IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	Case No. 1:20-cv-01630-JEB
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	)	
Defendants.	)	

MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION OR A STAY PENDING JUDICIAL REVIEW PURSUANT TO 5 U.S.C. § 705

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INTRODUCTION

On June 19, 2020, the Department of Health and Human Services (HHS) published a rule designed to enforce nondiscrimination provisions in healthcare and to remove regulatory burdens (the "2020 Rule," "Final Rule," or "Rule"). The Rule hews closely to the underlying text of Section 1557 of the Affordable Care Act ("ACA"), which incorporates protections from other statutes, namely, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments Act of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973. In 2016, a prior iteration of the Rule (the "2016 Rule") had attempted to impose a number of requirements not compelled by the ACA. The 2016 Rule was then vacated in part in late 2016—which included eliminating "gender identity" from its definition of "on the basis of sex"—after a court determined that HHS had exceeded its authority in issuing it.

Plaintiffs bring this suit in an attempt to invalidate the 2020 Rule, arguing that HHS should have included additional provisions, including what was vacated from the 2016 Rule. But plaintiffs, which consist mostly of medical professionals and organizations purporting to represent others, cannot explain how the 2020 Rule injures them—or even how any alleged harm would be caused by the government rather than third parties. Because plaintiffs' allegations do not establish standing, this Court need not reach the merits of their challenge.

But even if this Court had jurisdiction to entertain plaintiffs' claims, plaintiffs fail to establish a likelihood of success on the merits—a necessary showing to support the extraordinary remedy they demand. Because the 2020 Rule tracks the text of Section 1557 with respect to the provisions at issue in this case, plaintiffs cannot show that it is legally invalid. Nor can plaintiffs demonstrate that HHS acted arbitrarily and capriciously in issuing the Rule, given the thorough reasoning the Agency provided to support its decision. That plaintiffs have a number of policy disagreements with the 2020 Rule is insufficient to support a claim under the Administrative Procedure Act.

Plaintiffs' constitutional claims fare no better. Plaintiffs identify no action that might support an equal-protection or due-process claim. Nor can plaintiffs show that the 2020 Rule

violates the Free Speech Clause of the First Amendment, as the Rule neither mandates nor restricts speech. And plaintiffs' Establishment Clause claim lacks any support in precedent whatsoever.

Even if plaintiffs could show that their claims are likely to succeed on the merits, they would still be precluded from receiving a preliminary injunction. That is because the irreparable injury plaintiffs allege is both speculative and amorphous, and it depends entirely on the potential conduct of unnamed third parties not before this Court. Furthermore, plaintiffs cannot justify ignoring the impact an injunction would have on the general public, which would be deprived of the clarity and protection the 2020 Rule provides. If the court were to determine an injunction is warranted, the Rule's severability clause and the plaintiffs' sparse showing of injury demonstrate that nearly all of the Rule's text should be allowed to proceed, and with no nationwide injunction.

Plaintiffs have failed to satisfy the exceedingly high threshold that they must meet to enjoin agency action. Their request for a preliminary injunction should be denied.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

This case arises from HHS's efforts to implement Section 1557 of the Affordable Care Act. Section 1557 applies long-standing anti-discrimination principles to health programs or activities by incorporating four federal anti-discrimination laws into the ACA: Title VI, Title IX, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act. Specifically, Section 1557 directs that

> [e]xcept as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section [504 of the Rehabilitation Act of 1973 (29 U.S.C. 794)], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA] (or amendments). The

> enforcement mechanisms provided for and available under such title VI, title IX, section [504], or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a). Section 1557 states that the Secretary of HHS "may" (but not that he or she must) issue implementing regulations. § 18116(c). As relevant here, Title IX in turn provides that "[n]o person . . . shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681(a). Title IX states that it does not prohibit discrimination by religious organizations, § 1681(a)(3), and that nothing in it "shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion," § 1688.

A. HHS's 2016 Rule

Acting under its statutory authority to "promulgate regulations to implement" Section 1557, 42 U.S.C. § 18116(c), HHS issued a rule in May 2016, codified at 45 C.F.R. Part 92 ("the 2016 Rule"). *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016). As relevant here:

i. The 2016 Rule prohibited discrimination on the basis of sex, and explicitly defined "[o]n the basis of sex" to include "discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity." *Id*. at 31,467. The 2016 Rule further defined "gender identity" to include "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female…." *Id.* The 2016 Rule listed several specific examples of prohibited discrimination. *See, e.g.*, *id*. at 31,471 (codified at 45 C.F.R. § 92.207). HHS had

decided, for example, that covered entities violate Section 1557 if they "deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual." *Id*. (codified at 45 C.F.R. § 92.207(b)(5)). In addition to delineating some examples of what violated Section 1557, the 2016 Rule included a catchall provision providing that "[t]he enumeration of specific forms of discrimination . . . does not limit the general applicability of the prohibition" against covered discrimination. *Id.* at 31,472 (codified at 45 C.F.R. § 92.207(c)).

ii. The 2016 Rule promulgated Section 1557-specific enforcement mechanisms that blended new standards and preexisting standards from underlying civil-rights regulations, and imposed those standards alongside the underlying civil-rights regulations, which were left in place. *Id*. (codified at 45 C.F.R. § 92.301).

iii. The 2016 Rule defined covered entity to include "(1) [a]n entity that operates a health program or activity, any part of which receives Federal financial assistance; (2) [a]n entity established under Title I of the ACA that administers a health program or activity; and (3) [HHS]." *Id*. at 31,466 (codified at 45 C.F.R. § 92.4).

iv. The 2016 Rule included several notice requirements, including specific mandates for how covered entities must communicate with consumers and the public. *Id*. at 31,469 (codified at 45 C.F.R. § 92.8). For example, the 2016 rule required "taglines," in two or fifteen different languages, on all of a covered entity's "significant publications and significant communications," notifying individuals of their right to free language assistance. *Id.*

v. Even though Section 1557 incorporates Title IX, HHS declined "to incorporate Title IX's blanket religious exemption into [the 2016 R]ule." *Id*. at 31,380. The 2016 Rule provided

that "[i]nsofar as the application of any requirement under this part would violate applicable Federal and statutory protections for religious freedom and conscience, such application shall not be required." *Id.* at 31,466 (codified at 45 C.F.R. § 92.2(b)).

B. Development of the Challenged Rule

In December 2016, the United States District Court for the Northern District of Texas preliminarily enjoined enforcement of parts of the 2016 Rule on a nationwide basis, *Franciscan Alliance Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016). In May 2017, HHS moved to voluntarily remand that rule so that HHS could "assess the reasonableness, necessity, and efficacy" of the enjoined provisions, *Franciscan Alliance v. Price*, No. 7:16-cv-00108, ECF No. 92 (N.D. Tex. May 2, 2017), and in October 2019, the court vacated the rule's definition of "on the basis of sex" insofar as the definition included "gender identity" and "termination of pregnancy," *Franciscan*, 414 F. Supp. 3d 928, 947 (N.D. Tex. 2019), *Franciscan Alliance v. Azar*, No. 7:16–cv–00108, ECF No. 182 (N.D. Tex. Nov. 21, 2019). In June 2019, HHS published a Proposed Rule, which sought "to make substantial revisions to the Section 1557 Regulation and to eliminate provisions that are inconsistent or redundant with pre-existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability." 84 Fed. Reg. 27,846, 27,848–49 (June 14, 2019). In so doing, the agency also proposed retaining significant aspects of the 2016 Rule. *Id.* at 23,849. The Proposed Rule would "empower [HHS] to continue its robust enforcement of civil rights laws prohibiting discrimination on the basis of race, color, national origin, sex, age, or disability in [HHS]-funded health programs or activities, and would make it clear that such civil rights laws remain in full force and effect." *Id.*

C. The 2020 Rule

HHS received nearly 200,000 comments on the Proposed Rule. After carefully evaluating the extensive record, HHS published the Final Rule on June 19, 2020. 85 Fed Reg. 37,160, 37,160. Consistent with the Proposed Rule, the Final Rule makes several revisions to the Section 1557 regulations, ensuring robust protection of civil rights under the statute:

i. Rather than adopt new definitions for existing civil rights statutes, the 2020 Rule follows the approach of Section 1557 itself by simply incorporating those underlying statutes and regulations in large part. It thus "repeals the 2016 Rule's definition of 'on the basis of sex,' [and] declines to replace it with a new regulatory definition." *Id*. at 37,178. It also eliminates the gender identity provisions from the 2016 Rule, acknowledging that the decision in *Franciscan Alliance* foreclosed their inclusion. *See, e.g.*, *id.* at 37,164–65. HHS further explained, in the rule's preamble but not the regulatory text, that, while "the 2016 Rule required covered entities to 'treat individuals consistent with their gender identity' in virtually every respect," *id*. at 37,189, "certain single-sex medical procedures, treatments, or specializations are rooted" in a patient's biological sex, *id*. at 37,187, and "reasonable distinctions on the basis of sex" may sometimes be permissible "in the field of health services," *Id*. Accordingly, HHS "repeal[ed] a mandate that was, at least, ambiguous and confusing." *Id*.

HHS made clear, however, that regardless of its views, the inclusion of "gender identity" in the definition of "on the basis of sex" had already been vacated from the 2016 Rule, and that the Final Rule did nothing more than ensure that the Section 1557 regulations "conform to the plain meaning of the underlying civil rights statutes." *Id*. at 37,161; *see id*. at 37,180. Because the 2020 Rule merely replaces the 2016 Rule's explicit definition of "on the basis of sex" by hewing to the text of Section 1557, "to the extent that a Supreme Court decision is applicable in interpreting

the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court's construction." *Id*. at 37,168.

ii. The Final Rule "applies the enforcement mechanisms provided for, and available under" the statutes incorporated by reference into Section 1557 as relevant to this lawsuit, "with their respective implementing regulations." *Id*. at 37,202; *id*. at 37,245 (codified at 45 C.F.R. § 92.5). Such an approach "minimizes the patchwork effect of the 2016 Rule by using a familiar regulatory regime under those four statutes" and represents "what the statutory text contemplates." *Id*. at 37,202.

iii. The 2020 Rule "modifies the 2016 Rule's definition of entities covered by Section 1557," *id*. at 37,162, which will now extend to "(1) [a]ny health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by [HHS]; (2) any program or activity administered by [HHS] under Title I of the ACA; or (3) any program or activity administered by any entity established under such Title." *Id*. at 37,169, 37,244 (codified at § 92.3(a)). HHS changed this definition "in order to align it more closely with the statutory text." *Id*. at 37,162; *see also id.* at 37,169–71 (explaining text-based reasons for modifying the scope of applicability).

iv. The 2020 Rule repeals 45 C.F.R. § 92.8(d) of the 2016 Rule, "eliminat[ing] the burdensome requirement for covered entities to send notices and taglines with all significant communications," *id*. at 37,162, while maintaining longstanding requirements that "covered entities provide a notice of nondiscrimination," *id*. at 37,175–76. In so doing, the 2020 Rule removes the 2016 Rule's "unduly broad, sometimes confusing, and inefficient requirement that all significant communications contain taglines" and replaces it with a flexible standard "requir[ing] covered entities to provide taglines whenever such taglines are necessary to ensure meaningful

access by LEP individuals of a covered program or activity." *Id.* at 37,176. HHS made this change because of the "significant unanticipated expenses" associated with the 2016 Rule, which HHS determined was unnecessary to "ensure meaningful access by persons with LEP." *Id.*; *see also id.* (2016 Rule's "financial burden on covered entities was not justified by the protections or benefits it provided to LEP individuals").

v. The Final Rule states that the application of Section 1557's requirements "shall not be imposed or required" if doing so would conflict with certain statutes, including, as relevant here, certain laws protecting conscience and religious liberty. *Id.* at 37,246 (to be codified at 45 C.F.R. § 92.6(b)). The Rule preamble states that this change "emphasizes that the Section 1557 regulation will be implemented consistent with . . . conscience and religious freedom statutes." *Id.* 37,205. Although HHS is "always obligated to comply with relevant Federal statutes," HHS determined it appropriate to clarify this point in light of the reasons that the 2016 Rule was subject to litigation and injunctive relief. *See id.* The Final Rule also incorporates Title IX's religious exemption, and its abortion neutrality language, because by incorporating Title IX into Section 1557, "Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions" of Title IX. *Id.* at 37,193 (quoting *Franciscan Alliance*, 227 F. Supp. 3d at 690–91); *see also id.* at 37,207–08.

