

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 13-cv-02611-WJM-BNB

LITTLE SISTERS OF THE POOR HOME FOR THE AGED, et al.,

Plaintiffs,

v.

KATHLEEN SEBELIUS, et al.,

Defendants.

**DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR
SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT THEREOF**

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), defendants move to dismiss this action for lack of subject matter jurisdiction and failure to state a claim upon which relief may be granted. In the alternative, defendants move for summary judgment on all of plaintiffs' claims pursuant to Rule 56.

Plaintiffs ask this Court to enjoin regulations that are intended to accommodate religious exercise while helping to ensure that women have access to health coverage, without cost-sharing, for preventive services that medical experts deem necessary for women's health and well-being. Subject to an exemption for houses of worship and their integrated auxiliaries, and accommodations for certain other non-profit religious organizations, the regulations that plaintiffs challenge require certain group health plans and health insurance issuers to provide coverage, without cost-sharing (such as a copayment, coinsurance, or a deductible), for, among other things, all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

The regulations are the product of a decision by defendants to accommodate concerns expressed by non-profit religious organizations by relieving them of any responsibility to contract, arrange, pay, or refer for contraceptive coverage or services. The regulations also seek to ensure that women who participate in the group health plans of such organizations are not denied access to contraceptive coverage without cost-sharing. To invoke the accommodations, an organization merely needs to certify that it meets the eligibility criteria and share a copy of the certification with its issuer or third-party administrator (TPA). Once it does so, the organization's issuer or TPA takes on the responsibility to provide separate payments for contraceptive services to the organization's plan participants and beneficiaries. The objecting employer does not bear the cost (if any) of providing contraceptive coverage; nor does it administer, contract for, arrange, or refer for such coverage. While defendants continue to consider potential options to fully and appropriately extend the consumer protections provided by the regulations to self-insured church plans, they acknowledge that, at this time, they lack authority to require the TPAs of self-insured church plans, like plaintiff Christian Brothers Employee Benefit Trust ("Trust"), to make the separate payments for contraceptive services for participants and beneficiaries in such plans under the accommodation.

This case should be dismissed in its entirety or summary judgment should be granted to the government for several reasons. At the outset, plaintiffs lack standing to assert their claims. Because the Trust is a self-insured church plan, the government lacks authority to require any TPA of the Trust to make the separate payments for contraceptive services for participants and beneficiaries in the plan under the accommodation. Because the remaining plaintiffs offer coverage to their employees through the Trust, the injury of which plaintiffs complain—that the regulations somehow require them to facilitate access to contraceptive services to which they object on religious grounds or to contract, arrange, or pay for such services—simply does not apply to the plaintiffs here and, as a result, they lack standing.

For the same reason, even if plaintiffs had standing, their Religious Freedom Restoration Act (RFRA) claim would fail. Because the government cannot require any TPA of the Trust to

provide separate payments for contraceptive services to the participants and beneficiaries of the Trust, the regulations impose absolutely no burden on plaintiffs' religious exercise, much less a substantial burden as required under RFRA. In short, the regulations do not require plaintiffs to facilitate or act as a trigger for their employees to obtain contraceptive coverage, even if such a claim could establish a substantial burden under RFRA, which it cannot. Plaintiffs' First Amendment claims are equally meritless. Indeed, nearly every court to consider similar First Amendment challenges to the prior version of the regulations rejected the claims, and their analysis applies here. Nor do the regulations violate the Due Process or Equal Protection Clauses. Plaintiffs also cannot succeed on their APA claims. Plaintiffs lack standing to raise some of their arguments (for a reason in addition to the one explained above), and, in any event, the regulations are in accordance with federal law.

STANDARD OF REVIEW

Defendants move to dismiss this case for lack of subject matter jurisdiction and failure to state a claim upon which relief may be granted under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), respectively. The party invoking federal jurisdiction bears the burden of establishing its existence, and the Court must determine whether it has subject matter jurisdiction before addressing the merits of a claim. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95, 104 (1998). Under Rule 12(b)(6), "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To the extent that the Court must consider the administrative record in addition to the face of the complaint, defendants move, in the alternative, for summary judgment under Federal Rule of Civil Procedure 56. A party is entitled to summary judgment where the administrative record demonstrates "that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

MOVANT’S STATEMENT OF MATERIAL FACTS

1. Before the Patient Protection and Affordable Care Act (“ACA”), Pub. L. No. 111-148, 124 Stat. 119 (2010), many Americans did not receive the preventive health care they needed. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) (“IOM REP.”), AR at 317-18, 407.¹

2. Due largely to cost, Americans used preventive services at about half the recommended rate. *See* IOM REP. at 19-20, 109, AR at 317-18, 407.

3. Section 1001 of the ACA seeks to cure this problem by making preventive care accessible and affordable for many more Americans. 42 U.S.C. § 300gg-13(a)(4).

4. Specifically, the provision requires all group health plans and health insurance issuers that offer non-grandfathered health coverage to provide coverage for certain preventive services without cost-sharing, including, “[for] women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.” 42 U.S.C. § 300gg-13(a)(4).

5. Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services tasked the Institute of Medicine (IOM) with developing recommendations to implement the requirement to provide coverage, without cost-sharing, of preventive services for women. IOM REP. at 2, AR at 300.

6. After conducting an extensive science-based review, IOM recommended that HRSA guidelines include, as relevant here, “the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.” IOM REP. at 10-12, AR at 308-10.

7. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices (“IUDs”). *See* IOM REP. at 105, AR at 403.

¹ Where appropriate, defendants have provided parallel citations to the Administrative Record (AR), on file with the Court. *See* ECF No. 28.

8. IOM determined that coverage, without cost-sharing, for these services is necessary to increase access to such services, and thereby reduce unintended pregnancies (and the negative health outcomes that disproportionately accompany them) and promote healthy birth spacing. IOM REP. at 102-03, AR at 400-01.

9. On August 1, 2011, HRSA adopted guidelines consistent with IOM's recommendations, encompassing all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling," as prescribed by a health care provider, subject to an exemption relating to certain religious employers authorized by regulations issued that same day (the "2011 amended interim final regulations"). *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84.

10. To qualify for the religious employer exemption contained in the 2011 amended interim final regulations, an employer had to meet the following criteria:

- (1) The inculcation of religious values is the purpose of the organization;
- (2) the organization primarily employs persons who share the religious tenets of the organization;
- (3) the organization serves primarily persons who share the religious tenets of the organization; and
- (4) the organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011), AR at 220.

11. Group health plans established or maintained by religious employers (and associated group health insurance coverage) are exempt from any requirement to cover contraceptive services consistent with HRSA's guidelines. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84; 45 C.F.R. § 147.131(a).

