IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 13-cv-02105-REB-MJW

COLORADO CHRISTIAN UNIVERSITY,

Plaintiff,

v.

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
THOMAS PEREZ, Secretary of the United States Department of Labor,
UNITED STATES DEPARTMENT OF LABOR,
JACOB LEW, Secretary of the United States Department of the Treasury, and
UNITED STATES DEPARTMENT OF THE TREASURY,

Defendants.

DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT THEREOF
AND
DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), defendants hereby move to dismiss this action. In the alternative, defendants move for summary judgment on all of plaintiff's claims pursuant to Rule 56. This memorandum also responds to plaintiff's motion for partial summary judgment (ECF No. 27).

Plaintiff Colorado Christian University (CCU) asks 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 plaintiff challenges 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, like plaintiff, by relieving them of responsibility to contract, arrange, pay, or refer for contraceptive coverage or services. The regulations also ensure that women who participate in the group health plans of such organizations are not denied access to contraceptive coverage without cost-sharing. To be eligible for the accommodations, an organization merely needs to certify that it meets the eligibility criteria. Once it does so, the organization's issuer or third-party administrator (TPA) takes on the responsibility to provide contraceptive coverage to the organization's employees and covered dependents. 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.

Remarkably, plaintiff now declares that these accommodations themselves violate the Religious Freedom Restoration Act (RFRA). Plaintiff contends that the mere act of certifying that it is eligible for an accommodation is a substantial burden on its religious exercise because, once it makes the certification, its employees and students will be able to obtain contraceptive coverage through other parties. This extraordinary contention suggests that plaintiff not only seeks to avoid contracting, arranging, paying,

or referring for contraceptive coverage itself, but also seeks to prevent the women who work for, and attend, the university from obtaining such coverage, even if through other parties. At bottom, plaintiff's position seems to be that any asserted burden, no matter how *de minimis*, amounts to a substantial burden under RFRA. That is not the law. Congress amended the initial version of RFRA to add the word "substantially," and thus made clear that "any burden" would not suffice.

All of plaintiff's claims fail and thus should be dismissed; alternatively, the Court should enter summary judgment in favor of the government. With respect to plaintiff's RFRA claim, plaintiff cannot establish a substantial burden on its religious exercise—as it must—because the regulations do not require plaintiff to change its behavior in any significant way. Plaintiff is not required to contract, arrange, pay, or refer for contraceptive coverage. To the contrary, plaintiff is free to continue to refuse to do so, to voice its disapproval of contraception, and to encourage its employees and students to refrain from using contraceptive services. Plaintiff is required only to inform its issuer/third-party administrator that it does not intend to cover contraceptive services, which plaintiff has done or would have to do voluntarily even absent these regulations in order to ensure that it is not responsible for contracting, arranging, paying, or referring for such coverage. Plaintiff can hardly claim that it is a violation of RFRA to require it to do almost exactly what it would do in the ordinary course, absent the regulations.

Plaintiff's 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. Plaintiff also cannot succeed on its APA claims. Plaintiff lacks standing to raise some of its arguments, and in any event, the regulations are in accordance with federal law.

STATEMENT OF UNDISPUTED FACTS

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. Due largely to cost, Americans used preventive services at about half the recommended rate. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) ("IOM REP."), AR at 317-18, 407.[1] Section 1001 of the ACA seeks to cure this problem by making preventive care accessible and affordable for many more Americans. 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).

Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services requested that the Institute of Medicine (IOM) develop recommendations to implement the requirement to provide coverage, without cost-sharing, of preventive services for women. IOM REP. at 2, AR at 300. 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." *Id*. at 10-12, AR at 308-10. 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

[1] Where appropriate, defendants have provided parallel citations to the Administrative Record (AR), on file with the Court. *See* ECF No. 21.

outcomes that disproportionately accompany them) and promote healthy birth spacing. *Id*. at 102-03, AR at 400-01.

On August 1, 2011, HRSA adopted guidelines consistent with IOM's recommendations, 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.[2] 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. 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. *Id*. at 8728, AR at 215. 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), AR at 186-93; 78 Fed. Reg. 8456 (Feb. 6, 2013), AR at 165-85.[3]

---

[2] 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.

