

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’ REPLY IN SUPPORT OF THEIR MOTION TO DISMISS OR,
IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**

Defendants made clear in their motion that the regulations plaintiffs challenge do not require the third-party administrator (TPA) of a self-insured church plan, like the Christian Brothers Employee Benefit Trust (“Trust”), to make payments for contraceptive services for participants and beneficiaries in the plan. Plaintiffs nonetheless argue that their religious exercise is substantially burdened by the regulations. It is worth reflecting on this claim. The Little Sisters Plaintiffs (and any other eligible organization that participates in the Trust) need only self-certify that they are non-profit religious organizations with a religious objection to providing contraceptive coverage—a statement that they have repeatedly made in this litigation and elsewhere and that is entirely consistent with their religious beliefs—to be relieved of that requirement. Furthermore, neither the Christian Brothers Plaintiffs nor any other TPA of the Trust will be required to provide contraceptive coverage to plan participants and beneficiaries. And yet, somehow, plaintiffs contend not only that they are injured by this regulatory scheme—which they are not—but also that it amounts to a *substantial* burden on their religious exercise. This claim is simply implausible.

Plaintiffs’ opposition confirms that they are fighting an invisible dragon. Plaintiffs assert that signing the self-certification authorizes their TPA to make payments for contraceptive

services for participants and beneficiaries of the Trust. But it does no such thing. Because the Trust is a self-insured church plan, neither Christian Brothers Services nor any other TPA of the Trust is required by the regulations to make payments for contraceptive services for plan participants and beneficiaries. Plaintiffs, moreover, may inform Christian Brothers Services and any other TPA of the Trust that it is not required by the regulations to make such payments—although, as a plaintiff in this case, Christian Brothers Services is no doubt already aware of that fact. Indeed, Christian Brothers Services has made clear that it will not provide such payments, which, as explained, the regulations do not require it to do. Furthermore, the self-certification form explicitly states that, “on account of religious objections, the organization opposes providing coverage for some or all of any contraceptive services that would otherwise be required to be covered.” Ex. O, ECF No. 37-3. Plaintiffs therefore suffer no legally cognizable injury as a result of the challenged regulations and, in any event, state no valid legal claim. Accordingly, this case should be dismissed or summary judgment granted in favor of defendants.

REPLY CONCERNING UNDISPUTED FACTS

Pursuant to WJM Revised Practice Standards III.E.8.a, defendants reply to plaintiffs “Response to Defendants’ Statement of Material Facts” as follows:

Plaintiffs assert, as a threshold matter, that defendants’ motion to dismiss or, in the alternative, for summary judgment, should be converted entirely into a motion for summary judgment and then be deferred as premature. Opp’n at 38, ECF No. 42. But plaintiffs offer no compelling justification for their request. Defendants have moved to dismiss all of plaintiffs’ claims for lack of jurisdiction and failure to state a claim upon which relief may be granted; defendants seek summary judgment only *in the alternative* and only “[t]o the extent the Court *must* consider the administrative record.” Defs.’ Mot. at 3, ECF No. 30 (emphasis added). Virtually all of defendants’ arguments rely only on the pleadings, documents incorporated by reference into the complaint, and judicially noticeable matters—all of which the Court may consider in reviewing defendants’ motion to dismiss. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *see also, e.g., O’Brien v. U.S. Dep’t of Health & Human Servs.*,

894 F. Supp. 2d 1149 (E.D. Mo. 2012) (dismissing similar claims on Rule 12(b)(1) and (6) motion), *appeal pending*, No. 12-3357 (8th Cir.). Therefore, the Court need not consider the administrative record to dismiss each of plaintiffs' claims,¹ and no discovery is required for the Court to determine whether each of plaintiffs' claims withstands dismissal, nor—for that matter—to resolve any of plaintiffs' claims.

Moreover, plaintiffs' general assertion that the government cannot rely on the administrative record for purposes of seeking summary judgment in defense of an agency rulemaking, *see* Opp'n at 2, is incorrect. Plaintiffs challenge regulations that are the product of agency rulemaking governed by the Administrative Procedure Act (APA). Judicial review of such challenges should be limited to the administrative record, *see, e.g., Camp v. Pitts*, 411 U.S. 138, 142 (1973); 5 U.S.C. § 706, which contains all non-privileged information that the agencies considered in promulgating the new regulations. The government routinely relies upon, and courts routinely review, administrative record materials for purposes of summary judgment of constitutional and statutory claims in the context of challenges to agency rulemaking. "Under Plaintiff's evidentiary analysis, courts would never be able to analyze the administrative record because such record always consists of . . . out of court statements. Plaintiff's hearsay arguments are thus inapposite." *Adair v. El Pueblo Boys' & Girls' Ranch, Inc.*, 2008 WL 792031, *9 (D. Colo. Mar. 20, 2008).