12. In February 2012, the government adopted in final regulations the definition of "religious employer" contained in the 2011 amended interim final regulations while also creating a temporary enforcement safe harbor for non-grandfathered group health plans sponsored by

certain non-profit organizations with religious objections to contraceptive coverage (and any associated group health insurance coverage). *See* 77 Fed. Reg. 8725, 8726-27 (Feb. 15, 2012), AR at 213-14.

13. The government committed to undertake a new rulemaking during the safe harbor period to adopt new regulations to further accommodate non-grandfathered non-profit religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8728, AR at 215.

14. The regulations challenged here (the "2013 final rules") represent the culmination of that process. *See* 78 Fed. Reg. 39,870, AR at 1-31; *see also* 77 Fed. Reg. 16,501 (Mar. 21, 2012) (Advance Notice of Proposed Rulemaking), AR at 186-93; 78 Fed. Reg. 8456 (Feb. 6, 2013) (Notice of Proposed Rulemaking), AR at 165-85.

15. The 2013 final rules represent a significant accommodation by the government of the religious objections of certain non-profit religious organizations while promoting two important policy goals. *See* 78 Fed. Reg. 39,870, AR at 1-31.

16. The regulations provide women who work for non-profit religious organizations with access to contraceptive coverage without cost sharing, thereby advancing the government's interests in safeguarding public health and ensuring that women have equal access to health care. *See* 78 Fed. Reg. 39,870, AR at 1-31.

17. The regulations do so in a way that does not require non-profit religious organizations with religious objections to contract, arrange, pay, or refer for that coverage. *See* 78 Fed. Reg. 39,870, AR at 1-31.

18. The 2013 final rules simplify and clarify the religious employer exemption by eliminating the first three criteria and clarifying the fourth. *See* 78 Fed. Reg. at 39,874.

19. Under the 2013 final rules, a "religious employer" is "an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended," which refers to churches, their

integrated auxiliaries, and conventions or associations of churches, and the exclusively religious activities of any religious order. 45 C.F.R. § 147.131(a).

20. The changes made to the definition of religious employer in the 2013 final rules ensure “that an otherwise exempt plan is not disqualified because the employer’s purposes extend beyond the inculcation of religious values or because the employer hires or serves people of different religious faiths.” 78 Fed. Reg. at 39,874, AR at 6.

21. The 2013 final rules also establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by “eligible organizations” (and group health insurance coverage provided in connection with such plans). 78 Fed. Reg. at 39,875-80, AR at 7-12.

22. An “eligible organization” is an organization that satisfies the following criteria:
- (1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 147.130(a)(1)(iv) on account of religious objections.
 - (2) The organization is organized and operates as a nonprofit entity.
 - (3) The organization holds itself out as a religious organization.
 - (4) The organization self-certifies, in a form and manner specified by the Secretary, that it satisfies the criteria in paragraphs (b)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies.

45 C.F.R. § 147.131(b); *see also* 78 Fed. Reg. at 39,874-75, AR at 6-7.

23. Under the 2013 final rules, an eligible organization is not required “to contract, arrange, pay, or refer for contraceptive coverage” to which it has religious objections. 78 Fed. Reg. at 39,874, AR at 6.

24. To be relieved of any such obligations, the 2013 final rules require only that an eligible organization complete a self-certification form stating that it is an eligible organization and provide a copy of that self-certification to its issuer or TPA. 78 Fed. Reg. at 39,878-79, AR at 10-11.

25. In the case of a self-insured group health plan that is not a self-insured church plan, the organization's TPA, upon receipt of the self-certification, must provide or arrange separate payments for contraceptive services for participants and beneficiaries in the plan without cost-sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. *See* 78 Fed. Reg. at 39,879-80, AR at 11-12.

26. Any costs incurred by the TPA will be reimbursed through an adjustment to Federally-facilitated Exchange (FFE) user fees. *See* 78 Fed. Reg. at 39,880, AR at 12.

27. The regulations do not require the TPAs of self-insured church plans that have not made an election under 26 U.S.C. § 410(d)—like the Christian Brothers Employee Benefit Trust—to make separate payments for contraceptive services for participants and beneficiaries in such plans under the accommodation. *See* 78 Fed. Reg. at 39,879-39,880, AR at 11-12; 29 U.S.C. § 1003(b)(2).

28. The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, except the amendments to the religious employer exemption apply to group health plans and group health insurance issuers for plan years beginning on or after August 1, 2013. *See* 78 Fed. Reg. at 39,871-72, AR at 3-4.

29. Houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan. *See* 78 Fed. Reg. at 39,874, AR at 6.

30. By contrast, individuals in plans of eligible organizations that qualify for the accommodations are less likely than individuals in plans of religious employers to share their employer's faith and object to contraceptive coverage on religious grounds. *See* 78 Fed. Reg. at 39,874, 39,887, AR at 6, 19.

31. "Nothing in the[] final regulations prohibits an eligible organization from expressing its opposition to the use of contraception." 78 Fed. Reg. at 39,880 n.41, AR at 12.

32. The regulations only prohibit an employer's improper attempt to interfere with its employees' ability to obtain contraceptive coverage from a third party by, for example, threatening the TPA with a termination of its relationship with the employer because of the TPA's "arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries." See 26 C.F.R. § 54.9815-2713A(b)(1)(iii); 29 C.F.R. § 2950.715-2713A(b)(1)(iii).

33. Section 1303(b)(1) of the ACA provides that "nothing in this title . . . shall be construed to require a qualified health plan to provide coverage of [abortion services]." 42 U.S.C. § 18023(b)(1)(A)(i).

34. A "qualified health plan," within the meaning of this provision, is a health plan that has been certified by the health insurance exchange "through which such plan is offered" and that is offered by a health insurance issuer. 42 U.S.C. § 18021(a)(1).

35. Health insurance exchanges are to be set up by states or HHS no later than January 1, 2014. *Id.* § 18031.

36. The Weldon Amendment denies funds made available in the Consolidated Appropriations Act of 2012 to any federal, state, or local agency, program, or government that "subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." Pub. L. No. 112-74, §§ 506, 507, 125 Stat. 786, 1111-12 (Dec. 23, 2011).

37. The preventive services covered by the regulations "do not include abortifacient drugs." HealthCare.gov, Affordable Care Act Rules on Expanding Access to Preventive Services for Women (August 1, 2011), *available at* <http://www.hhs.gov/healthcare/facts/factsheets/2011/08/womensprevention08012011a.html>; *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320.

38. The list of FDA-approved contraceptives includes emergency contraceptives such as Plan B. *See* IOM REP. at 105, AR at 403.