[3] 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

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. The regulations provide women who work for non-profit religious organizations with access to contraceptive coverage without cost sharing, thereby advancing the government's compelling interests in safeguarding public health and ensuring that women have equal access to health care. The regulations do so in a narrowly tailored way that does not require non-profit religious organizations with religious objections to contract, arrange, pay, or refer for that coverage.

The 2013 final rules simplify and clarify the religious employer exemption by eliminating the first three criteria and clarifying the fourth. 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).

The 2013 final rules also establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by "eligible organizations." 78 Fed. Reg. at 39,875-80, AR at 7-12. 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.

---

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.

> (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.

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. To be relieved of 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. *Id*. at 39,878-79, AR at 10-11. Its participants and beneficiaries, however, will still benefit from separate payments for contraceptive services without cost sharing or other charge. *Id*. at 39,874, AR at 6. In the case of an insured health plan—like CCU's student health plan—the organization's health insurance issuer, upon receipt of the self-certification, must provide separate payments to plan participants and beneficiaries for contraceptive services without cost sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. *Id*. at 39,875-77, AR at 7-9. In the case of a self-insured group health plan—like CCU's employee health plan—the organization's TPA, upon receipt of the self-certification, will 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 id*. at 39,879-80, AR at 11-12. Any costs incurred by the TPA will be reimbursed through an adjustment to Federally-facilitated Exchange (FFE) user fees. *See id*. at 39,880, AR at 12.

STANDARD OF REVIEW

Defendants move to dismiss two of plaintiff's claims under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. *See infra* pp. 27-28. The party

invoking federal jurisdiction bears the burden of establishing its existence, and the Court must determine whether it has 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). Defendants also move to dismiss the case in its entirety for failure to state a claim upon which relief may be granted under Rule 12(b)(6). Under this Rule, "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 Rule 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).

ARGUMENT

I. Plaintiff's Religious Freedom Restoration Act Claim Is Without Merit

Under RFRA, Pub. L. No. 103-141, 107 Stat. 1488 (1993) (codified at 42 U.S.C. § 2000bb-1 et seq.), 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. of the Ind. Emp't Sec. Div.*, 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." *Kaemmerling*, 553 F.3d at 678; *see Garner v. Kennedy*, 713 F.3d 237, 241-42 (5th Cir. 2013) ("In order to show a substantial burden, the plaintiff must show that the challenged action 'truly pressures the adherent to significantly modify his religious behavior and significantly violate his religious beliefs.'").

Plaintiff cannot show—as it must—that the challenged regulations substantially burden its religious exercise. Plaintiff contends the Tenth Circuit's decision in *Hobby Lobby v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013) (en banc) is dispositive of this issue, but it is not. *Hobby Lobby* addressed the RFRA claim of for-profit corporations, which, unlike plaintiff here, are not eligible for the accommodations and thus are required by the regulations to contract, arrange, and pay for contraceptive coverage for their employees. The court had no occasion to consider whether the regulation's accommodations, which relieve eligible non-profit religious organizations like plaintiff of any obligation to contract, arrange, pay, or refer for contraceptive coverage, impose a substantial burden on religious exercise. They do not for the reasons discussed below.

The regulations do not impose a substantial burden on plaintiff because they do not require plaintiff to modify its behavior in any meaningful way. To put this case in its simplest terms, plaintiff challenges regulations that require it to do next to nothing, except what it would have to do even in the absence of the regulations. Plaintiff, as an eligible organization, is not required to contract, arrange, pay, or refer for contraceptive coverage. To the contrary, it is free to continue to refuse to do so, to voice its disapproval of contraception, and to encourage its employees and students to refrain from using contraceptive services. Plaintiff need only fulfill the self-certification requirement and provide the completed self-certification to its issuer/TPA. It need not provide payments for contraceptive services to its employees or students. Instead, third

parties—plaintiff's issuer/TPA—provide payments for contraceptive services at no cost to plaintiff. In short, with respect to contraceptive coverage, plaintiff need not do anything more than it did prior to the promulgation of the challenged regulations—that is, to inform its issuer/TPA that it objects to providing contraceptive coverage in order to ensure that it is not responsible for contracting, arranging, paying, or referring for such coverage. Thus, the regulations do not require plaintiff "to significantly modify [its] religious behavior." *Garner*, 713 F.3d at 241. The Court's inquiry should end here. A law cannot be a substantial burden on religious exercise when "it involves no action or forbearance on [plaintiff's] part, nor . . . otherwise interfere[s] with any religious act in which [plaintiff] engage[s]." *Kaemmerling*, 553 F.3d at 679.