Defendants also oppose plaintiffs' Rule 56(d) motion and will file a memorandum in opposition to that motion no later than December 6, 2013, fully explaining why discovery is not warranted in this case. At this point, in response to plaintiffs' suggestion that the administrative record may not be complete or accurate, *see* Opp'n at 2, defendants merely note that "absent clear evidence to the contrary, an agency is entitled to a strong presumption of regularity, that it properly designated the administrative record." *Pac. Shores Subdivision Cal. Water Dist. v. U.S. Army Corps of Eng'rs*, 448 F. Supp. 2d 1, 5 (D.D.C. 2006) (citations omitted); *see also*

¹ Furthermore, the possibility that the Court will disagree, and will eventually rely on the administrative record to resolve a particular claim, is not grounds for converting defendants' motion *entirely* into one for summary judgment.

Wildearth Guardians v. U.S. Forest Serv., 713 F. Supp. 2d 1243, 1254 (D. Colo. 2010) (“A party attempting to convince a reviewing court to expand the scope of its review properly bears a sizeable burden if it is to convince the court to forego the customary deference owed an agency’s determination of what constitutes the record.”). Moreover, although the Department of Health and Human Services (“HHS”) regularly files certifications with administrative records as a matter of practice, there is no legal requirement that an administrative record be certified at all, much less that the individual certifying the administrative record have personal knowledge of everyone involved in considering, formulating, or reviewing a regulation or administrative decision, or that the individual have personally reviewed every document related to the rules’ promulgation. *See Banner Health v. Sebelius*, 2013 WL 2112169, *11 (D.D.C. May 16, 2013).

5. Although the Institute of Medicine (“IOM”) was not obligated by the APA to provide an opportunity for public comment, IOM did in fact solicit and receive comments from the general public—both oral and written—and plaintiffs had an opportunity to be heard in that process. *Inst. of Med., Clinical Preventive Services for Women: Closing the Gaps 22-23* (2011) (“IOM REP.”), AR at 320-21. IOM also invited specific organizations to make presentations, but those invitations were made by IOM, independently of defendants and in the course of IOM’s independent scientific inquiry.

7. The challenged regulations do not require coverage of abortion or abortifacients. *See HRSA, Women’s Preventive Services: Required Health Plan Coverage Guidelines* (“HRSA Guidelines”), AR at 283-84; IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320; 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/womensprevention08012008a.html>; *see also* 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 any event, plaintiffs’ characterization of certain contraceptives as abortifacients or abortion-inducing drugs is not material to the resolution of this case. Plaintiffs object to providing coverage of all FDA-approved contraceptive methods and sterilization procedures. The precise reasons for plaintiffs’ objection are immaterial.

17. Plaintiffs’ assertions in this paragraph are addressed in the Argument section of this brief.

24-27. Plaintiffs’ assertions in these paragraphs are addressed in the Argument section of this brief.

29-30. Defendants object to plaintiffs’ response because it relies on material not included in the Administrative Record, i.e., the deposition of Mr. Cohen. The introduction of this extra-record evidence is inappropriate and should not be considered by the Court. Plaintiffs are challenging agency regulations, and thus this Court’s review is limited to the administrative record. *See, e.g., United States v. Carlo Bianchi & Co.*, 373 U.S. 709, 715 (1963). To the extent the Court considers plaintiffs’ response despite its reliance on extra-record evidence, it is disputed. Mr. Cohen was speaking about a prior version of the regulations.

Defendants also note that they received comments during the rulemaking process, stating that many non-profit religious organizations like hospitals, charities, and colleges do not hire employees on the basis of religion. *See, e.g.,* Comments of Wisconsin Catholic Conference, at 2 (June 15, 2012) (“We employ and aid Catholics and non-Catholics alike because our faith compels us to be of service to all.”) (AR Disk 3, ANPRM comments 1, at 416); Comments of La Salle University, at 1 (June 19, 2012) (noting that the “vast majority of Catholic colleges and universities” do not “serv[e] and employ[]” only those who share their faith, but “engage in dialogue with *all people* and with *all sources of truth*, rather than ‘primarily’ other Catholics”) (AR Disk 3, ANPRM comments 2, at 3505).

31-32. Plaintiffs' assertions in these paragraphs are addressed in the Argument section of this brief.

37-40. See Reply Concerning Undisputed Facts 7.

41. Plaintiffs' assertions in this paragraph are addressed in the Argument section of this brief.

RESPONSE CONCERNING ADDITIONAL DISPUTED FACTS

Pursuant to WJM Revised Practice Standards III.E.8.b, defendants respond to plaintiffs' "Statement of Additional Facts" as follows:

1-2. Undisputed, but not material other than to show that plaintiffs are religious organizations.

3-11. Undisputed.

12. Defendants dispute this sentence to the extent it suggests that the regulations require coverage of abortifacients or abortion-inducing drugs. The challenged regulations do not require coverage of abortion or abortifacients. See HRSA Guidelines, AR at 283-84; IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320; 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/womensprevention08012008a.html>; *see also* 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 any event, plaintiffs' characterization of certain contraceptives as abortifacients or abortion-inducing drugs is not material to the resolution of this case. Plaintiffs object to providing coverage of all FDA-approved contraceptive methods and sterilization procedures. The precise reasons for plaintiffs' objection are immaterial.