39. The basis for the inclusion of such drugs among safe and effective means of contraception dates back to 1997, when the FDA first explained why Plan B and similar drugs act as contraceptives rather than abortifacients. See Prescription Drug Products; Certain Combined Oral Contra for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610, 8611 (Feb. 25, 1997) (noting that “emergency contraceptive pills are not effective if the woman is pregnant” and that there is “no evidence that [emergency contraception] will have an adverse effect on an established pregnancy”); 45 C.F.R. § 46.202(f) (“Pregnancy encompasses the period of time from implantation until delivery.”).

40. In light of this conclusion by the FDA, HHS informed Title X grantees, which are required to offer a range of acceptable and effective family planning methods—and, except under limited circumstances, may not offer abortion—that they “should consider the availability of emergency contraception the same as any other method which has been established as safe and effective.” Office of Population Affairs, Memorandum (Apr. 23, 1997), <http://www.hhs.gov/opa/pdfs/opa-97-02.pdf>; *see also* 42 U.S.C. §§ 300, 300a-6.

41. Representative Weldon, the sponsor of the Weldon Amendment, did not consider the word “abortion” in the statute to include FDA-approved emergency contraceptives. See 148 Cong. Rec. H6566, H6580 (daily ed. Sept. 25, 2002) (“The provision of contraceptive services has never been defined as abortion in Federal statute, nor has emergency contraception, what has commonly been interpreted as the morning-after pill. . . . [U]nder the current FDA policy[,] that is considered contraception, and it is not affected at all by this statute.”).²

² Defendants have not included in the Movant’s Statement of Material Facts section of this brief facts that relate to the strict scrutiny analysis. Defendants reserve the right to assert such facts at a later date in light of the Supreme Court’s resolution of defendants’ pending petition for a writ of certiorari in *Hobby Lobby v. Sebelius*, and any subsequent Supreme Court decision in that case. *See infra* p. 14.

ARGUMENT

I. THE COURT LACKS SUBJECT MATTER JURISDICTION

This case should be dismissed at the outset for lack of standing. “[T]he irreducible constitutional minimum of standing” requires that a plaintiff (1) have suffered an injury in fact, (2) that is caused by the defendant’s conduct, and (3) that is likely to be redressed by a favorable ruling. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). As to the injury prong, a plaintiff must demonstrate that it has “suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical.” *Id.* at 560 (quotations omitted). Allegations of possible future injury do not suffice; rather, “[a] threatened injury must be certainly impending to constitute injury in fact.” *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) (quotation omitted).

The harm alleged by Little Sisters of the Poor Home for the Aged, Denver, and Little Sisters of the Poor, Baltimore, Inc., (collectively, “Little Sisters Plaintiffs”) is that, to avail themselves of the accommodations, the challenged regulations require them to engage in actions that “facilitate” and/or make them the “trigger” for the provision of payments for contraceptive services by a third party. *See* Compl. ¶¶ 109-146. Christian Brothers Services and the Trust (collectively, “Christian Brothers Plaintiffs”) allege that they are injured because the regulations require them to provide payments for contraceptive services and/or contract or otherwise arrange with a third party for such payments to be made with respect to the participants and beneficiaries of the Trust. *See id.* ¶¶ 147-164. The Trust, however, is a self-insured “church plan” under the Employee Retirement Income Security Act (ERISA) that has not made an election under 26 U.S.C. § 410(d). *Id.* ¶¶ 21-23. And defendants lack regulatory authority to require the TPAs of self-insured church plans that have not made such an election to make the separate payments for contraceptive services for participants and beneficiaries in such plans under the accommodation.

In general, under the challenged regulations, when a TPA receives a copy of the self-certification from an eligible employer that sponsors a self-insured group health plan, that TPA becomes an ERISA Section 3(16), 29 U.S.C. § 1002(16), plan administrator and claims

administrator for the purpose of providing the separate payments for contraceptive services. *See* 29 C.F.R. § 2510.3-16(b). Thus, the contraceptive coverage requirements can be enforced against such TPAs through defendant Department of Labor’s ERISA enforcement authority. *See* 78 Fed. Reg. 39,870, 39,879-39,880 (July 2, 2013), AR at 11-12. But church plans are specifically excluded from the ambit of ERISA. *See* 29 U.S.C. § 1003(b)(2). Thus, ERISA enforcement authority is not available with respect to the TPAs of self-insured church plans under the accommodation, and the government cannot compel such TPAs under such authority to provide contraceptive coverage to self-insured church plan participants and beneficiaries under the accommodation, including the employees of the Little Sisters Plaintiffs.

The Little Sisters Plaintiffs remain eligible for the accommodations under the final regulation promulgated by defendant Department of the Treasury, 26 C.F.R. § 54.9815-2713A, and therefore need not contract, arrange, pay, or refer for contraceptive coverage.³ And neither the Christian Brothers Plaintiffs nor any TPA of the Trust is required under the regulations to provide separate payments for contraceptive services or to contract or otherwise arrange with a third party for such payments to be made with respect to the participants and beneficiaries of the Trust. In short, under the challenged regulations, there is absolutely no connection between plaintiffs and contraceptive coverage. Thus, the injury of which plaintiffs complain—with respect to the Little Sisters Plaintiffs, that the regulations somehow require them to facilitate access to contraceptive services to which they object on religious grounds or, with respect to the Christian Brothers Plaintiffs, that the regulations require them to contract, arrange, or pay for contraceptive coverage—simply does not apply to plaintiffs here. Because plaintiffs lack standing to assert their claims, the case should be dismissed in its entirety.

³ The same can be said of any other entity that qualifies as an “eligible organization” under the accommodations and participates in the Trust church plan, whether or not that organization is a plaintiff in this action.

II. PLAINTIFFS' CLAIMS LACK MERIT

A. Plaintiffs' Religious Freedom Restoration Act Claim Fails

Under RFRA, Pub. L. No. 103-141, 107 Stat. 1488 (1993), the federal government “shall not substantially burden a person’s exercise of religion” unless that burden is the least restrictive means to further a compelling governmental interest. 42 U.S.C. 2000bb-1. Importantly, “only substantial burdens on the exercise of religion trigger the compelling interest requirement.” *Henderson v. Kennedy*, 253 F.3d 12, 17 (D.C. Cir. 2001). “A substantial burden exists when government action puts ‘substantial pressure on an adherent to modify his behavior and to violate his beliefs.’” *Kaemmerling v. Lappin*, 553 F.3d 669, 678 (D.C. Cir. 2008) (citing *Thomas v. Review Bd.*, 450 U.S. 707, 718 (1981)). “An inconsequential or *de minimis* burden on religious practice does not rise to this level, nor does a burden on activity unimportant to the adherent’s religious scheme.” *Id.*; see *Garner v. Kennedy*, 713 F.3d 237, 241-42 (5th Cir. 2013) (“the plaintiff must show that the challenged action ‘truly pressures the adherent to significantly modify his religious behavior and significantly violate his religious beliefs’”).

