirely consistent with the Rule's definition. At the outset, Plaintiff attributes undue limitation to the history of the Church Amendments. That statute, which was enacted at various times during the 1970s, was motivated by broad “debates over whether judicially recognized rights to abortions,

sterilizations, or related practices might lead to the requirement that individuals or entities participate in activities to which they have religious or moral objections.” 84 Fed. Reg. at 23,171. Rather than recognize this broad purpose, Plaintiff cites a lone floor statement by Senator Frank Church. *See* Pl.’s Opp’n 27. In the first place, this statement is entitled to limited weight: “scattered floor statements by individual lawmakers [are] the sort of stuff [that the Supreme Court has] called ‘among the least illuminating forms of legislative history.’” *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1661–62 (2017) (quoting *NLRB v. SW General, Inc.*, 137 S. Ct. 929, 943 (2017)) (referring to floor statements of an amendment’s sponsors). 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”

Plaintiff’s rhetoric regarding this definition soars far beyond the actual text of the definition. Plaintiff ignores Defendants’ *Chevron* arguments, *see* Defs.’ Mem. 25–26, and the Rule’s reasonable limitations, arguing that there *must* be a way to challenge this definition or else “the APA would be a nullity.” *See* Pl.’s Opp’n 29. This is nonsense. The APA’s waiver of sovereign immunity to challenge final agency action is not a requirement for agencies to promulgate regulations with the level of specificity that a particular plaintiff prefers. Agencies can offer guidance at any level of generality that they deem appropriate under the circumstances. Here, HHS has recognized that “[t]here is no universal definition of discrimination that governs all

Federal statutes” and accordingly developed a definition that “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. This is appropriate restraint, not an improper evasion of judicial review.

Plaintiff also argues that the definition “give[s] absolute priority to the religious views of objecting employees.” *See* Pl.’s Opp’n 30. This is incorrect. As explained in Defendants’ opening brief, the definition simply provides examples of what *might* 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. § 88.3). As referenced above, whether an action qualifies as discrimination is context-specific, depending on the relevant law, facts, and circumstances. *See id.* at 23,192. And to the extent that an entity must not discriminate against an individual based on that individual’s religious views, such a requirement comes from the Federal Conscience Statutes (among other laws), not the Rule.

3. “Health Care Entity”

Plaintiff’s threadbare arguments regarding HHS’s definition of “health care entity” likewise do not pass muster. Once again, Plaintiff ignores Defendants’ *Chevron* arguments, Defs.’ Mem. 27–28, and has yet to identify a single item on the Rule’s list that should not qualify as a “health care entity” under the Coats-Snowe or Weldon Amendments or § 1553 of the ACA.

Plaintiff’s argument that the lists in the Coats-Snowe or Weldon Amendments are the final word on what constitutes a “health care entity” is incorrect. As Defendants explained in their opening brief, the definitions of the term in the Coats-Snowe and Weldon Amendments include non-exhaustive lists of health care entities. *See* Defs.’ Mem. 26–28. Plaintiff suggests that these lists are in fact exhaustive, arguing that the term “include,” which proceeds each statutory list, is limiting. *See* Pl.’s Opp’n 28 & n.21. 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”).

4. “Referral or Refer For”

Last, Plaintiff argues that the Rule’s definition of “referral” or “refer for” is inconsistent with the text of the Federal Conscience Statutes. *See* Pl.’s Opp’n 28–29. Once again, Plaintiff’s failure to respond to Defendants’ *Chevron* arguments, Defs.’ Mem. 29–30, leads it to error. Plaintiff argues that the text of the Federal Conscience Statutes is “plain and highly specific,” suggesting that the Rule’s definition is unnecessary or overbroad. *See* Pl.’s Opp’n 29. Crucially, however, Plaintiff fails to explain any error in Defendants’ arguments that the Rule’s definition is consistent with congressional intent (i.e., that the dictionary definition of “refer” is consistent with the Rule’s definition and that an inter-textual reading of the relevant statutes supports the Rule’s definition), *see* Defs.’ Mem. 29–30.