Because the regulations place no burden *at all* on plaintiff, they plainly place no cognizable burden on its religious exercise. Plaintiff's contrary argument rests on an unprecedented and sweeping theory of what it means for religious exercise to be burdened. Not only does plaintiff want to be free from contracting, arranging, paying, or referring for contraceptive coverage for its employees and students—which, under these regulations, it is—but plaintiff would also prevent *anyone else* from providing such coverage to its employees and students, who might not subscribe to plaintiff's religious beliefs. That this is the *de facto* impact of plaintiff's stated objections is made clear by its assertion that RFRA is violated whenever plaintiff "set[s] in motion a chain of events resulting in its employees receiving free" products and services to which plaintiff objects. Pl.'s Br. at 8. This theory would mean, for example, that even the government would not realistically be able to provide contraceptive coverage to plaintiff's employees, because such coverage would be "set in motion," *id*., by plaintiff's refusal to provide such coverage themselves. But RFRA is a shield, not a sword, *see O'Brien v. HHS*, 894 F. Supp. 2d 1149, 1158-60 (E.D. Mo. 2012), and accordingly it does not prevent the

government from providing alternative means of achieving important statutory objectives once it has provided a religious accommodation. *Cf. Bowen v. Roy*, 476 U.S. 693, 699 (1986) ("The Free Exercise Clause simply cannot be understood to require the Government to conduct its own internal affairs in ways that comport with the religious beliefs of particular citizens.").

Plaintiff's RFRA challenge is similar to the claim that the D.C. Circuit rejected in *Kaemmerling*. There, a federal prisoner objected to the FBI's collection of his DNA profile. 553 F.3d at 678. In concluding that this collection did not substantially burden the prisoner's religious exercise, the court reasoned that "[t]he extraction and storage of DNA information are entirely activities of the FBI, in which Kaemmerling plays no role and which occur after the BOP has taken his fluid or tissue sample (to which he does not object)." *Id*. at 679. In the court's view, "[a]lthough the government's activities with his fluid or tissue sample after the BOP takes it may offend Kaemmerling's religious beliefs, they cannot be said to hamper his religious exercise because they do not pressure [him] to modify his behavior and to violate his beliefs." *Id*. (internal citation and quotation marks omitted). The same is true here, where the provision of contraceptive services is "entirely [an] activit[y] of [a third party], in which [plaintiff] plays no role." *Id*. As in *Kaemmerling*, "[a]lthough the [third party]'s activities . . . may offend [plaintiff's] religious beliefs, they cannot be said to hamper [its] religious exercise." *Id*.

Plaintiff—perhaps understanding the tenuous ground on which its RFRA claim rests, given that the regulations do not require it to contract, arrange, pay, or refer for contraceptive services—attempts to circumvent this problem by advancing the novel theory that the regulations require it to somehow "facilitate access" to contraceptive services, Pl.'s Br. at 10, and that it is this facilitation that violates plaintiff's religious beliefs. But under the challenged regulations plaintiff need only to self-certify that it

objects to providing coverage for contraceptive services and that it otherwise meets the criteria for an eligible organization, and to share that self-certification with its issuer/TPA. In other words, plaintiff must inform its issuer/TPA that it does not intend to cover or pay for contraceptive services, which it has done or would have to do voluntarily anyway even absent these regulations to ensure that it is not responsible for contracting, arranging, paying, or referring for contraceptive coverage. The sole difference is that plaintiff must inform its issuer/TPA that its intention not to include contraceptive coverage is due to its religious objections—a statement which it has already made repeatedly in this litigation and elsewhere. Any burden imposed by the purely administrative self-certification requirement—which should take plaintiff a matter of minutes—is, at most, *de minimis*, and thus cannot be "substantial" under RFRA.[4]

