

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT MASSACHUSETTS**

BAGLY, *et al.*,)
)
Plaintiffs,)
)
v.)
)
U.S. DEPARTMENT OF HEALTH)
AND HUMAN SERVICES, *et al.*,)
)
Defendants.)
_____)

Case No. 1:20-cv-11297-PS

**MEMORANDUM IN SUPPORT OF DEFENDANTS’ MOTION TO DISMISS
PLAINTIFFS’ AMENDED COMPLAINT**

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INTRODUCTION

While there is little doubt that plaintiffs have stated strong objections to the Department of Health and Human Services' (HHS) nondiscrimination rule (the "2020 Rule" or "Rule"), mere policy disagreement is not enough to satisfy the requirements for Article III jurisdiction. To establish standing, plaintiffs must demonstrate "injury in fact" as to each provision they seek to challenge—harm that is concrete, particularized, and "certainly impending." Plaintiffs also must show that the Rule actually will cause the injuries they allege, and that a decision from this Court is likely to redress their asserted injuries. But plaintiffs do not allege facts that sufficiently satisfy the close scrutiny demanded to establish standing to raise their claims. Indeed, the Complaint is devoid of any facts—let alone clearly alleged ones—supporting their claim of standing to challenge any of the 2020 Rule's provisions discussed in the Complaint. Because plaintiffs lack standing to contest the 2020 Rule, their claims should be dismissed.

What is more, several of the actions challenged by plaintiffs, such as HHS's decision not to explicitly define the statutory phrase "on the basis of sex" by rule, involve HHS's discretion to decline to proceed by rulemaking. To the extent they involve allegations that courts and HHS will ignore relevant Supreme Court jurisprudence when HHS interprets Section 1557 *in the future*, they are both unripe and implausible. Even assuming plaintiffs have standing to challenge HHS's decisions, this Court should conclude that such claims are not ripe for review at this premature stage, when adjudication or litigation very well may render this Court's opinion on those claims entirely advisory. The Court should dismiss plaintiffs' challenges because they are entirely contingent upon the outcome of future adjudication related to the meaning and reach of Section 1557.

Finally, even if the Court determines plaintiffs have standing to assert their equal protection allegations, plaintiffs' complaint must be dismissed for failure to state a claim. Ample good reasons for the 2020 Rule mean that HHS's actions are not inexplicable by anything but animus. And even assuming heightened scrutiny applies, as the Supreme Court has recently made clear in *DHS v. Regents of the University of California*, 140 S. Ct. 1891 (2020), plaintiffs' allegations,

either singly or in concert, fail to establish a plausible equal protection claim. Plaintiffs allege only facts from which it is implausible to infer that animus of any kind motivated HHS to promulgate the 2020 Rule.

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 by reference 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. *Id.* § 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 certain institutions controlled by a religious organization if the application of Title IX’s prohibition on discrimination would not be consistent with the religious tenets of the organization, *id.* § 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,” *id.* § 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 “on 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 several 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. Nor did it incorporate Title IX’s abortion exemption, 20 U.S.C. § 1688. The 2016 Rule merely generally 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 November 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,” ; *see also* Order, *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 946 (N.D. Tex. 2019), *Franciscan Alliance*, 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 Final 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. *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 during the rulemaking, the explicit inclusion of “gender identity” and “termination of pregnancy” 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, 37, 193. 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.” 85 Fed Reg. 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.” 85 Fed Reg. 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,” 85 Fed Reg. 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. 85 Fed Reg. 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.* at 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 All.*, 227 F. Supp. 3d at 690–91); *see also id.* at 37,207–08.

II. PROCEDURAL BACKGROUND

On July 9, 2020, a little more than a month before the 2020 Rule was scheduled to go into effect, plaintiffs filed this action asserting various challenges to the Rule under the APA. *See* Complaint, ECF No. 1. Plaintiffs filed an amended complaint on September 18, 2020, which is the currently operative complaint. *See* Amended Complaint, ECF No. 18 (“Am. Compl.” or “AC”). Plaintiffs are an individual and eight entities, including: (1) a transgender man, (2) three private healthcare facilities that serve LGBTQ+ (lesbian, gay, bisexual, transgender, queer, intersex, or gender-non-binary) people, (3) four organizations that provide various services to LGBTQ+ people, and (4) a membership organization that advocates the health and equality of LGBTQ+ people. *See* AC ¶ 19.

The Amended Complaint includes four counts, each raising challenges to the 2020 Rule under Section 706(2) of the APA, which authorizes courts to “hold unlawful and set aside agency action” on various grounds. *See* 5 U.S.C. § 706(2). Count I challenges various aspects of the rule, and asserts that it should be set aside under § 706(2)(A) as “not in accordance with law.” *See* AC ¶¶ 395-06. Count II alleges that the 2020 Rule should be set aside as arbitrary, capricious and an abuse of discretion under § 706(2)(A). *See id.* ¶¶ 407-14. Count III alleges that the rule violates the equal protection component of the Fifth Amendment’s Due Process Clause, and should thus be set aside under § 706(2)(B). *See id.* ¶¶ 415-23. Count IV challenges the 2020 Rule’s purported statement of enforcement policy, alleging that it should be set aside as not in accordance with the law under § 706(2)(A). *See id.* ¶¶ 424-27. Plaintiffs seek declaratory and injunctive relief, asking the Court to permanently enjoin the 2020 Rule. *See* Request for Relief at 106.

Defendants now move to dismiss the Amended Complaint in its entirety.

LEGAL STANDARDS

“The proper vehicle for challenging a court’s subject-matter jurisdiction is Federal Rule of Civil Procedure 12(b)(1).” *Valentin v. Hosp. Bella Vista*, 254 F.3d 358, 362 (1st Cir. 2001). And “Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law.” *Neitzke v. Williams*, 490 U.S. 319, 326 (1989).

“[T]he plaintiff bears the burden of plausibly alleging a viable cause of action” and “pleading facts necessary to demonstrate standing.” *Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 730 (1st Cir. 2016). “[A]t the pleading stage, the plaintiff bears the burden of establishing sufficient factual matter to plausibly demonstrate his standing to bring the action. Neither conclusory assertions nor unfounded speculation can supply the necessary heft.” *Id.* at 731. “Although . . . dismissal under Rules 12(b)(1) and 12(b)(6) are ‘conceptually different,’ . . . ‘the same basic principles apply in both situations.’” *Lyman v. Baker*, 954 F.3d 351, 359 (1st Cir. 2020) (quoting *Hochendoner*, 823 F.3d at 730–31).

ARGUMENT

I. PLAINTIFFS HAVE FAILED TO ESTABLISH SUBJECT MATTER JURISDICTION AS TO ANY OF THEIR CLAIMS, AND THUS, ALL CLAIMS SHOULD BE DISMISSED UNDER RULE 12(B)(1)

A. Plaintiffs Lack Standing

“Standing is a threshold question in every case; if a party lacks standing to bring a matter before the court, the court lacks jurisdiction to decide the merits of the underlying case.” *Equal Means Equal v. Dep’t of Educ.*, 450 F. Supp. 3d 1, 5 (D. Mass. 2020) (“*Equal Means Equal I*”) (Saris, C.J.) (internal formatting omitted) (quoting *United States v. AVX Corp.*, 962 F.2d 108, 113 (1st Cir. 1992)). 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). Here, plaintiffs fail to identify any “injury in fact” that is “fairly . . . trace[able]” to each challenged provision of the 2020 Rule and that will “be redressed by a favorable decision,” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992), and thus lack standing to advance any of their claims.

“Where, as here, a case is at the pleading stage, [a] plaintiff must clearly allege facts demonstrating each element.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (citation omitted), *as revised* (May 24, 2016). “[W]here standing is at issue, heightened specificity is obligatory at the pleading stage. The complainant must set forth reasonably definite factual allegations, either direct or inferential, regarding each material element needed to sustain standing.” *Draper v. Healey*, 827 F.3d 1, 3 (1st Cir. 2016) (quoting *AVX Corp.*, 962 F.2d at 115); *see also Twin Rivers Paper Co. v. SEC*, 934 F.3d 607, 612-13 (D.C. Cir. 2019) (“[A] party cannot rest on ‘abstract’” or “‘conclusory’ assertions of injury, . . . but must point to ‘specific, concrete facts demonstrating harm.’”) (citations omitted).