ARGUMENT

I. PLAINTIFFS LACK STANDING

Because "[s]tanding is not dispensed in gross," *Davis v. FEC*, 554 U.S. 724, 734 (2008) (quoting *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996)), plaintiffs "must demonstrate standing for each claim [they] seek[] to press" and for "each form of relief sought," *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). Plaintiffs, who fail to identify any "injury in fact" that is "fairly . . . trace[able]" to the 2020 Rule and that will "be redressed by a favorable decision," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992), lack standing to advance any of their claims.

A. Plaintiffs Cannot Show that the Government Caused their Alleged Injuries or that a Decision by this Court Will Redress Them.

A crucial element of standing is establishing a connection between the defendant, the conduct alleged, and the remedy sought. Specifically, a plaintiff must show that the defendant's conduct—rather than that of a third party—caused its injuries, and that a decision in the plaintiff's favor will redress those injuries. *See id.* Plaintiffs can do neither here.

First, plaintiffs cannot show that any remedy this Court orders is likely to redress the harm complained of. *See Lujan*, 504 U.S. at 561; *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976). Plaintiffs argue that HHS should have included additional language in the 2020 Rule that might dissuade healthcare providers from discriminating against the individuals plaintiffs purport to represent, *see* Pls.' Mem. ("Mot.") at 9, ECF No. 29-1, but there is no available remedy for achieving that end because the gender identity and termination of pregnancy provisions were vacated from the 2016 Rule by another court before this Rule was finalized, and the 2016 Rule itself omitted sexual orientation as a prohibited discrimination category. Enjoining the challenged 2020 Rule would leave plaintiffs with the non-vacated portions of the 2016 Rule and Section 1557 itself, neither of which contains the definition of sex plaintiffs prefer. *See, e.g.*, Salecedo Decl. ¶ 23 (the 2016 Final Rule did not "provide complete assurance that my fears [of discrimination] will not be realized.").

Second, plaintiffs cannot demonstrate that the 2020 Rule caused their alleged injuries. To establish standing, "there must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'" *Id.* at 560 (quoting *Simon*, 426 U.S. at 41–42). In *Simon v. E. Kentucky Welfare Rights Organization*, for example, the Supreme Court held that advocacy organizations lacked standing to challenge an IRS regulation they believed would induce hospitals to deny services because "injury at the hands of a hospital is insufficient by itself to establish a case or controversy [where] no hospital is a defendant." *See* 426 U.S. at 41; *see also Branton v. FCC*, 993 F.2d 906, 910–11

(D.C. Cir. 1993) ("The Supreme Court is particularly disinclined to find that the causation and redressability requirements are satisfied where a complainant challenges only an Executive Branch decision not to impose costs or penalties upon some third party.").

Just like in *Simon*, plaintiffs here do not allege that the government will injure them by refusing to provide medical services. Instead, plaintiffs claim that the various components of the 2020 Rule may lead healthcare providers to deny services to certain patients. *See, e.g.*, Compl. ¶ 193, ECF No. 1 ("The Revised Rule sends the message that discrimination on the basis of gender identity and sex stereotyping is permissible under federal law, which will increase the number of LGBTQ people who will be denied care."). To the extent this Rule could be said not to prohibit behavior plaintiffs fear, their dispute would be with healthcare providers who engage in those practices—not with the government. *See Weaver's Cove Energy, LLC v. R.I. Dep't of Envtl. Mgmt.*, 524 F.3d 1330, 1333 (D.C. Cir. 2008) ("A's injuring B does not create a case or controversy between B and C." (citing *Linda R.S. v. Richard D.*, 410 U.S. 614, 618 (1973)).

Third, even if this Court could order the agency to rewrite the 2020 Rule according to plaintiffs' specifications, such a result would not redress plaintiffs' alleged harm. In *Simon*, plaintiffs attempted to make the very same argument that plaintiffs make here—that a particular federal policy might encourage individuals to engage in allegedly objectionable conduct. *Compare Simon*, 426 U.S. at 42 ("The complaint here alleged only that petitioners, by the adoption of Revenue Ruling 69-545, had 'encouraged' hospitals to deny services to indigents."), *with* Compl. ¶ 271 ("Defendants' encouragement of discrimination against LGBTQ people deprives LGBTQ people of their right to equal dignity and stigmatizes them as second-class citizens."). As in *Simon*, a favorable judgment here would not ensure that these third-party providers would cease engaging in the conduct plaintiffs dislike. Moreover, it is possible that some providers could choose to avoid Section 1557 altogether by refusing to accept federal funds. *See* 42 U.S.C. 18116(a) (applying restrictions to "any health program or activity, any part of which is receiving Federal financial assistance"). While foregoing federal funds may not be an attractive option to many, doing so would be far from unprecedented—in other contexts organizations have chosen to do precisely

that so as to avoid federal regulation.[1]

Simply put, speculation that a yet-to-be-identified private provider may deny service to a patient at some point in the future is insufficient to establish standing vis-à-vis the government. Because "[e]ach of the inferential steps to show causation and redressability depends on premises as to which there remains considerable doubt," *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 138 (2011), there is no standing to support plaintiffs' challenge.

Finally, plaintiffs offer no basis to show they are harmed by any other provision of the Rule so as to justify an injunction—such as by the removal of the mandate for notices and taglines from significant healthcare communications. Plaintiffs have the burden to show harm from *each* of the provisions of the 2020 Rule they seek to enjoin, *see DaimlerChrysler*, 547 U.S. at 352, but they have barely attempted to do so for those provisions. Instead they focus most of their arguments on the gender identity—which was vacated from the 2016 Rule before this Rule was finalized.

B. Plaintiffs' Alleged Harm is Conjectural.

Even if plaintiffs could establish sufficient causation between their alleged injuries and the government's conduct, plaintiffs cannot show that they are likely to suffer actual harm. *See Lujan*, 504 U.S. at 560–61. Plaintiffs complain that the 2020 Rule fails to endorse their preferred definition of "on the basis of sex," fails to prohibit categorical coverage exclusions, eliminates language-access requirements, restricts what entities are covered by the Rule, and includes various religious exemptions. *See* Mot. at 12–28. Although plaintiffs contend that these changes "revers[e] protections against discrimination of historically marginalized communities and eliminat[e] access to language provisions," Compl. ¶ 248, they fail to show how injury would result.

The majority of plaintiffs consist of medical professionals and organizations purporting to represent them. These entities either target their services to patients in the LGBTQ community or generally oppose the harm they allege will occur. *See id.* ¶¶ 8–17. Plaintiffs cannot explain how

[1] For example, Hillsdale College, "[t]o maintain [its] institutional independence, . . . accept[s] no state or federal funding—even indirectly in the form of student grants or loans." Hillsdale College, "Scholarships & Financial Aid" https://www.hillsdale.edu/admissions-aid/financial-aid/.

the 2020 Rule might injure them as opposed to others not before the Court. The Rule imposes no new requirements on plaintiff organizations; instead, as plaintiffs acknowledge, the 2020 Rule *eliminates* requirements. (For example, "[t]he Revised Rule . . . eliminates the requirement that covered entities post notices informing individuals about nondiscrimination requirements and their rights . . . ." Compl. ¶ 20.) But plaintiff organizations remain free to voluntarily provide the notices required by the 2016 Rule. Because these organizations cannot explain how they will suffer from any injury alleged, they lack standing to challenge the 2020 Rule's failure to impose obligations that plaintiffs desire. *See DaimlerChrysler*, 547 U.S. at 352.

Moreover, each of the plaintiffs lacks standing to challenge any aspect of the 2020 Rule for the separate reason that the harm plaintiffs allege is conjectural. The mere threat of potential future harm is insufficient to establish standing; instead, plaintiffs must identify an injury that is "certainly impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 401 (2013) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). Plaintiffs come nowhere close to satisfying that standard. Instead, plaintiffs claim to fear actions third parties *may* take as a result of the Rule. Specifically, plaintiffs argue that some medical providers may choose to deny individuals certain procedures or coverage; that is to say, the 2020 Rule, according to plaintiffs, may increase the "*risk* of discrimination in health care." Mot. at 9 (emphasis added). But such an outcome is far from inevitable. It is no wonder, then, that plaintiffs cannot identify which providers are likely to engage in such discrimination, or which plaintiffs may be harmed as a result—the injury alleged is wholly speculative and therefore insufficient to support Article III standing. *See Lujan*, 504 U.S. at 560.

C. Plaintiff Organizations Lack Standing to Advance Their Claims.

Plaintiffs are either organizations representing medical professionals, organizations purporting to represent members of the LGBTQ community, or individual healthcare providers. None of these entities has established that it is in a position to represent *patients* who, according to plaintiffs, may be harmed by the 2020 Rule.

Third-Party Standing. Neither the plaintiff organizations that claim to represent medical professionals nor the medical professionals themselves, *see* Compl. ¶ 32, have standing to

represent patients. Generally, "a litigant must assert his or her own legal rights and interests, and cannot rest a claim to relief on the legal rights or interests of third parties." *Powers v. Ohio*, 499 U.S. 400, 410 (1991). Otherwise, "the courts might be called upon to decide abstract questions of wide public significance even though other governmental institutions may be more competent to address the questions and even though judicial intervention may be unnecessary to protect individual rights." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (internal quotation omitted). Although the Supreme Court has "not looked favorably upon third-party standing," *id.* at 130, "certain, limited exceptions" apply, *Powers*, 499 U.S. at 410.

To bring claims on behalf of third parties, plaintiffs must satisfy "three important criteria." *Powers*, 499 U.S. at 411. First, plaintiff healthcare providers "must have suffered an injury in fact, thus giving [them] a sufficiently concrete interest in the outcome of the issue in dispute." *Id.* (quotations omitted). Second, they "must have a close relation to the third party." *Id.* And third, "there must exist some hindrance to the third party's ability to protect his or her own interests." *Id.* None of these criteria is met here.