Contrary to plaintiff's suggestion, the mere fact that plaintiff claims that the self-certification requirement imposes a substantial burden on its religious exercise does not make it so. *See Conestoga*, 917 F. Supp. 2d 394, 413 (E.D. Pa. 2013) ("[W]e reject the notion . . . that a plaintiff shows a burden to be substantial simply by claiming that it is."). Under RFRA, plaintiff is entitled to its sincere religious beliefs, but it is not entitled to decide what does and does not impose a substantial burden on such beliefs. Although "[c]ourts are not arbiters of scriptural interpretation," *Thomas*, 450 U.S. at 716, "RFRA still requires the court to determine whether the burden a law imposes on a plaintiff's stated religious belief is 'substantial.'" *Conestoga*, 917 F. Supp. 2d at 413. Plaintiff would limit the Court's inquiry to two prongs: first, whether plaintiff's religious objection to the challenged regulations are sincere, and second, whether the regulations apply

[4] RFRA's legislative history makes clear that Congress did not intend a relaxed standard. The initial version of RFRA prohibited the government from imposing any "burden" on free exercise, substantial or otherwise. Congress amended the bill to add the word "substantially," "to make it clear that the compelling interest standards set forth in the act" apply "only to Government actions [that] place a substantial burden on the exercise of" religious liberty. 139 Cong. Rec. S14350-01, S14352 (daily ed. Oct. 26, 1993) (statement of Sen. Kennedy); *see also id*. (text of Amendment No. 1082).

significant pressure to plaintiff to comply. But plaintiff ignores a critical third criterion of the "substantial burden" test, which gives meaning to the term "substantial": whether the challenged regulations actually require plaintiff to modify its behavior in a significant—or more than *de minimis*—way. *See Living Water Church of God v. Charter Twp. Of Meridian*, 258 Fed. App'x 729, 734-36 (6th Cir. 2007) (reviewing cases); *see also, e.g.*, *Garner*, 713 F.3d at 241; *Westchester Day Sch. v. Vill. of Mamaroneck*, 504 F.3d 338, 348-49 (2d Cir. 2007).

The Tenth Circuit's decision in *Hobby Lobby* is not to the contrary. There, the court observed that, in determining whether an alleged burden is substantial, the court's "only task is to determine whether the claimant's belief is sincere, and if so, whether the government has applied substantial pressure on the claimant to violate that belief." 723 F.3d at 1137. But, because the for-profit corporation plaintiffs in that case were not eligible for the accommodations (and thus were required to contract, arrange, and pay for contraceptive coverage), the court did not address whether an accommodation that requires a plaintiff to do nothing beyond satisfying a purely administrative self-certification requirement imposes a substantial burden on religious exercise. Indeed, the *Hobby Lobby* court relied heavily on *Abdulhaseeb v. Calbone*, 600 F.3d 1301 (10th Cir. 2010), which makes clear that, for a law to impose a substantial burden, it must require some actual change in religious behavior—either forced participation in conduct or forced abstention from conduct. *See Hobby Lobby*, 723 F.3d at 1138 ("[A] government act imposes a 'substantial burden' on religious exercise if it: (1) '*requires participation* in an activity prohibited by a sincerely held religious belief,' (2) '*prevents participation in conduct* motivated by a sincerely held religious belief,' or (3) 'places substantial pressure on an adherent . . . *to engage in conduct* contrary to a sincerely held religious belief." (emphasis added) (citing *Abdulhaseeb*, 600 F.3d at 1315)).

Because the challenged regulations require that plaintiff takes the *de minimis* step that it would have to take even in the absence of the regulations, the regulations do not impose a substantial burden on plaintiff's religious exercise. Plaintiff's RFRA claim (Count I), therefore, should be dismissed or summary judgment granted to defendants.

The challenged regulations also do not impose a substantial burden on plaintiff's religious exercise because any burden is indirect and too attenuated to be substantial. The ultimate decision of whether to use contraception "rests not with [the employer], but with [the] employees" in consultation with their health care providers. *Conestoga*, 917 F. Supp. 2d at 414-15; *see e.g.*, *Autocam Corp. v. Sebelius*, 2012 WL 6845677, at *6 (W.D. Mich. Dec. 24, 2012) ("The incremental difference between providing the benefit directly, rather than indirectly, is unlikely to qualify as a substantial burden on the Autocam Plaintiffs."). Moreover, even if the challenged regulations were deemed to impose a substantial burden on plaintiff's 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 these arguments 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 arguments here merely to preserve them for appeal.

