IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

VITA NUOVA, INC., *Plaintiff*, v. ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services; UNITED STATES OF AMERICA, *Defendants*.	Case No. 4:19-cv-00532-O

DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT AND BRIEF IN SUPPORT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

Title X of the Public Health Service Act ("PHSA") authorizes the Department of Health and Human Services ("HHS") to make grants for family-planning services and issue regulations to implement the statute.[1] In section 1008 of the PHSA, Congress directed that "[n]one of the funds appropriated under [the Title X program] shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6.

In Claim 1 of its Amended Complaint, Plaintiff Vita Nuova Inc. ("Vita Nuova" or "Plaintiff") asks the Court to issue a declaration that it may not be excluded from the Title X program on account of its unwillingness to provide abortion referrals or abortion counseling, citing a 2000 HHS rule which included these requirements. *See* 65 Fed. Reg. 41,281 (July 3, 2000) ("2000 Rule"). But HHS has replaced the 2000 Rule with new regulations to which Plaintiff does not object, and those new regulations are now in effect nationwide.[2] *See* 84 Fed. Reg. 7714 (Mar. 4, 2019) ("2019 Rule"). The 2019 Rule does not *permit* (let alone require) referrals for abortion as a method of family planning or counseling that encourages or promotes abortion.

Vita Nuova does not object to the 2019 Rule and the Amended Complaint favorably discusses it at length. And even prior to the 2019 Rule, HHS's longstanding policy was not to enforce the 2000 Rule's abortion referral and counseling requirements against religiously objecting entities where those provisions conflict with the federal conscience protection laws Vita Nuova discusses in its Amended Complaint. Because Vita Nuova is not injured by—and thus lacks

[1] Defendants previously moved to dismiss Plaintiff's initial complaint, *see* ECF No. 14, and Defendants' arguments here overlap somewhat with those Defendants made in their initial motion to dismiss.

[2] Though the entire 2019 Rule is now in effect, compliance with the physical-separation requirement discussed below is not required until March 4, 2020.

standing to challenge—a regulatory feature that has been superseded (and would not have been enforced against Vita Nuova even before it was superseded), Claim 1 must be dismissed.

Plaintiff's remaining claims likewise fail for lack of Article III injury. Claim 2 of the Amended Complaint challenges 45 C.F.R. § 75.300(d), which provides that HHS grant recipients "must treat as valid the marriages of same-sex couples." But this provision applies only to recipients of Title X awards. According to the Amended Complaint, Vita Nuova has never applied for Title X funding and does not intend to do so until November 2020; Vita Nuova also does not adequately plead that it would even be qualified to receive any such award. And the Amended Complaint does not adequately allege that, at the time the lawsuit was filed, there was any credible threat that this regulation would be enforced against Vita Nuova. In any event, any claim Vita Nuova might have once had against section 75.300(d) is now moot. Since the Amended Complaint was filed, HHS has issued a notice indicating that HHS will not enforce section 75.300(d) while a rulemaking process is pending. Finally, Plaintiff purports in Claim 3 to mount a Religious Freedom Restoration Act ("RFRA") challenge to a hypothetical application of a provision of the Church Amendments, 42 U.S.C. § 300a-7(c), but Plaintiff's asserted injury is purely speculative.

Accordingly, the Court should dismiss the Amended Complaint in its entirety.

BACKGROUND

I. Statutory and Regulatory Background

In 1970, Congress enacted Title X of the PHSA to create a limited grant program for preconception family planning services. *See* Pub. L. No. 91-572, 84 Stat. 1504. The statute authorizes HHS to make grants and enter into contracts with public or private nonprofit entities "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including

natural family planning methods, infertility services, and services for adolescents)." 42 U.S.C. § 300(a). It also provides that "[g]rants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate." *Id.* § 300a-4(a).

Section 1008 directs that "[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. "That restriction was intended to ensure that Title X funds would 'be used only to support preventive family planning services, population research, infertility services, and other related medical, informational, and educational activities.'" *Rust v. Sullivan*, 500 U.S. 173, 178-79 (1991) (quoting H.R. Rep. No. 91-1667, at 8 (1970)).

The Secretary's initial regulations did not provide additional guidance on the scope of section 1008. Instead, they simply required that a grantee's application state that the Title X "project will not provide abortions as a method of family planning." 36 Fed. Reg. 18,465, 18,466 (Sept. 15, 1971). During this period, HHS construed section 1008 and its regulations "as prohibiting Title X projects from in any way promoting or encouraging abortion as a method of family planning" and "as requiring that the Title X program be 'separate and distinct' from any abortion activities of a grantee." 53 Fed. Reg. 2922, 2923 (Feb. 2, 1988) (describing previous HHS guidelines and internal memoranda).

In 1988, the Secretary issued a final rule that prohibited Title X projects from promoting, encouraging, advocating, or providing counseling on, or referrals for, abortion as a method of family planning. 53 Fed. Reg. at 2945 (42 C.F.R. §§ 59.8, 59.10). The regulations also required that grantees keep their Title X-funded projects "physically and financially separate" from all prohibited abortion-related activities. *Id.* (§ 59.9). The Supreme Court upheld these regulations

in *Rust*, concluding that they were authorized by Title X, were not arbitrary and capricious, and were consistent with the Constitution. 500 U.S. at 183-203.

In 1993, HHS suspended the 1988 regulations; accordingly, the prior guidance went back into effect. 58 Fed. Reg. 7455 (Jan. 22, 1993); 58 Fed. Reg. 7462 (Feb. 5, 1993) (interim rule). In 2000, HHS finalized a new rule, which required Title X projects to offer and provide upon request, "information and counseling regarding" specific options, including "[p]regnancy termination," followed by "referral upon request." 65 Fed. Reg. 41,270, 41,279 (July 3, 2000). This rule also eliminated the physical-separation requirement in the 1988 regulations. *See id.* at 41,275-76.

On June 1, 2018, the Secretary issued a notice of proposed rulemaking designed to "refocus the Title X program on its statutory mission—the provision of voluntary, preventive family planning services specifically designed to enable individuals to determine the number and spacing of their children." 83 Fed. Reg. 25,502, 25,505. After receiving and reviewing more than 500,000 comments, the Secretary issued the 2019 Rule in March 2019, 84 Fed. Reg. 7714.

The 2019 Rule prohibits Title X projects from providing referrals for, or engaging in activities that otherwise encourage or promote, abortion as a method of family planning. 84 Fed. Reg. at 7788-90 (42 C.F.R. §§ 59.5(a)(5), 59.14(a), 59.16(a)). The 2019 Rule permits, but does not require, "[n]ondirective pregnancy counseling," (42 C.F.R. § 59.14(b)(1)(i)), which may include the neutral presentation of information about abortion, provided it does "not encourage, promote or advocate abortion as a method of family planning." 84 Fed. Reg. at 7789 (42 C.F.R. § 59.16(a)(1)); *see id.* at 7745-46 (preamble). The 2019 Rule further requires that Title X projects remain physically separate from any abortion-related activities conducted outside the program. 84 Fed. Reg. at 7789 (42 C.F.R. § 59.15).

II. Litigation Concerning the 2019 Rule

On March 4, 2019, HHS published the 2019 Rule. Federal district courts in Oregon[3] and Washington[4] preliminarily enjoined the 2019 Rule nationwide, while another federal district court in California preliminarily enjoined it in California.[5] On June 20, 2019, the Ninth Circuit stayed all three injunctions pending appeal. *See California v. Azar*, 927 F.3d 1068 (9th Cir. 2019). The Ninth Circuit subsequently ordered those stay motions to be reheard en banc and instructed that the motions panel's opinion not be given precedential effect; but the en banc court clarified that it had not vacated the stay itself and clarified that it had left the stay in place pending the en banc court's disposition of the merits of the stay motion. *See* Order, *California v. Azar*, No. 19-15974 (9th Cir. July 11, 2019), ECF No. 86. Although a federal district court in Maryland preliminarily enjoined the Rule's application in Maryland, the Fourth Circuit likewise stayed that injunction. *See Mayor & City Council of Baltimore v. Azar*, No. 19-1614 (4th Cir. July 2, 2019), ECF No. 23.[6] A fifth district court denied a similar request for a nationwide preliminary injunction against enforcement of the 2019 Rule. *See Family Planning Ass'n of Maine v. HHS*, No. 19-cv-100, 2019 WL 2866832 (D. Me. July 3, 2019). The plaintiffs appealed the preliminary-injunction denial to the First Circuit but have since dismissed that appeal. The 2019 Rule, which Plaintiff does not challenge and in fact approves of, is thus in effect nationwide.