First, as discussed, plaintiff healthcare providers cannot demonstrate cognizable because they fail to establish a causal connection between the 2020 Rule and any government conduct injuring them, fail to show that any injury would be redressable, and fail to explain how their alleged injury is anything other than speculative. Second, plaintiff medical providers have not established a close relationship with the alleged third-party patients. While plaintiffs allege that the 2020 Rule will lead to injuries against some patients, that rule will not harm *their* patients because nothing in the Rule requires plaintiff medical providers to change any of their behavior. Third, to the extent any patients would have the desire and standing to sue defendants, plaintiff healthcare providers have not shown any hindrance to the ability of patients to assert their own claims. Indeed, a recent challenge to the Rule in the Eastern District of New York demonstrates that patients are capable of filing challenges to the 2020 Rule. *See Walker v. Azar*, 1:20-cv-02834. Plaintiff healthcare providers thus fail to show how they can assert claims on behalf of their patients.

Associational Standing. "The LGBTQ-services plaintiffs," Compl. ¶ 33, also cannot advance claims on behalf of patients. Membership organizations may assert standing on behalf of their members, but in order to do so they must show that at least one member "would otherwise have standing to sue in [his or her] own right." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343–44 (1977); *see Summers v. Earth Island Inst.*, 555 U.S. 488, 494–96 (2009). Associational standing doctrine thus requires that petitioners "*identify* members who have suffered the requisite harm." *Id.* at 499 (emphasis added); *see Am. Chemistry Council v. Dep't of Transp.*, 468 F.3d 810, 815, 820 (D.C. Cir. 2006) (holding that "an organization bringing a claim based on associational standing must show that at least one specifically-identified member has suffered an injury-in-fact"). Plaintiffs fail to do so here.

While plaintiffs submit fifteen declarations in support of their motion for a preliminary injunction, none is from an individual member claiming to be a potential patient who might be negatively impacted by the 2020 Rule. Nor does plaintiffs' complaint or preliminary injunction motion name such a patient. Instead, plaintiffs rely on broad claims about harm to unnamed patients. But "it is not enough to aver that unidentified members have been injured." *Chamber of Com. of U.S. v. EPA*, 642 F.3d 192, 199 (D.C. Cir. 2011). Instead, plaintiffs must "make *specific* allegations establishing that at least one *identified* member had suffered or would suffer harm." *Summers*, 555 U.S. at 498 (emphases added); *see FW/PBS, Inc. v. City of Dall.*, 493 U.S. 215, 235 (1990) (ruling that affidavit which "fails to identify the individuals" who allegedly were injured "falls short of establishing" standing). The LGBTQ-services plaintiffs fail to do so here.

II. PLAINTIFFS HAVE NOT DEMONSTRATED A LIKELIHOOD OF SUCCESS ON THE MERITS OF THEIR CLAIM THAT THE 2020 RULE VIOLATES THE APA

To receive the extraordinary remedy of a preliminary injunction, a party must first show that it is likely to succeed on the merits. *See Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011). Here, that means demonstrating that the 2020 Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "'The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment

for that of the agency.'" *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1036 (D.C. Cir. 2012) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Plaintiffs come nowhere close to satisfying this "highly deferential standard"—or establishing any other violation of the APA. *Zevallos v. Obama*, 793 F.3d 106, 112 (D.C. Cir. 2015) (citation omitted).

A. HHS's Decision Not to Define "On the Basis of Sex" Is Lawful.

The 2020 Rule contains a straightforward application of Title IX's prohibition against discriminating "on the basis of sex." 20 U.S.C. § 1681. HHS had reasonable justifications for the language it chose, which the Agency explained when it promulgated the Rule. Plaintiffs' argument that the 2020 Rule somehow runs afoul of Section 1557 under the APA is meritless.

In drafting the 2020 Rule's prohibition on sex discrimination, HHS chose to follow the statutory text. Section 1557 does not use the term "sex," but instead incorporates the prohibition contained in Title IX, which in turn provides: "No person in the United States shall, on the basis of sex, . . . be subjected to discrimination under any education program or activity receiving Federal financial assistance . . . ." 20 U.S.C. § 1681. By declining to include a definition of "on the basis of sex" in the 2020 Rule, the Rule "relies upon . . . the plain meaning of the term in the statute." 85 Fed. Reg. at 37,178.

Plaintiffs, unable to argue that a regulation which simply references the underlying statute is unlawful, instead argue that in failing to include a definition for "on the basis of sex," the 2020 Rule runs afoul of *Bostock v. Clayton County, Georgia*, 140 S. Ct. 1731 (2020). Specifically, plaintiffs contend that "[t]he Revised Rule . . . is not in accordance with law because it conflicts with the Supreme Court's ruling in *Bostock* that discrimination on the basis of a person's transgender status or sexual orientation is discrimination on the basis of sex." Mot. at 28. But plaintiffs provide no explanation as to why the 2020 Rule's lack of reference to "gender identity" and "sexual orientation" might render the regulation unlawful. The language of Title VII at issue in *Bostock* itself does not include those terms. Plaintiffs cite no authority that would require a regulation to expand upon statutory text. Indeed, HHS could have foregone issuing any rule at all

and instead simply relied on the text of Section 1557. *See* 42 U.S.C. § 18116(c) ("The Secretary *may* promulgate regulations to implement this section." (emphasis added)).

Because plaintiffs cannot identify anything impermissible in the 2020 Rule relating to "on the basis of sex," they instead take issue with language in the Rule's preamble, not its regulatory text. For example, plaintiffs claim that the 2020 Rule impermissibly "attempt[s] to deny the full protection of Section 1557 to LGBTQ individuals and patients in health care settings." Mot. at 28 (citing 85 Fed. Reg. at 37,218–22). But this Court's focus must remain on the text of the Rule itself, as a regulation's preamble "lacks the force and effect of law." *St. Francis Med. Ctr. v. Azar*, 894 F.3d 290, 297 (D.C. Cir. 2018); *see Wyeth v. Levine*, 555 U.S. 555, 575–77 (2009); *Nat. Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009). While a Rule's preamble may help determine whether an Agency's decision to adopt a particular approach was supported by adequate reasoning, it cannot render deficient otherwise legally permissible language contained in a regulation. In addition to arguing that the 2020 Rule is unlawful, plaintiffs claim that HHS's decision to issue the Rule was arbitrary and capricious. *See* Mot. at 14–16. Plaintiffs' argument fails because HHS's decision to issue the rule was supported by "reasoned decisionmaking." *Ctr. for Biological Diversity v. Blank*, 933 F. Supp. 2d 125, 150 (D.D.C. 2013); *see FCC v. Fox Televiision Stations, Inc.*, 556 U.S. 502, 513–16 (2009).

Plaintiffs first criticize HHS for relying, in part, on a decision from the Northern District of Texas as justification for not including a definition for "on the basis of sex." *See* Mot. at 14. What plaintiffs fail to acknowledge is that the decision they reference—*Franciscan Alliance*—vacated the language contained in the previous rule that plaintiffs now advocate for. *See* 414 F. Supp. 3d at 947. It was therefore entirely reasonable for HHS to justify not including an expanded definition of "on the basis of sex" when that portion of the 2016 Rule was no longer legally enforceable; indeed, *Franciscan Alliance* compelled HHS to follow such a course. As the Agency explained, "[t]his final ruling is binding on the Department despite the appellate proceedings still pending in that case: The Department's Section 1557 regulation, as currently operative, does not contain the 2016 Rule's definition of 'on the basis of sex' to encompass gender identity and

termination of pregnancy." 85 Fed. Reg. at 37,168. *Franciscan Alliance*'s prohibition on including plaintiffs' desired definition of "on the basis of sex" was therefore reason enough for HHS to release the 2020 Rule in its current form. *See Fox*, 556 U.S. at 513–16.

Plaintiffs next complain that it was arbitrary and capricious for HHS to move forward with the Rule knowing that a decision from the Supreme Court in *Bostock* was imminent, and that, "[i]n light of the Supreme Court's ruling in *Bostock*, HHS could have postponed publication of the Revised Rule." Mot. at 15. Plaintiffs fail to show that HHS's decision to move forward with the Rule was arbitrary and capricious. Notably, *Bostock* was a case about Title VII, not Title IX, and *Bostock*'s holding was limited to Title VII. So however the courts ultimately apply *Bostock*'s reasoning to Title IX and Section 1557, HHS acted reasonably in finalizing its rule without waiting for a decision that concerned a separate statute. Moreover, the Rule's preamble makes clear, the wording of the Rule would not conflict with whatever decision the Court reached: "Moreover, to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court's construction," *id*. at 37,168. Because, as HHS recognized, the Rule's language may be interpreted in conformity with *Bostock*, it was neither arbitrary nor capricious for HHS to decide against including a definition for "on the basis of sex" throughout the regulations amended by the Agency.

Moreover, plaintiffs' insistence that "*Bostock* conclusively rejects HHS's position" as outlined in the preamble regarding the proper extent of discrimination "on the basis of sex," Mot. at 14, is unfounded. Because the 2020 Rule has yet to be applied, it remains to be seen precisely how *Bostock*—which construed a provision of Title VII of the Civil Rights Act of 1964 in the employment context, 140 S. Ct. at 1737—might affect Section 1557, which applies Title IX's language as a funding provision in the context of healthcare. As HHS noted, while "Title VII case law has often informed Title IX case law with respect to the meaning of discrimination 'on the basis of sex,'" the definition of "sex" may "take[] on special importance in the health context." 85 Fed. Reg. at 37,168. The point is that *Bostock*'s applicability to contexts outside of employment

discrimination is a question for future courts to decide, as *Bostock* itself made clear. *See* 140 S. Ct. at 1753. It was neither arbitrary nor capricious for HHS to refrain from drafting a rule that attempted to predict prematurely what future precedent might dictate.

Plaintiffs' remaining arguments that HHS's decision not to include a definition of "on the basis of sex" was arbitrary and capricious fare no better. Plaintiffs claim that HHS improperly "ignored the considered views of other agencies and dozens of federal district and appellate courts, which held that discrimination on the basis of transgender status is a form of sex discrimination." Mot. at 15. But the position of federal agencies and courts alike was (and is) far from uniform. For example, as noted, a district court decision construing the 2016 Rule held the opposite. *See Franciscan Alliance*, 414 F. Supp. 3d at 947. HHS's acknowledgement that differing views existed and explanation of its rationale for hewing to the statutory text in adopting the 2020 Rule was more than sufficient to support its decision under "the deferential *State Farm* standard of review when reviewing arguments based on allegedly arbitrary or unreasoned agency action." *Americans for Clean Energy v. EPA*, 864 F.3d 691, 726 (D.C. Cir. 2017) (citing *State Farm*, 463 U.S. at 43). And in addition to providing an explanation for its decision, HHS acknowledged that its position had changed. *See* 85 Fed. Reg. at 37,161–62. Contrary to plaintiffs' assertion, *Fox* did not require HHS to provide anything more. *See* 556 U.S. at 514 ("We find no basis in the Administrative Procedure Act or in our opinions for a requirement that all agency change be subjected to more searching review."); *Ark Initiative v. Tidwell*, 816 F.3d 119, 127 (D.C. Cir. 2016) ("no specially demanding burden of justification ordinarily applies to a mere policy change").