Although plaintiffs raise claims challenging numerous aspects of the 2020 Rule, the allegations of harm in the Amended Complaint are for the most part not specifically linked to particular challenged provisions in that rule. *See* Am. Compl. ¶¶ 189-64. Instead, plaintiffs focus

most of their allegations on the elimination of gender identity from the definition of on the basis of sex—which was vacated from the 2016 Rule before the 2020 Rule was finalized. In any event, the Amended Complaint is devoid of any facts—let alone clearly alleged ones—supporting plaintiffs’ standing with respect to any of the many provisions of the 2020 Rule plaintiffs challenge.

(1) HHS’s Decision not to define “sex” or “on the basis of sex.”

As to the challenged failure to include a separate provision defining “discrimination on the basis of sex,” plaintiffs assert standing based primarily on generalized fears that the 2020 Rule will encourage future discrimination, and that such fears might deter patients from seeking necessary medical assistance. *See* AC ¶¶ 189-64. The individual plaintiff (Darren Lazor), for example, alleges a fear of future discrimination by healthcare providers in medical treatment, and by health insurers in coverage decisions. *See* AC ¶¶ 213-16. He alleges that he experienced discrimination in the past based on his transgender status when he sought medical treatment in 2012 and 2017. *See id.* ¶¶ 20-23. Likewise, plaintiff health care and service providers allege that their patients and clients fear the possibility of future discrimination, and describe alleged incidents of such discrimination in the past. *See id.* ¶¶ 217-28 (alleging that patients and members fear they will experience future discrimination). As this Court has recently emphasized in a similar challenge, however, such allegations of possible future injury are not sufficient to accord a party standing. *Equal Means Equal I*, 450 F. Supp. 3d at 10 (citing *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013)). The mere threat of potential future harm is insufficient; instead, plaintiffs must identify an injury that is “certainly impending.” *Clapper*, 568 U.S. at 401 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

Plaintiffs’ alleged fear of future discrimination does not identify any “certainly impending” harm of the sort required. To be sure, the Amended Complaint alleges that certain individuals have experienced incidents of discrimination by healthcare providers or insurers in the past. But it is well-settled that such claims do not establish a likelihood that plaintiffs will be subjected to such incidents in the future. *See Equal Means Equal v. Ferriero*, No. 20-CV-10015-DJC, 2020

WL 4548248, at *7 (D. Mass. Aug. 6, 2020) (“*Equal Means Equal I*”) (finding lack of standing because the “fact that [plaintiff] Weitbrecht suffered violence in the past does not establish that she is likely to suffer violence in the future”). Plaintiffs cite no basis to conclude that the 2020 Rule—which does not and could not modify the statutory prohibition on discrimination on the basis of sex that already exists in Section 1557—will subject these individuals to “certainly impending” acts of discrimination at the hands of healthcare providers. Plaintiffs merely allege that such individuals “believe” the 2020 Rule will “increase the likelihood” that they will experience similar discrimination at some point in the future. *See, e.g.*, AC ¶¶ 224, 226, 227. Such speculation does not support standing.

Plaintiffs’ standing allegations also fail for reasons quite apart from the speculative nature of the alleged future injuries. To establish standing, 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 Equal Means Equal II*, 2020 WL 4548248, at *4. Here, plaintiffs cannot plausibly allege either causation or redressability, as required to support standing.

First, the future discrimination that plaintiffs fear is not causally related to the 2020 Rule, but to the anticipated future actions of third parties, such as healthcare providers and insurers. *See Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976) (stating that Article III standing “requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court”). “Injuries that stem from independent acts of third parties are ordinarily not cognizable because they are neither fairly traceable to the defendant nor likely to be redressed by the requested relief.” *See Equal Means Equal II*, 2020 WL 4548248, at *6 (citation omitted); *see also, e.g., Katz v. Pershing, LLC*, 672 F.3d 64, 71–72 (1st Cir. 2012) (stating that “[b]ecause the opposing party must be the source of the harm, causation is absent if the injury stems from the independent action of a third party”); *NAACP, Boston Chapter v. Harris*, 607 F.2d 514, 519 (1st Cir. 1979) (stating that a federal court can only redress “injury that can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party

not before the court”) (quoting *Simon*, 426 U.S. at 41-42); *Martin v. Evans*, 241 F. Supp. 3d 276, 283 (D. Mass. 2017) (Saris, C.J.), (noting that an “injury causation chain [is impermissibly attenuated when] the injury . . . depend[s] on the government enforcing a law against another person with whom the plaintiffs might potentially interact”).¹

Plaintiffs’ own allegations reinforce this deficiency, further undermining any plausible inference of a causal connection to the 2020 Rule. The incidents of past discrimination identified in the Amended Complaint are not alleged to have occurred after, but rather before, the 2020 Rule went into effect. Thus, to the extent these plaintiffs allege past discrimination, it was clearly not attributable to the 2020 Rule, but solely to the independent choices of the healthcare and other service providers involved. *See Simon*, 426 U.S. at 41-42 (holding 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”). There is no reason to suppose that future acts of discrimination—should they even occur—will be any different. *See, e.g., Clapper*, 568 U.S. at 414 (stating that “we decline to abandon our usual reluctance to endorse standing theories that rest

¹ In *Whitman-Walker Clinic, Inc. v. HHS*, --- F. Supp. 3d ----, ----, 2020 WL 5232076, at *10 (D.D.C. Sept. 2, 2020), the district court found that several health-provider plaintiffs established Article III standing to challenge HHS’s decision not to include an explicit definition on “on the basis of sex” and the 2020 Rule’s explicit incorporation of Title IX’s religious exemption based on increased patient counts stemming from LGBTQ patients that purportedly fear “discrimination at the hands of external providers.” *Id.* at *12. This decision was erroneous because, even if the allegations were accepted as true, they were based on the subjective fears of third parties as opposed to the actual content and legal effect of the 2020 Rule. *See, e.g., Equal Means Equal v. Ferriero*, No. 20-cv-10015-DJC, 2020 WL 4548248, at *7 (D. Mass. Aug. 6, 2020) (“*Equal Means Equal II*”) (quoting *Laird v. Tatum*, 408 U.S. 1, 13-14 (1972)) (“allegations of subjective chill are not an adequate substitute for a claim of specific present objective harm or a threat of specific future harm”). With respect to HHS’s decision not to explicitly define “on the basis of sex” by rule, fear by third party LGBTQ patients is not objectively caused by the 2020 Rule because the Rule does *not* define “on the basis of sex” to exclude LGBTQ discrimination, and if Plaintiffs are “correct that *Bostock* means that Title IX and Section 1557 must incorporate protection for gender identity and sexual orientation discrimination, then that means that the 2020 Rule does, in fact, extend protection against discrimination to LGBTQ individuals via the Rule’s incorporation of Title IX by reference *Washington v HHS*, No. C20-1105JLR, 2020 WL 5095467, at *8 (W.D. Wash. Aug. 28, 2020).

on speculation about the decisions of independent actors”); *Equal Means Equal I*, 450 F. Supp. 3d at 8 (rejecting standing based on similar assumptions about third party choices).

Second, plaintiffs cannot show redressability for an additional reason. *See Lujan*, 504 U.S. at 561; *Simon*, 426 U.S. at 41–42. 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, 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. *See Order, Franciscan Alliance, Alliance*, No. 7:16-cv-00108, ECF No. 182, at 3 (N.D. Tex. Nov. 21, 2019) (“[T]he Court VACATES the Rule insofar as the Rule defines ‘On the basis of sex’ to include gender identity or termination of pregnancy.”); *see also Franciscan All.*, 414 F. Supp. 3d at 945. Enjoining the challenged 2020 Rule would thus 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.