Plaintiffs cannot possibly show—as they must—that the challenged regulations substantially burden their religious exercise for the same reason that they have not even alleged an injury sufficient for purposes of Article III standing. The Little Sisters Plaintiffs are eligible for the accommodation, and thus, they need not contract, arrange, pay, or refer for contraceptive coverage. Moreover, the government cannot require any TPA of the Trust, which is a self-insured church plan, to provide separate payments for contraceptive services to the participants and beneficiaries of the Trust, meaning that the Little Sisters Plaintiffs are not “trigger[ing]” or “facilitating” access to contraceptive coverage, Compl. ¶¶ 110, 120. Finally, because the Trust is a self-insured church plan, the challenged regulations do not require the Christian Brothers Plaintiffs or their TPAs to provide separate payments for contraceptive services or to contract or otherwise arrange with a third party for such payments to be made with respect to the participants and beneficiaries of the Trust. The regulations, therefore, impose absolutely no burden on plaintiffs’ religious exercise, let alone a substantial burden.

Plaintiffs contend the Tenth Circuit’s decision in *Hobby Lobby v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013) (en banc), is dispositive of the substantial burden inquiry here, but it is not. *Hobby Lobby* addressed the RFRA claim of for-profit corporations, which, unlike plaintiffs here, are not eligible for the accommodations—and thus are required by the regulations to contract, or otherwise arrange, and pay for, contraceptive coverage for their employees—and do not have a self-insured church plan. The *Hobby Lobby* court had no occasion to consider whether the regulations’ accommodations as applied to a self-insured church plan, which relieve eligible non-profit religious organizations like the Little Sisters Plaintiffs of any obligation to contract, arrange, pay, or refer for contraceptive coverage, and do not require church plan TPAs to provide separate payments for contraceptive services, impose a substantial burden on religious exercise. They do not for the reasons discussed above. Because the challenged regulations do not impose a substantial burden on plaintiffs’ religious exercise, plaintiffs’ RFRA claim (Count I) should be dismissed or summary judgment granted to defendants.

Even if the challenged regulations were deemed to impose a substantial burden on plaintiffs’ religious exercise, the regulations satisfy strict scrutiny because they are narrowly tailored to serve compelling governmental interests in public health and gender equality. Defendants recognize that a majority of the en banc Tenth Circuit rejected the government’s strict scrutiny argument in *Hobby Lobby*, and that this Court is bound by that decision. Defendants have filed a petition for a writ of certiorari that asks the Supreme Court to review the Tenth Circuit’s decision. Defendants raise the argument here merely to preserve it for appeal.

B. The Regulations Do Not Violate the Free Exercise Clause

A law that is neutral and generally applicable does not run afoul of the Free Exercise Clause even if it prescribes conduct that an individual’s religion proscribes or has the incidental effect of burdening a particular religious practice. *Emp’t Div. v. Smith*, 494 U.S. 872, 879 (1990). “Neutrality and general applicability are interrelated.” *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 531 (1993). A law is neutral if it does not target religiously motivated conduct either on its face or as applied. *Id.* at 533. A neutral law has as its purpose

something other than the disapproval of a particular religion, or of religion in general. *Id.* at 545. A law is generally applicable so long as it does not selectively impose burdens only on conduct motivated by religious belief. *Id.*

Unlike such selective laws, the preventive services coverage regulations are neutral and generally applicable. Indeed, nearly every court to have considered a free exercise challenge to the prior version of the regulations has rejected it, concluding that the regulations are neutral and generally applicable.⁴ “The regulations were passed, not with the object of interfering with religious practices, but instead to improve women’s access to health care and lessen the disparity between men’s and women’s healthcare costs.” *O’Brien*, 894 F. Supp. 2d at 1161. The regulations reflect expert medical recommendations about the medical necessity of contraceptive services, without regard to any religious motivations for or against such services. *See, e.g., Conestoga*, 917 F. Supp. 2d at 410 (“It is clear from the history of the regulations and the report published by the Institute of Medicine that the purpose of the [regulations] is not to target religion, but instead to promote public health and gender equality.”).

The regulations, moreover, do not pursue their purpose “only against conduct motivated by religious belief.” *Lukumi*, 508 U.S. at 545; *see United States v. Amer*, 110 F.3d 873, 879 (2d Cir. 1997) (concluding law that “punishe[d] conduct within its reach without regard to whether the conduct was religiously motivated” was generally applicable). The regulations apply to all non-grandfathered health plans that do not qualify for the religious employer exemption or the accommodations for eligible organizations. Thus, “it is just not true . . . that the burdens of the [regulations] fall on religious organizations ‘but almost no others.’” *Am. Family Ass’n v. FCC*, 365 F.3d 1156, 1171 (D.C. Cir. 2004) (quoting *Lukumi*, 508 U.S. at 536).

The Tenth Circuit has made clear that the existence of “express exceptions for objectively defined categories of [entities],” like grandfathered plans and religious employers, does not

⁴ *See MK Chambers Co. v. U.S. Dep’t of Health & Human Servs.*, 2013 WL 1340719, at *5 (E.D. Mich. Apr. 3, 2013); *Conestoga*, 917 F. Supp. 2d at 409-10; *Grote Indus., LLC v. Sebelius*, 914 F. Supp. 2d 943, 952-53 (S.D. Ind. 2012); *Autocam*, 2012 WL 6845677, at *5; *O’Brien*, 894 F. Supp. 2d at 1160-62; *see also Catholic Charities of Diocese of Albany v. Serio*, 859 N.E.2d 459, 468-69 (N.Y. 2006) (rejecting similar challenge to state law); *Catholic Charities of Sacramento, Inc. v. Superior Court*, 85 P.3d 67, 81-87 (Cal. 2004) (same).

negate a law's general applicability. *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1298 (10th Cir. 2004); *see also Grace United Methodist Church v. City of Cheyenne*, 451 F.3d 643, 651 (10th Cir. 2006) (refusing to “interpret *Smith* as standing for the proposition that a secular exemption automatically creates a claim for a religious exemption”); *Swanson v. Guthrie Indep. Sch. Dist.*, 135 F.3d 694, 698, 701 (10th Cir. 1998) (concluding school's attendance policy was not subject to strict scrutiny despite exemptions for “strict categories of students,” such as fifth-year seniors and special education students). The exception for grandfathered plans is available on equal terms to all employers, whether religious or secular. And the religious employer exemption and eligible organization accommodations serve to accommodate religion, not to disfavor it. Such categorical exceptions do not trigger strict scrutiny. *See, e.g., Autocam*, 2012 WL 6845677, at *5; *O'Brien*, 894 F. Supp. 2d at 1162.