Plaintiff also claims that the Rule covers additional people and conduct, pointing to the Weldon Amendment’s limited scope to abortions. *See* Pl.’s Opp’n 29. This is an erroneous reading of the Rule. Defendants explained in their opening brief that the definition of “referral” or “refer for,” like the definition of “discriminate” or “discrimination,” consists of a *non-exhaustive list* of items that *may* constitute “referral” or “refer for.” *See* Defs.’ Mem. 30. Defendants also explained that the definition is context-specific. *See id.* Thus, to the extent that the underlying statute is limited to abortion (e.g., the Weldon Amendment), the definition is likewise limited to that procedure. It does not expand the scope of who or what the Federal Conscience Statutes protect.

III. The Rule Is Consistent with Other Provisions of Law

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

Plaintiff presses on with its extraordinary claim that Section 1554 of the ACA—which neither mentions any of the Federal Conscience Statutes nor otherwise provides any indication that Congress intended to limit those, in some cases, decades-old restrictions—prevents HHS from implementing 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 18–19. It is worth pausing to consider the incredible breadth of Plaintiff’s argument: if Plaintiff were correct, Section 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—those statutes, in Plaintiff’s view, “impede access” to care. Plaintiff’s reading of Section 1554 would also effectively mean that HHS could not put any restrictions on Medicare or Medicaid funding through regulations, which Congress could not plausibly have intended.

Fortunately, as Defendants explained in their opening brief, there is no plausible reason to accept Plaintiff’s utterly draconian interpretation of Section 1554. *See* Defs.’ Mem. 30–33. In Section 1303(c)(2) of the ACA, Congress was absolutely clear that nothing in the ACA (including Section 1554) “shall be construed to have *any effect* on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of 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 that Section 1554 somehow interferes with implementation of the Federal Conscience Statutes through the Rule.

Plaintiff's only response is to claim—without citing to any authority—that the Rule is not a “law” within the meaning of Section 1303(c)(2) because it is a regulation and not a statute. *See* Pl.'s Opp'n 19. Plaintiff is incorrect.

As the Fourth Circuit explained in *United States v. Mitchell*, 39 F.3d 465 (4th Cir.1994), when a term is not defined by the statute, courts must give the word its plain meaning, unless legislative history demonstrates that Congress clearly intended a contrary meaning, *see id.* at 468–69. The ACA does not define the term “law,” or the phrase “Federal law,” used in Section 1303(c)(2), nor are Defendants aware of any legislative history related to the ACA that suggests those words have anything but their commonly understood meaning. *Cf. King v. Burwell*, 135 S. Ct. 2480, 2492 (2015) (commenting on the lack of useful legislative history on the ACA). Thus, because the commonly understood meaning of “law” includes “administrative regulations,” *Mitchell*, 39 F.3d at 468 (“Law’ is commonly defined to include administrative regulations.”), Plaintiff's attempt to explain why Section 1303(c)(2) does not preclude its argument fails.

B. Section 1557 of the ACA

Plaintiff's Section 1557 argument also fails out of the gate, and Plaintiff barely attempts to defend it in its brief. *See* Pl.'s Opp'n 20. Putting aside the fact that Plaintiff can point to no actual conflict between the Rule and Section 1557 in its facial challenge, Congress stated explicitly in Section 1303(c)(2) of the ACA that nothing in the ACA (including Section 1557) should have “any effect” on federal conscience protections. *See* 42 U.S.C. § 18023(c)(2). Plaintiff offers no reason to ignore Congress's clear instruction.