To be sure, *Franciscan Alliance* did not enjoin the 2016 Rule’s explicit inclusion of “sex stereotyping” in its definition of “on the basis of sex.” And two court decisions seized on that fact to bypass redressability concerns. *See Whitman-Walker Clinic, Inc. v. HHS*, --- F. Supp. 3d ----, 2020 WL 5232076, at *14 (D.D.C. Sept. 2, 2020); *Walker v. Azar*, --- F. Supp. 3d ----, ----, 2020 WL 4749859, at *7 (E.D.N.Y. Aug. 17, 2020). But these decisions fail to explain why the 2020 Rule in any way affects coverage of “sex stereotyping.” As explained, *infra* at 27-28, plaintiffs’ claim that “HHS . . . contends that discrimination ‘on the basis of sex’ does not encompass discrimination on the basis of sex stereotyping” is implausible. *See Am. Compl.* ¶ 268 (citing 85 Fed. Reg. at 37,183-86). Nowhere in the cited pages of the preamble did HHS purport to claim that discrimination on the basis of sex under Title IX does not encompass sex stereotyping. To the contrary, HHS explained that, “[t]o the extent that sex stereotyping is a recognized category of sex discrimination under longstanding Supreme Court precedent, this final rule commits [HHS] to continuing to vigorously enforce Title IX through Section 1557, and therefore the Department

estimates that this final rule will not have any material effect on the scope of sex stereotyping claims as authorized by Title IX and Section 1557.” 85 Fed Reg. at 37,239. There is no reason to believe that HHS or courts will construe Section 1557 to exclude sex stereotyping claims in light of HHS’s decision to decline to explicitly define “on the basis of sex” by rule to include sex stereotyping. Indeed, plaintiffs’ advocacy for ensuring Section 1557 is construed to cover discrimination based on gender identity and pregnancy/termination of pregnancy is *more likely* to bear fruit under the 2020 Rule than under the 2016 Rule because the 2020 Rule is *not* encumbered by the *Franciscan Alliance* partial vacatur order, and if plaintiffs are “correct that *Bostock* means that Title IX and Section 1557 must incorporate protection for gender identity and sexual orientation discrimination, then that means that the 2020 Rule does, in fact, extend protection against discrimination to LGBTQ individuals via the Rule’s incorporation of Title IX by reference.” *Washington v HHS*, No. C20-1105JLR, 2020 WL 5095467, at *8 (W.D. Wash. Aug. 28, 2020) (determining that a plaintiff challenging three provisions of the 2020 Rule lacked standing for the reasons Defendants argue here).

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, 1969-2 C.B. 117 (1969)], had ‘encouraged’ hospitals to deny services to indigents.”), *with* Am. Compl. ¶¶ 190 (the Rule “will embolden discrimination and harm LGBTQ+ patients”); 195 (the Rule “will embolden providers to deny healthcare to women, transgender men, and gender-nonbinary people who have previously had an abortion”); 262 (“by deleting the 2016 Rule’s explicit protections . . . from the definition of ‘on the basis of sex’ . . . [Defendants] embolden and encourage refusals of abortion care and coverage and information about abortion”).

As in *Simon*, a favorable judgment here would not ensure that these third-party providers would refrain from engaging in the conduct plaintiffs dislike. Indeed, as noted above, plaintiffs’

own allegations assert that they engaged in such discrimination before the promulgation of the 2020 Rule.

Simply put, speculation that a yet-to-be-identified third-party 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, the Amended Complaint alleges that several Plaintiff “advocacy organizations” have a special interest in the 2020 Rule that has frustrated their advocacy missions. Am. Compl. ¶¶ 242-264. But “[e]specially germane to the organizational injury inquiry is whether the injury is sufficiently concrete or merely an abstract social interest.” *Equal Means Equal II*, 2020 WL 4548248, at *9. “This is because although organizations may be formed to remedy certain problems or advance certain goals, mere interest in a problem is insufficient to support standing.” *See id.* Indeed, under *Sierra Club v. Morton*, 405 U.S. 727 (1972), “advocacy groups [lack] standing when they assert no interest other than an injury to [their] advocacy.” *See Equal Means Equal II*, 2020 WL 4548248, at *9 (and cases cited therein).

Accordingly, the Organizational Plaintiffs fail to establish standing to challenge the Rule because they do not allege that the Rule “perceptibly impair[ed]” any of their concrete “activities.” *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1983) (emphasis added). The Organizational Plaintiffs do not allege that the Rule interferes with the provision of any of their pre-existing legal or social services. They allege only that the Rule is inconsistent with their “social interests,” *id.*, *see, e.g.*, Am. Compl. ¶ 247-250 (allegations of injury stemming from educating the public), and that they thus anticipate spending resources in response to the Rule. But “[parties] cannot manufacture standing merely by inflicting harm on themselves” by “incur[ring] [costs] in response to a” policy. *Clapper*, 568 U.S. at 416; *see also Havens*, 455 U.S. at 378 (organizational standing involves “the same inquiry as the case of an individual”); *Lane v. Holder*, 704 F.3d 668, 675 (4th Cir. 2012).

Even assuming that the Organizational Plaintiffs have alleged concrete injuries to their activities providing concrete services that are not on the *Sierra Club* side of the standing divide, their alleged injuries are still insufficient to establish standing. That is because, to establish organizational standing, a plaintiff must clearly allege facts indicating that “its mission has been ‘frustrated’ by the challenged conduct *and* it has expended resources to combat it.” *Equal Means Equal I*, 450 F. Supp. 3d at 7. And “simply expending resources based on an *anticipated* harm is not enough to establish standing.” *Id.* But here, the Transgender Emergency Fund (“TEF”), for example, has only alleged that it has spent *less* money. *See, e.g.*, Am. Compl. ¶ 244 (alleging that TEF has seen a “decrease in expenditures”); *see also id.* (alleging a “decrease[] to approximately \$25 in 2018, and \$0 in 2020”); *id.* ¶ 246 (TEF “also *will need to* divert resources”) (emphasis added). And it merely “anticipates that it will need to reallocate funds and devote more resources to financing clients’ copayments for hormone replacement therapy,” *id.* ¶ 245, among other financing payments. Similarly, the Campaign for Southern Equality (“CSE”) speculates that the Rule “will also harm [its] grassroots grant program”—but there are no allegations that the program has *actually* been impacted in any way. *See id.* ¶ 251; *see also id.* ¶ 252 (“anticipat[ing] diverting additional staffing and funding resources toward training”). But “anticipat[ing]” a need is *not* a concrete allegation of expenditure of resources to combat a frustrated organizational mission. *See Equal Means Equal I*, 450 F. Supp. 3d at 7. The feared harms that the organization anticipates spending resources on indeed may never occur to TEF or CSE at all. *See Ouellette v. Mills*, 22 F. Supp. 3d 36, 42 n. 3 (D. Me. 2014) (no standing where “Complaint contains no allegations that [Plaintiffs’] resources have been diverted to combat an already-occurring harm. Rather,” Plaintiff “allegedly expended its resources . . . in an attempt to head off possible future . . . injuries feared by its members.”).

(2) *Scope of entities subject to Section 1557.*

The 2020 Rule “modifies the 2016 Rule’s definition of entities covered by Section 1557,” 85 Fed. Reg. 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.” 85 Fed. Reg. 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. Plaintiffs challenge HHS’s construction of the scope of entities subject to Section 1557 as contrary to law and arbitrary and capricious. Am. Compl. ¶¶ 318-327.

Scope of federal entities covered by Section 1557. Plaintiffs challenge the 2020 Rule’s construction of the scope of federal entities covered by Section 1557. *Id.* ¶¶ 319, 325. But the Amended Complaint’s only allegation of injury from this change is an abstract one: That plaintiff Indigenous Women Rising (“IWR”) has been injured because “[b]y removing the threat of HHS enforcement and making it more difficult to obtain a judicial remedy, the rule signals that the law does not protect against pregnancy discrimination in [the Indian Health Service (“IHS”)] and opens the door to further discrimination against Native people.” Am. Compl. ¶ 260. But this injury is based upon layer upon layer of speculation. A “signal” is not a concrete injury to IWR. IWR has not alleged facts supporting either organizational or associational standing to challenge the scope of federal entities covered by Section 1557. *See infra* at 19-20. And the fact that government entities like the IHS may not discriminate on the basis of sex as a result of the Equal Protection Clause, only adds to the speculation regarding the impact of the Rule on any Plaintiff.

(3) *Scope of the term “health program or activity.”*

Plaintiffs also challenge the 2020 Rule’s construction of the scope of the term “health program or activity.” Am. Compl. ¶¶ 320-325. The Amended Complaint alleges that plaintiffs Fenway Health and CrescentCare will be injured by HHS’s construction of the scope of covered entities because “some third-party payors for Fenway Health [and CrescentCare] patients will understand the [2020] Rule to mean that they are no longer constrained from offering plans that categorically exclude gender-affirming care or other sex-based treatment that HHS incorrectly asserts to be exempt from Section 1557’s scope.” Am. Compl. ¶¶ 235, 237. And “[s]uch diminished coverage will generate harm to Fenway Health in the form of decreased

reimbursement, as well as significant administrative time associated with understanding, applying, and appealing associated coverage decisions.” *Id.* ¶ 235. By the same token, plaintiff CrescentCare alleges it “will allocate more resources and administrative time to case management and legal services that help patients understand, apply, and appeal associated coverage decisions.” *Id.* ¶ 237. And “some patients will seek out CrescentCare to avoid newly emboldened discrimination from other providers.” *Id.* Similarly, liberally construed,² the Amended Complaint alleges that the 2020 Rule’s construction of the term “health program or activity” will “reduce the total amount of insurance reimbursement that [Plaintiff] Callen-Lorde might otherwise receive.” *Id.* ¶ 236.