Finally, even if the regulations were not neutral or generally applicable, plaintiffs' free exercise claim still would fail because, as explained above, the regulations do not substantially burden plaintiffs' religious exercise. *See Axson-Flynn*, 356 F.3d at 1294 (explaining that, even where a law is not neutral or generally applicable, strict scrutiny applies only if the law substantially burdens religious exercise); *Levitan v. Ashcroft*, 281 F.3d 1313, 1320 (D.C. Cir. 2002) (same); *Goodall v. Stafford County School Bd.*, 60 F.3d 168, 173 (4th Cir. 1995) (same).

For these reasons, plaintiffs' free exercise claims (Counts II, III, IV, and VI) fail.⁵

C. The Regulations Do Not Violate the Establishment Clause, the Due Process Clause, or the Equal Protection Clause

“The clearest command of the Establishment Clause is that one religious *denomination* cannot be officially preferred over another.” *Larson v. Valente*, 456 U.S. 228, 244 (1982) (emphasis added). A law that discriminates among religions by “aid[ing] one religion” or

⁵ Plaintiff's so-called “unbridled discretion” claim, Compl. ¶¶ 287-292 (Count XI), also fails. First, plaintiffs misunderstand the regulations when they assert that they provide HRSA “unbridled discretion over which organizations can [be] accommodated.” Compl. ¶ 288. That is incorrect. The regulations permitted HRSA to create a religious employer exemption, and HRSA did so in its August 1, 2011 action. *See HRSA Guidelines*. Any employer that meets the criteria of a “religious employer” is exempt from the contraceptive-coverage requirement. *See id.; see, e.g., Grote*, 2012 WL 6725905, at *8. Second, plaintiffs' allegation that defendants acted in a discriminatory manner by creating the religious employer exemption is without merit. As explained below, the religious employer exemption does not grant any denominational preference or otherwise discriminate among religions.

“prefer[ring] one religion over another” is subject to strict scrutiny. *Id.* at 246; *see also Olsen v. DEA*, 878 F.2d 1458, 1461 (D.D.C. 1989) (observing that “[a] statutory exemption authorized for one church alone, and for which no other church may qualify,” creates a “denominational preference”). Thus, for example, the Supreme Court has struck down on Establishment Clause grounds a state statute that was “drafted with the explicit intention” of requiring “particular religious denominations” to comply with registration and reporting requirements while excluding other religious denominations. *Larson*, 456 U.S. at 254; *see also Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 703-07 (1994) (striking down statute that “single[d] out a particular religious sect for special treatment”). The Court, on the other hand, has upheld a statute that provided an exemption from military service for persons who had a conscientious objection to all wars, but not those who objected to only a particular war. *Gillette v. United States*, 401 U.S. 437 (1971). The Court explained that the statute did not discriminate among religions because “no particular sectarian affiliation” was required to qualify for conscientious objector status. *Id.* at 450-51. “[C]onscientious objector status was available on an equal basis to both the Quaker and the Roman Catholic.” *Larson*, 456 U.S. at 247 n.23; *see also Cutter v. Wilkinson*, 544 U.S. 709, 724 (2005) (upholding RLUIPA because it did not “confer[] . . . privileged status on any particular religious sect” or “single[] out [any] bona fide faith for disadvantageous treatment”).

Like the statutes at issue in *Gillette* and *Cutter*, the preventive services coverage regulations do not grant any denominational preference or otherwise discriminate among religions. It is of no moment that the religious employer exemption and accommodations for eligible organizations apply to some employers but not others. “[T]he Establishment Clause does not prohibit the government from [differentiating between organizations based on their structure and purpose] when granting religious accommodations as long as the distinction[s] drawn by the regulations . . . [are] not based on religious affiliation.” *Grote*, 914 F. Supp. 2d at 954; *accord O’Brien*, 894 F. Supp. 2d at 1163; *see also, e.g., Children’s Healthcare Is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084, 1090-93 (8th Cir. 2000); *Droz v. Comm’r of IRS*, 48 F.3d 1120,

1124 (9th Cir. 1995) (concluding that religious exemption from self-employment Social Security taxes did not violate the Establishment Clause even though “some individuals receive exemptions, and other individuals with identical beliefs do not”); *Catholic Charities of the Diocese of Albany*, 859 N.E.2d at 468-69 (“This kind of distinction—not between denominations, but between religious organizations based on the nature of their activities—is not what Larson condemns.”). Here, the distinctions established by the regulations are not so drawn.

The regulations’ definitions of religious employer and eligible organization “do[] not refer to any particular denomination.” *Grote*, 914 F. Supp. 2d at 954. The exemption and accommodations are available on an equal basis to organizations affiliated with any and all religions. The regulations, therefore, do not discriminate among religions in violation of the Establishment Clause. Indeed, every court to have considered an Establishment Clause challenge to the prior version of the regulations—which also included a requirement that the organization be an organization as described in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended—has rejected it. *See, e.g., O’Brien*, 894 F. Supp. 2d at 1162; *Conestoga*, 917 F. Supp. 2d at 416-17; *Grote*, 914 F. Supp. 2d at 954; *see also Walz v. Tax Commission of NY*, 397 U.S. 664, 672-73 (1970) (upholding property tax exemption “to religious organizations for religious properties used solely for religious worship”); *Liberty Univ., Inc. v. Lew*, 2013 WL 3470532, at *17-18 (4th Cir. July 11, 2013) (upholding another religious exemption in ACA where it made “no explicit and deliberate distinctions between sects” (quotation omitted)). For these reasons, plaintiffs’ Establishment Clause claims (Counts IV, V, VI, and VII) fail.

Like plaintiffs’ Establishment Clause claim, its due process and equal protection claims are based on the theory that the regulations discriminate among religions. Because, as shown above, the regulations do not so discriminate, plaintiffs’ due process and equal protection claims warrant only rational basis review. *See, e.g., Johnson v. Robison*, 415 U.S. 361, 375 n. 14 (1974); *St. John’s United Church of Christ v. City of Chicago*, 502 F.3d 616, 638 (7th Cir. 2007) (applying rational basis review to equal protection claim where free exercise claim failed); *Hsu v. Roslyn Union Free Sch. Dist. No. 3*, 85 F.3d 839, 868 (2d Cir. 1996) (applying rational basis

test to law that did not discriminate among religions). The regulations satisfy rational basis review because defendants could rationally have concluded that, as a general matter, houses of worship and their integrated auxiliaries are more likely than other religious organizations, such as religious charities, schools, and hospitals, to employ people of the same faith who share their objection to the use of contraceptive services. *See, e.g., Banker's Life and Cas. Co. v. Crenshaw*, 486 U.S. 71, 85 (1988); *Gonzalez-Droz v. Gonzalez-Colon*, 660 F.3d 1, 10 (1st Cir. 2011); *see also* 78 Fed. Reg. at 39,874, 39,887, AR at 6, 19. Accordingly, Counts VII and VIII should be dismissed or summary judgment granted to defendants.⁶

D. The Regulations Do Not Violate the Right to Free Speech or Expressive Association

Plaintiffs' free speech claims fare no better. The right to freedom of speech "prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.* ("FAIR"), 547 U.S. 47, 61 (2006). But the preventive services coverage regulations do not "compel speech"—by plaintiffs or any other person, employer, or entity—in violation of the First Amendment. Nor do they limit what plaintiffs may say. Plaintiffs remain free under the regulations to express whatever views it may have on the use of contraceptive services (or any other health care services) as well as its views about the regulations.