C. EMTALA

Plaintiff claims that the Rule somehow conflicts with the Emergency Medical Treatment and Active Labor Act (EMTALA). Pl.'s Opp'n 20–22. Not so. 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. 34–35. 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 abide by EMTALA’s requirements without any reasonable fear that doing so would run afoul of the Federal Conscience Statutes. Plaintiff states that Defendants were required to “harmonize” EMTALA with the Federal Conscience Statutes even “*before* issuing the Rule.” Pl.’s Opp’n 21. Besides being beside the point, Plaintiff’s argument only highlights the weakness in its argument. To the degree there were any conflict with EMTALA (and there is not), that conflict would be between EMTALA and the Federal Conscience Statutes, which Plaintiff does not challenge.²

IV. The Rule is the Product of Reasoned Decisionmaking.

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, of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted); *see also Jimenez-Cedillo v. Sessions*, 885 F.3d 292, 298 (4th Cir. 2018); Defs.’ Mem. 37–44. Plaintiff’s arguments to the contrary are meritless. HHS supported each challenged aspect of the Rule with sound and detailed reasoning, and Plaintiff’s attempt to

² In its Complaint, Plaintiff claimed that the Rule also conflicts with a provision of the Medicaid Statute, 42 U.S.C. § 1396u-2(b)(3)(B), and a similar provision of the Medicare statute, *id.* § 1395w-23(j)(3)(C), Compl. ¶ 176, ECF No. 1, as well as with Title VII of the Civil Rights Act of 1964. *See id.* ¶ 177. Defendants’ explained in their opening brief why those claims are meritless. *See* Defs.’ Mem. 35–37. Plaintiff did not respond to Defendants’ arguments in their most recent brief and therefore appear to have abandoned those claims. The Court should therefore enter summary judgment in Defendants’ favor on those claims.

couch its policy disagreements as an APA challenge must fail. *See 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. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016); *Jimenez-Cedillo*, 885 F.3d at 298. Plaintiff claims that HHS’s “reliance on the same, now-ten-years-old evidence to reach the opposite conclusions—with no explanation of why its assessment of those facts in 2011 was incorrect—is arbitrary and capricious.” Pl.’s Opp’n 11. But the Secretary is “entitled . . . to give more weight” to certain concerns that were raised in previous rulemakings, “even on precisely the same record.” *Organized Vill. of Kake*, 795 F.3d at 968. 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. Moreover, in promulgating the Rule challenged here, the agency did not merely rely on the same record used in the past. In addition to a survey conducted in 2009 and comments received in the 2008 and 2011 rulemakings, the agency factored in (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, and (3) comments received during the 2018–19 rulemaking.³ *See* 84

³ *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

Fed. Reg. 23175–79; *see also* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3,880, 3,887–891 (2018). HHS’s explanations also adequately accounted for any reliance interests that health care entities may have in connection with the 2011 Rule. The Rule “explain[s] the ‘good reasons for the new policy,’” *Encino*, 136 S. Ct. at 2127 (quoting *Fox Television Stations*, 556 U.S. at 515), including the fact that the Rule clarifies the scope of the Federal Conscience Statutes so that health care entities can better understand how to comply with the Statutes and continue to receive applicable federal funding, *see* 84 Fed. Reg. at 23,175. Moreover, HHS considered the burden that the Rule may impose on healthcare entities, *see infra* sect. IV.B, including the burden of becoming familiar with the Rule, 84 Fed. Reg. at 23,239, and mitigated the burden where feasible. *See Casa De Maryland v. U.S. Dep’t of Homeland Sec.*, 924 F.3d 684, 705 (4th Cir. 2019).

Plaintiff separately assails HHS’s reliance on recent complaints that OCR received to argue that the agency failed to acknowledge record evidence that allegedly contradicts its assertions. Pl.’s Opp’n 8–11. But again, HHS considered the complaints received in conjunction with all of the factors discussed above and merely noted that the complaints *alleged* violations of the Federal

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 Statutes] 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”).

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.