But all of these allegations are insufficient because they rely on “speculation about the decisions of independent actors.” *Equal Means Equal I*, 450 F. Supp. 3d at 8 (quoting *Clapper*, 568 U.S. at 414). Specifically, the alleged injuries rely on pure speculation that insurers are discriminating against or limiting healthcare coverage for LGBTQ individuals. And the Amended Complaint includes zero allegations indicating that any health insurer has changed its coverage because of the 2020 Rule or plans on changing its insurance coverage. Indeed, the Amended Complaint was filed on September 18, 2020, about a month after the 2020 Rule became effective, yet Plaintiffs do not provide one “specific [allegation] that a third-party provider or insurer [is] discriminat[ing] against or limit[ing] its healthcare coverage for LGBTQ individuals.” *See Washington*, 2020 WL 5095467, at *8 (determining that a plaintiff challenging three provisions of the 2020 Rule lacked standing for the reasons Defendants argue here). “Plaintiffs do not allege that there has been an observed decrease” in coverage by any healthcare insurer, “nor do they allege that” insurers “are in fact” changing their insurance coverage as a result of the 2020 Rule. *See Equal Means Equal I*, 450 F. Supp. 3d at 8. “Simply asserting, without any elaboration that individuals will experience discrimination at the hands of . . . health insurers does not ‘suffice to establish the substantial probability’ that discrimination will actually occur as required to establish standing.” *Whitman-Walker*, 2020 WL 5232076, at *18 (quoting *Chamber of Commerce v. EPA*,

² Paragraph 236 is ambiguous as to which portion of the 2020 Rule it refers.

642 F.3d 192, 201 (D.C. Cir. 2011)); *see Massachusetts v. HHS*, 923 F.3d 209, 221-28 (1st Cir. 2019) (describing the type of concrete facts that must be alleged and then proven at each step of a causal chain to establish standing by way of a “substantial risk of . . . injury”).

(4) Legal standards for enforcement of Section 1557 violations.

Where the 2016 rule blended the enforcement mechanisms available under the underlying civil rights statutes and regulations, the 2020 Rule requires Section 1557 claims to be brought using the enforcement mechanisms available under each respective relevant incorporated civil rights statute(s). The Amended Complaint claims that this change violates the APA because it is contrary to law and arbitrary and capricious. Am. Compl. ¶¶ 304-313. However, the Amended Complaint’s only allegation of injury related to this provision of the 2020 Rule is that: “[b]y removing the unitary standard, the [2020] Rule will . . . make it more difficult for Native people who can become pregnant to bring claims of intersectional discrimination.” *Id.* ¶ 259. Presumably, this allegation is intended to allege a purported injury to plaintiff IWR. *See id.* ¶¶ 257-259.

Far from “clearly alleg[ing] facts demonstrating each element” of standing, *Spokeo*, 136 S. Ct. at 1547, this allegation “is murky, to say the least.” *See Whitman-Walker*, 2020 WL 5232076, at *19. The Complaint includes no facts clearly alleging how IWR’s “mission has been ‘frustrated’ by the challenged [provision] and that it has expended resources to combat it.” *Equal Means Equal I*, 450 F. Supp. 3d at 7 (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982)). And because “an organization’s use of resources for litigation . . . or advocacy is not sufficient to give rise to an Article III injury,” *see Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015), the Amended Complaint’s allegation that the Rule makes it “more difficult for Native people [that presumably IWR would intervene to advocate on behalf of] who can become pregnant to bring claims of intersectional discrimination,” Am. Compl. ¶ 259, is insufficient, even assuming any lawsuit against a hypothetical third-party was certainly impending, *see Equal Means Equal II*, 2020 WL 4548248, at *9 (“lobbyist or advocacy groups [do not have] standing when they assert no injury other than an injury to its advocacy”).

To the extent IWR is attempting to invoke associational standing, the Amended Complaint is insufficient because it fails to “identify” at least one specific “member who has suffered the requisite harm.” *Draper*, 827 F.3d 3 (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009)). The Court is being asked to assume not only that an unnamed Native American will come across a healthcare provider that will discriminate against her at some uncertain point in the future,³ but also that the healthcare provider’s discriminatory conduct will have occurred because of the Rule’s return to the enforcement mechanisms provided for, and available under, longstanding civil rights statutes and the Department’s implementing regulations, and that this person will be a member of IWR. This causal chain is far from predictable and “[t]he proper context for quarrels surrounding the legal standard for Section 1557 claims would be an actual lawsuit bringing such a claim.” *Whitman-Walker*, 2020 WL 5232076, at *20.

The Final Rule also eliminated provisions in the 2016 Rule that explicitly stated that an individual or entity may bring a civil action in a United States District Court to challenge a violation of Section 1557. 85 Fed. Reg. at 37,203. But HHS did not determine, in the 2020 Rule, that private rights of action are not available to plaintiffs. Instead, HHS declined to take a position by rule. HHS “no longer intends to take a position in its regulations on the issue of whether Section 1557 provides a private right of action.” 85 Fed. Reg. at 37,203. Plaintiffs challenge HHS’s decision not to take a position on this question. Am. Compl. ¶ 267. To the extent Section 1557 permits a private right of action, plaintiffs can assert claims under the statute itself, meaning they have suffered no injury from the Final Rule.

Plaintiffs allege that the 2020 Rule’s “vague position regarding the private right of action and enforcement mechanisms will lead to [generalized] confusion regarding how those who have been discriminated against can seek redress under the statute.” Compl. ¶ 184. But “[i]t would be a strange thing indeed if uncertainty were sufficiently certain harm to constitute an injury in fact.”

³ See *Twin Rivers Paper Company Co. v. SEC*, 934 F.3d 607, 613 (D.C. Cir. 2019) (quoting *Chamber of Commerce v. EPA*, 642 F.3d 192, 199 (D.C. Cir. 2011) (“It is ‘not enough to aver than unidentified members have been injured.’”))

See N. Eng. Power Generators Ass'n v. FERC, 707 F.3d 364, 369 (D.C. Cir. 2013); *see also Gerber Prods. Co. v. Perdue*, 254 F. Supp. 3d 74, 81 (D.D.C. 2017) (“[U]ncertainties that arise from regulatory decisions are not the kind of concrete and particularized injuries to establish an injury in fact.”).

Plaintiffs cannot plausibly establish a concrete injury-in-fact caused by a regulation that takes no position one way or the other on whether its authorizing statute includes an implied private right of action. Private rights of action are created by Congress, not agencies. *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001). And HHS explained that the 2020 Rule does not (and cannot) eliminate any private right of action created by Congress. To the contrary, “[t]o the extent that Section 1557 permits private rights of action, plaintiffs can assert claims under Section 1557 itself rather than under the Department’s Section 1557 regulation.” 85 Fed. Reg. at 37,203. Plaintiffs cannot plausibly make any “effort to explain why providers or insurers would be willing to risk revising their practices or policies” in some way *because of* the lack of a private right of action *in the rule*, in light of the continued plausibility that the statute itself includes such an implied right of action. *See Washington v. HHS*, No. C20-1105 JLR, 2020 WL 5095467, at *8 (W.D. Wash. Aug. 28, 2020); *see also Clapper*, 568 U.S. at 413 (no standing where plaintiffs “can only speculate as to whether [a] court will” make a certain conclusion). And plaintiffs’ challenge to the 2020 Rule’s failure to specify that compensatory damages are available under Section 1557, *see* Am. Compl. ¶¶ 310-11, fails for the same reasons. “The proper context for quarrels surrounding the [availability of compensatory damages] for Section 1557 claims would be an actual lawsuit bringing such a claim.” *See, Whitman-Walker*, 2020 WL 5232076, at *20.