As plaintiffs point out, to avail themselves of the accommodations, the Little Sisters Plaintiffs must self-certify that they meet the definition of "eligible organization." But, contrary to plaintiffs' assertion, the self-certification does not in any sense "trigger payments" for contraceptive services, *see* Compl. ¶ 275, as the government cannot require any TPA of the Trust, which is a self-insured church plan, to provide payments for contraceptive services. Completion of the simple self-certification form, moreover, is "plainly incidental to the . . . regulation of conduct," *FAIR*, 547 U.S. at 62, not speech. Indeed, every court to review a free speech challenge to the prior contraceptive-coverage regulations has rejected it, in part, because

⁶ Plaintiffs also allege that, by requiring them to facilitate practices in violation of their religious beliefs, the regulations interfere with plaintiffs' "internal decisions" in violation of the Religion Clauses. Compl. ¶¶ 250-258 (Count VI). But that is merely a restatement of plaintiffs' substantial burden and free exercise theories, which fail for reasons explained already.

the regulations deal with conduct. *See, e.g., MK Chambers*, 2013 WL 1340719, at *6; *Briscoe v. Sebelius*, 927 F. Supp. 2d 1109 (D. Colo. 2013); *Conestoga*, 917 F. Supp. 2d at 418; *Autocam*, 2012 WL 6845677, *8; *O'Brien*, 894 F. Supp. 2d at 1165-67. The accommodations likewise regulate conduct by relieving an eligible organization of any obligation to contract, arrange, pay, or refer for contraceptive coverage to which it has religious objections. Accordingly, plaintiffs' self-certifying their eligibility for an accommodation, which is incidental to the regulation of conduct, does not violate their speech rights. *See FAIR*, 547 U.S. at 61-63.

Similarly flawed is plaintiffs' claim that they are barred from expressing particular views to their TPA. *See* Compl. ¶ 276. Defendants have been clear that "[n]othing in these final regulations prohibits an eligible organization from expressing its opposition to the use of contraception." 78 Fed. Reg. at 39,880 n.41, AR at 12. What the regulations prohibit is an employer's improper attempt to interfere with its employees' ability to obtain contraceptive coverage from a third party by, for example, threatening the TPA with a termination of its relationship with the employer because of the TPA's "arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries." *See* 26 C.F.R. § 54.9815-2713A(b)(1)(iii); 29 C.F.R. § 2590.715-2713A(b)(1)(iii).

As an initial matter, plaintiffs lack standing to assert this claim (for a reason in addition to the one explained *supra* pp. 11-12). Because the Trust is a self-insured church plan, the regulations do not require any TPA of the Trust to provide separate payments for contraceptive services or to contract or otherwise arrange with a third party for such payments to be made with respect to Trust participants and beneficiaries. And the Christian Brothers Plaintiffs have alleged that they will not provide contraceptive coverage or pay for contraceptive services because their religious beliefs prohibit them from doing so. *See* Compl. ¶¶ 27, 30. Therefore, any assertion that the non-interference provision will affect the speech of plaintiffs here is far too speculative for purposes of Article III standing. *See Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1147 (2013).

Even if plaintiffs had standing to assert this claim, it would fail on the merits. Addressing an analogous argument in the context of the National Labor Relations Act, the Supreme Court concluded that an employer's threatening statements to its employees regarding the effects of unionization fell outside the protection of the First Amendment because they interfered with employee rights. *NLRB v. Gissel Packing Co.*, 395 U.S. 575, 618 (1969). The Court explained that there was no First Amendment violation because the employer was "free to communicate . . . any of his general views . . . so long as the communications do not contain a 'threat of reprisal or force or promise of benefit.'" *Id.*; see also *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978). The same is true here. Because the regulations do not prevent plaintiffs from expressing their views regarding the use of contraceptive services, but rather, protect employees' right to obtain payments for contraceptive services through issuers/TPAs, there is no infringement of plaintiffs' right to free speech.

The regulations also do not violate plaintiffs' right to expressive association. The regulations do not interfere in any way with the composition of plaintiffs' workforce. See *Boy Scouts of Am. v. Dale*, 530 U.S. 640, 656 (2000) (forcing organization to accept gay man as scoutmaster violated freedom of expressive association); *Roberts*, 468 U.S. at 623 (statute that forced group to accept women subject to strict scrutiny). The regulations do not force plaintiffs to hire employees they does not wish to hire, and plaintiffs are free to associate to voice their disapproval of the use of contraception and the regulations. Even the statute at issue in *FAIR*, which required law schools to allow military recruiters on campus if other recruiters were allowed on campus, did not violate the law schools' right to expression association. 547 U.S. at 68-70. The preventive services coverage regulations do not even implicate plaintiffs' right. See *MK Chambers v. HHS*, No. 13-cv-11379-BPH-MJH, Order Denying Mot. for Prelim. Inj. at 12-13, ECF No. 46 (Sept. 13, 2013) (rejecting expressive association challenge to prior version of regulations); *Diocese of Albany*, 859 N.E. 2d at 465 (upholding similar state law because it "does [not] compel [plaintiffs] to associate, or prohibit them from associating, with anyone"). For these reasons, plaintiffs' free speech and expressive association claims (Counts IX and X) fail.

E. Plaintiffs' APA Claims Fail

1. The regulations were promulgated in accordance with the APA

Plaintiffs assert that defendants failed to comply with the APA's notice and comment procedures, both in relation to the challenged regulations and in relation to the HRSA Guidelines. Plaintiffs also claim that defendants improperly delegated their authority when they sought the expertise of the IOM. All of these allegations are baseless. The APA's rulemaking provisions generally require that agencies provide notice of a proposed rule, invite and consider public comments, and adopt a final rule that includes a statement of basis and purpose. *See* 5 U.S.C. § 553(b), (c). Defendants complied with these requirements.