Plaintiffs criticize HHS's statement that it "knows of no data showing that the proper enforcement of Federal nondiscrimination law according to statutory text will disproportionately burden individuals on the basis of sexual orientation and/or gender identity," 85 Fed. Reg. at 37,182; *see* Mot. at 23, and complain that HHS "did not take into account the costs or harms to transgender patients," *id.* Once again, as HHS made clear, the "change" plaintiffs now complain of was nonexistent: the prior rule was legally unenforceable and, in any event, did not include language applying Section 1557's coverage to sexual orientation per se. *See* 85 Fed. Reg. at

37,182. As HHS explained in the preamble, "[b]ecause the 2016 Rule explicitly declined to make sexual orientation a protected category, and because the Rule's gender identity provision has been legally inoperative since December 31, 2016, to the extent that LGBT individuals suffer future harms, it cannot be attributed to the Department's finalizing this rule, as opposed to other causes." *Id.* Such a position was entirely reasonable. And, as HHS further noted, covered entities will likely implement policies to comply with applicable law, which often includes state antidiscrimination laws, *id.* at 37,225. Neither Section 1557 nor the APA requires more.[2]

B. Section 1557 Did Not Authorize HHS to Promulgate Prohibitions on Categorical Coverage Exclusions.

Plaintiffs criticize the 2020 Rule for failing to include a provision preventing covered entities from prohibiting certain gender transition procedures and services. *See* Mot. at 16–18. Because Section 1557 does not require such a provision, and because HHS justified its decision not to include it, plaintiffs' argument fails.

Although HHS's 2016 Rule included a provision prohibiting covered entities from "[h]av[ing] or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition," 45 C.F.R. § 92.207(b)(4), that mandate was not required by Section 1557. As HHS explained in issuing the 2020 Rule, "[t]here is no statutory authority to require the provision or coverage of such procedures under Title IX protections from discrimination on the basis of sex." 85 Fed. Reg. at 37,198. Plaintiffs make no argument to the contrary, and HHS's determination was, at the very least, a reasonable one entitled to deference. *See Chevron, U.S.A., Inc. v. Nat. Resources Def. Council, Inc.*, 467 U.S. 837, 844 (1984).

Instead of arguing that Section 1557 compels the inclusion of a prohibition on coverage exclusions, plaintiffs contend that HHS's decision not to include one was arbitrary and capricious.

[2] Plaintiffs also argue that HHS described "increased discrimination" resulting from the 2020 Rule as a "net cost savings." Mot. at 24; *see* 85 Fed. Reg. at 37,225. But HHS never stated that the Rule would lead to "increased discrimination." Instead, HHS took the position that certain conduct was not "discrimination" for purposes of Section 1557, 85 Fed. Reg. at 37,194 & n.201, with the caveat that the Rule may be interpreted in accordance with whatever *Bostock* and subsequent case law requires, *id.* at 37,168.

See Mot. at 16–18. That argument fails because HHS provided a reasoned explanation for its decision. HHS explained that "the 2016 Rule did not give sufficient evidence to justify, as a matter of policy, its prohibition on blanket exclusions of coverage for sex-reassignment procedures." 85 Fed. Reg. at 37,198. In concluding that coverage exclusions were "outdated and not based on current standards of care," 81 Fed. Reg. at 31,429, HHS in 2016 had attempted to shut down debate over the efficacy of treatments for gender dysphoria. The 2020 Rule, which returns coverage determinations on these issues to insurers, recognizes the lack of a scientific consensus on these important questions. *See* 85 Fed. Reg. at 37,187.

Plaintiffs take exception with a number of authorities referenced by HHS on the scientific debate. For example, plaintiffs attempt to downplay CMS's 2016 decision not to issue a "National Coverage Determination (NCD) on sex reassignment surgery for Medicare beneficiaries with gender dysphoria," 85 Fed. Reg. at 37,187 & n.157, arguing that such a decision does not indicate that transgender treatments are ineffective, *see* Mot. at 17. But HHS never claimed that was the case. Instead, HHS simply and accurately noted that CMS had concluded that ''there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.'' 85 Fed. Reg. at 37,187. That is to say, CMS concluded that the jury is still out. Plaintiffs do not refute this conclusion.

Plaintiffs criticize HHS's reference to a 2018 Department of Defense Report, which likewise concluded that there is "considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments . . . remedy the multifaceted mental health problems associated with gender dysphoria." *Id.* (quoting Dep't of Def., *Report and Recommendations on Military Service by Transgender Persons* (Feb. 22, 2018), https://perma.cc/7369-K2VC ("DoD Rep."). Plaintiffs claim that the report is unreliable because it was produced at the request of the President and based on "*military judgment*." Mot. at 17–18. But as the report itself makes clear, it relied on both the judgment of the military and the expert

advice of "military medical professionals, and civilian medical professionals with experience in the care and treatment of individuals with gender dysphoria." DoD Rep. at 18.

Plaintiffs criticize HHS's citation of a study finding that children who "socially transition in childhood faced dramatically increased likelihood of persistence of gender dysphoria into adolescence and adulthood." 85 Fed. Reg. at 37,187 (citing Thomas D. Steensma, "Factors Associated with Desistance and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study,'' 52(6) *Journal of the American Academy of Child & Adolescent Psychiatry* 582–90 (2013)). Plaintiffs reject HHS's characterization of the study, claiming that HHS implies "that 'coming out' about one's gender identity in childhood somehow makes things worse later in life." Mot. at 18. HHS has stated nothing of the sort, and plaintiffs avoid engaging with the finding of the study that HHS cited—that social transitioning is tied to the persistence of gender dysphoria. *See, e.g.*, Steensma, *supra* at 586–87 ("Boys who transitioned had significantly higher scores than those who had not transitioned"). In light of such a finding, it was not unreasonable for HHS to recognize that medical professionals may be cautious before encouraging children to socially transition, especially in light of the fact that 73–98% of children who experience gender dysphoria ultimately desist. *See id.* at 582.

In contrast to the evidence about medical disagreement that HHS identified, plaintiffs' primary authority in support of their position is an advocacy group, the "World Professional Association for Transgender Health" (WPATH). That organization has been the subject of criticism for potential conflicts of interest stemming from its financial backers and for publishing scientifically unsupported medical guidance. *See, e.g.*, Steven Swinford, "Gender Recognition Act Changes Halted After Child Fears," *The Times* (Feb. 22, 2020) https://www.thetimes.co.uk/edition/news/gender-recognition-act-changes-halted-after-child-fears-w6qbx0g7h (WPATH's guidelines "fell far below the benchmark for British healthcare guidelines used by" the National Institute for Health and Clinical Excellence). As HHS noted in issuing the 2020 Rule, the 2016 Rule had "relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding." 85 Fed. Reg. at 37,198; *see*

id. at 37,197 & n. 232 (collecting criticism of WPATH from clinicians).

Finally, plaintiffs' contention that HHS failed to consider reliance interests, *see* Mot. at 18, is simply wrong. As a preliminary matter, it would have been unreasonable for anyone to rely on a rule that had been gutted by a preliminary injunction (and ultimately a vacatur) shortly after its issuance. *See Franciscan Alliance*, 227 F. Supp. 3d at 696. HHS noted that commenters expressed their view that some individuals may have "placed their reliance" on the old rule, but explained that reliance by some could not be used to keep in place a regulation that "exceeded the Department's authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, imposed unjustified and unnecessary costs, and conflicted with applicable court decisions." 85 Fed. Reg. at 37,166. That reasoned consideration was sufficient to satisfy HHS's duty under the APA to "take account of legitimate reliance on prior interpretation." *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 742 (1996).

In issuing the 2020 Rule, HHS recognized that scientific debate over the efficacy of many treatments for gender dysphoria continues. In light of this, HHS decided not to "take a definitive view on any of the medical questions . . . about treatments for gender dysphoria." 85 Fed. Reg. at 37,188. That plaintiffs attempt to rebut some of the authorities cited in the Rule only confirms that the debate has not been resolved. Because the 2020 Rule represents a reasoned approach to a complex and controversial issue, it is not arbitrary and capricious. [3]

C. Plaintiffs Cannot Show that Any Language-Access Changes Violate the APA.

There are two additional regulatory changes that plaintiffs potentially challenge. Neither of plaintiffs' potential arguments has merit, and one is arguably waived.

The first regulatory change that Plaintiffs challenge is the repeal of the notice-and-tagline requirements the 2016 Rule created. These provisions applied to a covered entity's "significant publications and significant communications," a term that was not defined. 81 Fed. Reg. at 31,469

[3] HHS also explained that the 2016 Rule could be read to require medical professionals to engage in procedures beyond their expertise. *See* 85 Fed. Reg. at 37,187. Plaintiffs never explain why such a concern was illegitimate.

(45 C.F.R. § 92.8(f)(1)(i), (g)). Depending on the size of the publication or communication, the covered entity was required to include a notice that either listed seven different rights and procedures relating to nondiscrimination and language access or, for smaller communications and publications, contained a shorter nondiscrimination statement. 85 Fed. Reg. at 31,469 (45 C.F.R. § 92.8). And, again depending on the size of the publication or communication, the covered entity had to include in either fifteen or two languages a "tagline," which the 2016 Rule defined as "short statements written in non-English languages that indicate the availability of language assistance services free of charge." 85 Fed. Reg. at 31,468 (45 C.F.R. § 92.4). The 2019 NPRM proposed eliminating those notice and tagline requirements, walking through an analysis of the costs and benefits of the provisions and of eliminating them. 84 Fed. Reg. at 27,868, 27,878–83. The 2020 Rule finalized the elimination of these requirements, again walking through the costs and benefits in light of the comments the agency received. 85 Fed. Reg. at 37,227–34.

Plaintiffs cannot show that this repeal was arbitrary and capricious. As discussed earlier, to provide a reasoned explanation for a regulatory change, HHS need only "display awareness that it *is* changing position" and "show that there are good reasons for the new policy." *Fox*, 556 U.S. at 515 (emphasis in original). There is no dispute here that HHS acknowledged it was changing positions. *See, e.g.*, 84 Fed. Reg. at 27,868 ("The Department proposes to repeal *in toto* the Section 1557 provisions on taglines, the use of language access plans, and notices of nondiscrimination."). So, plaintiffs must show either that HHS lacked good reasons for the policy change or that the agency "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. "In evaluating whether the agency has met this standard, the court must 'not . . . substitute its [own] judgment for that of the agency.'" *Mayo v. Reynolds*, 875 F.3d 11, 19–20 (D.C. Cir. 2017) (quoting *State Farm*, 463 U.S. at 43) (alterations in original).

Plaintiffs fail to make out a claim under either standard. The Federal Register is replete with good reasons for HHS's regulatory changes. HHS determined that the 2016 Rule had dramatically underestimated—by more than $600 million per year—the recurring yearly costs imposed by the notice-and-tagline provisions. 84 Fed. Reg. at 27,857–58. And HHS explained that

the notice-and-tagline provisions were difficult to implement for entities already subject to similar requirements from the federal and state governments, the repetitive nature of the notices and taglines was causing their target audience to ignore them, there was little evidence that the notices and taglines were increasing the use of language-access resources, there was little evidence that the mailing of taglines with fifteen different languages provided justifiable marginal returns on comprehension, and recipients of the notices mistakenly believed that the phone number for OCR was the number to call for inquiries directed to their insurance issuer or healthcare provider. 84 Fed. Reg. at 27,859–60. Plaintiffs have not explained how these reasons are somehow inadequate to show HHS's thinking during the regulatory process, and HHS need not establish that these reasons are "*better* than the reasons for the old" policy, merely that "the agency believes [the new policy] to be better, which the conscious change of course adequately indicates." *Fox*, 556 U.S. at 515. In sum, the notice-and-tagline provisions had high costs and little evidence of any benefits, which is an appropriate reason for an agency to change course.