(5) *Incorporation of Title IX’s Exemptions.*

The Complaint alleges that the 2020 “Rule’s incorporation of the Title IX religious and abortion exemptions will embolden and, in some cases allow, hospitals, insurers, and others to discriminate against patients based on sex by using religious or anti-abortion beliefs as justifications to refuse care or coverage.” Am. Compl. ¶ 191. Plaintiffs allege that “[t]his will disproportionately harm LGBTQ+ people and people who have obtained or are seeking

reproductive health services, including abortion and other pregnancy related care.” *Id.* But this allegation is not particularized to any of the named plaintiffs. And even if it were particularized, “[s]imply asserting, without any elaboration, that individuals will experience discrimination . . . does not ‘suffice to establish the substantial probability’ that discrimination will actually occur as required to establish standing.” *Whitman-Walker*, 2020 WL 5232076, at *18;⁴ *see Massachusetts*, 923 F.3d at 221-28 (describing the type of concrete facts that must be alleged and then proven at each step of a causal chain to establish standing by way of a “substantial risk of . . . injury”).

(6) *Elimination of protections against discrimination on the basis of association*

The Amended Complaint includes a claim that the 2020 Rule violates the APA because HHS “offered no reasoned basis for rescinding the 2016 Rule’s prohibitions on discrimination on the basis of association.” Am. Compl. ¶¶ 280, 354. But the Amended Complaint is utterly devoid of any allegations—let alone clear ones—explaining how any plaintiff has suffered an injury caused by this aspect of the 2020 Rule. Plaintiffs thus lack standing to challenge it.

(7) *Notice and Taglines*

The Amended Complaint claims that the 2020 Rule’s modifications to notice and taglines requirements is arbitrary and capricious. Am. Compl. ¶¶ 331-38, 349-50, 354, 409. The Amended Complaint includes allegations that the 2020 Rule’s modifications to “the notice and taglines requirement will eliminate and weaken protections for individuals, especially [limited English proficiency (‘LEP’)] individuals.” *Id.* ¶ 206; *see also id.* ¶ 207 (the 2020 Rule’s “repeal of these

⁴ In *Whitman-Walker*, the court found that at least one plaintiff had standing to challenge the 2020 Rule’s explicit incorporation of Title IX’s religious exemption. But in this case, plaintiffs do not allege injuries similar to those demonstrated in *Whitman-Walker*. And, in any event, the court’s decision that those injuries were sufficiently proven and fairly traceable to the defendant were erroneous and inconsistent with law in this circuit. For one thing, the proof of actual causation offered by plaintiffs in *Whitman-Walker* come nowhere close to the type of proof that is required to demonstrate concrete injury because plaintiffs never identified a single covered entity that is certain to use the religious exemption. *See Massachusetts v. HHS*, 923 F.3d 209, 223-25 (1st Cir. 2019) (concrete injury from religious exemption demonstrated where plaintiffs could show it was “highly likely that at least three employers in the Commonwealth with self-insured plans (that is, exempt from state regulation due to ERISA) will use expanded exemptions”).

protections will deny LEP individuals access to materials that help them better understand basic health information, access preventative services and avoid adverse effects.”). But it includes no clear allegations indicating how any of the named Plaintiffs have been injured by the 2020 Rule’s changes to the notice and taglines requirements. To be sure, the Amended Complaint alleges that eight Plaintiffs serve “LGBTQ+ people, including individuals and families with LEP.” Am. Compl. ¶ 19. But this allegation is insufficient to establish organizational standing because it does not clearly allege facts indicating how, at a minimum, any organizational plaintiffs’ “mission has been ‘frustrated’ by the challenged conduct *and* it has expended resources to combat it.” *Equal Means Equal I*, 450 F. Supp. 3d at 7. Nor have plaintiffs made any allegations to establish associational standing to challenge the 2020 Rule’s modifications to the notice and taglines requirements because the Amended Complaint fails to “at the very least, ‘identify a member who has suffered the requisite harm’” and allege facts supporting the member’s standing to challenge this change. *Draper*, 827 F.3d at 3 (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009)).

(8) Conforming Amendments to Related Regulations

The Amended Complaint claims that conforming amendments the agency made to related regulations are contrary to law and arbitrary and capricious. Am. Compl. ¶¶ 339-46, 409. But the Amended Complaint is utterly devoid of any allegations—let alone clear ones—explaining how any plaintiff has suffered an injury caused by the changes to these provisions in the 2020 Rule. Plaintiffs thus lack standing to challenge these provisions as well.

Because plaintiffs lack standing to challenge any of the provisions of the 2020 rule at which their Amended Complaint takes aim, this case should be dismissed in its entirety for lack of subject matter jurisdiction. This Court should reject plaintiffs’ invitation to issue an advisory opinion on their laundry list of policy disagreements with HHS’s administration of Section 1557.

B. Plaintiffs' Challenges to HHS's Decision not to Define "On the Basis of Sex" and Several of HHS's Other Decisions are Not Ripe for Review

Several of plaintiffs' claims fail at the threshold for an additional reason as well—they are not ripe. Section 1557 prohibits covered entities from discriminating, among other things, on the basis of sex. Although the 2016 Rule provided a non-exhaustive definition of what that term means, HHS declined to include a definition of "on the basis of sex" in the 2020 Rule. *See* 85 Fed. Reg. at 37,244 (to be codified at § 92.2). The Rule instead "relies upon[] the plain meaning of the term in the statute," 85 Fed. Reg. at 37,178, consistent with Section 1557(c)⁵ and black letter law permitting agencies discretion to decline to proceed by rulemaking, *see NLRB v. Bell Aerospace Co. Div. of Textron*, 416 U.S. 267, 294 (1974) ("[T]he choice between rulemaking and adjudication lies in the first instance within the [agency's] discretion."); *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947) ("[T]he choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency."). 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, in the preamble to the 2020 Rule, HHS recognized that, "to the extent 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." 85 Fed. Reg. at 37,168.

With that context in mind, the Court should dismiss on ripeness grounds plaintiffs' challenge to HHS's decision to decline to include a definition of "on the basis of sex" in the 2020 Rule, which is premised on plaintiffs' speculation that the 2020 Rule does not cover sexual orientation, gender identity, sex stereotyping, pregnancy, false pregnancy, termination of pregnancy, or childbirth discrimination.

[T]he ripeness requirement is designed "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial

⁵ Section 1557(c) provides that HHS "may"—not must—"promulgate regulations to implement this section."

interference until an administrative decision has been formalized and its effect felt in a concrete way by the challenging parties.”

Ohio Forestry Ass’n v. Sierra Club, 523 U.S. 726, 732-33 (1998) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967)). “Determining whether administrative action is ripe for judicial review requires [courts] to evaluate (1) the fitness of the issues for judicial decision and (2) the hardship of the parties of withholding court consideration.” *Nat’l Park Hosp. Ass’n v. U.S. Dep’t of Interior*, 538 U.S. 803, 808 (2003). Both hardship *and* fitness of the issues for decision must exist for pre-enforcement review to be ripe. *See Socialist Labor Party v. Gillian*, 406 U.S. 583, 588 (1972) (admitting the existence of standing (and thus of injury) but deeming the matter unripe because issue was unfit for judicial decision); *McInnis-Misenor v. Maine Med. Ctr.*, 319 F.3d 63, 70 (1st Cir. 2003) (“Both prongs of the test must be satisfied, although a strong showing on one may compensate for a weak on the other.”).

(1) Hardship.

Plaintiffs’ injuries—even assuming they are sufficient to establish standing—are insufficient to establish hardship from awaiting litigation of their claim until after some concrete instance of actual discrimination. Plaintiffs allege nothing more than abstract confusion and uncertainty stemming from HHS’s decision in the 2020 Rule not to define “on the basis of sex.” *See, e.g.*, Am. Compl. ¶ 2 (2020 Rule “sows confusion”); *id.* ¶ 11 (Rule will “exacerbate” discrimination based on pregnancy “by sowing confusion about the protections against and remedies for discrimination”); *id.* ¶ 190 (Rule “will create confusion about the scope of protections against discrimination under federal law”). But “mere uncertainty as to the validity of a legal rule” does not “constitute[] a hardship for purposes of the ripeness analysis.” *Nat’l Park Hosp. Ass’n*, 538 U.S. at 811. To be sure, it is “easier, and certainly cheaper, to mount one legal challenge against the [2020 Rule] now, than to pursue many challenges to each” plausible instance of hypothetical future discrimination by a health program or activity to establish the meaning of “on the basis of sex” though adjudication or litigation under Section 1557. *Ohio Forestry Ass’n*, 523 U.S. at 734-35. But courts have “not considered this kind of litigation cost saving sufficient by itself to justify review in a case that would otherwise be unripe.” *Id.*

(2) *Fitness of the Issues for Decision.*

Whether or not the hardship criterion is satisfied is ultimately irrelevant because the nature of the issue on which plaintiffs seek review—HHS’s decision *not* to define the meaning of a statutory term by rule, but to permit its meaning to develop through case-by-case adjudication—is precisely “the kind of ‘abstract disagreement over administrative policies,’ . . . that the ripeness doctrine seeks to avoid.” *Ohio Forestry Ass’n*, 523 U.S. at 736 (quoting *Abbott Labs.*, 387 U.S. at 148); *see also Time Warner Entm’t Co., L.P. v. FCC*, 93 F.3d 957, 974 (D.C. Cir. 1996) (quoting *Chamber of Commerce v. Reich*, 57 F.3d 1099, 1100 (D.C. Cir. 1995)) (pre-enforcement review unripe where claim is *not* “sufficiently fleshed out for the court to see the concrete effects and implications of its decision”).