13. Disputed to the extent plaintiffs claim to “facilitate” coverage for contraceptive services, as this is simply plaintiffs’ characterization of what the challenged regulations require. Defendants explain in the Argument section of this brief why plaintiffs’ characterization is incorrect. This paragraph is further disputed to the extent plaintiffs characterize any FDA-approved contraceptive methods as “abortifacients,” *see* Defendants’ Response Concerning Additional Disputed Facts 12, but the precise reasons for plaintiffs’ religious objection are immaterial.

14-16. Undisputed.

17. Disputed to the extent plaintiffs claim the regulations require them to “distribute, encourage, facilitate, and/or reduce the cost of” coverage for contraceptive services, as this is simply plaintiffs’ characterization of what the challenged regulations require. Defendants explain in the Argument section of this brief why plaintiffs’ characterization is incorrect. This paragraph is further disputed to the extent plaintiffs characterize any FDA-approved contraceptive methods as causing abortions, *see* Defendants’ Response Concerning Additional Disputed Facts 12, but the precise reasons for plaintiffs’ religious objection are immaterial.

18. Disputed. Defendants explain in the Argument section of this brief why plaintiffs’ characterization of the challenged regulations is incorrect.

19. Disputed to the extent plaintiffs claim to “participate” in a scheme to provide coverage for contraceptive services, as this is simply plaintiffs’ characterization of what the challenged regulations require. Defendants explain in the Argument section of this brief why plaintiffs’ characterization is incorrect.

20. Disputed. The self-certification form speaks for itself. As defendants have explained repeatedly, the regulations do not require the TPAs of self-insured church plans, like the Trust, to provide or arrange payments for contraceptive services for plan participants and beneficiaries.

21. Disputed to the extent plaintiffs claim the regulations require them to “provide,” “authorize,” or “participat[e] in” the provision of contraceptive coverage, as this is simply

plaintiffs' characterization of what the challenged regulations require. Defendants explain in the Argument section of this brief why plaintiffs' characterization is incorrect.

22. Disputed to the extent plaintiffs characterize what the challenged regulations require. Defendants explain in the Argument section of this brief why plaintiffs' characterization of the challenged regulations is incorrect.

23. Disputed to the extent plaintiffs suggest, without any supporting evidence, that Express Scripts, Inc., will in fact provide payments for contraceptive services for plan participants and beneficiaries even though defendants have made clear it is not required by the regulations to do so.

24. Disputed. The tax described in 26 U.S.C. § 4980D applies at a rate of \$100 per day "with respect to each individual to whom such failure relates." 26 U.S.C. § 4980D(b).

25. Disputed. The tax described in 26 U.S.C. § 4980D applies at a rate of \$100 per day "with respect to each individual to whom such failure relates." 26 U.S.C. § 4980D(b).

26. Disputed. The tax described in 26 U.S.C. § 4980D applies at a rate of \$100 per day "with respect to each individual to whom such failure relates." 26 U.S.C. § 4980D(b). The "losses" asserted by the Christian Brothers Plaintiffs are speculative because, as defendants have explained, the regulations do not require the TPAs of self-insured church plans, like the Trust, to provide or arrange payments for contraceptive services for plan participants and beneficiaries.

27. Defendants do not dispute that the government made the projections for 2011 and 2013 to which plaintiffs refer. Defendants note that a majority of group health plans will have lost their grandfather status by the end of 2013. *See* 75 Fed. Reg. 34,538, 34,552 (June 17, 2010); *see also* Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2012 Annual Survey at 7-8, 190 (indicating that 58 percent of firms had at least one grandfathered health plan in 2012, down from 72 percent in 2011, and that 48 percent of covered workers were in grandfathered health plans in 2012, down from 56 percent in 2011), AR at 663-64, 846.

28. Defendants do not dispute the government estimates to which plaintiffs refer. Defendants note that 26 U.S.C. § 4980H(c)(2) does not exempt small employers from the preventive services coverage regulations. *See* 42 U.S.C. § 300gg-13(a); 78 Fed. Reg. 39,870, 39,887 n.49 (July 2, 2013), AR at 19. Like large businesses, non-exempt, non-accommodated small businesses that offer non-grandfathered health coverage to their employees are required to provide coverage for recommended preventive services, including contraceptive services, without cost-sharing. *See* 78 Fed. Reg. at 39,887 n.49, AR at 19.

29. Defendants object to this paragraph because it relies on material not included in the Administrative Record. The introduction of this extra-record evidence is inappropriate and should not be considered by the Court. Plaintiffs are challenging agency regulations, and thus this Court's review is limited to the administrative record. *See, e.g., Carlo Bianchi, 373 U.S. at 715.* To the extent the Court considers this paragraph despite its reliance on extra-record evidence, it is immaterial. Furthermore, plaintiffs' selective quotation of the Secretary's remarks is incomplete and disputed. Defendants refer the Court to the full transcript, which speaks for itself.

30. Defendants do not dispute that the Church Alliance submitted comments during the rulemaking process. The comments speak for themselves.