And while Defendants already 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.⁴ While the complaints in the record are not the sole reason for the Secretary’s decision to promulgate the Rule, they represent one factor the Secretary considered in determining that “there is a significant

⁴ Defendants cited some of those complaints in their opening brief as examples, *see* Defs.’ Mem. 53, and 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 healthcare providers exercising conscience rights to engage in compelled speech and referrals); AR 542,285, Ex. 8 (complaint against State of 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 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).

need to amend the 2011 Rule to ensure knowledge of, compliance with, and enforcement of” the Federal Conscience Statutes. 84 Fed. Reg. at 23,175.⁵

B. HHS Considered All Important Aspects of the Problem.

Plaintiff also complains that HHS failed to consider the Rule’s purported impact on patient health and on health care providers. Pl.’s Opp’n 12–16. These arguments all fail.

Patient Health. First, Plaintiff continues to claim that the agency failed to consider the Rule’s impact on “patient access to care.” Pl.’s Opp’n 13. But as Defendants already explained in their opening brief, HHS *did* consider the major aspects of this issue and reasonably concluded that the Rule would not harm access to care, in part because 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, because the Statutes make it easier for health care professionals to perform their jobs while staying true to their religious or moral beliefs, and in part because 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.

⁵ Plaintiff attacks two of the three complaints that Defendants highlighted in their opening brief as examples of potentially relevant complaints. Pl.’s Opp’n 9 n.4. But the complaints indicate both general and specific concerns about the conscience rights of individuals in the health care field. The 2018 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. A at 11, ECF No. 44-2. And the 2018 complaint by a Washington State Department of Corrections employee alleging discrimination based on the employee’s objection to providing hormone therapy to incarcerated transgendered persons could potentially relate to the Federal Conscience Statutes that protect conscience 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.

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. 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.* 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. Plaintiff’s policy disagreement over the agency’s conclusion does not warrant invalidation of the Rule.⁶ *See Owner-Operator Indep. Drivers Ass’n*, 494 F.3d at 210–11.

⁶ Plaintiff argues that HHS failed to consider the alleged risks of applying the Federal Conscience Statutes to emergency health situations and “creat[ed], through the absence of any exception for emergencies, a real risk that patients will be denied care in emergency situations, in contravention of EMTALA.” Pl.’s Opp’n 14. But HHS explained that it “generally agrees . . . that the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and antidiscrimination laws,” 84 Fed. Reg. at 23,183. Moreover, the agency made clear that the emergency transportation of individuals who may hypothetically seek an objected-to service or procedure or the “emergency transportation of persons experiencing unforeseen complications after, for example, an abortion procedure,” would not generally implicate the definition of ‘assist in the performance of’ an abortion, because “the complications in need of treatment would be . . . unforeseen and unintended.” 84 Fed. Reg. at 23,187.

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,” 84 Fed. Reg. 23,810, and Plaintiff offers no contrary studies, in the record or elsewhere. Plaintiff does not explain why the agency would 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, 23,241. In response to the 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. 84 Fed Reg. at 23,214–15. 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.” 84 Fed. Reg. at 23,277. Contrary to Plaintiff’s assertions, HHS did not “ignore[.]” commenters’ concerns “that the Rule will be impracticable and exceedingly costly,” Pl.’s Opp. 16; rather, it took steps to mitigate the Rule’s burdens on healthcare entities and explained why the Rule’s benefits outweighed the remaining burdens on healthcare entities, *see* 84 Fed. Reg. at 23,239–46. Plaintiff’s attacks on HHS’s burden analysis attempt to elevate Plaintiff’s judgment over that of the agency and accordingly must fail.

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

Plaintiff’s constitutional 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 Plaintiff’s constitutional claims and whether there would be any harm to Plaintiff in the interim. For the Spending Clause, this analysis turns on when a concrete enforcement proceeding would arise that would potentially cause Plaintiff to lose funding. For the Establishment Clause, ripeness turns on whether the agency’s definition of “discrimination” would affect hiring and staffing by purportedly elevating objector’s religious beliefs over Plaintiff’s preferred hiring and staffing plans. There is no basis for the Court to adjudicate Plaintiff’s premature claims in either instance.