II. 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.[5] "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

[5] *See MK Chambers Co. v. U.S. Dep't of Health & Human Servs.*, 2013 WL 1340719, at *5 (E.D. Mich. Apr. 3, 2013); *Eden Foods, Inc. v. Sebelius*, 2013 WL 1190001, at *4-5 (E.D. Mich. Mar. 22, 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; *Korte v. U.S. Dep't of Health & Human Servs.*, 912 F. Supp. 2d 735, 744-47 (S.D. Ill. 2012); *Hobby Lobby Stores, Inc. v. Sebelius*, 870 F. Supp. 2d 1278, 1289-90 (W.D. Okla. 2012), *rev'd on other grounds*, 2013 WL 3216103; *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).

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 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.

"[C]arving out an exemption for defined religious entities [also] does not make a law non-neutral as to others." *Grote*, 914 F. Supp. 2d at 953 (quotation omitted). Indeed, the religious employer exemption "presents a strong argument in favor of neutrality" by "demonstrating that the object of the law was not to infringe upon or restrict practices because of their religious motivation." *O'Brien*, 894 F. Supp. 2d at 1161 (quotations omitted); *see Conestoga*, 917 F. Supp. 2d at 410 ("The fact that exemptions were made

for religious employers . . . . shows that the government made efforts to accommodate religious beliefs, which counsels in favor of the regulations' neutrality."). The regulations are not rendered unlawful "merely because the [religious employer exemption] does not extend as far as Plaintiff[] wish[es]." *Grote*, 914 F. Supp. 2d at 953.[6]

Plaintiff's reliance on *Lukumi*, 508 U.S. 520, is of no help, as this case is a far cry from *Lukumi*, where the legislature specifically targeted the religious exercise of members of a single church (Santeria) by enacting ordinances that used terms such as "sacrifice" and "ritual," *id*. at 533-34, and prohibited few, if any, animal killings other than Santeria sacrifices, *id*. at 535-36. Here, there is no indication that the regulations are anything other than an effort to increase women's access to and utilization of recommended preventive services. *See, e.g.*, *O'Brien*, 894 F. Supp. 2d at 1161; *Conestoga*, 917 F. Supp. 2d at 410. And it cannot be disputed that defendants have made extensive efforts—through the religious employer exemption and the eligible organization accommodations—to accommodate religion in ways that will not undermine the goal of ensuring that women have access to coverage for recommended preventive services without cost sharing.[7] Accordingly, plaintiff's free exercise claims (Counts II, III, IV, and VI) fail.[8]

[6] Plaintiff seeks to undermine the government's rationale for distinguishing between houses of worship and other non-profit religious organizations by suggesting that "CCU employees presumably are just as likely to adhere to the teachings CCU itself embraces." Pl.'s Br. at 16. Even assuming this was true (instead of merely presumed) and even assuming it meant that all of plaintiff's employees share the organization's specific religious beliefs regarding the use of certain contraceptive services, it does not render the distinctions drawn by the government—which are based on the general characteristics of houses of worship as compared to those of other non-profit religious organizations, like hospitals, schools, and charities, *see* 78 Fed. Reg. at 39,874, 39,887, AR at 6, 19, and not the characteristics of the specific plaintiff here—unlawful. *See, e.g., Turner Construction Co. v. United States*, 94 Fed. Cl. 561, 571 (Fed. Cl. 2010) (observing that a reviewing court is not to "sift through an agency's rationale with a fine-toothed comb;" instead, the relevant question is whether the agency articulated a rational connection between the facts found and the choice made). Moreover, defendants' decision to incorporate long-standing concepts from the tax code that refer to churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order, in an effort to avoid entangling inquiries regarding the religious beliefs of plaintiff's employees, is reasonable.

