

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

STATE OF NEW YORK, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 1:20-cv-5583-AKH
)	
U.S. DEPARTMENT OF HEALTH)	
AND HUMAN SERVICES, <i>et al.</i> ,)	
)	
Defendants.)	
_____)	

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT**

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INTRODUCTION

While there is little doubt that Plaintiffs have strong opinions about 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—here twenty-two states and the District of Columbia—must demonstrate “injury in fact” as to each provision they seek to challenge. That injury must be concrete, particularized, and imminent. Plaintiffs must also show that the Rule will actually cause the injuries they allege, and that a decision from this Court is likely to redress their asserted injuries. But Plaintiffs do not clearly allege facts that sufficiently establish standing to raise their claims. Indeed, the Complaint is devoid of any facts—let alone clearly alleged ones—that support their standing to challenge any of the 2020 Rule’s provisions.

Washington State—a state with policy views aligning closely with those of Plaintiffs—brought suit independently of Plaintiffs in this case to challenge the 2020 Rule. It sought to invoke the jurisdiction of the United States District Court for the Western District of Washington based on a theory of standing that is similar to Plaintiffs’ here. And three months ago, that court correctly found that Washington State lacked standing to challenge all three of the 2020 Rule’s provisions it sought to preliminarily enjoin. *Washington v. U.S. Dep’t of Health and Human Servs.*, No. 2:20-cv-1105, 2020 WL 5095467 (W.D. Wash. Aug. 28, 2020). For the same reasons, the Plaintiff States here also lack standing to contest the 2020 Rule, and their claims should be dismissed.

What is more, several of the actions challenged by Plaintiffs, such as HHS’s decision not to define “on the basis of sex” by rule, involve HHS’s discretion to decline to proceed by rulemaking. To the extent these claims involve allegations that courts and HHS will ignore relevant Supreme Court jurisprudence in interpreting 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 these claims are not ripe for review at this premature stage, when adjudication or litigation very well may render this Court’s opinion entirely advisory. The Court should dismiss these challenges because they are entirely contingent upon the outcome of future

adjudication of Section 1557 claims.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

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

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

42 U.S.C. § 18116(a). Section 1557 states that the Secretary of HHS “may” (but not that he or she must) issue implementing regulations. *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 tenants 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 “[o]n the basis of sex” to include “discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.” *Id.* at 31,467. The 2016 Rule further defined “gender identity” to include “an individual’s internal sense of gender, which may be male, female, neither, or a combination of male and female....” *Id.* The 2016 Rule listed several specific examples of prohibited discrimination. *See, e.g., id.* at 31,471 (codified at 45 C.F.R. § 92.207). HHS had decided, for example, that covered entities would 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.* at 31,472 (codified at 45 C.F.R. § 92.207(b)(5)). In addition to delineating some examples of what violated Section 1557, the 2016 Rule included a catchall provision providing that “[t]he enumeration of specific forms of discrimination . . . does not limit the general applicability of the prohibition” against covered discrimination. *Id.* (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 adopted those standards across the board, 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 Rule].” *Id.* at 31,380. Nor did it incorporate Title IX’s abortion exemption, 20 U.S.C. § 1688. The 2016 Rule provided that “[i]nsofar as the application of any requirement under this part would violate applicable Federal 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 All. 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, Defendant’s Motion for Voluntary Remand and Stay, *Franciscan All., Inc. v. Price*, No. 7:16-cv-00108, (N.D. Tex. May 2, 2017), ECF No. 92, and in October 2019, the Court vacated the rule’s definition of “on the basis of sex” insofar as the definition included “gender identity” and “termination of pregnancy,” *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 947 (N.D. Tex. 2019); Order, *Franciscan All., Inc. v. Price*, 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 27,849. The Proposed Rule would “empower [HHS] to continue its robust enforcement of civil rights laws prohibiting discrimination on the basis of race, color, national origin, sex, age, or disability in [HHS]-funded health programs or activities, and would make it clear that such civil rights laws remain in full force and effect.” *Id.*

C. The 2020 Rule

HHS received nearly 200,000 comments on the Proposed Rule. After carefully evaluating the extensive record, HHS published the Final Rule on June 19, 2020. 85 Fed Reg. 37,160. 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.* at 37,185. Accordingly, HHS “repeal[ed] a mandate that was, at least, ambiguous and confusing.” *Id.* at 37,187.