Plaintiff reiterates its assertion that “huge swaths of federal funding,” Pl.’s Opp’n 32, could hypothetically be affected by the Rule. But Plaintiff has known about the potential volume of money affected by, for example, the Weldon Amendment since it first began accepting applicable funds. The key question is the immediacy of any risk to those funds. Plaintiff concedes, as it must,

that no action has yet been taken against it. Nor does Plaintiff dispute that multiple steps would have to occur before any such loss of federal funds could come to pass, even if enforcement action against it were initiated. 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 why it could not seek judicial relief *then*. Resolving Plaintiff's Spending Clause claim now would only entangle the Court in an abstract disagreement that may never arise.

Similar ripeness considerations about the lack of specific enforcement action have led at least two courts to decline to decide challenges to the underlying Federal Conscience Statutes on grounds that are equally applicable here. *See NFPRHA v. Gonzales*, 468 F.3d 826, 827 (D.C. Cir. 2006); *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, at *3 (N.D. Cal. Mar. 18, 2008). Plaintiff's attempt to distinguish these cases falls flat. Plaintiff argues that the definition of "discrimination" and other terms in the Rule presents an "immediate regulatory burden[]" that was purportedly lacking in *NFPRHA*. Pl.'s Opp'n 33. Quite the contrary, *NFPRHA* involved a challenge to the entire Weldon Amendment, which originated various conscience-based restrictions on the federal funds provided in the annual appropriations act, and thus distinctly *did* place immediate regulatory burdens on regulated entities. Likewise, Plaintiff suggests that *California* is inapposite because there was no clear indication in that case of the interaction between EMTALA and the Weldon Amendment, Pl.'s Opp'n at 33, but that is the same situation here—there is no indication that compliance with EMTALA will constitute "discrimination" under the Weldon Amendment. When and if such an enforcement action came to pass, this Court could then take up Plaintiff's challenge.

Plaintiff argues in a variety of ways that the volume of funding at risks prevents it from taking what it characterizes as a “wait and see” approach. But that is precisely what *NFPRHA* and *California* concluded was appropriate—those courts required entities regulated under the Weldon Amendment, which affects a substantial volume of funding, to wait until potential enforcement ripened into the clear context of a specific factual circumstance. *Contra* Pl.’s Opp’n 33 n.23 (“When, as here, a Rule requires compliance on threat of withdrawal of all federal funding, the undue coercion prohibited by the Spending Clause immediately [sic], because the requirement to elect whether to continue to accept funds that are conditioned on compliance is itself immediate, and ongoing.”).

Plaintiff argues that applying ripeness doctrine to this case would “violate the rule barring claim-splitting.” Pl.’s Opp’n 31. But claim splitting need not bar bringing a claim that was not previously justiciable. *See, e.g., Companion Prop. & Cas. Ins. Co. v. Wood*, No. 3:17-CV-00514-CMC, 2017 WL 4168526, at *6 (D.S.C. Sept. 20, 2017). And contrary to Plaintiff’s argument, factual development would greatly assist the Court, as demonstrated by the dispute between the parties concerning the scope of the affected funding and whether the Rule has changed the affected funding.

VI. The Rule Does Not Violate the Spending Clause.

In its Spending Clause arguments, Pl.’s Opp’n 42–47, Plaintiff re-affirms that it does not challenge the Federal Conscience Statutes, and doubles-down on its insistence that the Rule is an unconstitutional departure from the Statutes. But Plaintiff fails to actually identify any relevant differences between the Rule and the Statutes for Spending Clause purposes.

Plaintiff begins by arguing that the Rule is coercive because of the amount of money that it potentially affects. Pl.’s Opp’n 42–43. But the Federal Conscience Statutes affect precisely the same amounts and sources of funding as the Rule. The Rule does not, as Plaintiff contends,

“expand[] the Weldon Amendment’s consequences . . . to two dozen now-expanded federal conscience laws.” Pl.’s Opp’n 43. Each Statute remains linked to the funding sources that it previously covered, and to the extent that remedies under other regulations, such as the HHS UAR, exist, those other regulations are not altered by the Rule or challenged by Plaintiff. This is inherent in the nature of the Rule, which 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 Plaintiff does not challenge the constitutionality of the Weldon Amendment. *Cf.* Pl.’s. Opp’n 43 & n.28. Indeed, HHS’s sensitivity to the Spending Clause provides no reason to rush to judgment on the Rule given that it has never been applied in a specific factual circumstance.