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[3] *See Oregon et al. v. Azar et al.*, No. 6:19-cv-00317-MC, ECF No. 142 (D. Or.).

[4] *See Washington v. Azar*, No. 1:19-cv-03040-SAB, ECF No. 54 (E.D. Wash.).

[5] *See California v. Azar*, No. 3:19-cv-01184, ECF No. 103 (N.D. Cal.). The California court subsequently narrowed the scope of its injunction. *See* No. 3:19-cv-01184, ECF No. 115.

[6] Both the Fourth Circuit and the Ninth Circuit have heard oral argument in the relevant appeals.

III. This Action

Vita Nuova filed this action on July 3, 2019. *See* ECF No. 1. After Defendants filed a motion to dismiss, *see* ECF No. 14, Vita Nuova filed an Amended Complaint, *see* ECF No. 16 ("Amended Compl."). The Amended Complaint alleges that Vita Nuova "is a Christian, pro-life organization that wishes to participate in the federal government's Title X program." *Id.* at 1. Vita Nuova further states that it wishes to participate in the Title X program without providing abortion counseling or referrals. *Id.* at 2. It appears that Vita Nuova was incorporated on July 2, 2019, the day before this lawsuit was filed.[7] The Amended Complaint alleges that Vita Nuova plans to apply for Title X funding (for the first time) in November 2020. Amended Compl. ¶ 31.

As noted above, in Claim 1 Vita Nuova seeks a declaration that various federal laws "prohibit the government from excluding Vita Nuova from the Title X program on account of its unwillingness to provide abortion referrals or abortion counseling." Amended Compl. ¶ 38. Vita Nuova's remaining two claims are: (1) a challenge to 45 C.F.R. § 75.300(d), which Vita Nuova asserts would require it to recognize same-sex marriages if it participated in an HHS grant program; and (2) a RFRA challenge to a provision of the Church Amendments, 42 U.S.C. § 300a-7(c)(1), which Vita Nuova asserts would require it to allow its employees to perform or assist in elective abortions if it participated in an HHS grant program. *Id.* ¶¶ 39-57. As to this latter claim, Vita Nuova seeks to represent a putative class consisting of "every current and future entity in the United States that: (i) Opposes abortion for sincere religious reasons; and (2) Is receiving or intends to apply for a grant, contract, loan, or loan guarantee under the" PHSA and several other statutes HHS administers. *Id.* ¶ 60.

[7] *See* https://www.bizapedia.com/tx/vita-nuova.html (last visited Nov. 11, 2019).

LEGAL STANDARD

Defendants move for dismissal of this action under Rule 12(b)(1). A court dismisses a case under Rule 12(b)(1) for lack of subject matter jurisdiction if it "lacks the statutory or constitutional power to adjudicate the case." *Home Builders Ass'n of Miss. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998) (citation omitted). "It is the responsibility of the complainant clearly to allege facts demonstrating that he is a proper party to invoke judicial resolution of the dispute and the exercise of the court's remedial powers," *Renne v. Geary*, 501 U.S. 312, 316 (1991) (quotation marks omitted), and so the burden of proof on a Rule 12(b)(1) motion to dismiss rests with the party asserting jurisdiction. In ruling on a 12(b)(1) motion, a court may rely upon: "(1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Barrera–Montenegro v. United States*, 74 F.3d 657, 659 (5th Cir. 1996) (quotation marks omitted). The Court should "consider the Rule 12(b)(1) jurisdictional attack before addressing any attack on the merits." *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001).

ARGUMENT

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction." *Raines v. Byrd*, 521 U.S. 811, 818 (1997) (*quoting Simon v. Eastern Ky. Welfare Rights Organization*, 426 U.S. 26, 37 (1976)). "Of the doctrines that have evolved under Article III, . . . the requirement that the litigant have standing is perhaps the most important." *Henderson v. Stalder*, 287 F.3d 374, 378 (5th Cir. 2002). "Standing to sue must be proven, not merely asserted, in order to provide a concrete case or controversy and to confine the courts' rulings within our proper judicial sphere." *Doe v. Tangipahoa Parish Sch. Bd.*, 494 F.3d 494, 496-97 (5th Cir. 2007) (en banc). To establish

standing, "a plaintiff must show: (1) [he] has suffered, or imminently will suffer, a concrete and particularized injury-in-fact; (2) the injury is fairly traceable to the defendant's conduct; and (3) a favorable judgment is likely to redress the injury." *Miss. State Democratic Party v. Barbour*, 529 F.3d 538, 544 (5th Cir. 2008) (citation omitted).

The Amended Complaint alleges no concrete and imminent injury, let alone one that is fairly traceable to Defendants and that a favorable judgment would redress. Claim 1 of the Amended Complaint in substance challenges a regulatory feature that has been superseded and that, even prior to that change, Vita Nuova would not have had standing to challenge. Vita Nuova's challenges to 45 C.F.R. § 75.300(d) and 42 U.S.C. § 300a-7(c) likewise fail for lack of injury.

I. Claim 1 Must Be Dismissed

In Claim 1, Vita Nuova seeks a declaration that various federal laws "prohibit the government from excluding Vita Nuova from the Title X program on account of its unwillingness to provide abortion referrals or abortion counseling." Amended Compl. ¶ 38. But the 2019 Rule permits Vita Nuova to participate in the Title X program without engaging in these activities—indeed, it *prohibits* Title X providers from engaging in referrals for abortion as a method of family planning or counseling that promotes or encourages abortion. *See* p. 4, *supra*. And because the Ninth Circuit clarified after this lawsuit was filed that its earlier en banc order had not vacated the three-judge panel's stay, *see* p. 5, *supra*, there was no injunction of the 2019 Rule in effect at the time Plaintiff filed its suit. Thus, at that time, Plaintiff plainly suffered no injury from the feature of the 2000 regulation to which it objects, as it had been superseded by the 2019 Rule. Plaintiff thus lacks standing to bring Claim 1.

Settled mootness doctrine confirms the point. "Mootness has been described as the doctrine of standing set in a time frame: The requisite personal interest that must exist at the

commencement of the litigation (standing) must continue throughout its existence (mootness)." *Arizonans for Official English v. Arizona*, 520 U.S. 43, 68 n.22 (1997) (quotation marks and citation omitted). And "[t]ypically, when a party challenges a law as unconstitutional and seeks declaratory and prospective injunctive relief, a superseding statute or regulation moots the case" because "[w]hen a challenged law is preempted, it cannot inflict further injury redressable by declaration or injunction." *Checker Cab Operators, Inc. v. Miami-Dade Cnty.*, 899 F.3d 908, 915 (11th Cir. 2018) (cleaned up); *accord Int'l Women's Day Mar. Planning Comm. v. City of San Antonio*, 619 F.3d 346, 357 (5th Cir. 2010) ("[W]e conclude that any as-applied challenge to the enforcement of the repealed 1988 ordinance is moot."); *McCorvey v. Hill*, 385 F.3d 846, 849 (5th Cir. 2004) ("Suits regarding the constitutionality of statutes become moot once the statute is repealed."); *New England Reg'l Council of Carpenters v. Kinton*, 284 F.3d 9, 18 (1st Cir. 2002) (observing that "it would be pointless . . . to enjoin the enforcement of a [policy] that is no longer in effect"); 13C Fed. Prac. & Proc. Juris. § 3533.6 (3d ed.) ("Mootness principles have direct and often obvious application in dealing with attacks on legislative rules that have expired or been repealed. Mootness has overtaken attacks on expired statutes, ordinances, court rules, and administrative acts." (footnotes omitted)).[8]

In this case, the Amended Complaint does not dispute that any abortion referral or counseling requirement was supplanted by the 2019 Rule. Nor does Plaintiff take issue with the

[8] Most of the cases addressing challenges to repealed regulations and statutes have grounded their analysis in terms of mootness rather than Article III standing, presumably because the typical pattern in such cases involves a law or regulation that is repealed during the lawsuit. Because the regulation pertinent to Claim 1 was superseded *before* this lawsuit, the appropriate doctrine in this case is standing rather than mootness. In any event, "[m]ootness" is "the doctrine of standing set in a time frame." *Arizonans for Official English*, 520 U.S. at 68 n.22 (quotation marks omitted). Thus, if this Court were to conclude that the mootness framework governs, the result (dismissal for lack of subject matter jurisdiction) would be the same.