31. Defendants do not dispute that the Little Sisters Plaintiffs submitted comments during the rulemaking process. The comments speak for themselves.

32. Defendants object to this paragraph because it relies on material not included in the Administrative Record. The introduction of this extra-record evidence is inappropriate and should not be considered by the Court. Plaintiffs are challenging agency regulations, and thus this Court's review is limited to the administrative record. *See, e.g., Carlo Bianchi, 373 U.S. at 715.* To the extent the Court considers this paragraph despite its reliance on extra-record evidence, it is immaterial. Furthermore, plaintiffs' selective emphasis of the Secretary's remarks is disputed. Defendants refer the Court to the full transcript, which speaks for itself.

Rulemaking is an ongoing and dynamic process, and defendants considered comments both as they were submitted throughout the comment period in response to the NPRM, and as they had been submitted in response to the ANPRM. When the Secretary spoke, she was reflecting where defendants' process was at the time—informed by all the comments defendants had received and considered, including the approximately 200,000 comments defendants had received and considered even before the NPRM was issued, 78 Fed. Reg. 8456, 8459 (Feb. 6, 2013). Moreover, plaintiffs' assertion that the outcome of the rulemaking was predetermined is belied by a simple comparison of the NPRM and the final regulations. The NPRM, for example, proposed three possible approaches for accommodating self-insured group health plans established or maintained by eligible organizations, *id.* at 8463-8464, and the final regulations represent the selection of one of those approaches—a choice made “after reviewing the comments on the three proposed approaches,” 78 Fed. Reg. at 39,879.

ARGUMENT

I. PLAINTIFFS LACK STANDING TO CHALLENGE THE REGULATIONS

Defendants demonstrated in their opening brief that plaintiffs have not alleged an injury sufficient to establish standing. The regulations do not require the Little Sisters Plaintiffs to engage in actions that facilitate or trigger payments for contraceptive services by third parties, and the Christian Brothers Plaintiffs are not required by the regulations to provide or arrange payments for contraceptive services for plan participants and beneficiaries. In short, because the Trust is a self-insured church plan, the injuries of which plaintiffs complain—that the regulations somehow require them to facilitate access to contraceptive services or to contract, arrange, or pay for such services—simply do not exist.

Plaintiffs maintain that they are injured by signing the self-certification form, which they contend “instructs” their TPA to provide separate payments for contraceptive services. Opp’n at 20. But it does just the opposite. The self-certification form expressly states that, “on account of religious objections, the organization opposes providing coverage for some or all of any contraceptive services that would otherwise be required to be covered.” Ex. O, ECF No. 37-3.

And the government has made clear that the regulations do not require Christian Brothers Services or any other TPA of the Trust to make payments for contraceptive services for plan participants and beneficiaries. That is because the government's authority to require TPAs to make such payments derives from ERISA, 78 Fed. Reg. at 39,879-39,880, AR at 11-12, and church plans are specifically excluded from regulation under ERISA, 29 U.S.C. § 1003(b)(2). Finally, Christian Brothers Services has made equally clear that it will not make such payments voluntarily, *see* Compl. ¶¶ 27, 30, and plaintiffs' suggestion that another TPA of the Trust may provide payments for contraceptive services despite not being legally required to do so is pure speculation, *see Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1147 (2013). Plaintiffs, therefore, have not shown—as it is their burden to do—that their signing of the self-certification instructs their TPA to do anything or that their TPA will provide payments for contraceptive services absent any legal requirement to do so. Because plaintiffs do not assert that merely signing the self-certification—aside from its purported consequences, which defendants have shown are not consequences at all—constitutes the “invasion of a *legally protected interest*,” plaintiffs lack standing to challenge the regulations. *Raines v. Byrd*, 521 U.S. 811, 819 (1997) (emphasis added).

Plaintiffs also assert that they are injured because the regulations prevent them from asking their TPA not to provide payments for contraceptive services. Opp'n at 20. But this allegation does not amount to an “actual or imminent” injury either. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). “Nothing in [the 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. Moreover, the Little Sisters Plaintiffs may inform Christian Brothers Services and any other TPA of the Trust that it is not required by the regulations to make payments for contraceptive services for plan participants and beneficiaries. And, as defendants have explained, the Christian Brother Plaintiffs have already made clear that they will not provide or arrange such payments because their religious beliefs prohibit them from doing so. Plaintiffs make no effort in their opposition to come to grips with these realities or the result—that plaintiffs' claim

that the regulations will affect their speech is far too speculative to establish standing. *See Clapper*, 133 S. Ct. at 1147.