In addition, plaintiffs cannot show that HHS failed to consider "how repealing the notice, tagline, and language access requirements will decrease access to health care information," Mot. at 24, because HHS addressed those very arguments. An agency satisfies its obligations to "consider an important aspect of the problem" when the agency expressly acknowledges the allegedly important issue and explains its reasoning relating to that aspect of the problem. *See, e.g.*, *Am. Petroleum Inst. v. EPA*, 684 F.3d 1342, 1350 (D.C. Cir. 2012) (holding that an agency had not "failed to consider" an argument where the agency "gave the specific reasons for which it disagreed" with the basis for the argument). HHS did not ignore the possibility that eliminating the notice-and-tagline provisions could "result in decreased access to, and utilization of, healthcare" by vulnerable populations or deprive LEP individuals of knowledge about "their rights to language assistance." Mot. at 24–25. Instead, in the NPRM, HHS outlined the evidence showing that the notice and tagline provisions were providing little to no marginal benefit in promoting access. 84 Fed. Reg. at 27,859–60, 27,882 (discussing evidence that notice-and-tagline provisions had not led to increase in utilization of translation services, and that tagline requirements

sometimes mandated language spoken by only a few dozen people in the state). And in the 2020 Rule, HHS further reasoned that existing notice requirements under the relevant nondiscrimination statutes and regulations would provide broad notification of individuals' rights to be free from discrimination. 85 Fed. Reg. at 37,204. In short, plaintiffs' complaint is not that HHS failed to address significant aspects of any problem, but that they disagree with HHS's decision. That is a request that this Court substitute its own judgment for the agency's, which is not permissible. *Mayo*, 875 F.3d at 19–20.

The second regulatory change that plaintiffs challenge under their descriptor of "notice, tagline, and language access requirements," Mot. at 24, is unidentified and thus should be considered waived. Plaintiffs identify only in the vaguest terms what they mean by their complaint about HHS's "elimination of . . . language access provisions," Mot. at 19. It is unclear whether they are still referring to the notice-and-tagline provisions, or they could be referring to the 2020 Rule's provisions regarding remote interpreting services, *see* 84 Fed. Reg. at 27,866, or the elimination of the requirement that OCR evaluate compliance with Section 1557 in part by referencing whether the covered entity has a "written language access plan," *see* 85 Fed. Reg. at 37,212. By failing to identify the challenged provision, let alone how HHS allegedly failed with respect to that challenged provision, plaintiffs have waived this argument, or at least have failed to show a likelihood of success on the merits.

If plaintiffs intended to challenge the provision relating to language access plans, HHS has provided good reasons for the change. The agency determined that the repeal of that provision would save covered entities $14.7 million annually. 84 Fed. Reg. at 27,883. At the same time, its own existing guidance would still "encourage recipients to produce language access plans" as part of covered entities' ongoing obligation to provide for language access, even though the 2020 Rule would remove the requirement that the Office for Civil Rights consider the existence of a written language access plan in evaluating that compliance. 85 Fed. Reg. at 37,212. That approach is a reasonable one that takes into account the effect that repealing the provision could have on the ability of people with limited English proficiency to communicate with covered entities. Plaintiffs

theorize that the 2020 Rule will dramatically decrease the effective delivery of medicine for people with low English proficiency, and thereby impose attenuated costs that HHS has not quantified, but an agency need not weigh the costs of an outcome the agency has reasonably determined will not occur.

In sum, plaintiffs' cursory objections to specified and unspecified portions of the 2020 Rule do not show any deficiency under the APA. The Court should reject Plaintiffs' request that it enjoin the Rule simply because plaintiffs wish HHS had made different choices.

D. The 2020 Rule Properly Construes the Scope of Section 1557.

Plaintiffs take exception with two aspects of the 2020 Rule's determination of what constitutes a "covered entity." Because both provisions faithfully construe Section 1557, neither of plaintiffs' arguments has merit.

First, plaintiffs complain that the 2020 Rule impermissibly "attempts to limit Section 1557's nondiscrimination protections only to health programs or activities of HHS *administered under Title I of the ACA*." Mot. at 19 (emphasis added). Contrary to plaintiffs' contention, the language HHS selected represents the most reasonable construction of Section 1557, which provides that nondiscrimination protections apply to "any health program or activity, any part of which is receiving Federal financial assistance, …., [and] any program or activity that is administered by an Executive Agency or any entity established under this title [*sc.*, Title I]." 42 U.S.C. § 18116(a). If the second category were read piecemeal, Section 1557 would apply to "any program or activity that is administered by an Executive Agency"—i.e., *all federal action*, regardless of its connection to healthcare or HHS (as well as to any program or activity that is administered by any entity established under Title I). Clearly, Congress did not intend to have HHS regulate non-healthcare-related discrimination in programs administered by other agencies. If Congress had wanted to subject *all* federal activity to Section 1557's restrictions, it would have said so clearly rather than burying such an expansive provision within the ACA, which everywhere else deals exclusively with healthcare; it also, presumably, would not have given HHS express authority to adopt implementing regulations if the statute was meant to govern other agencies. *See*

42 U.S.C. § 18116. "Congress . . . does not alter the fundamental details of a regulatory scheme," let alone the sum total of federal activity, "in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001). Thus, Section 1557 necessarily must be read in context.

To avoid an improperly expansive reading of the provision, HHS construed Section 1557 to mean "any health program or activity, any part of which is receiving Federal financial assistance … provided by the Department," "[a]ny program or activity administered *by the Department under Title I of the* [*Patient Protection and Affordable Care Act*]," and "[a]ny program or activity administered by any entity established under such Title." 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3) (emphasis added). Plaintiffs complain that such a construction represents a departure from "the plain language of Section 1557." Mot. at 19. But even the 2016 Rule—which plaintiffs defend—"acknowledged implicitly what the Department now states more clearly: The grammar of the relevant sentence in the Section 1557 statutory text concerning limits to its scope is less clear than it could have been." 85 Fed. Reg. at 37,170. To address that ambiguity, the prior rule applied Section 1557 to "every *health* program or activity administered *by the Department*; and every *health* program or activity administered by a Title I entity.'' 45 C.F.R. § 92.2(a) (emphasis added). While such a construction avoided applying Section 1557 to *all* federal programs and activities, which plaintiffs seemingly agree would be impermissible, it required injecting the word "health" into the relevant portion of the text, even though Congress had not included the word in the clause. *See* 85 Fed. Reg. at 37,170. In the 2020 Rule, HHS instead chose to rely upon the limitation already in the text—that is, Title I programs and activities. *See id.* That approach is, if not the only permissible construction, at least a reasonable construction of the statute that warrants deference. *See Chevron*, 467 U.S. at 844.

Second, plaintiffs argue that the 2020 Rule's exclusion of health insurers was unreasonable. *See* Mot. at 20–21. That argument fails too. As noted above, Section 1557 protections extend, in relevant part, to "any health program or activity" receiving federal financial assistance. 42 U.S.C. § 18116(a). The 2020 Rule construes the phrase as "encompass[ing] all of the operations of entities

principally engaged in the business of providing healthcare that receive Federal financial assistance." 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(b)). The Rule goes on to explain that "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare." *Id.* at 37,244–45.[4]

Plaintiffs argue that providing "health insurance" coverage is the same thing as the provision of "healthcare." Mot. at 20. But, as plaintiffs themselves acknowledge, health insurance is, at most, "a health-*related* program or activity." *Id.* (emphasis added). While insurance often plays an important role in the provision of healthcare, paying insurance claims is not the same thing as providing care to patients. One would not say that an auto insurance company provides transportation or that homeowner's insurance provides lodging. That same logic applies here.

HHS's interpretation is further confirmed by reference to other statutes. The Civil Rights Restoration Act, for instance, follows the same course. *See* 85 Fed. Reg. at 37,171. Plaintiffs suggest that 42 U.S.C. § 300gg-91 signifies that health insurance is "healthcare." Mot. at 20. But as HHS explained, § 300gg-01 must be read in context. Specifically, that statute "defines 'medical care' as 'amounts paid for' certain medical services, which is an appropriate definition in the health insurance field but not in the healthcare field generally. . . . When a doctor provides 'medical care,' she is not providing 'amounts paid for' medical services." 85 Fed. Reg. at 37,172. HHS's construction of Section 1557 to exclude health insurers is, at a minimum, reasonable and entitled to deference. *See Chevron*, 467 U.S. at 844.

E. The 2020 Rule's Religious Exemptions Do Not Violate the APA.

Plaintiffs cannot succeed on their claim that HHS failed to provide a reasoned explanation for incorporating religious exemptions into the 2020 Rule. HHS acknowledged that it was changing positions and proffered "good reasons" for its new policy, which is all that the APA

[4] Certain health insurance products would remain subject to Section 1557. For example, a Qualified Health Plan "would be covered by the rule because it is a program or activity administered by an entity established under Title I (*i.e.*, an Exchange), pursuant to § 92.3(a)(3)."

requires. *Fox*, 556 U.S. at 515. Specifically, HHS explained that its previous exclusion of the Title IX religious exemption was not based on the best reading of the statute, that the exclusions had made the rule vulnerable to legal attack (and had already led to an injunction), and that expressly incorporating religious exemptions would better protect the rights of religious objectors.

HHS determined that its previous refusal to incorporate Title IX's religious exemptions was based on a flawed reading of Title IX. "[A]n agency may justify its policy choice by explaining why that policy 'is more consistent with statutory language' than alternative policies." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 175 (2007)). Plaintiffs contend that Title IX's exemption is inappropriate in the healthcare setting because Title IX's exemption "is framed for educational institutions," Mot. at 21, which is the same approach the 2016 Rule took, 81 Fed. Reg. at 31,380. But HHS explained why it disagreed with that argument. 85 Fed. Reg. at 37,207. By its own terms, Title IX applies to "any education program or activity receiving Federal financial assistance," 20 U.S.C. § 1681(a), and Title IX has long been understood to apply outside of core educational institutions. Indeed, Title IX defines a "program or activity" under § 1681(a) to include "all of the operations" of "an entire corporation, partnership, or other private organization" that "is principally engaged in the business of providing education, *health care*, housing, social services, or parks and recreation." 20 U.S.C. § 1687(3)(A)(ii) (emphasis added). That provision shows that Title IX's presence in healthcare settings was expressly anticipated. And the history of Title IX's application shows the same. And the Third Circuit, for example, recently held that Title IX applied to a medical resident's claim against the private teaching hospital at which she was employed, which was affiliated with a university and administered the program at least in part for the purpose of educating residents. *Doe v. Mercy Catholic Med. Ctr.*, 850 F.3d 545, 558 (3d Cir. 2017). In sum, HHS considered plaintiffs' argument about the supposed limitation of Title IX to education institutions, and HHS determined in its sound judgment that plaintiffs' argument was mistaken.