2019 Rule on this point. Indeed, the Amended Complaint favorably discusses the 2019 Rule at length, both in general, *see* Amended Compl. ¶¶ 17-23, and with respect to this issue in particular, *id.* ¶¶ 18-20. Plaintiff thus has not alleged a concrete and imminent injury stemming from the defunct provisions of the 2000 Rule related to this issue.

Urging otherwise, Vita Nuova primarily contends that it needs declaratory relief notwithstanding the 2019 Rule because "[t]he ongoing lawsuits against the 2019 rule raise the prospect that a court will vacate the rule or resurrect the nationwide injunctions against its enforcement." *Id.* ¶ 33. This argument fails.

Initially, this is not a proper basis for seeking declaratory relief. The Supreme Court has articulated an "established doctrine that persons subject to an injunctive order issued by a court with jurisdiction are expected to obey that decree until it is modified or reversed, even if they have proper grounds to object to the order." *GTE Sylvania, Inc. v. Consumers Union of U.S., Inc.*, 445 U.S. 375, 386 (1980). It is in this context that the Supreme Court has found that the remedy for an injunction deemed improper is direct appeal, rather than collateral attack. *Cf. Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 218-19 (1995) (decisions of federal courts are "subject to review only by superior courts in the Article III hierarchy"); *Marino v. Ortiz*, 484 U.S. 301, 304 (1988) (per curiam) ("The rule that only parties to a lawsuit, or those that properly become parties, may appeal an adverse judgment, is well-settled."); *Rooker v. Fidelity Trust Co.*, 263 U.S. 413 (1923); *D.C. Court of Appeals v. Feldman*, 460 U.S. 462, 482 (1983). Thus, every court of appeals, including the Fifth Circuit, has suggested that district courts should avoid interfering with the remedial authority of other district courts. *See, e.g., W. Gulf Maritime Ass'n v. ILA Deep Sea Local 24*, 751 F.2d 721, 728-29 (5th Cir. 1985) (holding that federal district courts have an

obligation to "avoid rulings which may trench upon the authority of sister courts").[9] To the extent Plaintiff is concerned about the outcome of suits challenging the 2019 Rule, Plaintiff could present its arguments as an amicus supporting the Government in any ongoing proceedings in cases challenging the 2019 Rule. But Plaintiff may not use this litigation to collaterally attack a (hypothetical) adverse decision in another federal court.

In any event, the Court need not decide this issue because there is a second and more straightforward reason to reject this argument: the result of the ongoing lawsuits will not affect Vita Nuova's ability to participate in the Title X program. As explained in the 2019 Rule, 84 Fed. Reg. at 7,716, HHS acknowledged as early as 2008 that the "regulatory requirement that grantees

[9] *See also Zambrana v. Califano*, 651 F.2d 842, 844 (2d Cir. 1981) ("Generally, principles of comity and judicial economy make courts reluctant to exercise jurisdiction over claims involving the orders of coordinate courts."); *TPM Holdings, Inc. v. Intra-Gold Indus., Inc.*, 91 F.3d 1, 4 (1st Cir. 1996) ("Where the overlap between the two suits is nearly complete, the usual practice is for the court that first had jurisdiction to resolve the issues and the other court to defer."); *E.E.O.C. v. University of Pennsylvania*, 850 F.2d 969 (3d Cir. 1988) (describing past Supreme Court decision as setting forth principle that "no precise rule governs relations between federal district courts possessing jurisdiction, but the general principle is to avoid duplicative litigation."); *Feller v. Brock*, 802 F.2d 722, 727-28 (4th Cir. 1986) ("Prudence requires that whenever possible, coordinate courts should avoid issuing conflicting orders."); *Carver v. Knox Cty.*, 887 F.2d 1287, 1293 (6th Cir. 1989) (noting the "intolerable situation" of a state subject to conflicting injunctions and explaining that "the only common sense approach" is for the courts to speak "with a single voice"); *Great N. Ry. Co. v. Nat'l R.R. Adjustment Bd.*, 422 F.2d 1187, 1193 (7th Cir. 1970) ("The purposes of the rule [of comity] are to avoid unnecessarily burdening courts and to avoid possible embarrassment from conflicting results."); *Missouri ex rel. Nixon v. Prudential Health Care Plan, Inc.*, 259 F.3d 949, 953 (8th Cir. 2001) (noting "the general policy against concurrent federal litigation"); *Bergh v. Washington*, 535 F.2d 505, 507 (9th Cir. 1976) ("When an injunction sought in one federal proceeding would interfere with another federal proceeding, considerations of comity require more than the usual measure of restraint, and such injunctions should be granted only in the most unusual cases."); *MAI Basic Four, Inc. v. Basis, Inc.*, 962 F.2d 978, 987 (10th Cir. 1992) (citing to *Commodity Futures Trading Com'n v. Chilcott Portfolio Mgmt., Inc.*, 713 F.2d 1477, 1484 (10th Cir. 1983), which in turn quotes *Bergh*, 535 F.2d at 507); *S. Mills, Inc. v. Nunes*, 586 F. App'x 702, 706 (11th Cir. 2014) (approving the district court's decision to "avoid[] multiplicitous proceedings and potentially conflicting judgments"); *UtahAmerican Energy, Inc. v. Dep't of Labor*, 685 F.3d 1118, 1124 (D.C. Cir. 2012) (cautioning against simultaneous suits that would "potentially produce contradictory decisions" and "in turn, generate dueling appeals").

must provide counseling and referrals for abortion upon request . . . is inconsistent with the health care provider conscience protection statutory provisions." 73 Fed. Reg. 78,072, 78,087 (Dec. 19, 2008). HHS subsequently made clear in the preamble to another rule that the 2019 Rule "did not alter HHS's preexisting policy dating back at least to 2008 of not enforcing requirements of the 2000 regulations where they may conflict with the Federal conscience statutes." 84 Fed. Reg. 23,170, 23,191 n.64 (May 21, 2019).[10]

In short, HHS, through an exercise of its enforcement discretion, did not require religiously objecting entities like Vita Nuova to provide abortion referrals or abortion counseling even *prior* to the 2019 Rule. HHS thus has not read the since-stayed district-court injunctions as mandating imposition of these requirements in the circumstances presented here. Indeed, HHS informed those courts that HHS did not understand the injunctions to require alteration of its longstanding enforcement policy,[11] and none of the courts (or, for that matter, any of the plaintiffs in those cases) objected. Accordingly, even if a court subsequently vacates the 2019 Rule or reinstates the nationwide injunctions against its enforcement, there is no reason to expect that any such hypothetical decision would have the effect of requiring religiously objecting entities like Vita Nuova to provide abortion referrals or abortion counseling.

Finally, Plaintiff's suggestion that "the 2019 rule is certain to be revoked if a Democratic Administration takes office in January 2021," *id.* ¶ 34, is likewise not a basis for jurisdiction here. It should go without saying that entertaining hypothetical challenges based on speculation about what hypothetical future administrations might do is not a legitimate enterprise for Article III

[10] That rule has been challenged and vacated by a federal district court in New York. *See State of New York et al. v. HHS et al.*, No. 19-cv-4676, ECF No. 248 (S.D.N.Y.). A federal court in Washington has indicated that it will vacate the rule as well. Defendants do not rely on that rule here, but merely cite the preamble to note HHS's history of nonenforcement

[11] *See, e.g.*, No. 1:19-cv-01103-RDB, ECF No. 42 (D. Md. May 2, 2019).

courts. This assertion, moreover, depends on three layers of speculation. As to the first two layers, it is contingent on both future political events and the rulemaking choices of a hypothetical future administration. And as to the third, even if a future administration were to revoke the 2019 Rule, Plaintiff would still not be required to provide abortion referrals or counseling to remain in the Title X program unless that hypothetical administration *also* were to abandon "HHS's preexisting policy dating back at least to 2008 of not enforcing requirements of the 2000 regulations where they may conflict with the Federal conscience statutes." *See* p. 12, *supra*. This kind of conjectural claim clearly is not ripe for review. Indeed, even challenges to *proposed* rules are generally deemed premature. *Ctr. for Auto Safety v. Nat. Highway Traffic Safety Admin.*, 710 F.2d 842, 846 (D.C. Cir.1983) (noting that "the issuance of a notice of proposed rulemaking . . . often will not be ripe for review because the rule may or may not be adopted or enforced"). *A fortiori*, Plaintiff's speculative argument here should be rejected.