Lastly, plaintiffs contend that the regulations “on their face apply to *all* TPAs, with no exception for church plan TPAs,” Opp’n at 21, but they do not. The preamble to the 2013 final rules makes clear that the authority for requiring TPAs of self-insured group health plans to make separate payments for contraceptive services is ERISA. *See, e.g.*, 78 Fed. Reg. at 39,879 (stating defendants adopted the approach from the NPRM that relies on ERISA); *id.* (explaining that a TPA “becomes an ERISA section 3(16) plan administrator and claims administrator” for contraceptive coverage); *id.* at 39,880 (indicating that the “legal authority” to regulate TPAs of self-insured group health plans comes from “ERISA”). And church plans are specifically excluded from the ambit of ERISA by statute. *See* 29 U.S.C. § 1003(b)(2). Thus, the “purpose and context” of the regulations, in conjunction with the “whole . . . text,” demonstrate that the requirement that TPAs make separate payments for contraceptive services does not apply to the TPAs of self-insured church plans. *Dolan v. U.S. Postal Service*, 546 U.S. 481, 486 (2006). Moreover, defendants have made clear that this interpretation of the regulations is the proper one, and courts “defer to an agency’s interpretation of its own regulation[s],” even when “advanced in a legal brief.” *Chase Bank USA, N.A. v. McCoy*, 131 S.Ct. 871, 880 (2011); *see also Auer v. Robbins*, 519 U.S. 452, 461-62 (1997).

II. THE REGULATIONS DO NOT VIOLATE RFRA

According to plaintiffs, their RFRA claim boils down to one question: do plaintiffs assert a religious objection to the regulations? And, because plaintiffs have decided that complying with the regulations violates their religious beliefs, the Court’s inquiry is at an end. But this is not the law.

As an initial matter, plaintiffs’ asserted religious objection to the regulations is based on a misunderstanding about what the regulations require as to self-insured church plans like the Trust. The Little Sisters Plaintiffs claim that signing the self-certification violates their religious beliefs because it “authorizes” a third party to make payments for contraceptive services for plan

participants and beneficiaries of the Trust, or “triggers” the provision of contraceptive coverage. Maguire Decl. ¶ 9, ECF No. 37-1. But, as explained above, these assertions are incorrect. The self-certification states that the certifying organization opposes providing contraceptive coverage on religious grounds, the regulations do not require Christian Brothers Services or any other TPA of the Trust to make payments for contraceptive services, and Christian Brothers Services clearly has no intent to make such payments. Because plaintiffs’ purported religious objections are based on a misconception of the regulations, they have not established any burden on their religious exercise, much less a substantial one.

Nor is it the case, as plaintiffs suggest, that the Court should ignore plaintiffs’ misconception of the regulations and merely credit, without inquiry, plaintiffs’ assertion that the regulations substantially burden their religious exercise. *See Conestoga Wood Specialties Corp. v. Sebelius*, 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, a 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. Nor may a plaintiff demand that a court join it in its misconception of what a given law will actually mean for that plaintiff. Here, plaintiffs, having informed the Court of what they think the regulations mean, would all but eliminate the Court’s inquiry into what the regulations actually require, and would then limit the Court’s substantial burden inquiry to two prongs: first, whether plaintiffs’ religious objection to their incorrect understanding of the challenged regulations is sincere, and second, whether their incorrect understanding of the regulations applies significant pressure on plaintiffs to comply. But plaintiffs ignore a critical third criterion of the “substantial burden” test, which gives meaning to the term “substantial”: whether the challenged regulations actually require plaintiffs to modify their behavior in a significant—or more than *de minimis*—way. *See, e.g., Living Water Church*

of *God v. Charter Twp. Of Meridian*, 258 Fed. App'x 729, 734-36 (6th Cir. 2007) (reviewing cases); *Garner v. Kennedy*, 713 F.3d 237, 241 (5th Cir. 2013).²

They do not. The Little Sisters Plaintiffs need only sign the self-certification, which states that they are non-profit religious organizations with religious objections to providing contraceptive coverage, and provide a copy of the self-certification to their TPA. The regulations do not require Christian Brothers Services or any other TPA of the Trust to make or arrange payments for contraceptive services for plan participants and beneficiaries, Christian Brothers Services has made clear that it will not do so, and plaintiffs have presented no evidence to demonstrate that any other TPA of the Trust will do so. Therefore, the regulations require no more of the Little Sisters Plaintiffs than they would have to do in the absence of the regulations—that is, to inform their TPA that they do not intend to cover contraceptive services in order to ensure that they are not responsible for contracting, arranging, paying, or referring for such coverage. Plaintiffs can hardly claim that it is a violation of RFRA to require them to do almost exactly what they would do in the ordinary course, absent the regulations. Furthermore, under the regulations, the Christian Brothers Plaintiffs are not required to provide or arrange payments for contraceptive services, so there is also no burden on their religious exercise.³

III. THE REGULATIONS DO NOT VIOLATE THE FREE EXERCISE CLAUSE

Defendants explained in their opening brief that 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. Plaintiffs make no effort to meaningfully address this authority, instead blithely asserting that the at least eight decisions rejecting the

² *Hobby Lobby v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013) (en banc), is not to the contrary. 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 723 F.3d at 1138 (citing *Abdulhaseeb*, 600 F.3d at 1315)).