“The fitness prong of th[e] inquiry implicates both constitutional and prudential justiciability concerns.” *Algonquin Gas Transmission, LLC v. Weymouth*, 919 F.3d 54, 62 (1st Cir. 2019). “Article III principles require [courts] first to ask ‘whether the claim involves uncertain and contingent events that may not occur as anticipated or may not occur at all,’ thus rendering any opinion [the court] might offer advisory.” *Id.* (quoting *Ernst & Young v. Depositors Econ. Prot. Corp.*, 45 F.3d 530, 536 (1st Cir. 1995)); *see also City of Fall River, Mass. v. FERC*, 507 F.3d 1, 6 (1st Cir. 2007) (quoting *McInnis-Misenor v. Me. Med. Ctr.*, 319 F.3d 63, 70 (1st Cir. 2003)) (“In the fitness inquiry, prudential concerns focus on the policy of judicial restraint from unnecessary decisions.”).

“Among other things, the fitness of an issue for judicial decision depends on whether it is ‘purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency’s action is sufficiently final.’” *Atl. States Legal Found. v. EPA*, 325 F.3d 281, 284 (D.C. Cir. 2003) (quoting *Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1204 (D.C. Cir. 1998)). To be sure, the questions in this case are purely legal, “[b]ut even purely legal issues may be unfit for review.” *Id.*; *see also Ernst & Young v. Depositors Econ. Prot. Corp.*, 45 F.3d 530, 537 (1st Cir. 1995) (“The notion that disputes which turn on purely legal questions are

always ripe for judicial review is a myth.”). Here, the issues are not fit for judicial review because of the latter two factors.

In this case, plaintiffs’ challenge to HHS’s decision not to define “on the basis of sex” by rule is not ripe for review because “further administrative action is needed to clarify the agency’s position.” *Aulenback, Inc. v. FHA*, 103 F.3d 156, 167 (D.C. Cir. 1997) (quoting *Action All. of Senior Citizens of Greater Phila. v. Heckler*, 789 F.2d 931, 940 (D.C. Cir. 1986)). As in *Aulenback*, HHS denies promulgating the policy plaintiffs attribute to it. *See id.*; *see also Truckers United for Safety v. FHA*, 139 F.3d 934, 937-38 (D.C. Cir. 1998) (challenge to agency guidance particularly unripe where petitioners claim guidance clearly establishes a certain policy, but government disagrees, and the guidance “do[es] not [establish purported policy] with the clarity necessary for the court to intercede without first giving the agency a chance to apply its regulations in a concrete factual situation”).

Plaintiffs allege that the 2020 Rule “removes protections against discrimination based on gender identity and sex stereotyping.” Am. Compl. ¶ 10; *see also id.* ¶ 268 (citing 85 Fed. Reg. at 37,180). With respect to gender identity, the 2020 Rule’s “position” from the regulation’s preamble that plaintiffs cite was qualified: “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.” 85 Fed. Reg. at 37,168. And if any such decision “means that Title IX and Section 1557 must incorporate protection for gender identity and sexual orientation discrimination, then that means that the 2020 Rule does, in fact, extend protection against discrimination to LGBTQ individuals via the Rule’s incorporation of Title IX by reference.” *Washington*, 2020 WL 5095467, at *8.

Similarly, with respect to sex stereotyping, plaintiffs cannot plausibly claim that “HHS . . . contends that discrimination ‘on the basis of sex’ does not encompass discrimination on the basis of sex stereotyping.” *See* Compl. ¶ 268 (citing 85 Fed. Reg. at 37,183-86). Nowhere in the cited pages of the preamble did HHS purport to claim that discrimination on the basis of sex under Title IX does not encompass sex stereotyping. To the contrary, HHS explained that, “[t]o the extent

that sex stereotyping is a recognized category of sex discrimination under longstanding Supreme Court precedent, this final rule commits [HHS] to continuing to vigorously enforce Title IX through Section 1557, and therefore the Department estimates that this final rule will not have any material effect on the scope of sex stereotyping claims as authorized by Title IX and Section 1557.” 85 Fed Reg. at 37,239. There is no reason to believe that HHS or courts will construe Section 1557 to exclude sex stereotyping claims in light of HHS’s decision to decline to explicitly define “on the basis of sex” by rule to include sex stereotyping. Considering the implausibility of HHS determining in a concrete case that Section 1557’s prohibition on sex discrimination excludes “sex stereotyping,” principles of judicial restraint demand that this Court, at a minimum, await any such concrete determination and not undertake the abstract exploration plaintiffs presently request.

The Amended Complaint accurately alleges that the 2020 Rule “refuses to confirm that discrimination on the basis of sex necessarily prohibits discrimination on the basis of termination of pregnancy, instead stating that it ‘declines to speculate’ about when it would consider such discrimination unlawful under Section 1557.” Am. Compl. ¶ 272. Any claim related to this allegation is not ripe unless and until a concrete case is presented for adjudication—that is, until HHS *does* take a position on that and related questions. As HHS explained, even though the 2020 Rule “does not adopt a position on whether discrimination on the basis of termination of pregnancy can constitute discrimination on the basis of sex, it does not mean that OCR could not consider such claims of discrimination.” 84 Fed. Reg. at 27,870 n.159. Indeed, Plaintiffs acknowledge that HHS stated that “it will ‘fully enforce its statutory authorities concerning any discriminatory denial of access to women’s health services, including those related to pregnancy.’” Am. Compl. ¶ 279. Plaintiffs complain that HHS does not “provid[e] guidance” *now* on these issues, which is “the purpose of agency rulemaking,” *id.* ¶ 272, but that position fails to account for black letter law permitting agencies discretion to proceed by rulemaking or adjudication. *See supra*, at 24. This Court should decline plaintiffs’ invitation to entangle itself in its abstract disagreement over administration policies just because they would prefer guidance now.

If adjudication of concrete cases establishes that the 2020 Rule covers the very type of discrimination plaintiffs fear it does not cover, this case would be entirely advisory. *See Texas v. United States*, 523 U.S. 296, 300 (1998) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580-81 (1985)) (“A claim is not ripe for adjudication if it rests upon ‘contingent future events that may not occur as anticipated, or indeed may not occur at all.’”); *see also Trans Union LLC v. FTC*, 295 F.3d 42, 51 (D.C. Cir. 2002) (“Unless and until [agency] determines [meaning of regulatory term], and at what level, the issue is not fit for the court to consider”); *Ernst & Young*, 45 F.3d at 537 (“[I]f a plaintiff’s claim, though predominantly legal in character, depends on future events that may never come to pass, or that may not occur in the form forecasted, then the claim is unripe.”). Plaintiffs’ claims that HHS failed to engage in reasoned decision-making by failing to consider *Bostock* are entirely irrelevant if adjudication or litigation establishes that the plain meaning of Section 1557 covers sex stereotyping, sexual orientation discrimination, gender identity discrimination, and termination of pregnancy discrimination. Am. Compl. ¶¶ 273-74; *see Texas*, 523 U.S. at 301 (“The operation of the statute is better grasped when viewed in light of a particular application.”). The case that plaintiffs bring “is, at this stage, largely hypothetical, and such cases are seldom fit for federal judicial review.” *Ernst & Young*, 45 F.3d at 538. For these reasons, resolution of the meaning of on the basis of sex in Section 1557 should await a concrete dispute about a particular instance of discrimination.

Moreover, “consideration of the issue would benefit from a more concrete setting.” *Atl. States*, 325 F.3d at 284 (citation omitted). Indeed, the Supreme Court had the benefit of concrete cases to determine that sexual orientation and transgender discrimination is encompassed in sex discrimination under Title VII—and it declined to go further, emphasizing “the benefit of adversarial testing” in other specific contexts *before* drawing further conclusions. *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1753 (2020). So too here.