II. Claim 2 Must Be Dismissed Because Vita Nuova Has Not Adequately Pled That the Challenged Regulation Requires Anything of Vita Nuova and This Claim is Now Moot in Any Event

Claim 2 of the Amended Complaint purports to challenge 45 C.F.R. § 75.300(d). Compl. ¶¶ 39-47. Section 75.300(d) provides, in full, as follows:

> In accordance with the Supreme Court decisions in *United States v. Windsor* and in *Obergefell v. Hodges*, all recipients must treat as valid the marriages of same-sex couples. This does not apply to registered domestic partnerships, civil unions or similar formal relationships recognized under state law as something other than a marriage.

45 C.F.R. § 75.300(d).

Even assuming for the sake of argument that Vita Nuova would have had standing to challenge section 75.300(d) when this action was filed, Claim 2 is now moot. On November 1, 2019, HHS issued a Notice of Non-Enforcement (Exhibit A) informing the public that section

75.300(d) (among other provisions) will not be enforced because "the rulemaking that resulted in [this provision] raises significant concerns about compliance with the Regulatory Flexibility Act." Exhibit A at 1. The same day, HHS published a Notice of Proposed Rulemaking (Exhibit B) to, inter alia, amend section 75.300(d).[12] HHS's public announcement of non-enforcement based on concerns about the prior rulemaking process moots any previous controversy concerning section 75.300(d). *See, e.g.*, *Ragsdale v. Turnock*, 841 F.2d 1358, 1365-66 (7th Cir. 1988) (stating that, even though the State had not acted to amend the challenged statute and regulations in that case, "[w]e believe that the defendants' now public policy of non-enforcement of the [statute and regulations], particularly in view of the reasons therefor (i.e., that enforcement is barred by clear Supreme Court precedent), moots any challenge to that requirement").

In any event, even prior to these actions, Vita Nuova still had not alleged any actual injury from this provision because the Amended Complaint does not adequately plead that section 75.300(d) required Vita Nuova to do anything at all. As an initial matter, as noted above, the Amended Complaint notes that Vita Nuova has never applied for Title X funds or sought to be a subrecipient under a Title X grant. The Amended Complaint also does not plead facts demonstrating that Vita Nuova would be a qualified applicant (or subrecipient) for Title X funds if it did apply. Under these circumstances, any claim that section 75.300(d)—which applied only to "recipients" of HHS awards—would have caused injury to Vita Nuova is wholly speculative.

Further, even if the Amended Complaint *did* plead facts showing that section 75.300(d) would have applied to Vita Nuova, the Amended Complaint does not allege that there is any credible threat that the regulation will be enforced against Vita Nuova. Where, as here, a party brings a pre-enforcement challenge to a regulation, in order to establish an Article III injury, the

[12] The proposed rule, inter alia, would "require compliance with all applicable nondiscrimination statutes and Supreme Court decisions." Exhibit B at 8.

party must show there is a credible threat that the regulation will be enforced against it. *See Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158-59 (2014); *Empower Texans, Inc. v. Nodolf*, 306 F. Supp. 3d 961, 965 (W.D. Tex. 2018). Here, Vita Nuova has failed to allege any credible threat of enforcement on the part of HHS. Vita Nuova has identified no instance in which HHS previously penalized an award recipient because the recipient does not recognize same-sex marriages. Absent a credible threat that HHS would have enforced section 75.300(d) against Vita Nuova, Claim 2 must be dismissed. And for the reasons previously stated, this Claim is in any event now moot.

III. Claim 3 Must Be Dismissed Because Plaintiff's Asserted Injury is Wholly Speculative

Claim 3 of the Amended Complaint challenges 42 U.S.C. § 300a-7(c). *See* Compl. ¶¶ 57-62. That provision is part of what are commonly known as the Church Amendments, which prohibit discrimination based on religious beliefs or moral convictions regarding sterilization procedures, abortion, or, more generally, health services or research activities. The discrimination proscribed by this provision includes discrimination based on an individual's performance (or assistance in) such a procedure or activity, an individual's refusal to perform (or assist in) such a procedure or activity, and an individual's religious beliefs or moral convictions about such procedures more generally. 42 U.S.C. § 300a-7. Plaintiff asserts that the portion of 42 U.S.C. § 300a-7(c) and that prevents discrimination against individuals who perform or assist in the performance of abortions—which has been existence since 1973—violates RFRA. *See* Compl. ¶¶ 49-65.

Here again, Plaintiff has failed to allege any concrete and imminent injury sufficient to confer Article III standing. First, the Amended Complaint does not adequately allege that Plaintiff has been forced to employ individuals who perform or assist in the performance of abortions.

Indeed, given Plaintiff's recent creation and its lack of prior participation in HHS programs, it is unclear whether Plaintiff has any employees at all. Nor does Plaintiff allege that any prospective employees have attempted to secure employment with Plaintiff despite performing or assisting with such services. Plaintiff's allegation that it must act contrary to its sincere religious beliefs in order to participate in the Title X program—which Plaintiff has never participated in before—is therefore purely speculative. *See, e.g.*, *Williams v. Lew*, 819 F.3d 466, 473 (D.C. Cir. 2016) (constitutional challenge to statute failed for lack of standing where claim of future injury was "entirely conjectural"). Claim 3 of Plaintiff's Amended Complaint should be dismissed for lack of standing.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss this case in its entirety.

Dated: November 12, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

On November 12, 2019, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Andrew M. Bernie
Andrew M. Bernie

EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 75

NOTICE OF NONENFORCEMENT

AGENCY: Office of the Secretary, HHS

ACTION: Notice of exercise of enforcement discretion under the Regulatory Flexibility Act with respect to certain regulatory provisions.

SUMMARY: This notification is to inform the public that the U.S. Department of Health and Human Services has determined that the rulemaking that resulted in the regulatory provisions promulgated at 81 F.R. 89393 (Dec. 12, 2016) raises significant concerns about compliance with the Regulatory Flexibility Act. The provisions will not be enforced pending a repromulgation that complies with the Act.

FOR FURTHER INFORMATION CONTACT: Richard Brunage at (202) 401-6107.

SUPPLEMENTAL INFORMATION:

The Department of Health and Human Services has determined that the rulemaking which promulgated or amended 45 C.F.R. §§ 75.101(f), 75.110(a), 75.300(c) and (d), 75.305(a), 75.365, 75.414(c) and (f), and 75.477, published at 81 F.R. 89393 (Dec. 12, 2016), raises significant concerns about compliance with the requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. § 601 *et seq*. The Department has accordingly determined to exercise its enforcement discretion not to enforce the regulations until they have been repromulgated with a proper RFA analysis.

I. STATUTORY BACKGROUND

The RFA generally requires that when an agency issues a proposed rule, or a final rule (after publishing a proposed rule) pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the Federal Register. 5 U.S.C. §§ 603, 604. The RFA is a "[p]urely procedural" statute, but "set[s] out precise, specific steps an agency must take." *Nat'l Telephone Co-op Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009) (internal quotation marks omitted). Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA)[1]; (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. § 601(3)-(6).[2] The requirement does not apply if the head of the agency "certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." *Id.* § 605(b). The agency must, however, publish the certification in the Federal Register at the time of publication of the proposed or final rule, "along with a statement providing the factual basis for such certification." *Id.* The RFA also requires the agency to

[1] Depending on the industry, SBA considers businesses to be small by virtue of having less than between $7.5 million and $38.5 million in average annual revenue.
[2] The Department considers a rule to have a significant economic impact on a substantial number of small entities if at least 5% of small entities experience an impact of more than 3% of revenue.

provide the certification and the statement with the factual justification to the SBA Chief Counsel for Advocacy. *Id.*

If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA's waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the Federal Register at the time of promulgation or, if the rule is promulgated in response to an emergency that makes timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. §§ 604(a), 608(b).[3] In addition, the RFA provides for judicial review of an agency's compliance with its provisions under some circumstances, which can result in a court ordering the agency to take corrective action by remanding the rule to the agency and deferring enforcement of the rule against small entities. *Id.* § 611(a)(4).