The Rule, like the Federal Conscience Statutes, is unambiguous, and Plaintiff had ample notice of the conditions attached to federal funds. As Defendants have previously explained, Defs.’ Mem. 50–51, the standard for conditions on federal funds is not perfect clarity or perfect notice. *See W. Virginia Dep’t of Health & Human Res. v. Sebelius*, 649 F.3d 217, 223–24 (4th Cir. 2011) (“Given the structure of the grant program, the Federal Government simply could not prospectively resolve every possible ambiguity concerning particular applications”). Plaintiff attempts to distinguish *West Virginia Department of Health and Human Resources*, Pl.’s Opp’n at 45, but does not explain why it matters that that case was a post-enforcement challenge. And Plaintiff does not argue that it was unaware of the existence of the anti-discrimination requirements in the Federal Conscience Statutes.

Although Plaintiff restates its contention from its APA claim that the Rule substantively expands the requirements of the Federal Conscience Statutes, but that argument still fails for the reasons stated above. Plaintiff’s complaint that some of the Rule’s definitions are lacking in clarity

and specificity, Pl.’s Opp’n 44, is ironic because the Statutes—which Plaintiff accepts—lack even those definitions. Similarly lacking is Plaintiff’s objection to the agency’s reasonable position that using a sub-recipient cannot nullify the requirements of the Federal Conscience Statutes, Pl.’s Opp’n 44–45, because Plaintiff’s hypothesis that it would be punished for its sub-recipient’s actions if it had no notice of the violation is purely speculative, and the agency in fact made changes to the Rule’s provisions regarding sub-recipients to address similar concerns from commenters. *See* 84 Fed. Reg. at 23,220.

Nor are the conditions on federal funds retroactive—Plaintiff acknowledges that it has 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 Plaintiff’s argument assumes (wrongly) the success of Plaintiff’s merits arguments that the Rule goes beyond simply implementing Congress’s instructions. 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).

Finally, the Rule, like the Federal Conscience Statutes, is sufficiently related to the government’s interests in alleviating potential burdens of conscience on individual and

institutional health care entities. Plaintiff argues that, for example, grants for HIV/STD prevention are at risk even though their purpose is not to protect conscience rights, but does not explain why the government's interest cannot encompass both improved health care and greater conscience protections. In any event, this complaint is mis-aimed at the Rule, when it is the Federal Conscience Statutes that have linked each affected funding stream to the applicable anti-discrimination conditions. Plaintiff argues that the Rule, which clarifies how HHS will enforce the Federal Conscience Statutes as applied to funds that HHS administers will somehow affect Plaintiff's funds from the Departments of Labor and Education. Pl.'s Opp'n 47. But the Rule applies only to HHS administered, conducted, or funded programs. *See* 84 Fed. Reg. at 23,170 ("This final rule revises existing regulations to ensure vigorous 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 HHS UAR, may affect other funds, those other regulations are not challenged by Plaintiff.

VII. The Rule Does Not Violate the Establishment Clause.

Plaintiff fails to successfully grapple with the tension between its insistence that the Rule somehow violates the Establishment Clause and its apparent concession that the Federal Conscience Statutes do not. Plaintiff devotes a single footnote to this issue, halfheartedly averring that Plaintiff "does not challenge the statutes' constitutionality but rather objects to HHS's unbridled expansion of those statutes' reach in ways that cannot be squared with Establishment Clause proscriptions." Pl.'s Opp'n 38 n.26. But Plaintiff makes no effort to explain these supposed expansions or how they interact with the Establishment Clause.