³ Plaintiffs' reliance on *Zubik v. Sebelius*, 2013 WL 618696 (W.D. Pa. Nov. 21, 2013); *Gilardi v. HHS*, 2013 WL 5854246 (D.C. Cir. Nov. 1, 2013); and *Korte v. Sebelius*, 2013 WL 5960692 (7th Cir. Nov. 8, 2013), is misplaced. None of those cases involved eligible organizations that offer health coverage through a self-insured church plan, and thus, the courts had no occasion to address the arguments defendants raise here. In any event, defendants believe those cases were wrongly decided for the reasons defendants explained in those cases.

same free exercise claim plaintiffs assert here are unpersuasive because other courts did not reach the free exercise claim. *See* Opp'n at 33 n.12. This assertion is baseless.

O'Brien, 894 F. Supp. 2d 1149, is instructive. There, the court determined that the regulations “are neutral,” because they “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.” *Id.* at 1161. Rejecting the same argument plaintiffs make here, the court further determined that “the religious employer exemption does not compromise the neutrality of the regulations by favoring certain religious employers over others. Rather, . . . the religious employer exemption presents a strong argument in favor of neutrality.” *Id.*; *see also Grote Indus., LLC v. Sebelius*, 914 F. Supp. 2d 943, 953 (S.D. Ind. 2012) (“[C]arving out an exemption for defined religious entities [also] does not make a law non-neutral as to others.”); *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 *O'Brien* court also concluded that the regulations were generally applicable despite exceptions for grandfathered plans and religious employers. 894 F. Supp. 2d at 1161. The court explained that the exceptions do not suggest disfavor of religion because they apply to all employers that satisfy the requirements, “regardless of those employers’ personal religious inclinations.” *Id.* at 1162; *see Autocam Corp. v. Sebelius*, 2012 WL 6845677, at *5 (W.D. Mich. Dec. 24, 2012) (“[C]ategorical exemptions . . . do[] not mean that [a] law does not apply generally.”) (citing *United States v. Lee*, 455 U.S. 252, 261 (1982)). Plaintiffs’ arguments to the contrary are no more persuasive here than they were in *O'Brien* or any of the other cases that have upheld the regulations against Free Exercise Clause challenges.⁴

⁴ Plaintiffs appear to suggest that the government has created a discretionary system of individual exceptions with respect to the regulations, *see* Opp'n at 33 & n.11, but it has not. A system of individual exemptions is one that enables the government to make a subjective, case-by-case inquiry of the reasons for the relevant conduct, like the “good cause” standard applied in many states for determining an individual’s eligibility for unemployment compensation. *Emp’t Div. v. Smith*, 494 U.S. 872, 884 (1990); *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1297 (10th Cir. 2004). No such system exists here. The challenged regulations do not leave defendants with any discretion to decide who is exempt or who is accommodated because the regulations set out the criteria for both determinations. *See* Defs.’ Mot. at 16 n.5. There is, therefore, no merit to plaintiffs’ unbridled discretion claim either.

IV. THE REGULATIONS DO NOT VIOLATE THE ESTABLISHMENT CLAUSE, THE DUE PROCESS CLAUSE, OR THE EQUAL PROTECTION CLAUSE

The copious authority cited in defendants’ opening brief, *see* Defs.’ Mot. at 16-18, amply demonstrates that the Establishment Clause prohibits only denominational preferences; it does not prevent the government from distinguishing between types of religious organizations by exempting houses of worship irrespective of their denomination and accommodating non-profit religious charities, universities, and hospitals irrespective of their denomination, as defendants have done in the challenged regulations.

Larson v. Valente, on which plaintiffs rely, fully supports the government’s position. *See, e.g.*, 456 U.S. 228, 244 (1982) (“one religious denomination cannot be officially preferred over another”); *id.* at 245-46 (referring to “constitutional prohibition of denominational preferences” and “principle of denominational neutrality”); *id.* at 245 (“[L]egislators . . . are required to accord to their own religions the very same treatment given to small, new, or unpopular denominations.”); *id.* at 246 (“[T]he government must be neutral when it comes to competition between sects.”); *id.* (“[T]he fullest realization of true religious liberty requires that government . . . effect no favoritism among sects[.]”). Although the law at issue in *Larson* did not refer to any particular religious denomination on its face, it violated the constitutional prohibition against denominational preferences because it “effect[ed] the selective legislative imposition of burdens and advantages upon particular denominations.” *Id.* at 254. The provision was drafted to “includ[e] particular religious denominations and exclud[e] others.” *Id.* Indeed, the Court discussed the legislative history of the statute, which showed that language was changed during the legislative process “for the sole purpose of exempting the [Roman Catholic] Archdiocese from the provisions of the Act.” *Id.* at 254; *see also Children’s Healthcare Is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084 (8th Cir. 2000) (upholding “sect-neutral” statute after striking

Plaintiffs make no effort to save their interference with internal church affairs claim (Count VI), and thus, it should be dismissed. *Hill v. ITT Federal Servs. Int’l Corp.*, 2007 WL 951125, at *3 n.4 (D. Colo. Mar. 27, 2007) (deeming failure to respond to argument a concession).

down prior “sect-specific” one). There is no similar discrimination among denominations here. The religious employer exemption is available on equal terms to employers of all denominations.