Similarly, HHS determined in its sound judgment that Section 1557 had to be applied consonant with RFRA. 85 Fed. Reg. at 37,207. "RFRA specifies that it 'applies to all Federal law,

and the implementation of that law, whether statutory or otherwise,'" and "[t]he ACA does not explicitly exempt RFRA." *Little Sisters of the Poor Saints Peter and Paul Home v. Pa.*, __ U.S. __, 2020 WL 3808424, at *11 (July 8, 2020) (quoting 42 U.S.C. § 2000bb-3(a)). HHS therefore determined that it was appropriate to state that Section 1557 will be implemented consistent with RFRA, which is a sufficiently good reason for a change in an agency's position under the APA.

Another good reason offered by HHS was that the exclusion of religious exemptions had caused the 2016 Rule to be vacated in part in *Franciscan Alliance*. 85 Fed. Reg. at 37,207. The Supreme Court has recognized that agencies may legitimately consider past court decisions regarding the need for religious exemptions when crafting regulations. When the Supreme Court recently upheld the conscience exemptions to the contraceptive mandate, the Court noted that its own past decisions "all but instructed the Departments to consider RFRA going forward." *Little Sisters of the Poor*, __ U.S. at __, 2020 WL 3808424, at *11. It was, the Court held, "hard to see how the Departments could promulgate rules consistent with these decisions if they did not overtly consider these entities' rights under RFRA." *Id.* Indeed, the Court opined that failing to consider the Court's instruction would make the regulation "susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem." *Id.* at *12. The same is true here—the 2016 Rule had been vacated for failing to provide religious exemptions, and it was not unreasonable for HHS to take that into account in providing religious exemptions for the new rule.

Another good reason offered for the rule was the desire to "protect . . . providers' medical judgment and their consciences." 85 Fed. Reg. at 37,206. The protection of religious beliefs and the rights of conscience more generally is widely recognized as a legitimate government objective. For example, the Supreme Court has repeatedly upheld the propriety of religious exemptions from constitutional challenge, stating that "lifting a regulation that burdens the exercise of religion" is a "proper purpose" of government action. *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 338 (1987). And Congress has repeatedly demonstrated through legislation that accommodation of religion is an important and legitimate goal of the

government—for example, it has passed wide-ranging protections for religious liberty, such as RFRA and RLUIPA, and has also explicitly created religious exemptions in many individual statutes, such as the religious exemptions to Title VII and Title IX. Protecting the religious beliefs of people otherwise burdened by government regulation is a sufficient reason to justify HHS's change here.

Plaintiffs have not identified in the 2020 Rule's religious exemptions any "factual findings that contradict those which underlay [the agency's] prior policy." *Fox*, 556 U.S. at 515. Plaintiffs' only claim about factual findings behind the 2016 Rule is that HHS made a factual finding that "a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results." Mot. at 21 (quoting 81 Fed. Reg. at 31,380). But that statement in the 2016 Rule did not present itself as a factual finding or present any evidence in support. It was instead a policy statement, a speculative prediction about how the enforcement system might look under a given legal rule. *See Nat'l Ass'n of Home Builders*, 682 F.3d at 1038 (agency not required to make more "detailed" showing where it "did not rely on new facts, but rather on a reevaluation of which policy would be better in light of the facts").

And even if HHS were required to respond specifically to its previous speculation, HHS satisfied that burden by discussing the evidence it received from healthcare providers that showed a widespread practice among religious institutions of adhering to nondiscrimination principles and seeking only narrow exemptions from providing particular types of services due to sincere religious objections. 85 Fed. Reg. at 37,206. That discussion is likewise responsive to the concerns plaintiffs say HHS ignored—i.e., that the 2020 Rule supposedly "decreases protections for patients while increasing exemptions for providers," or that there's insufficient evidence that the 2020 Rule will "protect both providers' medical judgment and their consciences." Mot. at 21–22. HHS reasonably concluded that accommodating conscience objections is a legitimate goal that should not have been omitted from the 2016 Rule, and that including religious exemptions is unlikely to lead to widespread diminishing of healthcare options for individuals.

Finally, plaintiffs cannot prevail on their conclusory allegation that the 2020 Rule "runs counter to medical ethics, standards of care, and other statutes, like the Emergency Medical Treatment and Labor Act." Mot. at 22. They have not explained how the 2020 Rule violates any of those identified items, and indeed have not even explained how purportedly "run[ning] counter to medical ethics [and] standards of care" would make the Rule violate the APA. *See, e.g.*, *Nat'l Parks Conservation Ass'n v. United States Forest Serv.*, No. CV 15-01582(APM), 2015 WL 9269401, at *3 (D.D.C. Dec. 8, 2015) (holding that plaintiffs do not satisfy the likelihood-of-success standard with a conclusory allegation that the agency action violated a statute).

F. The 2020 Rule Does Not Violate Sections 1554 or 1557.

Finally, plaintiffs' argument that the 2020 Rule generally fails to comply with Sections 1554 and 1557 of the ACA fails because the Rule represents a faithful application of the ACA.

First, plaintiffs claim that the 2020 Rule runs afoul of Section 1554 of the ACA, which prohibits HHS from promulgating a regulation that "creates unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impedes timely access to health care services," or "interferes with communications regarding a full range of treatment options between the patient and the provider." 42 U.S.C § 18114(1)–(3). Specifically, plaintiffs argue that HHS has "invit[ed] health care insurers and providers to discriminate against LGBTQ people seeking health care." Mot. at 26. Rather than explaining which provisions of the rule "invite" discrimination, plaintiffs rely on broad criticisms contained in their declarations. But "§ 1554 is meant to prevent direct government interference with health care," *California v. Azar*, 950 F.3d 1067, 1094 (9th Cir. 2020) (en banc), and plaintiffs fail to identify any direct interference here. Indeed, if "[t]he most natural reading of § 1554 is that Congress intended to ensure that HHS . . . does not improperly impose regulatory burdens on doctors and patients," the 2020 Rule's elimination of regulatory mandates and return to broad incorporation of the specified civil rights statutes goes far toward achieving this end. *See* 85 Fed. Reg. at 37,166.

Second, plaintiffs complain that the 2020 Rule conflicts with Section 1557 because it does

not create a unitary cause of action for discrimination claims. *See* Mot. at 26–28. Plaintiffs misread the statute, which states that "[t]he enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of [Section 1557]." 42 U.S.C. § 18116(a). The most straightforward construction of the provision suggests that individuals may employ the enforcement mechanism available under each statute, depending on what cause of action the individual intends to bring. Reading the statute to require a unitary standard, as plaintiffs advocate and the prior rule provided for, would have required courts to apply Title VI mechanisms to, for example, Title IX claims. *See* 85 Fed. Reg. at 37,202. As HHS has explained, the statute cannot be read as "blend[ing] new standards and preexisting standards from underlying civil rights regulations, and impos[ing] those standards alongside the underlying regulations . . . left in place." *Id.*

Accordingly, a majority of the courts that have interpreted Section 1557 agree with HHS's approach. *See Briscoe* v. *Health Care Serv. Corp.*, 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017) ("Taken together, the first two sentences of § 1557 unambiguously demonstrate Congress's intent 'to import the various different standards and burdens of proof into a Section 1557 claim, depending upon the protected class at issue.'" (quoting *Southeastern Pennsylvania Transp. Auth. v. Gilead Sciences Inc.*, 698–99 (E.D. Pa. 2015)); *York v. Wellmark, Inc.*, No. 4:16-cv-00627-RGE-CFB, 2017 WL 11261026, at *18 (S.D. Iowa Sept. 6, 2017) ("Congress clearly intended to incorporate the statutes' specific enforcement mechanisms rather than create a general catch-all standard applicable to all discrimination claims.''); *see also Galuten on Behalf of Estate of Galuten v. Williamson Med. Ctr.*, No. 3:18-cv-00519, 2019 WL 1546940, at *5. (M.D. Tenn. Apr. 9, 2019) (same); *E.S. by and through R.S.* v. *Regence BlueShield*, No. C17-01609 RAJ, 2018 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *Doe v. BlueCross BlueShield of Tenn., Inc.*, No. 2:17-cv-02793-TLP-CGC, 2018 WL 3625012, at *6 (W.D. Tenn. July 30, 2018). Plaintiffs rely on only one case to support their interpretation. But while that unpublished decision from the District of Minnesota, *Rumble v. Fairview Health Services*, favored plaintiffs' interpretation, it concluded that "the language of Section 1557 is ambiguous, insofar as each of the four statutes utilize

different standards for determining liability, causation, and a plaintiff's burden of proof." No. 14-cv-2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015). Because the 2020 Rule's interpretation of that language, which avoids blending standards between the various statutes Section 1557 draws from is, at the very least, a reasonable one, it is entitled to deference. *See Chevron*, 467 U.S. at 844.

III. PLAINTIFFS HAVE NOT DEMONSTRATED A LIKELIHOOD OF SUCCESS ON THE MERITS OF THEIR CONSTITUTIONAL CLAIMS

In addition to their APA claims, plaintiffs advance a series of constitutional challenges to the 2020 Rule. None of them has merit.

A. The 2020 Rule Does Not Violate Plaintiffs' Right to Equal Protection.

Plaintiffs' equal protection claims fall short. Equal protection prohibits *government* from discriminating against a class of persons without adequate justification. But Plaintiffs' equal protection claim appears to be based on speculation about what *other*, *nongovernmental* actors might do. And that speculation seems to ignore that both Section 1557 and its implementing rule expressly prohibit discrimination on the basis of race, color, national origin, sex, age, and disability.

Plaintiffs do not argue that Section 1557 violates the Constitution, and because the 2020 Rule does nothing more than repeat the text of the statute, it does not do so either. Plaintiffs claim that the rule involves "discrimination against LGBTQ people" by "carving them out," Mem. at 28, but neither Section 1557 nor the 2020 Rule "isolate[s LGBTQ people] or subject[s] them, as a discrete group, to special or subordinate treatment." *See Schweiker v. Wilson*, 450 U.S. 221, 231 (1981).[5] Rather, LGBTQ "individuals remain protected by the same civil rights laws as any other

[5] Because neither Section 1557 nor the Final Rule include a classification on the basis of sexual orientation or transgender status, it is unnecessary to determine the level of scrutiny that might apply to one. But contrary to Plaintiffs' erroneous suggestions, *see* Mem. at 28–29, nothing in *Bostock* altered the rule in this circuit that classifications on the basis of sexual orientation or transgender status are subject to rational basis scrutiny. *See Steffan v. Perry*, 41 F.3d 677, 684-85 (D.C. Cir. 1994) (en banc); *Padula v. Webster*, 822 F.2d 97, 103-14 (D.C. Cir. 1987). Nothing in *Bostock*'s analysis of the text of Title VII has any bearing on the reach of the Constitution. *See Bostock*, 140 S. Ct. at 1753 ("The only question before us is whether an employer who fires someone simply for being homosexual or transgender has discharged or otherwise discriminated

individual, and [HHS] will vigorously enforce their statutory and regulatory civil rights." 85 Fed. Reg. at 37192.