II. ABSENCE OF RFA ANALYSIS OR CERTIFICATION

The rulemaking that promulgated and amended 45 C.F.R. §§ 75.101(f), 75.110(a), 75.300(c) and (d), 75.305(a), 75.365, 75.414(c) and (f), and 75.477, published at 81 F.R. 89393 (Dec. 12, 2016), raises significant concerns about compliance with the requirements of the RFA, 5 U.S.C. § 601 *et seq*. The Department neither performed the RFA analysis described in 5

[3] Section 608(b) provides that, "[e]xcept as provided in section 605(b), an agency head may not waive the requirements of section 604 of this title [regulatory flexibility analysis for final rules]. An agency head may delay the completion of the requirements of section 604 of this title for a period of not more than one hundred and eighty days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 of this title impracticable. If the agency has not prepared a final regulatory analysis pursuant to section 604 of this title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency." 5 U.S.C. § 608(b).

U.S.C. §§ 602-604, nor expressly certified that the rules "will not . . . have a significant economic impact on a substantial number of small entities" and provided a statement with the factual basis for such certification as provided for by § 605(b). *See* 81 F.R. 89,393 (Dec. 12, 2016). The rulemaking simply declared that it would "not have a significant economic impact beyond HHS's current regulations," without even mentioning small entities or grappling with the obvious interests of such entities that should have been protected by the RFA process. The Department is accordingly exercising its enforcement discretion and as such, these regulatory provisions will not be enforced, pending repromulgation.

The Department failed to make the certification, and provide the factual statement, described by the statute.

Where an agency engaged in notice and comment rulemaking pursuant to § 553 does not perform a RFA analysis, the head of the agency normally must certify that a rule will not have a significant impact on small entities, and the agency must ordinarily provide a statement that lays out the facts that support the certification. The agency's Federal Register publication must, thus, include a certification under § 605(b) that discusses the impact of a rule on a substantial number of small entities *and* "a statement providing the factual basis for such certification." While this is not a high bar, the Government must, at a minimum, show that it made a reasonable, good faith effort to consider at least some facts relevant to small entities impacted by the rule. *Compare North Carolina Fisheries Ass'n, Inc. v. Daley*, 16 F. Supp. 2d 647, 651-53 (E.D. Va. 1997) (finding that certification was noncompliant because it did not discuss any facts regarding the impact on small entities in the time period subject to the rule), *with Nat. Women, Infants and Children Grocers Ass'n v. Food and Nutrition Serv.*, 416 F. Supp. 2d 92, 108-09 (D.D.C. 2006)

(holding that certification complied because it explained that the challenged rule applied to the states, which had varying market conditions), *and Cactus Corner, LLC v. U.S. Dep't of Agric.*, 346 F. Supp. 2d 1075 (E.D. Cal. 2004) (finding that certification complied because it defined and discussed the small wholesalers impacted by the rule and made predictions about the likely impact of the rule).

In the preamble to the December 12, 2016 final rules, the Department stated it had an obligation under the RFA to "provide a final regulatory flexibility analysis or to certify that the rule[s] will not have a significant economic impact on a substantial number of small entities." 81 F.R. at 89394. It then listed a subset of the regulatory changes: aligning the grants regulation at part 75 "with various regulatory and statutory provisions," implementing Supreme Court decisions, and codifying long-standing policies. Without explaining whether or how these regulatory changes might apply to small entities, the Department simply concluded that, "[i]n order to ensure that the public receives the most value, it is essential that HHS grant programs function as effectively and efficiently as possible, and that there is a high level of accountability to prevent waste, fraud, and abuse. The additions provide enhanced direction for the public and will not have a significant economic impact beyond HHS's current regulations." *See* 81 F.R. at 89394.[4]

This statement in the Federal Register raises serious questions about compliance with the RFA's requirement that the agency head must certify that the rules will not have a significant economic effect on a substantial number of small entities. The statement fails to mention the

[4] The RFA discussion in the preamble to the proposed rule was virtually identical. *See* Health and Human Services Grants Regulation, 81 F.R. 45270, 45272 (July 13, 2016).

economic impact on small entities in particular or to even acknowledge that the regulation would apply to small entities. Furthermore, there is nothing in the final rules that provides a factual basis for any inference that the rules would not have a significant economic impact on a substantial number of small entities. Indeed, if anything, there are indications that the rulemaking likely did have a significant economic impact on a substantial number of small entities. The absence of a factual basis for a required section 605 certification, too, would be inconsistent with the requirements of the RFA. *See* 5 U.S.C. § 605(b).

The rules were not submitted to the SBA Chief Counsel for Advocacy.

When a certification is required, the RFA further requires that the agency "provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration." 5 U.S.C. § 605(b). The Chief Counsel for Advocacy of the SBA maintains records of the proposed and final rules submitted to it pursuant to the RFA. The Office of the Chief Counsel has informed the Department's General Counsel that it does not have a record of having received the rules pursuant to the RFA.

The rules may have affected a significant number of small entities.

The provisions in the final rules may have affected a significant number of small entities, which underscores why Congress prohibited agency heads from waiving the requirement to conduct an otherwise required regulatory impact analysis except in the narrow circumstance where an agency can provide the factual basis for a certification by the agency head that there is

no significant economic impact on a substantial number of small entities.[5] For example, section 75.477(b) precludes a grantee from including as allowable costs those payments that it may make to the Internal Revenue Service in lieu of providing minimum essential coverage (MEC) to its employees. While nearly all large employers offer their employees MEC, in 2015, among companies with 50 to 199 employees, around 8 percent did not. The 8 percent equates to approximately 14,000 small businesses. *See* http://files.kff.org/attachment/report-2015-employer-health-benefits-survey at 44; https://www.sba.gov/advocacy/firm-size-data (2014). Moreover, if an entity (including governmental or non-profit entities) with at least 50 full-time employees failed to meet the MEC requirements, it could be assessed a penalty equal to the number of its full-time employees for the year (minus up to 30 employees) times $2,000 if at least one full-time employee purchased health coverage with premium tax credits through the health insurance exchange. Any reasonable certification under § 605(b) necessarily would have had to reflect the potential impact on those 14,000 small businesses from this single provision.

A similar showing would have been sensible to perform with respect to the other regulatory provisions contained in the rulemaking that culminated in the December 12, 2016 final rules. Indeed, the data that existed at the time of the rulemaking revealed that various provisions could, in fact, affect a significant number of small entities. For example, section 75.414(c) limits reimbursement for indirect costs on training grants to eight percent. The proposed rule (*see* 81 F.R. 45,270 (July 13, 2016)) indicated that the amendment to subsection

[5] Even in the case of an emergency, the agency must conduct a regulatory flexibility analysis. Congress simply gave the agency an additional 180 days to conduct the analysis in case of an emergency, underscoring how important Congress considered the regulatory flexibility analysis to be. *See* 5 U.S.C. § 608(b).

(c) reflected HHS's longstanding policy. However, under the Richardson Waiver (*see* 36 Fed. Reg. 2,532 (Feb. 5, 1971)), such policy, absent rulemaking, is not binding. Thus, there was no valid, binding limit on reimbursement of indirect costs prior to the issuance of this rule, and no corresponding showing of the economic implications for small entities, including non-profits, of this new limitation on overhead reimbursement. A proper RFA analysis likely should have considered the effect that moving from a nonbinding policy to binding rule would have on small entities. *Cf. Am. Federation of Labor v. Chertoff*, 552 F. Supp. 2d 999, 1013 (N.D. Cal. 2007) (noting "serious questions [about] whether DHS violated the RFA" when it refused to conduct a final flexibility analysis about a rule that "as good as mandates costly compliance with a new 90-day timeframe"). There was also no showing concerning sections 75.300(c) and (d), which may impose compliance costs on recipients by subjecting the recipients to conflicting statutory and non-statutory requirements.

The regulatory provisions promulgated in the final rules will not be enforced pending rulemaking.

As described above, unless waived pursuant to section 605(b), the RFA generally requires an agency to prepare a final regulatory flexibility analysis. *See* 5 U.S.C. §§ 604(a), 611(a). The preparation of such analysis may be delayed by up to 180 days after the publication of the final rule in cases of emergency. *See* 5 U.S.C. § 608(b). Moreover, flawed RFA analyses have been the basis for judicial review of rulemakings.