The same principles bar pre-enforcement judicial review of several of plaintiffs’ other claims, specifically: HHS’s decision not to explicitly prohibit categorical coverage exclusions by rule; HHS’s decision not to take a position on implied private rights of action by rule; HHS’s

decision on the legal standards applicable for enforcing Section 1557 claims; HHS’s decision as to whether compensatory damages are available for Section 1557 claims; and HHS’s decision not to include provisions barring associational discrimination by rule. Adjudication or litigation may establish that Section 1557’s prohibition on sex discrimination renders categorical coverage exclusion of gender-affirming care illegal. And litigation over concrete claims of discrimination may establish whether a private right of action exists for enforcing Section 1557 regardless of the 2020 Rule’s silence on that issue. Finally, the “proper context for quarrels surrounding the legal standard for Section 1557 claims [and, in equal measure, the extent to which compensatory damages are available and whether categorical coverage exclusions or associational discrimination is prohibited by Section 1557,] would be an actual lawsuit bringing such a claim.” *See Whitman-Walker*, 2020 WL 5232076, at *20. Plaintiffs allege no hardship from awaiting concrete decisions by courts or HHS as to the construction of Section 1557 after concrete instances of discrimination before seeking judicial review, other than abstract confusion or uncertainty. Any such uncertainty is insufficient to provide plaintiffs with Article III standing; “uncertainty” is also insufficient to establish the higher threshold of “constitut[ing] a hardship for purposes of the ripeness analysis.” *Nat’l Park Hosp. Ass’n*, 538 U.S. at 811.

II. COUNTS III AND IV SHOULD BE DISMISSED UNDER RULE 12(B)(6).

In addition to its jurisdictional defects, the Complaint fails to state claims upon which relief may be granted. “Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law.” *Neitzke v. Williams*, 490 U.S. 319, 326 (1989). And “[t]o survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

A. The Complaint Does Not State an Equal Protection Claim.

Plaintiffs’ equal protection claim, Count III, Am. Compl. ¶¶ 415-23, falls short. Plaintiffs’ allegations do not amount to a legally sufficient claim that Section 1557 violates the Constitution, and because the 2020 Rule does nothing more than repeat the text of the statute, Plaintiffs’

allegations likewise cannot constitute a claim that the Rule violates the Constitution. Plaintiffs claim in bare terms that the Rule “discriminates on the basis of sex,” *id.* ¶ 420, but Plaintiffs identify no way in which either Section 1557 nor the 2020 Rule “isolates [one sex] or subject[s] them, as a discrete group, to special or subordinate treatment.” *See Schweiker v. Wilson*, 450 U.S. 221, 231 (1981).⁶ Rather, “individuals [of any sex, sexual orientation, or gender identity] remain protected by the same civil rights laws as any other individual, and [HHS] will vigorously enforce their statutory and regulatory civil rights.” 85 Fed. Reg. at 37,192.

The Amended Complaint also fails to plausibly allege that the 2020 Rule was motivated by discriminatory animus. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (holding that “facial plausibility” is the relevant standard for pleading claims of invidious discrimination). As an initial matter, because plaintiffs have not alleged that the 2020 Rule was motivated by discrimination against a suspect class, rational basis scrutiny is appropriate, *see supra* note 6, and the agency action violates equal protection only if it is “inexplicable by anything but animus toward the class it affects [and accordingly] lacks a rational relationship to legitimate state interests.” *Romer v. Evans*, 517 U.S. 620, 632 (1996). Here, HHS provided a non-discriminatory explanation for each of the 2020 Rule’s provisions. *See, e.g.*, 84 Fed. Reg. at 27,849 (changes to Rule eliminating explicit constructions of Section 1557 “may minimize litigation risk.”); 85 Fed. Reg. at 37,187, 37,196-98) (explaining reasons for removing explicit prohibitions on categorical coverage exclusions); 84 Fed. Reg. at 27,857, 27,862 (explaining reasons for removing notice and taglines requirement); 85 Fed. Reg. at 37,170 (explaining that HHS construed the scope of federal entities covered by Section 1557 in a manner that is more consistent with the statutory text); 85 Fed. Reg. at 37,172 (explaining that HHS construed the scope of health programs or activities covered by Section 1557 in a manner that is more consistent with the statutory text); 84 Fed. Reg. at 27,860

⁶ Because neither Section 1557 nor the Final Rule includes 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 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 Massachusetts v. HHS*, 682 F.3d 1, 9 (1st Cir. 2012); *Cook v. Gates*, 528 F.3d 42, 61-62 (1st Cir. 2008).

(2020 Rule “ensur[es] better compliance with the mandates of Congress, avoid[s] further litigation, relieve[s] regulatory burdens, reduce[s] confusion, reduce[s] uncertainty about the scope of Section 1557, promote[s] substance compliance, and improve[s] the consistency of regulatory requirements between entities required to comply with the civil rights laws as a result of Section 1557 and those directly subject to only to the underlying civil rights laws.”).⁷ And to the extent plaintiffs have standing to assert ripe claims, the doctrine of constitutional avoidance dictates that the reasonableness of these explanations are better addressed as claims that the agency acted arbitrarily under the APA, rather than under the Constitution. See *Cooper Hosp./Univ. Med. Ctr. v. Burwell*, 179 F. Supp. 3d 31, 46 (D.D.C. 2016) (“if the challenge is to agency action, the equal-protection challenge is subsumed within the APA challenge”), *aff’d sub nom. Cooper Hosp. Univ. Med. Ctr. v. Price*, 688 F. App’x 11 (D.C. Cir. 2017). Accordingly, Count III should be dismissed.

But even assuming strict scrutiny was applicable—which it is not—plaintiffs have failed to adequately plead discriminatory animus. “To plead animus” in such a circumstance, “a plaintiff must raise a plausible inference that an ‘invidious discriminatory purpose was a motivating factor’ in the relevant decision.” *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1915 (2020) (quoting *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 266 (1977))⁸. “Possible evidence includes disparate impact on a particular group, ‘departures from the normal procedural sequence,’ and ‘contemporary statements from members of the decisionmaking body.’” *Id.* (quoting *Arlington Heights*, 429 U.S. at 266-68). In this case, plaintiffs allege that animus is

⁷ “[A]s matters of public record, statements in the Federal Register can be examined on 12(b)(6) review.” *Marshall Cty Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 n. 6 (D.C. Cir. 1993).

⁸ The *Arlington Heights* framework for analyzing whether a discriminatory purpose has fatally tainted government action requires alleged discrimination against a suspect class that is subject to strict judicial scrutiny. See *Regents of Univ. of Cal.*, 140 S. Ct. at 1915-16; *Arlington Heights*, 429 U.S. at 268-71. So even if this Court were to ignore *Massachusetts v. HHS*, 682 F.3d at 9 (1st Cir. 2012) and conclude that the Amended Complaint alleges discrimination against a class subject to intermediate scrutiny, the *Arlington Heights* framework would be inapplicably burdensome to the government. Nevertheless, because the Amended Complaint fails to allege facts demonstrating a plausible equal protection claim even under the *Arlington Heights* framework, plaintiffs’ equal protection claim must be dismissed.

evidenced by (1) statements and actions of the President, the White House, the Department of Justice, the Department of Education, the Census Bureau, the Department of Housing and Urban Development, and the Department of Labor, Am. Compl. ¶¶ 365-76; (2) several statements of Defendant Severino primarily from before he took his post as Director of HHS’s Office for Civil Rights, *id.* ¶¶ 377-79, 387-88; and (3) several purported policies and decisions of HHS, *id.* ¶¶ 380-86.

As an initial matter, plaintiffs’ claims arise under the APA, so “the focal point for judicial review should be on the administrative record” not extra-record statements introduced “initially in the reviewing court.” *Camp v. Pitts*, 4111 U.S. 138, 142 (1973). These principles are not disregarded just because plaintiffs raise a constitutional claim; 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).⁹

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—and even if strict scrutiny would be appropriate here—which it would not be—“none of [plaintiffs’] points, either singly or in concert, establishes a plausible equal protection claim.” *Regents of Univ. of Cal.*, 140 S. Ct. at 1915. First, the cited statements and actions of the President, the White House, and various other administrative agencies “are unilluminating.” *Id.* at 1916. Only the Secretary of Health and Human Services Alex Azar and Director of the HHS Office for Civil Rights Roger Severino were vested with authority to make the decision at issue. So statements and actions by others do not give rise to an inference of discriminatory motive on behalf of the relevant decisionmakers. *See Batalla Vidal v.*

⁹ Numerous courts 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).