Plaintiffs argue in the alternative that the regulations do discriminate among denominations by distinguishing between denominations that exercise their beliefs primarily through houses of worship and denominations, like the Catholic Church, that “exercise their religion via other ministries such as health care services.” Opp’n at 24. This argument is baseless. The fact that some Catholic entities, like a diocese, are exempt while other Catholic entities, like hospitals, charities, and universities, are accommodated does not amount to discrimination among *denominations*. See, e.g., *East Tex. Baptist Univ.*, No. 4:12-cv-03009 (S.D. Tex.) (suit by accommodated, but not exempt, Baptist university challenging regulations).⁵

V. THE REGULATIONS DO NOT VIOLATE THE RIGHT TO FREE SPEECH OR EXPRESSIVE ASSOCIATION

Plaintiffs’ opposition reveals that their free speech claim, like many of their other claims, is based on a misunderstanding of what the regulations require as to self-insured church plans. Plaintiffs contend signing the self-certification violates their free speech rights because it will “request” or “authorize others to provide [contraceptive coverage]” to plaintiffs’ employees. Opp’n at 35. But, as explained above, that is not the case.

Defendants do not understand plaintiffs to claim that signing a form that states only what plaintiffs have already stated in this litigation and elsewhere—i.e., that plaintiffs are non-profit religious organizations that oppose providing contraceptive coverage on religious grounds—violates their right to free speech. But, even if plaintiffs did make such a claim, it would fail, as the one-time self-certification requirement is plainly incidental to the regulation of conduct, not speech. The self-certification is in no sense a “stand-alone” speech requirement. Rather, it is part

⁵ Plaintiffs make almost no effort to save their due process and equal protection claims. See Opp’n at 35 n.13. They do not dispute that defendants “could rationally have concluded” that, as a general matter, houses of worship and their integrated auxiliaries are more likely than other religious organizations, like hospitals, charities, and universities, to employ people of the same faith who share their objection to contraceptives. See *Gonzalez-Droz v. Gonzalez-Colon*, 660 F.3d 1, 10 (1st Cir. 2011). Moreover, defendants’ decision to incorporate long-standing concepts from the tax code that refer to churches and their integrated auxiliaries, in an effort to avoid the type of entangling inquiries that commenters objected to, is similarly rational. That is all the Due Process and Equal Protection Clauses require.

of a regulatory scheme governing the provision of health coverage, and it serves to relieve certifying organizations from certain conduct otherwise required by law and to “verify compliance” with the criteria for the accommodation. 78 Fed. Reg. at 39,875. Courts have unanimously concluded that this regulatory scheme regulates conduct, not speech. *See* Defs.’ Mot. at 20 (citing cases).

Plaintiffs fail to address the additional standing argument defendants made with respect to plaintiffs’ non-interference claim, *see* Defs.’ Mot. at 20, and, thus, that claim should be dismissed for this reason alone. *See Hill*, 2007 WL 951125, at *3 n.4. The claim also fails on the merits. The regulations do not prohibit plaintiffs from expressing their views on the use of contraceptive services or the regulations to anyone, including their TPAs. The Little Sisters Plaintiffs, moreover, may inform their TPAs (including Express Scripts) that they are not required by the regulations to make payments for contraceptive services for plan participants and beneficiaries. Thus, the non-interference provision in no sense prevents plaintiffs from speaking with their TPAs about the obligations imposed—or not imposed—on the TPA by the challenged regulations.⁶

Finally, plaintiffs’ expressive association claim fails for at least two reasons. First, as explained above, neither Christian Brothers Services nor any other TPA of the Trust is required by the regulations to provide payments for contraceptive coverage. Thus, the regulations do not interfere in any way with plaintiffs’ ability to associate to share and express their religious beliefs. Second, and more broadly, plaintiffs cite no authority for their novel theory that the freedom of association extends so far as to require the Court to inquire only whether plaintiffs’ association is expressive and whether the regulations impair that expression. “A government action does not interfere with the right of expressive association unless it directly or indirectly interferes with group membership.” *Miller v. City of Cincinnati*, 622 F.3d 524, 538 (6th Cir. 2010); *see Roberts v. U.S. Jaycees*, 468 U.S. 609, 622-23 (1984). Indeed, the expressive

⁶ Even if the Court were to find, over the government’s objection, that the non-interference provision violates the Free Speech Clause, the appropriate remedy would be to hold that the provision cannot be applied to the employers in this case because they have self-insured church plans, not to strike down the regulations in their entirety.

association cases cited by plaintiffs involved laws that interfered with group membership. *See Boy Scouts of Am. v. Dale*, 530 U.S. 640, 648 (2000) (law required organization to accept gay man as scoutmaster); *Pleasant v. Lovell*, 876 F.2d 787, 804 (10th Cir. 1989) (collection of information on “the identities and activities of [group’s] members” led to “reluctan[ce] to associate with the group”). Because the challenged regulations do not interfere with the composition of plaintiffs’ workforces or the Trust, plaintiffs’ expressive association claim fails.