As to the challenged regulations, defendants issued the ANPRM on March 21, 2012, and solicited comments on it. 77 Fed. Reg. 16,501. Defendants then considered those comments and issued the NPRM on February 6, 2013, requesting comments on the proposals contained in it. 78 Fed. Reg. 8456, 8457. Defendants received over 400,000 comments, and the preamble to the 2013 final rules contains a detailed discussion of the comments and of defendants' responses to them. *See* 78 Fed. Reg. 38,969, 39,871-39,888 (July 2, 2013). The mere fact that the regulations as ultimately issued may not satisfy the preferences of each and every commenter is certainly not evidence that those comments were not considered. Given the range of interests and views among commenters, it is unlikely—if not impossible—that any regulation will be fully in line with the comments made by every commenter.

As to the HRSA Guidelines, because there were no existing HRSA guidelines relating to preventive care and screening for women, HRSA sought the scientific and medical expertise of the IOM. This is not at all unusual, as entities like HRSA frequently contract with non-governmental entities, including the IOM, for this type of technical input. Seeking such input is not a delegation of HRSA's authority, but rather a consultation. After considering the IOM's recommendations, HRSA independently made the decision to adopt guidelines based on those recommendations, subject to the religious employer exemption. Moreover, nothing in the APA, or any other statute, requires HRSA to have subjected IOM's recommendations to notice and

comment procedures before adopting them in the guidelines. The APA’s notice-and-comment requirements apply only to rulemaking, 5 U.S.C. § 553(b), and a “rule” is defined in the APA, in relevant part, as being “designed to implement, interpret, or prescribe law or policy,” *id.* § 551(4). The guidelines neither do nor are designed to do any such thing, and as such they do not constitute a “rule” within the meaning of the APA; they are simply clinical recommendations of a scientific body. The substantive obligations that are imposed on group health plans and health insurance issuers were imposed by Congress, in 42 U.S.C. § 300gg-13(a) and in corresponding provisions of ERISA and the Internal Revenue Code, which expressly and automatically imported the content of various guidelines (including the HRSA Guidelines), including new content after a specified period of time. Indeed, in the same provision, Congress also imported by reference clinical recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. *Id.* The clinical recommendations of these entities are not generally required to be subject to notice and comment, and there is no suggestion that Congress intended otherwise here for any of the referenced recommendations.⁷

2. *The regulations are neither arbitrary nor capricious*

Plaintiffs’ claim that the regulations are arbitrary and capricious is belied by the policymaking path discussed above, which illustrates that the regulations are neither arbitrary nor capricious. *See Motor Vehicle Mfrs. Ass’n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action must be upheld so long as “the agency’s path may reasonably be discerned”); *Biodiversity Legal Found. v. Babbitt*, 146 F.3d 1249, 1257 (10th Cir. 1998) (under APA, reviewing court’s role “is not to assess the wisdom of policy choices”). The preamble to the rules also sets out that path in detail, *see* 78 Fed. Reg. at 39,871-88, and there can be no serious question that it can be reasonably discerned. Similarly, plaintiffs’ brazen claim that

⁷ In contrast, other provisions of the ACA use clear language when referring to the promulgation of substantive rules. *See, e.g.*, 42 U.S.C. § 300gg-1(b)(3) (“The Secretary shall promulgate regulations with respect to enrollment periods”); *id.* § 300gg-14(b) (“The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available”); *id.* § 300gg-17(d). That Congress explicitly did not use such language here indicates it did not intend the HRSA Guidelines to be “rules” within the meaning of the APA.

defendants failed to consider the constitutional and statutory implications of the regulations is flatly contradicted by the record, which explicitly discusses that very issue. *See* 78 Fed. Reg. at 39,886-88. Just as the fact that plaintiffs is disappointed that the regulations are not in keeping with all of their comments does not mean that defendants failed to consider those comments, plaintiffs' contrary policy preferences do not render the regulations arbitrary or capricious.

3. *Plaintiffs Lack Standing To Raise Their Statutory Authority Claims*

Plaintiffs make three allegations in which they claim that defendants lacked statutory authority to enact parts of the regulations. Specifically, plaintiffs allege that defendants lack statutory authority (1) “to coerce [TPAs] . . . to pay or provide for [contraceptive services] for individuals with whom they have no contractual or fiduciary relationship, Compl. ¶ 313; (2) “to prevent insurance issuers and [TPAs] from passing on the costs” of providing contraceptive services, *id.* ¶ 314; and (3) “to allow user fees from the federal exchanges to be used” by TPAs “to purchase contraceptive . . . services for employees not participating in the exchanges,” *id.* ¶ 315. Plaintiffs, however, lack standing to assert these claims (for a reason in addition to the one explained *supra* pp. 11-12).

First, the Little Sisters Plaintiffs and the Trust lack standing to raise these claims because they challenge the government's regulation of third parties (i.e., issuers and TPAs), rather than of plaintiffs themselves. The claims thus run afoul of the “general rule that a party must assert [its] own legal rights and interests, and cannot rest [its] claim to relief on the legal rights or interests of third parties.” *Hinck v. United States*, 550 U.S. 501, 510 n.3 (2007) (quotation omitted); *see also Warth v. Seldin*, 422 U.S. 490, 499 (1975). It is undisputed that the Little Sisters Plaintiffs and the Trust are neither issuers nor TPAs, and these plaintiffs cannot demonstrate any reason why those entities are unable to assert their own claims if they so desire. Thus, the Little Sisters Plaintiffs and the Trust lack standing to raise these claims.

Second, Christian Brothers Services, which administers the Trust, also does not have standing to raise these claims, even assuming it is a TPA. *See* Compl. ¶ 148. As explained above, because the Trust is a self-insured church plan, the regulations do not require Christian Brothers

Services or any other TPA of the Trust to provide separate payments for contraceptive services or to contract or otherwise arrange with a third party for such payments to be made with respect to the participants and beneficiaries of the Trust. And Christian Brothers Services lacks standing to challenge the government’s authority to regulate other TPAs by requiring them to make such payments under the accommodation. *See Hinck*, 550 U.S. at 510 n.3 (explaining that a plaintiff “cannot rest [its] claim to relief on the legal rights or interests of third parties”). In addition, Christian Brothers Services has alleged that it will not elect to provide separate payments for contraceptive services to participants and beneficiaries of the Trust voluntarily because its religious beliefs prohibit it from doing so. *See Compl.* ¶¶ 27, 30. Because Christian Brothers Services will not be paying for contraceptive services under the regulations, it is not affected by—and certainly not injured by—the parts of the regulations that prevent TPAs from passing on the costs of providing contraceptive coverage or allow TPAs to obtain reimbursement for payments for contraceptive services through adjustments to FFE user fees. Christian Brothers Services thus lacks standing to raise these claims as well. *See Davis v. FEC*, 554 U.S. 724, 734 (2008) (“A plaintiff must demonstrate standing for each claim he seeks to press.”).