Because the Department has serious concerns about whether the RFA analysis performed here complied with the RFA, the Department is announcing that it will not enforce the regulatory

provisions, pending repromulgation of the Rule. The majority of the Department's grantees are small entities,[6] and the RFA process undertaken with respect to this Rule raises significant concerns about whether their interests were protected in the manner the statute prescribes. Rather than apply a nonenforcement policy only to small entities, however, the Department is exercising its discretion to not enforce the rules with respect to any grantees until the rules have been properly re-promulgated with an impact analysis that hews to the requirements of the RFA. Applying these rules differently to agency grantees depending on size would be unfair, create increased compliance costs for all entities as they seek to determine whether they are or are not still subject to the rules, and impose additional administrative burdens on the Department disproportionate to the benefit of enforcement.

Accordingly, the regulatory actions, promulgated through the December 12, 2016 final rules, 81 F.R. 89393, namely, the additions of 45 CFR §§ 75.101(f), 75.300(c) and (d), 75.414(c)(1)(i) through (iii), and 75.477, and the amendments to 45 CFR §§ 75.110(a), 75.305(a), 75.365, and 75.414(f), will not be enforced pending repromulgation.[7]

Dated: _____

[6] *See, e.g.*, https://taggs.hhs.gov/ReportsGrants/GrantsByRecipClass.
[7] Elsewhere in this edition of the Federal Register, the Department publishes a notice of proposed rulemaking to begin the process of repromulgating, as appropriate, these rules.

Eric D. Hargan,

Deputy Secretary,

Department of Health and Human Services.

EXHIBIT B

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Financial Resources

45 CFR Part 75

RIN 0991-AC16

Health and Human Services Grants Regulation

AGENCY: Division of Grants, Office of Grants Policy, Oversight, and Evaluation, Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: This is a notice of proposed rulemaking to repromulgate or revise certain regulatory provisions of the Department of Health and Human Services found at 45 C.F.R. Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

DATES: Comments must be submitted on or before [OFR – insert date that is 30 days after publication in the Federal Register].

ADDRESSES: Comments must be identified by RIN 0991-AC16. Because of staff and resource limitations, comments must be submitted electronically to *www.regulations.gov*. Follow the "Submit a comment" instructions.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. Before or after the close of the comment period, the Department of Health and Human Services will post all

comments that were received before the end of the comment period on *www.regulations.gov*. Follow the search instructions on that Web site to view the public comments.

FOR FURTHER INFORMATION CONTACT: Richard Brunage at (202) 401-6107.

SUPPLEMENTARY INFORMATION:

This is a notice of proposed rulemaking by which the Department proposes to repromulgate provisions of 45 C.F.R. Part 75 that were set forth in a final rule published in the **Federal Register** at 81 FR 89393 (Dec. 12, 2016) (Final Rule). The Department, in a notice published in today's edition of the **Federal Register**, publishes its decision to exercise its enforcement discretion to not enforce the regulatory provisions adopted or amended by the Final Rule due to HHS's serious concerns about compliance with certain requirements of the Regulatory Flexibility Act, 5 U.S.C. §§ 601–12. In this notice, the Department proposes to repromulgate some of the provisions of the Final Rule, not to repromulgate others, and to replace or modify certain provisions that were included in the Final Rule with other provisions.

I. Background

On December 26, 2013, the Office of Management and Budget (OMB) issued the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (UAR or uniform regulations) that "set standard requirements for financial management of Federal awards across the entire federal government." 78 FR 78590 (Dec. 26, 2013). On December 19, 2014, the Department, in conjunction with OMB and other federal award-making agencies, issued an interim final rule to implement

the UAR. Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Final Rule, 79 FR 75867 (Dec. 19, 2014).

On July 13, 2016, the Department issued a notice of proposed rulemaking ("NPRM"), proposing additional changes to its implementation of the UAR. 81 FR 45270 (July 13, 2016). That rule proposed changes to:

- § 75.102, concerning requirements related to the Indian Self Determination and Education Assistance Act (ISDEAA);
- § 75.300, concerning certain public policy requirements and Supreme Court cases, and § 75.101, concerning the applicability of those provisions to the Temporary Assistance for Needy Families Program (Title IV-A of the Social Security Act, 42 U.S.C. §§ 601–19);
- § 75.305, concerning the applicability to states of certain payment provisions;
- § 75.365, concerning certain restrictions on public access to records;
- § 75.414, concerning indirect cost rates for certain grants; and
- § 75.477, concerning shared responsibility payments and payments for failure to offer health coverage to employees.

On December 12, 2016, the Department finalized all of these provisions without substantive change, except that the Department explained it was choosing not to finalize

the proposed change to § 75.102 at that time.[1] (81 FR 89393) The Final Rule went into effective on January 11, 2017.

In a notice published elsewhere in today's edition of the Federal Register, the Department explains that HHS is exercising enforcement discretion regarding compliance with the Final Rule, due to serious concerns about the Final Rule's compliance with the requirements of the Regulatory Flexibility Act, 5 U.S.C. §§ 601–12. With respect to the Final Rule, the Department is concerned about whether it provided a sufficient rationale and certification that the rule would not have a significant economic impact on a substantial number of small entities,[2] or a sufficient final regulatory flexibility analysis at the time of publication of the Final Rule in the Federal Register. As a result, the Department is choosing not to enforce the provisions of the Final Rule. *See* 5 U.S.C. §§ 608(b) and 611. However, merely because a regulation is not being enforced does not mean that it has been repealed or replaced. The Final Rule still appears in the Code of Federal Regulations. Therefore, this NPRM should be properly viewed as a proposal to modify or to repeal certain provisions in the Final Rule.

II. Summary of the Notice of Proposed Rulemaking

The Department proposes to repromulgate some (but not all) of the regulatory provisions included in the Final Rule and to issue new and amended provisions.

[1] The Final Rule also made a technical change not set forth in the proposed rule, amending § 75.110(a) by removing "75.355" and adding, in its place, "75.335."

[2] To the extent that the Department believed that the Final Rule did not have a significant economic impact on a substantial number of small entities, the certification and statement with the factual basis for such certification was also not provided to the Chief Counsel for Advocacy of the Small Business Administration, contrary to the requirements of the Regulatory Flexibility Act. *See* 5 U.S.C. § 605(b).

A. Technical correction, § 75.110.

The Department is proposing to retain, without change, § 75.110, as it corrected a typographical error in the pre-2017 rule.

B. Statutory and national public policy requirements, § 75.300, and related provisions at § 75.101.

The Department is modifying § 75.300 and proposing not to retain § 75.101(f) from the Final Rule. This is because the Department has faced several complaints, requests for exceptions, and lawsuits concerning § 75.300(c) and (d). The Department is also currently preliminarily enjoined from enforcing § 75.300(c) in the State of Michigan as to a particular subgrantee's protected speech and religious exercise. *See Buck v. Gordon*, No. 1:19-cv-286 (W.D. Mich. Sept. 26, 2019) (ECF No. 70) ("Defendant Azar shall not take any enforcement action against the State under 45 C.F.R. § 75.300(c) based upon [plaintiff's] protected religious exercise . . . ."). Some non-Federal entities have expressed concerns that requiring compliance with certain non-statutory requirements of those paragraphs violates the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb, *et seq.*, or the U.S. Constitution, exceeds the Department's statutory authority, or reduces the effectiveness of programs, for example, by reducing foster care placements in the Title IV-E program of HHS's Administration for Children and Families. The existence of these complaints and legal actions indicates that § 75.300(c) and (d) imposed regulatory burden and created a lack of predictability and stability for the Department and stakeholders with respect to these provisions' viability and enforcement.

Some members of the public have submitted comments to the Department citing possible burdens created by paragraphs (c) and (d) as they were included in the Final Rule.[3] To date, the Department has granted, pursuant to 45 C.F.R. § 75.102(b), one request for an exception to the application of the religious nondiscrimination requirement of § 75.300(c).[4] That grant of an exception has been challenged under the Administrative Procedure Act. Some Federal grantees have stated that they will require their subgrantees to comply with the non-statutory requirements of § 75.300(c) and (d), even if it means some subgrantees with religious objections will leave the program(s) and cease providing services rather than comply. The Department believes that such an outcome would likely reduce the effectiveness of programs funded by federal grants by reducing the number of entities available to provide services under these programs. The Department is also aware that certain grantees and subgrantees that may cease providing services if forced to comply with § 75.300(c) and (d) are providing a substantial percentage of services pursuant to some Department-funded programs and are effective partners of federal and state government in providing such services.