Plaintiffs' assertion that "the exclusion of LGBTQ people from the nondiscrimination protections under Section 1557 is motivated by the Trump administration's and HHS officials' clear animus against LGBTQ people," Mem. at 29, is based on a faulty premise and, in any event, is unsupported by any "points, singly or in concert, [that] establish a[n]" equal protection claim. *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1915 (2020). For example, plaintiffs' assertion that defendant Severino has a purported "history of anti-LGBTQ sentiments, advocacy, and comments," Mem. at 29, is "supported" only by the fact that he criticized the 2016 Rule (notably, in a facially nondiscriminatory way).—such as concerns about its potential conflicts with "moral, and religious beliefs about biology"—and about prior DOJ enforcement of Title IX. *Id*. at 29–30. And in any event, plaintiffs' claims arise under the APA, so "the focal point for judicial review should be the administrative record" not extra-record statements introduced "initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). These principles are not disregarded because plaintiffs raise constitutional claims; judicial review under the APA, after all, expressly includes claims that agency action is "contrary to constitutional right." 5 U.S.C. § 706(2)(B).[6] Moreover, the statements by defendant Severino are mere legal and policy disagreements, and there is nothing in the APA prohibiting persons with different policy views from holding government positions.

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against that individual 'because of such individual's sex'" as that phrase is used in a particular provision of Title VII); *see also Washington v. Davis*, 426 U.S. 229, 238 (1976) (reversing Court of Appeals because it "erroneously applied the legal standards applicable to Title VII cases in resolving the constitutional issue before it").

[6] Numerous courts—including this Court—have restricted review to the administrative record in cases raising constitutional claims. *See, e.g.*, *Bellion Spirits, LLC v. United States*, 335 F. Supp. 3d 32, 44 (D.D.C. 2018); *Chiayu Chang v. USCIS.*, 254 F. Supp. 3d 160, 161 (D.D.C. 2017); *Ketcham v. U.S. Nat'l Park Serv.*, No. 16-CV-17-SWS, 2016 WL 4268346, at *1-2 (D. Wyo. Mar. 29, 2016); *Jarita Mesa Livestock Grazing Ass'n v. U.S. Forest Serv.*, 58 F. Supp. 3d 1191, 1237–38 (D.N.M. 2014); *Tafas v. Dudas*, 530 F. Supp. 2d 786, 803 (E.D. Va. 2008); *Harvard Pilgrim Health Care of New Eng. v. Thompson*, 318 F. Supp. 2d 1, 10 (D.R.I. 2004).

Even if the plaintiffs had established a substantial likelihood of a "strong showing of bad faith or improper behavior" necessary to justify extra-record review, *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2574 (2019)—which they have not—"the cited statements are unilluminating," *Regents*, 140 S. Ct. at 1916. These statements—"remote in time and made in [the] unrelated context[]" of defendant Severino's life as a private citizen, *see id*.—reflect reasonable criticisms about the prior rule in a complex area of social policy, including the effect of the rule on "sincerely held religious beliefs," *see Masterpiece Cakeshop, Ltd. v. Colo. Civil Rights Comm'n*, 138 S. Ct. 1719, 1729 (2018); nothing about Severino's prior public statements indicates that the Final Rule reflects animus toward the LGBTQ community. Indeed, the *Bostock* majority itself cautioned that it was "deeply concerned with preserving the promise of the free exercise of religion," which "lies at the heart of our pluralistic society," and acknowledged fears surrounding the intersection of its construction of Title VII with the "religious convictions" of employers. 140 S. Ct. at 1754; *see also id.* at 1782 (Alito, J., dissenting) (explaining that Section 1557 challenges based on sex reassignment procedures "present difficult religious liberty issues because some employers and healthcare providers have strong religious objections to sex reassignment procedures"). Presumably, plaintiffs do not contend that these statements by Justices of the Supreme Court amount to a "strong showing of bad faith or improper behavior."

While relying on statements remote in time and context, plaintiffs ignore the fact that the 2016 Rule was subject to a preliminary injunction and ultimately partial vacatur based on a court's finding that it was contrary to Section 1557. *See supra* Pt. II.A.i. Aligning the regulation with the text of Section 1557 in an effort to minimize litigation risk is a much more "obvious alternative explanation" for the Final Rule than animus. *See Ashcroft v. Iqbal*, 556 U.S. 662, 682 (2009) (citation omitted). As explained throughout the rulemaking, and *supra*, HHS's Final Rule is rationally related to several legitimate government interests. *See Cooper Hosp./Univ. Med. Ctr. v. Burwell*, 179 F. Supp. 3d 31, 47 (D.D.C. 2016) (citations omitted) (describing "review of an equal protection claim in the context of agency action").

B. The 2020 Rule Does Not Violate Plaintiffs' Right to Due Process.

Plaintiffs' due process claim is likewise meritless. Although plaintiffs assert that the 2020 Rule "encourag[es] health care providers and insurers to interfere with and unduly burden patients' access to medically necessary health care," Mot. at 31, they fail to identify which provision of the Rule purportedly leads to that alleged result—indeed, plaintiffs fail to cite the Rule at all during the course of their due process argument. Plaintiffs contend that such "interfere[nce]" violates an alleged constitutional "right to live openly and express oneself consistent with one's sexual orientation or gender identity." Mot. at 31. In support of this proposition, plaintiffs rely on a single district court decision that does not support their claim. *See id.* (citing *Arroyo Gonzalez v. Rossello Nevares*, 305 F. Supp. 3d 327, 333 (D.P.R. 2018)).

In *Arroyo Gonzalez*, the court held that the Commonwealth of Puerto Rico could not prevent Puerto Ricans from changing the sex listed on their birth certificates. 305 F. Supp. 3d at 333–34. Even if that decision were binding on this Court, it would have no application to the facts of this case, as the 2020 Rule does not prevent plaintiffs or anyone else from expressing themselves consistent with their sexual orientation or gender identity. Plaintiffs' due process challenge necessarily fails.

C. The 2020 Rule Does Not Violate Plaintiffs' Right to Free Speech.

The 2020 Rule does not direct healthcare providers to use particular language with patients, let alone require that patients use particular language in describing their sex, gender identity, sexual orientation, or any other characteristic. Those determinations have been left where they always should be—to the patient and his or her doctor. Yet plaintiffs argue that the 2020 Rule "chills" patient speech. Mot. at 31. Plaintiffs point to no language in the Rule that might lead to such a result.

The First Amendment provides that "Congress shall make no law . . . abridging the freedom of speech." While the Supreme Court has held that certain government conduct may impermissibly "chill" free speech, "[a]llegations of a subjective 'chill' are not an adequate substitute for a claim of specific present objective harm or a threat of specific future harm." *Laird*

v. Tatum, 408 U.S. 1, 13–14 (1972). Instead, to advance a cognizable free speech claim, plaintiffs must identify "a governmental policy that . . . regulate[s], constrain[s], or compel[s] . . . action on their part." *Amnesty Int'l*, 568 U.S. at 419. Plaintiffs come nowhere close to doing so here.

Plaintiffs fail to identify which provision of the 2020 Rule threatens government action against those who engage in particular speech. Presumably plaintiffs take issue with HHS's decision not to include a definition for "on the basis of sex." 85 Fed. Reg. at 37,162–63. But that aspect of the 2020 Rule does not prohibit—or even suggest—that particular language be used when interacting with patients, or that patients face consequences from the government if they engage in certain speech. Nor does any other provision of the Rule, for that matter. Instead, healthcare providers and patients alike are free to use the speech of their choosing. Plaintiffs' "subjective chill, fear, is not sufficient" to support their First Amendment claim, whatever unidentified fear it may be based on. *Am. Lib. Ass'n v. Barr*, 956 F.2d 1178, 1196 (D.C. Cir. 1992). Finally, were there any concern, HHS went out of its way to ensure that First Amendment rights would be protected by including language in the Rule making clear that relevant provisions "shall be construed consistently with, as applicable, the First Amendment to the Constitution." 85 Fed. Reg. at 37,243.

Plaintiffs offer a sundry assortment of cases in an attempt to argue otherwise. *See* Mot. 31–32. None supports plaintiffs' First Amendment claim. For example, plaintiffs cite *Hartley v. Wilfert*, but in that case the government had impermissibly chilled speech when Secret Service officers "ominously" informed a demonstrator that "if she intended to remain on the sidewalk discussing her concerns, she would have to give 'background data including name, date of birth and Social Security number, fill out a card, and submit to questions,'" which "would be put into Secret Service records" and result in her being "'considered one of the crazies.'" 918 F. Supp. 2d 45, 53–54 (D.D.C. 2013). In *Henkle v. Gregory*, high school officials told a gay high school student "numerous times to keep his sexuality to himself" and retaliated against him for failing to do so. *Henkle v. Gregory*, 150 F. Supp. 2d 1067, 1075–76 (D. Nev. 2001). And *Doe v. Yunits*, an unpublished state court decision construing the *Massachusetts* Constitution, held that a plaintiff

had a viable claim where junior high officials prevented the biological male "from wearing items of clothing that are traditionally labeled girls' clothing, such as dresses and skirts, padded bras, and wigs." No. 001060A, 2000 WL 33162199, at *4 (Mass. Super. Oct. 11, 2000), *aff'd sub nom. Doe v. Brockton Sch. Comm'n*, No. 2000-J-638, 2000 WL 33342399 (Mass. App. Nov. 30, 2000). Unlike these cases, the 2020 Rule does not pressure plaintiffs to engage in particular speech, nor does it attach consequences to plaintiffs' failure to do so. Simply put, nothing in the 2020 Rule does anything to restrict plaintiffs' First Amendment rights.

D. The 2020 Rule Does Not Violate the Establishment Clause.

Plaintiffs cannot show a likelihood of success on their Establishment Clause claim, because it is well settled that the federal government may provide religious exemptions without offending the Establishment Clause. The Supreme Court's cases "leave no doubt that in commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice." *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 705 (1994); *see also Amos*, 483 U.S. at 334 ("'This Court has long recognized that the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause."' (quoting *Hobbie v. Unemployment Appeals Comm'n of Fla.*, 480 U.S. 136, 144-45 (1987))).

Here, the 2020 Rule merely makes clear that existing statutory protections for religious objectors apply to the 2020 Rule, so plaintiffs must show that those existing statutory provisions violate the Establishment Clause. And their motion makes out nothing to distinguish the exemptions here from the many that have been upheld against Establishment Clause challenges. *See, e.g.*, *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005) (RLUIPA); *Corporation of Presiding Bishop v. Amos*, 483 U.S. 327, 339 (1987) (Title VII's religious exemption); *Walz v. Tax Comm'n*, 397 U.S. 664, 672–80 (1970) (state property tax exemption for religious organizations); *Gillette v. United States*, 401 U.S. 437, 460 (1971) (exemption from military draft for religious conscientious objectors).

Plaintiffs' only argument is that the 2020 Rule somehow allows religious belief to serve as

an impermissible trump card and does not adequately account for the rights of third parties. That argument is doubly inaccurate. First, many of the challenged religious exemptions themselves may already incorporate or require a balancing of interests. For example, RFRA's analysis requires consideration of both the burden on religious objectors and the government's interest. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 691 (2014) ("Under RFRA, a Government action that imposes a substantial burden on religious exercise must serve a compelling government interest."). Plaintiffs' failure to address the supposed failings of the challenged exemptions in any detail just highlights that they have not shown a likelihood of success on the merits.