As an initial matter, Plaintiff cannot explain how the Rule (or the Federal Conscience Statutes) could improperly favor religion over non-religion when the Rule is generally neutral

between religion and non-religion.⁷ *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 provides accommodations for 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 Plaintiff cites no contrary case finding an Establishment Clause violation as to a statute or regulation that accommodates objections whether based on religion or not. For the same reasons, the Rule does not “coerce” anyone to adhere to certain religious practices, and if, as Plaintiff suggests, that coercion is caused by the amount of the funding at issue, Pl.’s Opp’n 41–42, then the Statutes would be equally problematic.

Plaintiff continues to argue that the Establishment Clause bars *any* burdens on a third party, Pl.’s Opp’n 35–39, 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 Corp. of Presiding Bishop of Church of Jesus Christ of Latter-Day Saints v. Amos*,

⁷ 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 Plaintiff. 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).

483 U.S. 327, 334–35 (1987). 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 of difficulty accessing care).

Plaintiff’s citation to *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985) and *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 11 (1989) is unavailing. Both of those cases involved a benefit offered only to the religiously inclined—a day without work, in *Thornton*, and a tax break in *Texas Monthly*. The Court in *Texas Monthly* discussed a line of cases that upheld generally applicable tax breaks, citing *Thornton* to explain that “were [the] benefits confined to religious organizations . . . we would not have hesitated to strike them down for lacking a secular purpose and effect.” *Texas Monthly*, 489 U.S. at 11; *see 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.

Even if Plaintiff were correct, and the problem in *Thornton* was that the law imposed an “absolute duty” to provide a day off, Pl.’s Opp’n 36, the “absoluteness” of the accommodations here is determined by the Federal Conscience Statutes. Plaintiff offers no explanation of how, for example, the Statutes alone would alleviate the need to double staff some positions, although it

cites double staffing as a problem caused by the Rule. Pl.'s Opp'n 37. Plaintiff's attempt to explain away *Kong v. Scully*, 341 F.3d 1132 (9th Cir. 2003), and *Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308 (9th Cir. 1974), further demonstrates this problem, as neither court found it necessary to consider the potential burdens on third parties (such as, in *Chrisman*, the patient's need to find another hospital to sterilize her, or, in *Kong*, increased taxes to cover payments to non-medical facilities).

Plaintiff misstates the law by asserting that the government can act to protect religious liberty through religious accommodations "only to alleviate substantial *government-imposed* burdens on religious practice." Pl.'s Opp'n 39–40 (emphasis added). Title VII, 42 U.S.C. § 2000e *et seq.*, is one clear counterexample where the government has required *private* entities not to discriminate based on their employee's religious beliefs. Plaintiff cites cases analyzing the Religious Land Use and Institutionalized Persons Act and the Religious Freedom Restoration Act, but those statutes are not a ceiling on the government's power to accommodate religious freedom. And, of course, this flaw would equally exist in the Statutes, which are not limited to lifting government-imposed burdens. Likewise, Plaintiff argues that the Rule favors certain denominations with the services it covers, Pl.'s Opp'n 40, but it is the Statutes that dictate the covered services. Nor does the Rule evince sectarian bias any more than a federal requirement that school lunch include fruits and vegetables favors Seventh-day Adventism, Jainism, or other faith groups that encourage vegetarianism. In any event, 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.

VIII. The Court May Not Consider Plaintiff’s Extra-Record Declarations In Assessing The Merits.

The Court should not consider Plaintiff’s declarations when assessing the merits of Plaintiff’s claims against the Rule, because review of such claims is limited to the administrative record before the agency—not extra-record materials first submitted in court such as the declarations provided by Plaintiff. *See, e.g.*, Pl.’s Opp’n 37 (citing declarations in Plaintiff’s Establishment Clause argument); Pl.’s Opp’n 43 (citing declarations in Plaintiff’s Spending Clause argument).