The Department accordingly proposes that § 75.300 include different provisions in paragraphs (c) and (d) than those that were included in the Final Rule. The

[3] *See* https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&s=75.300&dct=PS&D=HHS-OS-2017-0002.

[4] That waiver is available on the State of South Carolina's website at https://governor.sc.gov/sites/default/files/Documents/newsroom/HHS%20Response%20Letter%20to%20McMaster.pdf.

Department takes this action as an exercise of its discretion to establish requirements for its grant programs and to establish enforcement priorities with respect to those programs.

This notice proposes that paragraph (c) state, "It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services, to the extent doing so is prohibited by federal statute."

The Department considers this proposed language for paragraph (c) appropriate because it affirms that HHS grants programs will be administered consistent with the Federal statutes that govern the programs, including the nondiscrimination statutes that Congress has adopted and made applicable to the Department's programs, RFRA, and with all applicable Supreme Court decisions. The proposed language would provide guidance for compliance when non-statutory public policy requirements conflict with statutory requirements (*e.g.*, RFRA). Section 75.300(a) does not, on its face and standing alone, provide a clear pathway for compliance in such situations. The adoption of regulatory language that makes compliance more predictable and simpler for federal grant recipients is generally consistent with the concept of controlling regulatory costs and relieving regulatory burdens. Exec. Order No. 13771, 82 Fed. Reg. 9339 (Feb. 3, 2017).

This notice also proposes that paragraph (d) state, "HHS will follow all applicable Supreme Court decisions in administering its award programs."

Paragraph (d) as included in the Final Rule specified two Supreme Court decisions. But the Department is committed to complying not just with those decisions,

but with all applicable Supreme Court decisions and all applicable court orders. Because Federal courts issue new decisions daily, and courts often adjust, clarify, expand upon, or narrow prior holdings, the Department believes that, if its Department-wide regulations include general provisions addressing compliance with Supreme Court decisions, the regulations should do so without singling out specific cases, since it is not possible to list every applicable case, nor to change the regulations each time new decisions are issued.[5]

In light of the considerations discussed above, the Department proposes to modify paragraphs (c) and (d) to require compliance with all applicable nondiscrimination statutes and Supreme Court decisions. The Department believes the proposed language of paragraphs (c) and (d) would allow its programs to comply with all applicable laws and court decisions, to minimize disputes and litigation, and to remove regulatory barriers. OMB's UAR, at 2 CFR § 200.300, does not impose specific public policy requirements beyond U.S. statutory requirements. The Department considers it appropriate for paragraph (c) to similarly focus on statutory requirements and for paragraph (d) to inform grantees that the Department complies with applicable Supreme Court decisions in administering its grant programs.

The Department does not propose to include paragraph (f) in § 75.101, which was included in the Final Rule to ensure that the specific statutory requirements of the Temporary Assistance for Needy Families Program (Title IV-A of the Social Security

[5] In this regard, the Department distinguishes between the regulations it promulgates that are generally applicable to all of the Department's activities, such as all of its grants and grant-making programs, and regulations that are promulgated to implement a particular program – and between Supreme Court decisions that are generally applicable to the federal government and those that specifically address and bind the Department (or a component of the Department) with respect to a specific program.

Act, 42 U.S.C. 601-619) governed applicable grants. This language would not be necessary under the proposed language of § 75.300(c), because the latter would already be limited to applicable statutory nondiscrimination requirements.

C. Payment, § 75.305.

The Department is proposing to repromulgate 45 CFR § 75.305 as it currently appears in the Code of Federal Regulations. Because the language prior to the Final Rule applied the provisions of Treasury-State Cash Management Improvement Act agreements and default procedures codified at 31 CFR part 205 and TM 4A-2000, and such agreements may not contain specific provisions addressed by § 75.305, the Department seeks to modify the language to ensure clarity. In doing so, to the extent that the governing provisions are silent as to the payment provisions described in the UAR, there should be no effect on states, as they had been subject to these same provisions pursuant to 45 CFR § 92.21. However, the Department proposes the clarification so that all states are aware of the necessity to, for example, expend refunds and rebates prior to drawing down additional grant funds.

D. Restrictions on public access to records, § 75.365.

The Department proposes to repromulgate 45 CFR 75.365 as it currently appears in the Code of Federal Regulations. That section clarifies the limits on the restrictions that can be placed on nonfederal entities that limit public access to records pertinent to certain federal awards. That section also implements Executive Order 13,642 (May 9, 2013), and corresponding law. *See, e.g.*, https://www.federalregister.gov/documents/2013/05/14/2013-11533/making-open-and-

machine-readable-the-new-default-for-government-information, and Departments of Labor, Health, and Human Services, and Education Appropriations Act of 2014, Public Law 113-76, Div. H, Sec. 527 (requiring "each Federal agency, or in the case of an agency with multiple bureaus, each bureau (or operating division) funded under this Act that has research and development expenditures in excess of $100,000,000 per year [to] develop a Federal research public access policy"). Although this language was not included in subsequent appropriations acts, the Department considers it an appropriate exercise of agency discretion and implementation of the Executive Order. The proposed language would codify permissive authority for the Department's awarding agencies to require public access to manuscripts, publications, and data produced under an award, consistent with applicable law. The Department recognizes that this provision could be interpreted as having a financial impact on small entities. These requirements, however, have been operational since the publication of the Final Rule, and therefore grantees would not need to make any changes to their current practice in response to this rulemaking. As a result, this portion of this rulemaking, if finalized, would have no impact other than informing the public of the Department's stance on public access to manuscripts, publications, and data produced under awards.

E. Indirect (Facilities & Administration) costs, § 75.414.

The Department is proposing to repromulgate language from the Final Rule amending 45 CFR 75.414(c) as it currently appears in the Code of Federal Regulations. That provision restricted indirect cost rates for certain grants. It is long-standing HHS policy to restrict training grants to a maximum eight percent indirect cost rate. In

addition to proposing to implement this limit for training grants, the Department proposes to impose this same limitation on foreign organizations and foreign public entities, which typically do not negotiate indirect cost rates, and to add clarifying language to § 75.414(f), which would permit an entity that had never received an indirect cost rate to charge a de minimis rate of ten percent, in order to ensure that the two provisions do not conflict. In this proposed rule, the American University, Beirut, and the World Health Organization are exempted specifically from the indirect-cost-rate limitation because they are eligible for negotiated facilities and administration (F&A) cost reimbursement. This proposed restriction on indirect costs, as indicated by 45 CFR 75.101, would flow down to subawards and subrecipients. The Department recognizes that this provision could be interpreted as having a financial impact on small entities. These limits, however, have been operational since the publication of the Final Rule, and therefore grantees would not need to make any changes to their current practice in response to this rulemaking. As a result, this portion of this rulemaking, if finalized, would have no impact other than informing the public of the Department's stance on indirect cost rates for certain grants.

F. Payments for failure to offer health coverage to employees, § 75.477.

The Department proposes to repromulgate language from the Final Rule specifying a selected item of cost for codification in the cost principles as 45 CFR 75.477, regarding shared responsibility payments by employers. The Department does not, however, propose to repromulgate a related provision from the Final Rule concerning shared responsibility payments for individuals.

In 2013, the Department announced in a program policy document that any payments or assessments imposed on an individual or individuals pursuant to 26 U.S.C. § 5000A(b) as a result of any failure to maintain minimum essential coverage as required by 26 U.S.C. § 5000A(a) were not allowable costs under a particular grant program. *See* HAB Policy Notice 13-04, at 2-3. Consistent with that policy, in 2016 in the Final Rule, 45 CFR 75.477, the Department excluded as allowable expense under a grant both payments imposed on an individual or individuals pursuant to 26 U.S.C. § 5000A(b) and payments imposed on employers that fail to offer health coverage to their employees pursuant to 26 U.S.C. § 4980H.