4. *The regulations do not violate restrictions relating to abortion*

Plaintiffs contend the regulations violate the APA because they conflict with two federal statutes dealing with abortion: section 1303(b)(1) of the ACA, and the Weldon Amendment to the Consolidated Appropriations Act of 2012. Plaintiffs appear to reason that, because the preventive services coverage regulations require group health plans to cover emergency contraception, such as Plan B, and certain IUDs, they in effect require plaintiffs to provide coverage for abortions in violation of federal law.

Plaintiffs’ claim based on section 1303(b)(1) of the ACA should be rejected at the outset because plaintiffs lack prudential standing to assert it. The doctrine of prudential standing requires that a plaintiff’s claim fall within “the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.” *Ass’n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970). But the necessary link between plaintiffs and section

1303(b)(1) is missing here. *See O'Brien*, 894 F. Supp. 2d at 1167-68 (holding that plaintiff lacked prudential standing to raise similar claim). Section 1303(b)(1) provides that “nothing in this title . . . shall be construed to require a qualified health plan to provide coverage of [abortion services],” 42 U.S.C. § 18023(b)(1)(A)(i), but plaintiffs are neither health insurance issuers nor purchasers of a qualified health plan.⁸ It therefore does not fall within the zone of interests to be protected by the statute in question.

Even if the Court were to reach the merits of both of these claims, plaintiffs’ premise that the contraceptive coverage regulations require abortion coverage is fundamentally incorrect. The regulations do not require that any health plan cover abortion as a preventive service, or that it cover abortion at all, as that term is defined in federal law. Rather, the regulations require only that non-grandfathered, non-exempt and non-accommodated group health plans cover all FDA-approved “contraceptive methods, sterilization procedures, and patient education and counseling,” as prescribed by a health care provider. *See* HRSA Guidelines. And the government has made clear that the preventive services covered by the regulations do not include abortifacient drugs.⁹ Although plaintiffs believe that Plan B, ella, and certain IUDs are abortifacient drugs or cause abortions, neither the government nor this Court is required to accept that characterization, which is inconsistent with the FDA’s scientific views and with federal law. While plaintiffs’ religious beliefs may define abortion more broadly than federal law to include emergency contraception and certain IUDs, statutory interpretation requires that terms be construed as a matter of law and not in accordance with any particular individual’s views or beliefs. *E.g.*, *Gov’t Empls. Ins. Co. v. Benton*, 859 F.2d 1147, 1149 (3d Cir. 1988).

In recommending what contraceptive services should be covered by health plans without cost-sharing, the IOM Report identified the contraceptives that have been approved by the FDA

⁸ A “qualified health plan,” within the meaning of this provision, is a health plan that has been certified by the health insurance exchange “through which such plan is offered” and that is offered by a health insurance issuer. 42 U.S.C. § 18021(a)(1). Health insurance exchanges are to be set up by states or the federal government no later than January 1, 2014. *Id.* § 18031. The Trust is not offered on a health insurance exchange and is not offered by a health insurance issuer, and so is not a “qualified health plan.”

⁹ HealthCare.gov, ACA Rules on Expanding Access to Preventive Services for Women (August 1, 2011), <http://www.hhs.gov/healthcare/facts/factsheets/2011/08/womensprevention08012011a.html>; IOM REP. at 22.

as safe and effective. *See* IOM REP. at 10. And the list of FDA-approved contraceptives includes emergency contraceptives such as Plan B. *See id.* at 105, AR 403. The basis for the inclusion of such drugs as safe and effective means of contraception dates back to 1997, when the FDA first explained why Plan B and similar drugs act as contraceptives rather than abortifacients. *See* Prescription Drug Products; Certain Combined Oral Contra for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610, 8611 (Feb. 25, 1997) (noting that “emergency contraceptive pills are not effective if the woman is pregnant” and that there is “no evidence that [emergency contraception] will have an adverse effect on an established pregnancy”); 45 C.F.R. § 46.202(f) (“Pregnancy encompasses the period of time from implantation until delivery.”). In light of this conclusion by the FDA, HHS informed Title X grantees, which are required to offer a range of acceptable and effective family planning methods—and may not offer abortion except under limited circumstances (e.g., rape, incest, or when the life of the woman would be in danger)—that they “should consider the availability of emergency contraception the same as any other method which has been established as safe and effective.” Office of Population Affairs, Memorandum (Apr. 23, 1997), <http://www.hhs.gov/opa/pdfs/opa-97-02.pdf>; *see also* 42 U.S.C. §§ 300, 300a-6. Because they reflect a settled understanding of FDA-approved contraceptives that is in accordance with existing federal laws prohibiting federal funding for certain abortions, the regulations are consistent with over a decade of regulatory policy and practice and thus cannot be deemed contrary to any law dealing with abortion.¹⁰ *See Bhd. of R.R. Signalmen v. Surface Transp. Bd.*, 638 F.3d 807, 815 (D.C. Cir. 2011) (giving particular deference to an agency’s longstanding interpretation) (citing *Barnhart v. Walton*, 535 U.S. 212, 220 (2002)).

In sum, plaintiffs’ APA claims (Counts XII, XIII, XIV, XV, and XVI) fail.

¹⁰ Representative Weldon, the sponsor of the Weldon Amendment, himself did not consider the word “abortion” in the statute to include FDA-approved emergency contraceptives. *See* 148 Cong. Rec. H6566, H6580 (daily ed. Sept. 25, 2002) (“The provision of contraceptive services has never been defined as abortion in Federal statute, nor has emergency contraception, what has commonly been interpreted as the morning-after pill. . . . [U]nder the current FDA policy[,] that is considered contraception, and it is not affected at all by this statute.”). His statement leaves little doubt that the Weldon Amendment was not intended to apply to emergency contraceptives. *See Fed. Energy Admin. v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976) (indicating that a statement of one of the legislation’s sponsors deserves to be accorded substantial weight in interpreting a statute).

STATEMENT REGARDING CONSULTATION

Pursuant to WJM Revised Practice Standard III.D.1, counsel for defendants conferred with counsel for plaintiffs prior to filing this motion. Plaintiffs' counsel indicated that plaintiffs oppose the motion, and the parties were unable to resolve the issues raised in the motion.

Dated: November 8, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE (CM/ECF)

I hereby certify that on November 8, 2013, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following e-mail addresses:

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and I hereby certify that I have mailed or served the document or paper to the following non-CM/ECF participants in the manner (mail, hand-delivery, etc.) indicated by nonparticipant's name:

None.

/s/ Michelle R. Bennett
MICHELLE R. BENNETT
Trial Attorney