Nielsen, 291 F. Supp. 3d 260, 278 (E.D.N.Y. 2018), *rev'd on other grounds but affirmed on this matter Regents of Univ. of Cal.*, 140 S. Ct. at 1916).

Plaintiffs do rely upon several alleged statements of Defendant Severino, *see* Am. Compl. ¶¶ 377-79. But these “cited statements are unilluminating” as well. *Regents of Univ. of Cal.*, 140 S. Ct. at 1916. Because they were all made in 2016, before Severino was Director of HHS’s Office for Civil Rights, they are “remote in time and made in the unrelated context[.]” of Severino’s life as a private citizen. *Id.* at 1916. So they “do not qualify as ‘contemporary statements’ probative of the decision at issue.” *Compare id.* at 1916, *and* Am. Compl. ¶¶ 377-79 (failing to allege contemporary statements because they were all made before Defendant was vested with authority to make the decision at issue), *with Masterpiece Cakeshop, Ltd v. Colo. Civil Rights Comm’n*, 138 S. Ct. 1719, 1729 (2018) (contemporary statement made by decisionmaker when it “surfaced at the [decisionmaking body’s] formal, public hearings” when “convened publically to consider” the plaintiff’s “case”).

Even assuming that they were contemporary statements, the statements by Defendant Severino on which plaintiffs rely are mere legal and policy disagreements, and there is nothing in the Constitution prohibiting persons with different policy views from holding government positions and making policy. These statements, when examined in full context, reflect reasonable criticisms about the prior rule (and other policies) in a complex area of social policy, including the effect of the rule on “sincerely held religious beliefs,” *see Masterpiece Cakeshop*, 138 S. Ct. at 1729; 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, acknowledging the interaction of Title VII with express statutory exemptions for religious organizations, the First Amendment, and the Religious Freedom Restoration Act as issues for future cases. 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 discriminatory animus.

Other policies or decisions by HHS that plaintiffs rely on also are not illuminating. Some are entirely distinct policies, remote in time and in unrelated contexts, like decisions to pause and reexamine agency policies upon the commencement of a new administration, *see* Am. Compl. ¶ 380 (discussing decision not to publish regulation from prior administration). Others involve HHS’s purported decision “has ceased to update its webpage on the health and well-being for LGBTQ+ people,” *id.* Even assuming this last allegation is true, failure to update a website is hardly evidence of discriminatory purpose. Indeed, any allegation that HHS failed to single out the LGBTQ+ community for special treatment, *see also id.* ¶ 381-83, “as a matter of law and logic, does not violate [equal protection] in any conventional sense” because, if anything, equal protection makes suspect any decision by government to single out a certain class of persons for special treatment. *See Coalition for Economic Equity v. Wilson*, 122 F.3d 692, 702 (9th Cir. 1997).

The Amended Complaint’s allegations also completely mischaracterize Defendant Severino’s public statements. For example, the Complaint alleges that “Severino said that he was not aware of any claims filed with OCR regarding LGBTQ+ discrimination.” Am. Compl. ¶ 388. But that allegation is not plausible in light of the cited source; the source article actually reported Severino’s statement as “I’m not aware of any claims that have been filed alleging any LGBT identity issues *where somebody sought protection under the conscience protection statutes.*” *See* <https://www.rollcall.com/2019/04/17/trump-civil-rights-official-wants-to-defend-abortion-opponents-and-religious-freedom/> (emphasis added). In any event, it’s far from clear how this statement reflects discriminatory animus of any kind.¹⁰

¹⁰ To the extent plaintiffs are alleging a disparate impact on the LGBTQ community, it is well established that equal protection disparate impact claims are not permitted under the Constitution. *See e.g., Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 265, 97 S. Ct. 555,

B. Count IV Should be Dismissed in Part to the Extent it Challenges Cherry-Picked Text that is Qualified and, thus, Does Not Constitute Final Agency Action; Challenges to that Cited Preamble Text are Not Reviewable under the APA.

In Count IV, Plaintiffs allege that “HHS adopted a general enforcement policy based on its reading of Section 1557 in the [2020] Rule and will ‘return to enforcing’ Section 1557 using ‘the biological binary meaning of sex,’ without regard for discrimination on the basis of, *inter alia*, sexual orientation or transgender status.” Am. Compl. ¶ 425(a) (citing 85 Fed. Reg. at 37,180).

But plaintiffs have not plausibly alleged final agency action with respect to HHS’s purported post-*Bostock* enforcement policy regarding gender identify and sexual orientation discrimination complaints. “The APA limits judicial review to ‘final agency action for which there is no other adequate remedy in court.’” *Soundboard Ass’n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018) (quoting 8 U.S.C. § 704), *cert. denied sub nom. Soundboard Ass’n v. F.T.C.*, 139 S. Ct. 1544 (2019). “[W]ithout final agency action, ‘there is no doubt that appellant would lack a cause of action under the APA.’” *Id.* (quoting *Reliable Automatic Sprinkler Co. v. CPSC*, 324 F.3d 726, 731 (D.C. Cir. 2003)). “Agency actions are final if two independent conditions are met: (1) the action ‘markets the consummation of the agency’s decisionmaking process’ and is not ‘of a merely tentative or interlocutory nature;’ and (2) it is an action ‘by which rights or obligations have been determined, or from which legal consequences will flow.’” *Id.* (quoting *Bennett v. Separ*, 520 U.S. 154, 177-78 (1997)). “[B]oth prongs of the *Bennett* test” must be satisfied for action to be considered final. *Id.* (quoting *Sw. Airlines Co. v. U.S. Dep’t of Transp.*, 832 F.3d 270, 275 (D.C. Cir. 2016)).

First, the statements plaintiffs cite were qualified. HHS explained that “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 the application of the Court’s construction.” *See* 85 Fed. Reg. at 37,168. This qualification makes clear that the preamble’s other statements—cherry-picked in the Amended Complaint—were “of a merely

563, 50 L. Ed. 2d 450 (1977) (“Proof of [] discriminatory intent or purpose is required to show a violation of the Equal Protection Clause.”) *Washington v. Davis*, 426 U.S. 229, 242 (1976).

tentative . . . nature.” *Soundboard Ass’n*, 888 F.3d at 1267 (citation omitted).

Second, in light of the qualification, the cited statements in the preamble have “no legal impact.” *Nat’l Mining Ass’n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (citation omitted). The statements do “not tell regulated parties what they must do or may not do in order to avoid liability” under Section 1557. *Id.* To the contrary, if *Bostock* “means that Title IX and Section 1557 must incorporate protection for gender identity and sexual orientation discrimination, then that means that the 2020 Rule does, in fact, extend protection against discrimination to LGBTQ individuals via the Rule’s incorporation of Title IX by reference.” *Washington*, 2020 WL 5095467, at *8. So nothing that plaintiffs cite establishes any final agency action by HHS *in light of Bostock* and its progeny.

Even if this Court finds that the preamble statements plaintiffs’ cite are final agency action, which they are not, they are still not reviewable. “The APA divides agency action . . . into three boxes: “legislative rules, interpretative rules, and general statements of policy.” *McCarthy*, 758 F.3d at 251. “In terms of reviewability, legislative rules and sometimes even interpretive rules may be subject to pre-enforcement judicial review, but general statements of policy are not.” *Id.* At most, the statements constitute part of a general statement of policy, and accordingly are not reviewable under the APA.¹¹ *See id.* at 251-53 (summarizing cases distinguishing legislative rules from nonreviewable general statements of policy).

CONCLUSION

For the foregoing reasons, this Court should dismiss the Amended Complaint.

Dated: October 14, 2020

Respectfully submitted,

¹¹ Count IV also claims that a second “general enforcement policy is contrary to Section 1557.” Am. Compl. ¶ 425(b). Specifically, the Amended Complaint contends that “HHS adopted a general enforcement policy that will ‘enforce Section 1557’s discrimination requirements against’ a different, narrower, set of entities” than the scope of entities plaintiffs believe are covered by Section 1557. *Id.* Defendants interpret this claim as a challenge to the 2020 Rule under 5 U.S.C. § 706(2)(A). Although plaintiffs lack standing to bring it, *see supra*, at 9-23, if this Court finds plaintiffs do have standing to challenge this provision of the 2020 Rule, defendants will address this claim later in this proceeding at summary judgment.

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