[7] *Fraternal Order of Police v. City of Newark*, 170 F.3d 359 (3d Cir. 1999), on which plaintiff relies, addressed a policy that created a secular exemption but refused all religious exemptions. The challenged regulations, in contrast, contain an exemption and accommodations that specifically seek to

III. 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 "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

---

accommodate religion. Thus, there is simply no basis in this case to infer a discriminatory object behind the regulations. *See Conestoga*, 917 F. Supp. 2d at 409-10.

[8] Plaintiff's so-called "unbridled discretion" claim under the Free Exercise and Free Speech Clauses, Compl. ¶¶ 272-277 (Count XI), also fails. First, plaintiff misunderstands the regulations when it asserts that they provide HRSA "unbridled discretion over which organizations can [be] accommodated." Compl. ¶ 272. 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, plaintiff's 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.

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 New York*, 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)).[9] For these reasons, plaintiff's Establishment Clause claims (Counts IV, V, VI, and VII of the Complaint) fail.

Like plaintiff's 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, plaintiff's 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) ("Where a plaintiff's First Amendment Free

[9] Plaintiff stretches *Colorado Christian University v. Weaver*, 534 F.3d 1245 (10th Cir. 2008), well beyond its facts in asserting that the case stands for the proposition that the Establishment Clause prohibits the government from distinguishing among different types of organizations that adhere to the same religion. The court's decision in *Weaver* was limited to "laws that facially regulate religious issues," *id*. at 1257, and, particularly, those that do so in a way that denies certain religious institutions public benefits that are afforded to all other institutions, whether secular or religious. The court in *Weaver* said nothing about the constitutionality of exemptions from generally applicable laws that are designed to accommodate religion, as opposed to discriminate against religion. A requirement that any religious exemption that the government creates must be extended to all organizations—no matter their structure or purpose—would severely hamper the government's ability to accommodate religion. *See Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 334 (1987) ("There is ample room under the Establishment Clause for 'benevolent' neutrality which will permit religious exercise to exist without sponsorship and without interference."); *Diocese of Albany*, 859 N.E.2d at 464 ("To hold that any religious exemption that is not all-inclusive renders a statute non-neutral would be to discourage the enactment of any such exemptions—and thus to restrict, rather than promote, freedom of religion.").

Exercise claim has failed, the Supreme Court has applied only rational basis scrutiny in its subsequent review of an equal protection fundamental right to religious free exercise claim based on the same facts."); *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.[10]

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

Plaintiff's 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 plaintiff or any other person, employer, or entity—in violation of the First Amendment. Nor do they limit what plaintiff may say. Plaintiff remains 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. Plaintiff, moreover, may encourage its employees and students not to use contraceptive services.

[10] Plaintiff also alleges that, by requiring it to facilitate practices in violation of its religious beliefs, the regulations interfere with plaintiff's "internal decisions" in violation of the Religion Clauses. Compl. ¶¶ 237-245 (Count VI). But that is merely a restatement of plaintiff's substantial burden and free exercise theories, which fail for reasons explained already.

As plaintiff points out, Pl.'s Br. at 19, to avail itself of an accommodation, an organization must self-certify that it meets the definition of "eligible organization." But completion of the simple self-certification form 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 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 the obligation to contract, arrange, pay, or refer for contraceptive coverage to which it has religious objections. Plaintiff's assertion that self-certifying its eligibility for an accommodation, which is incidental to the regulation of conduct, violates its speech rights lacks merit. *See FAIR*, 547 U.S. at 61-63.

Similarly flawed is plaintiff's claim that it is barred from expressing particular views to its insurance issuer. Pl.'s Br. at 19. 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 issuer/TPA with a termination of its relationship with the employer because of the issuer's or 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).

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 plaintiff from expressing its 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 plaintiff's right to free speech.

The regulations also do not violate the right to expressive association. "The right to speak is often exercised most effectively by combining one's voice with the voices of others." *FAIR*, 547 U.S. at 68. "If the government were free to restrict individuals' ability to join together and speak, it could essentially silence views that the First Amendment is intended to protect." *Id*. The Supreme Court, therefore, has recognized a First Amendment right to associate for the purpose of speaking. *Roberts v. U.S. Jaycees*, 468 U.S. 609, 618 (1984).