VI. THE REGULATIONS DO NOT VIOLATE THE APA

Plaintiffs contend that the regulations are not in accordance with law “because they conflict with federal laws exempting church benefit plans from ERISA.” Opp’n at 24. But, as explained above, *see supra* p. 12, the regulations do not require the TPAs of self-insured church plans to provide or arrange payments for contraceptive services, and defendants’ interpretation of their own regulations is entitled to deference. Furthermore, the self-certification requirement is not “meaningless” as applied to employers that offer health coverage through a self-insured church plan. Opp’n at 25. As explained in the final rules, the self-certification requirement serves, among other things, to relieve certifying organizations from the requirement otherwise imposed by law to provide coverage for contraceptive services and to “verify compliance” with the criteria for the accommodation. 78 Fed. Reg. at 39,875.

Plaintiffs are also wrong when they assert that the distinction drawn by the regulations between exempt organizations and eligible organizations is not borne out by the evidence. The sole piece of evidence they point to is the comment submitted by the Council for Christian Colleges and Universities, which stated that a requirement for membership in the organization is that the administrators and faculty “share the Christian faith” of the institution. Opp’n at 27 n.6. But the mere fact that a distinction drawn in the regulations may not comport with the comments submitted by one, or even more than one, commenter is far from evidence that the distinction is arbitrary or capricious. After all, defendants received comments throughout the development of these regulations from other religious non-profit organizations that stated that they impose no such requirement. *See Reply Concerning Undisputed Facts* 29-30.

Furthermore, as defendants have explained, the HRSA Guidelines are not legislative rules within the meaning of the APA, and thus, are not required to be subject to notice and comment rulemaking. The HRSA Guidelines are not “designed to implement, interpret, or prescribe law or policy,” 5 U.S.C. § 551(4); rather, the substantive obligations that are imposed on group health plans and health insurance issuers were imposed by Congress in statutory provisions that automatically import the content of various clinical guidelines. Indeed, the case on which plaintiffs rely, *Mission Grp. Kansas, Inc. v. Riley*, 146 F.3d 775 (10th Cir. 1998) (quoting *Hoctor v. Dep’t of Agric.*, 82 F.3d 165 (7th Cir. 1996)), is not only inapposite, but illustrates the distinction. *Hoctor* dealt with a rule that had the force of law of its own accord and that was promulgated pursuant to a statute that authorized the agency “to promulgate such rules, regulations, and orders as [it] may deem necessary in order to effectuate the purposes of [the Act].” 82 F.3d at 167. No such language appears in the statute here; in other words, the statute did not, as plaintiffs suggest, instruct HRSA to create guidelines. Other parts of the ACA contain such commanding language akin to that in the statute at issue in *Hoctor*, see Defs.’ Mot. at 23 n.7, but the statutory provisions here notably do not, and simply incorporate by reference the content of a number of clinical guidelines which, on their own, do not have the force of law.⁷

⁷ Plaintiffs’ argument regarding the Weldon Amendment brushes aside decades of regulatory policy and practice summarized in defendants’ opening brief. Speaking in support of, and as a co-sponsor of, what was then an independent bill with essentially identical language to the Weldon Amendment, see Abortion Non-Discrimination Act, H.R. 4691, 107th Cong. (2002), Representative Weldon called it “a tremendous misinterpretation or a tremendous stretch of the imagination” to suggest that the statutory language would impact the provision of contraceptive services. 148 Cong. Rec. H6566, H6580 (daily ed. Sept. 25, 2002). And he explained that “[t]he morning-after pill is not defined by the FDA as abortion. It is defined as contraception. It is something different. So to interpret this statute to claim that it is going to prohibit access is to take essentially a religious entity’s doctrine and put that into the statute, and it is just not there. It is not in the language.” *Id.* at H6571; see also *id.* at H6580 (“Now, some religious groups may interpret [emergency contraception] as abortion, but we make no reference in this statute to religious groups or their definitions; and under the current FDA policy that is considered contraception, and it is not affected at all by this statute.”). Plaintiffs disregard all of this as an out-of-date floor statement from 2002, ignoring both the fact that the language of the Abortion Non-Discrimination Act discussed in 2002 is nearly identical to the language of the Weldon Amendment that was subsequently enacted, and repeatedly reenacted thereafter, and the fact that Representative Weldon was the author, sponsor, and namesake of the nearly identical Weldon Amendment. The Supreme Court has made clear that the statements of the sponsor of a piece of legislation deserve to be accorded substantial interpretive weight. *Fed. Energy Admin. v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976). Moreover, plaintiffs’ claim that the ACA gives issues of a qualified health plan the right to define what is and is not an “abortion” as a matter of law is baseless. The statute ensures only that the issuer may decide whether to offer coverage for abortion, unless the state prohibits it. There is absolutely no suggestion that Congress intended to so dramatically shift to regulated entities themselves the locus of statutory interpretation that is generally left to agencies charged with implementing the statute and, if need be, to the courts. *Cf. Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 468 (2001) (Congress does not “hide elephants in mouseholes.”).

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CERTIFICATE OF SERVICE (CM/ECF)

I hereby certify that on November 27, 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