Congress subsequently reduced to $0 the penalties or assessments imposed on individuals as a result of their failure to maintain minimum essential coverage, effective after December 31, 2018. Pub. L. 115-97, 131 Stat. 2092 (Dec. 22, 2017). Accordingly, the Department does not propose to repromulgate the provision from the Final Rule, at § 75.477(a), excluding such payments or assessments as allowable costs under an HHS grant. Given that the penalty imposed on individuals for failure to maintain minimum essential coverage was reduced to $0, effective after December 31, 2018, and it is possible that some individuals are still making such payments for tax year 2018, the Department seeks comment on whether to repromulgate the provision, with a sunset date to ensure that the cost of the individual penalty is excluded from allowable costs for tax years when such penalties could be imposed.

The Department does propose to repromulgate language from the Final Rule excluding, from allowable costs under an HHS grant, employer payments for failure to

offer health coverage to employees as required by 26 U.S.C. § 4980H. The Internal Revenue Service began to enforce the Internal Revenue Code provision in 2017, after the issuance of the Final Rule. The Department recognizes that the HHS regulatory provision – excluding such employer shared responsibility payments from allowable costs under HHS grants – could be interpreted as having a financial impact on small entities. These requirements, however, have been operational since the publication of the Final Rule, and therefore grantees would not need to make any changes to their current practice in response to this rulemaking. As a result, this portion of this rulemaking, if finalized, would have no impact other than informing the public of the Department's stance on financing shared responsibility payments using grant funding.

III. Request for Comment

The Department seeks comment on this proposed rule, including its likely impacts as compared to the previous Final Rule. The Department is particularly interested in comments relating to the comparative effects and impact of its own enforcement discretion, specifically were the previous Final rule to be fully enforced, as well as whether HHS were to fully exercise its enforcement discretion regarding the Final Rule.

IV. Regulatory Impact Analysis

The Department has examined the impacts of the proposed rule as required under Executive Order 12866 on Regulatory Planning and Review (Sept. 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (Jan. 18, 2011), Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354, 5 U.S.C. §§ 601-

612), section 202 of the Unfunded Mandates Reform Act of 1995 (Mar. 22, 1995, Publ. L. 104-04), Executive Order 13132 on Federalism (Aug. 4, 1999), the Congressional Review Act (5 U.S.C. § 804(2)), the Assessment of Federal Regulation and Policies on Families, and the Paperwork Reduction Act of 1995.

Executive Orders 12866 and 13563 Determination

Pursuant to Executive Order 12866, the Department has designated this final rule to be economically non-significant. This rule has been designated as a "significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. Similarly, under Executive Order 13563, this proposed rule harmonizes and streamlines rules, and promotes flexibility by removing unnecessary burdens.

Executive Order 13771

The White House issued Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This rule, while significant under Executive Order 12866, will impose de minimis costs and therefore is not anticipated to

be a regulatory or deregulatory action under Executive Order 13771. Public comments will inform the ultimate designation of this rule.

Regulatory Flexibility Act

The Department has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (RFA) (5 U.S.C. § 601–612). The RFA requires an agency to describe the impact of a proposed rulemaking on small entities by providing an initial regulatory flexibility analysis unless the agency expects that the proposed rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. §§ 603(a), 605(b). If an agency must provide an initial regulatory flexibility analysis, this analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. As discussed, the proposed rule would

- Require grantees to comply with applicable federal statutory nondiscrimination provisions.
- Provide that HHS complies with applicable Supreme Court decisions in administering its grant programs.

- Not re-impose the exclusion from allowable costs of the now-repealed tax imposed on individuals for failure to maintain minimum essential coverage.
- Otherwise re-promulgate the provisions of the Final Rule.

Affected small entities include all small entities which may apply for HHS grants; these small entities operate in a wide range of sections involved in the delivery of health and human services. Grantees are required to comply with applicable federal statutory nondiscrimination provisions by operation of such laws and pursuant to 45 CFR 75.300(a); HHS is required to comply with applicable Supreme Court decisions. Thus, there would be no economic impact associated with proposed sections 75.300(c) and (d). Since the individual tax for failure to comply with the individual mandate has been reduced to $0, there would be no economic impact associated with not proposing to re-impose an allowable costs exclusion for such payments. Moreover, the provisions of the proposed rule have been operational since the publication of the Final Rule, and therefore grantees, including small entities, would not need to make any changes to their current practice in response to this rulemaking. Thus, the Department anticipates that this rulemaking, if finalized, would have no impact beyond providing information to the public. The Department anticipates that this information will allow affected entities to better deploy resources in line with established requirements for HHS grantees. As a result, HHS has determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small entities.

The Department seeks comment on this analysis of the impact of the proposed rule on small entities, and the assumptions that underlie this analysis.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. § 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $154 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The Department has determined that this proposed rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of $154 million or more in any one year. Accordingly, the Department has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has federalism implications. The Department has determined that this proposed rule does not impose such costs or have any Federalism implications.

Congressional Review Act

The Congressional Review Act defines a "major rule" as "any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets." 5 U.S.C. § 804(2). The Department has determined that this proposed rule is not likely to result in an annual effect of $100,000,000 or more and is not otherwise a major rule for purposes of the Congressional Review Act.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Department has determined that these proposed regulations will not have an impact on family well-being, as defined in the Act.

Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR 1320 Appendix A.1), the Department has reviewed this proposed rule and has determined that there are no new collections of information contained therein.

V. List of Subjects in 45 CFR Part 75

Accounting, Administrative practice and procedure, Cost principles, Grant programs, Grant programs—health, Grants administration, Hospitals, Nonprofit organizations reporting and recordkeeping requirements, and State and local governments.

VI. Proposed Rule

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend part 75 of title 45 of the Code of Federal Regulations as follows:

PART 75—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR HHS AWARDS

1. The authority citation for 45 CFR part 75 continues to read as follows:

Authority: 5 U.S.C. § 301.

2. Amend § 75.110 by removing "75.355" and adding, in its place, "75.335".

3. Amend § 75.300 by adding paragraphs (c) and (d) to read as follows:

§ 75.300 Statutory and national public policy requirements.

* * * * *

(c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services, to the extent doing so is prohibited by federal statute.

(d) HHS will follow all applicable Supreme Court decisions in administering its award programs.

4. Revise § 75.305 to read as follows:

§ 75.305 Payment.

(a)(1) For States, payments are governed by Treasury-State CMIA agreements and default procedures codified at 31 CFR part 205 and TFM 4A-2000 Overall Disbursing Rules for All Federal Agencies.

(2) To the extent that Treasury-State CMIA agreements and default procedures do not address expenditure of program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds, such funds must be expended before requesting additional cash payments.

* * * * *

5. Revise § 75.365 to read as follows:

§ 75.365 Restrictions on public access to records.

Consistent with § 75.322, HHS awarding agencies may require recipients to permit public access to manuscripts, publications, and data produced under an award. However, no HHS awarding agency may place restrictions on the non-Federal entity that limits public access to the records of the non-Federal entity pertinent to a Federal award identified in

§§ 75.361 through 75.364, except for protected personally identifiable information (PII) or when the HHS awarding agency can demonstrate that such records will be kept confidential and would have been exempted from disclosure pursuant to the Freedom of Information Act (5 U.S.C. § 552) (FOIA) or controlled unclassified information pursuant to Executive Order 13556 if the records had belonged to the HHS awarding agency. The FOIA does not apply to those records that remain under a non-Federal entity's control except as required under § 75.322. Unless required by Federal, State, local, or tribal statute, non-Federal entities are not required to permit public access to their records identified in §§ 75.361 through 75.364. The non-Federal entity's records provided to a Federal agency generally will be subject to FOIA and applicable exemptions.

6. In § 75.414, add paragraphs (c)(1)(i) through (iii) and revise the first sentence of paragraph (f) to read as follows:

§ 75.414 Indirect (F&A) costs.

* * * * *

(c) * * *

(1) * * *

(i) Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000;

(ii) Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC

exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000; and,

(iii) Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

* * * * *

(f) In addition to the procedures outlined in the appendices in paragraph (e) of this section, any non-Federal entity that has never received a negotiated indirect cost rate, except for those non-Federal entities described in paragraphs (c)(1)(i) and (ii) and section (D)(1)(b) of appendix VII to this part, may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. * * *

* * * * *

7. Add § 75.477 to read as follows:

§ 75.477 Payments for failure to offer health coverage to employees.

Any payments or assessments imposed on an employer pursuant to 26 U.S.C. § 4980H as a result of the employer's failure to offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan are not allowable expenses under Federal awards from an HHS awarding agency.

Dated: _____

_____

Alex M. Azar II,

Secretary,

Department of Health and Human Services.