The preventive services coverage regulations, however, do not interfere with plaintiff's right of expressive association. The regulations do not interfere in any way with the composition of plaintiff's workforce, faculty, or student body. *See Boy Scouts of Am. v. Dale*, 530 U.S. 640, 656 (2000) (holding Boy Scouts' freedom of expressive association was violated by law requiring organization to accept gay man as a scoutmaster); *Roberts*, 468 U.S. at 623 (concluding statute that forced group to accept women against its desires was subject to strict scrutiny). The regulations do not force plaintiff to hire employees it does not wish to hire or to admit students it does not desire

to be a part of its school. Moreover, plaintiff, as well as its employees and students, 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 plaintiff's right. *See MK Chambers v. U.S. Dep't of Health & Human Servs.*, 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, plaintiff's free speech and expressive association claims (Counts IX and X) fail.

V. Plaintiff's APA Claims Fail

A. The Regulations Were Promulgated In Accordance With The APA

Plaintiff asserts 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. Plaintiff also claims 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.[11]

B. The Regulations Are Neither Arbitrary Nor Capricious

Plaintiff's 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, plaintiff's brazen claim that 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 plaintiff is disappointed that the regulations are not in keeping with all of its comments does not mean that defendants failed to consider those

[11] 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 under paragraphs (1) and (2)."); id. § 300gg-14(b) ("The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a)."); *id*. § 300gg-17(d). That Congress explicitly did not use such language here indicates that it did not intend the HRSA Guidelines to be "rules" within the meaning of the APA.

comments, plaintiff's contrary policy preferences do not render the regulations arbitrary or capricious.

C. Plaintiff Lacks Standing To Raise Its Statutory Authority Claims

Plaintiff makes three allegations in which it claims that defendants lacked statutory authority to enact parts of the regulations that apply to issuers and TPAs. But plaintiff's attempt to challenge the government's regulation of third parties, rather than of plaintiff itself, runs 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). Each of plaintiff's three allegations raises the claims of issuers and TPAs. *See* Compl. ¶¶ 298-300. It is undisputed, however, that plaintiff is neither an issuer nor a TPA, and plaintiff cannot demonstrate any reason why those entities are unable to assert their own claims if they so desire. Thus, plaintiff lacks standing to raise these claims.

D. The Regulations Do Not Violate Restrictions Relating To Abortion

Plaintiff contends 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. Plaintiff appears 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 plaintiff to provide coverage for abortions in violation of federal law.

Plaintiff's claim based on section 1303(b)(1) of the ACA should be rejected at the outset because plaintiff lacks 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 plaintiff 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 plaintiff is neither a health insurance issuer nor a purchaser of a qualified health plan.[12] 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, plaintiff's 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.[13] Although plaintiff believes 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

[12] 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 no later than January 1, 2014. *Id*. § 18031. Plaintiff's health plans were not purchased on a health insurance exchange, and so none is a "qualified health plan."

[13] HealthCare.gov, Affordable Care Act Rules on Expanding Access to Preventive Services for Women (August 1, 2011), http://www.hhs.gov/healthcare/facts/factsheets/2011/08/womensprevention08012011a.html (last visited Sept. 20, 2013); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of permissible recommendations).

federal law. While plaintiff's 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 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 (last visited Sept. 20, 2013); *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.[14] *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, plaintiff's APA claims (Counts XII, XIII, XIV, XV, and XVI) fail.

CONCLUSION

For the foregoing reasons, defendants respectfully ask that the Court deny plaintiff's motion for partial summary judgment, and grant defendants' motion to dismiss or, in the alternative, for summary judgment on all of plaintiff's claims.

Respectfully submitted this 4th day of November 2013,

STUART F. DELERY
Assistant Attorney General

JOHN F. WALSH
United States Attorney

JENNIFER RICKETTS
Director

SHEILA M. LIEBER
Deputy Director

/s/ Michelle R. Bennett
MICHELLE R. BENNETT
Trial Attorney (CO Bar No. 37050)
United States Department of Justice
20 Massachusetts Avenue NW
Washington, D.C. 20530
Tel: (202) 305-8902
Fax: (202) 616-8470
Email: michelle.bennett@usdoj.gov

[14] 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).

CERTIFICATE OF SERVICE (CM/ECF)

I hereby certify that on November 4, 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:

ebaxter@becketfund.org

erassbach@becketfund.org

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