The second problem with plaintiffs' argument is that they have not shown that the Establishment Clause requires a religious exemption to have a built-in mechanism for weighing religious objections against the effect that an application of the exemption might have on particular third parties. Indeed, the religious exemption upheld in *Amos*—the religious exemption within Title VII, 42 U.S.C. § 2000e-1(a)—lacks such a weighing mechanism. That statutory provision contains no means for a potentially affected employee to make a showing that he will suffer too serious a harm to allow the application of the statute to his case.

The Supreme Court in *Amos* addressed the case most relied upon by plaintiffs, *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985), and found it inapposite for considering the constitutionality of a religious exemption. *Amos*, 483 U.S. at 337 n.15. That was because *Caldor* invalidated a provision that created an *obligation* on the basis of religion, namely, the provision in *Caldor* required employers to give a day off on any employee's chosen Sabbath. In contrast, the statute in *Amos* and the statutory provisions at issue now are "government acts with the proper purpose of lifting a regulation that burdens the exercise of religion." *Amos*, 483 U.S. at 338. Plaintiffs cannot show that the government violated the Establishment Clause by lifting a previous regulation (the 2016 Rule) that it concluded risked burdening religion.

In sum, plaintiffs' Establishment Clause challenge would imperil numerous statutory religious exemptions and would run contrary to Supreme Court precedent. Plaintiffs cannot escape the fact that "the Court has held that exempting religious organizations from compliance with

neutral laws does not violate the Constitution." *Hankins v. Lyght*, 441 F.3d 96, 108 (2d Cir. 2006).

IV. PLAINTIFFS HAVE NOT DEMONSTRATED IRREPARABLE HARM

A preliminary injunction cannot be entered based on a mere "possibility" of irreparable harm. *Winter*, 555 U.S. at 22. Instead, the threat of irreparable injury must be "real," "substantial," and "immediate." *City of L.A. v. Lyons*, 461 U.S. 95, 111 (1983). Plaintiffs' "speculative" assertions of harm by unknown individuals come nowhere close to satisfying that standard here. *Id.*

First, plaintiffs assert an amorphous claim that the *mere existence* of the 2020 Rule will create irreparable harm because it will cause plaintiffs "significant distress, hopelessness, hypervigilance, depression, generalized anxiety disorder, and trauma." Mot. at 34. But plaintiffs fail entirely to identify what aspect of the 2020 Rule would cause such injury. And emotional distress alone—even if based on sincere concerns—is insufficient to establish irreparable harm. *See Friends of Animals v. U.S. Bureau of Land Mgmt.*, 232 F. Supp. 3d 53, 66 (D.D.C. 2017).

Second, plaintiffs contend that the 2020 Rule will "invite[] discrimination" and "reduce[] access to care." Mot. at 35. To the extent that plaintiffs complain about the Rule not including a definition of "on the basis of sex," plaintiffs fail to articulate how defendants will cause irreparable harm because the prior rule that plaintiffs prefer has been vacated in relevant part and would not control even if the 2020 Rule were invalidated. *See Franciscan Alliance*, 414 F. Supp. 3d at 947. As to plaintiffs' other criticisms, plaintiffs speculate that third parties—not the government—will engage in conduct they oppose. *See supra* I.A. "[S]peculation about how third parties might respond to" agency action is insufficient to establish irreparable harm. *John Doe Co. v. Consumer Fin. Protec. Bureau*, 849 F.3d 1129, 1134–35 (D.C. Cir. 2017); *see Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 298 (D.C. Cir. 2006) ("At most, the Navy's purported practice reduces Appellants' *opportunities* for promotion, which are themselves dependent upon the number of Chaplain Corps vacancies Congress and the Navy authorize each year."); *Wisconsin Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985) ("Injunctive relief 'will not be granted against something merely feared as liable to occur at some indefinite time.'" (quoting *Connecticut*

v. Massachusetts, 282 U.S. 660, 674 (1931))). Tellingly, plaintiffs' alleged instances of discrimination, *see, e.g.*, Mot. at 36 (noting that plaintiffs have been "misgendered"), necessarily could not have been caused by the 2020 Rule, which has yet to take effect.

Third, plaintiffs claim that they will suffer irreparable harm because the 2020 Rule will interfere with the operation of their organizations. *See* Mot. at 38–41. Plaintiffs allege that the Rule will "require additional expenditures," *id.* at 39, of "already limited resources," *id.* at 40, but plaintiffs nowhere attempt to quantify these expenditures in their motion or numerous declarations, further confirming the "speculative nature" of their alleged harm, *Lyons*, 461 U.S. at 111. And mere economic loss, especially when caused by the action of third parties, is insufficient. *John Doe Co.*, 849 F.3d at 1134–35. Instead, a plaintiff must show that the "very existence" of their business is threatened, *Soundboard Assn. v. U.S. Fed. Trade Commn.*, 254 F. Supp. 3d 7, 13 (D.D.C. 2017) (quoting *Wis. Gas Co.*, 758 F.2d at 674), even if losses may never be recoverable through litigation, *Nat'l Mining Ass'n v. Jackson*, 768 F. Supp. 2d 34, 52 (D.D.C. 2011). Plaintiffs do not allege that their organizations will cease to exist as a result of the 2020 Rule.

Plaintiffs additionally claim that the 2020 Rule "impedes plaintiffs' ability to care for and treat LGBTQ patients." Mot. at 39. But the 2020 Rule *reduces* burdens on providers.[7] It is unclear why plaintiffs would cease providing services they deem important simply because the Rule no longer requires them to do so.

Finally, plaintiffs allege that they will suffer irreparable harm because Title VII provides insufficient protections, *see* Mot. at 41–42, but plaintiffs make no allegation in their complaint concerning Title VII's supposedly inadequate reach. Plaintiffs' criticism is properly directed at Congress—not the 2020 Rule.

V. THE BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR DEFENDANTS

The balance of hardships and the public interest weigh against issuing an injunction here. Where the government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435

[7] Indeed, HHS calculates that Rule "relieves approximately $2.9 billion in undue regulatory burdens (over five years)." 85 Fed. Reg. at 37,161.

(2009). There is inherent harm to an agency in preventing it from implementing regulations that Congress has found to be in the public interest to direct that agency to develop. *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); *see also Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers) (stating that the Government will "suffer[] a form of irreparable injury" if it "is enjoined by a court from effectuating statutes enacted by representatives of its people."). Here, in particular, HHS has determined that the 2016 Rule imposed substantial costs on covered entities without yielding sufficient benefits, failed to protect religious interests, interfered with the medical and ethical judgment of health professionals, and unjustifiably expanded its own jurisdiction. Although the vacatur in *Franciscan Alliance* means that plaintiffs cannot get some of their preferred regulatory provisions reinstated even with a preliminary injunction of the 2020 Rule, the harms mitigated by the 2020 Rule will still return in substantial force if this Court grants preliminary relief. That is unquestionably harm that outweighs plaintiffs' asserted injuries, which, as discussed above, are noncognizable, unsupported by anything other than conclusory allegations, or insufficiently substantial to warrant an injunction. *See supra* IV.

VI. NATIONWIDE RELIEF IS INAPPROPRIATE

Even if the Court were to disagree with Defendants' arguments, any preliminary injunctive relief should be no broader than necessary to provide plaintiffs with relief and therefore should extend only to the named plaintiffs. "A plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018), and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994); *see also Trump v. Hawaii*, 138 S. Ct. 2392, 2429 (2018) (Thomas, J., concurring) (noting that nationwide injunctions "are legally and historically dubious"); *DHS v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring in the granting of a stay) ("Universal injunctions have little basis in traditional equitable practice"). These principles apply with even greater force to a preliminary injunction, an equitable tool designed merely to "preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981).

Entering broad relief would be particularly inappropriate here because the Rule is being challenged in other courts. *See Walker v. HHS*, No. 1:20-cv-2834 (E.D.N.Y.); *BAGLY v. HHS*, No. 1:20-cv-11297 (D. Mass.); *Washington v. HHS*, No. 1:20-cv-1105 (W.D. Wash.); *New York v. HHS*, 1:20-cv-5583 (S.D.N.Y.). If the government prevails in all four other jurisdictions, a nationwide injunction would render those victories meaningless as a practical matter. *See New York*, 140 S. Ct. at 601 (Gorsuch, J., concurring in the granting of a stay) ("If a single successful challenge is enough to stay the challenged rule across the country, the government's hope of implementing any new policy could face the long odds of a straight sweep."). It would also preclude appellate courts from testing plaintiffs' challenges to the Rule's operation in other jurisdictions. Issuing preliminary relief with nationwide effect would thus prevent important "legal questions from percolating through the federal courts." *Hawaii*, 138 S. Ct. at 2425 (Thomas, J., concurring). Moreover, non-plaintiff entities may prefer for the Rule to take effect, affording them certainty regarding the obligations of covered entities in protecting important nondiscrimination rights. For the same reasons, a stay of the effective date pursuant to 5 U.S.C. § 705 is not warranted. *Affinity Healthcare Servs., Inc. v. Sebelius*, 720 F. Supp. 2d 12, 15 n.4 (D.D.C. 2010) ("Motions to stay agency action pursuant to these provisions are reviewed under the same standards used to evaluate requests for interim injunctive relief.").

In addition, should the Court enjoin any portion of the Rule, it should allow the remainder to go into effect. In determining whether severance is appropriate, courts look to both the agency's intent and whether the regulation can function sensibly without the excised provision(s). *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001). There is no question that the agency intended the rule to be severable, as it retained the 2016 Rule's severability provision. 85 Fed. Reg. at 37,245 (codified at 45 C.F.R. § 92.3(d)). Likewise, plaintiffs have not explained how enjoining the discrete portions of the 2020 Rule they challenge would prevent the other portions of the 2020 Rule from functioning sensibly. The 2020 Rule covers a broad range of issues relating to obligations under Section 1557 of the ACA, and plaintiffs challenge only a few discrete portions of that Rule. Plaintiffs have not explained how, for example, enjoining the Rule's

repeal of notice-and-tagline provisions would affect whether the Rule's incorporation of religious exemptions could function sensibly. Plaintiffs also have not challenged every provision of the Rule, and they bear the burden to establish an entitlement to an injunction. *Winter*, 555 U.S. at 20; *cf. Printz v. United States*, 521 U.S. 898, 935 (1997) (Courts "have no business answering" questions about the validity of provisions that concern only "the rights and obligations of parties not before [them]"). Plaintiffs have identified no functional reason the entire Rule must fall if the Court were to agree only with plaintiffs' attacks on particular provisions, and this Court should accordingly not issue relief beyond any of those challenged provisions.

CONCLUSION

Plaintiffs' motion should be denied.

Dated: July 24, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 24th day of July, 2020, I caused the foregoing document to be served on counsel for plaintiffs by filing with the court's electronic case filing system.

/s/ William K. Lane
William K. Lane III

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	Case No. 1:20-cv-01630-JEB
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	)	
Defendants.	)	

[PROPOSED] ORDER

Having considered Plaintiffs' Motion for a Preliminary Injunction or, in the Alternative, a Stay Pending Judicial Review Pursuant to 5 U.S.C. § 705, in the above-captioned case, and this Court having reviewed the papers filed by the parties and, if held, heard arguments from counsel, Plaintiffs' motion is hereby DENIED.

Date: _____

_____
JAMES E. BOASBERG
UNITED STATES DISTRICT JUDGE