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 long ago held that the whole record means “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). The Supreme Court has reiterated this conclusion in subsequent decisions. In *Camp v. Pitts*, for example, the Court explained 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.” 411 U.S. 138, 142 (1973). And in *Florida Power & Light Co. v. Lorion*, 470 U.S. 729 (1985), the Court stated that “[t]he task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.” *Id.* at 743–44; *see also Sanitary Bd. of City of Charleston v. Wheeler*, 918 F.3d 324, 334 (4th Cir. 2019) (“Review of agency action typically depends on an administrative record.”)⁸

⁸ There are narrow exceptions permitting the consideration of extra-record material in rare cases, *Fort Sumter Tours, Inc. v. Babbitt*, 66 F.3d 1324, 1336 (4th Cir. 1995) (citing *Public Power Council v. Johnson*, 674 F.2d 791, 793 (9th Cir. 1982)), but Plaintiff does not assert that any of those exceptions apply here (and they do not).

Plaintiff's constitutional claims, too, are governed by the APA—the APA provides the private right of action necessary for Plaintiff to assert these claims for equitable relief with respect to final agency action. Defendants are aware of no statute other than the APA that would provide Plaintiff with a private right of action to raise these constitutional claims, and Plaintiff cites none. Multiple courts across the country have held that § 706 of the APA, by its plain language, restricts the review of constitutional claims to the administrative record. *See Chang v. United States Citizenship & Immigration Servs.*, 254 F. Supp. 3d 160, 161 (D.D.C. 2017); *see also Harkness v. Sec'y of Navy*, 858 F.3d 437, 451 n.9 (6th Cir. 2017) (explaining that a constitutional claim “is properly reviewed on the administrative record”), *cert. denied*, No. 17-955, 2018 WL 3013822 (June 18, 2018); *Jarita Mesa Livestock Grazing Ass'n v. U.S. Forest Serv.*, 58 F. Supp. 3d 1191, 1232–33 (D.N.M. 2014); *Evans v. Salazar*, No. Co8-0372, 2010 WL 11565108, at *2 (W.D. Wash. July 7, 2010); *Harvard Pilgrim Health Care of New England v. Thompson*, 318 F. Supp. 2d 1, 10 (D.R.I. 2004); *Charlton Mem'l Hosp. v. Sullivan*, 816 F. Supp. 50, 51 (D. Mass. 1993). A contrary rule—one that admits a special 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*, 58 F. Supp. 3d at 1238.

IX. Any Relief Accorded to Plaintiff Should be Limited.

A. The Court Should Grant Relief Only As To Specific Portions of the Rule It Deems Unlawful, If Any.

For all the reasons described above, and in Defendants' opening brief, the Rule is lawful. Plaintiff insists, 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* 48 n.31; *see also* 84

Fed. Reg. at 23,272. Plaintiff faults Defendants for providing only a “conclusory severance argument.” Pl.’s Opp’n 48 n.31. But Plaintiff ignores that it is *Plaintiff’s* 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 Plaintiff 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. Plaintiff has provided no reasoned basis for their insistence that the Rule must either survive or fall as a whole, where HHS has explicitly explained that it intended for the constituent parts to survive independently. *See* Defs.’ Mem. 56–57.

B. Any Relief Should Not Extend Beyond the Parties Before the Court.

Again, although the Rule is lawful for the reasons Defendants have explained, if the Court were to disagree, any relief should be limited to the specific Plaintiff before the Court. Plaintiff insists that nationwide relief is the “usual” remedy under the APA. But Plaintiff ignores 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 the City of Baltimore’s particular alleged injury, violating established principles of equitable

discretion. *See* Defs.’ Mem. 55–56. And nationwide relief would effectively stop courts in other jurisdictions assessing similar challenges from evaluating those separate claims. *See id.* at 56.⁹

CONCLUSION

For the foregoing reasons, the Court should grant Defendants’ motion and deny Plaintiff’s motion.

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Respectfully submitted,

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⁹ 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. 57. Plaintiff did not respond and therefore has conceded this point.