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.” *Id.* at 37,168.

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

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

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

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

v. The Final Rule states that the application of Section 1557’s requirements “shall not be imposed or required” if doing so would conflict with certain statutes, including, as relevant here, certain laws protecting conscience and religious liberty. *Id.* at 37,245 (to be codified at 45 C.F.R. § 92.6(b)). The Rule’s preamble states that this change “emphasizes that the Section 1557 regulation will be implemented consistent with . . . conscience and religious freedom statutes.” *Id.* 37,205. Although HHS is “always obligated to comply with relevant Federal statutes,” HHS determined it was appropriate to clarify this point in light of the prior litigation over the 2016 Rule. *See id.* The Final Rule also incorporates Title IX’s religious exemption, and its abortion neutrality language, because by incorporating Title IX into Section 1557, “Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions” of Title IX. *Id.* at 37,193 (quoting *Franciscan Alliance*, 227 F. Supp. 3d at 690–91); *see also id.* at 37,207–08.¹

II. PROCEDURAL BACKGROUND

On July 20, 2020, less than a month before the 2020 Rule was scheduled to go into effect, Plaintiffs—twenty-two states and the District of Columbia—filed this action asserting various

¹ Some aspects of the 2020 Rule have been preliminarily enjoined by two courts. One court has preliminarily enjoined HHS’s repeal of the 2016 Rule’s definition of discrimination “on the basis of sex” insofar as it includes “discrimination on the basis of sex stereotyping” and the 2020 Rule’s explicit incorporation of Title IX’s religious exemption. *See Whitman-Walker Clinic, Inc. v. U.S. Dep’t of Health and Human Servs.*, --- F. Supp. 3d ---, 2020 WL 5232076, at *45 (D.D.C. Sept. 2, 2020), *appeal filed*, No. 20-5331 (D.C. Cir. Nov. 9, 2020). Another court has preliminarily enjoined “the repeal of the 2016 definition of discrimination on the basis of sex,” “gender identity,” and “sex stereotyping,” *Walker v. Azar*, --- F. Supp. 3d ---, ---, 2020 WL 4749859, at *10 (E.D.N.Y. Aug. 17, 2020), and “the repeal of 45 C.F.R. § 92.206,” *Walker v. Azar*, 2020 WL 6363970, at *4 (E.D.N.Y. Oct. 29, 2020). The government has appealed these decisions.

challenges to the Rule under the Administrative Procedure Act (“APA”). *See* Compl. for Decl. & Inj. Relief (“Compl.”), ECF No. 1.

Plaintiffs’ first claim for relief challenges the 2020 Rule’s definition of the scope of entities covered by Section 1557; the explicit incorporation of Title IX’s religious and abortion exemptions; HHS’s decision not to define discrimination “on the basis of sex” by rule; and the modifications to notice and taglines requirements—claiming these aspects of the 2020 Rule should be set aside under § 706(2)(A) as “not in accordance with law.” *See id.* ¶¶ 257-65. Plaintiffs’ second claim for relief challenges only the 2020 Rule’s explicit incorporation of Title IX’s religious exemption as “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right” under § 706(2)(C). *See id.* ¶¶ 266-71. Plaintiffs’ third claim for relief challenges various aspects of the 2020 Rule as arbitrary and capricious under § 706(2)(A) for, among other things, allegedly failing to justify departure from the prior rule or to consider important aspects of the problem. *See id.* ¶¶ 272-79. Finally, Plaintiffs’ fourth claim for relief alleges that the 2020 Rule violates the equal protection component of the Fifth Amendment’s Due Process Clause. *See id.* ¶¶ 280-84. Plaintiffs seek declaratory and injunctive relief as well as an order vacating and setting aside the 2020 Rule. *Id.* at 92.

Defendants now move to dismiss the Complaint in its entirety for lack of jurisdiction.

LEGAL STANDARDS

“A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it.” *Bellin v. Zucker*, 457 F. Supp. 3d 414, 418 (S.D.N.Y. 2020) (quoting *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000)). Plaintiff bears the burden of proving that subject matter jurisdiction exists. *Id.* When reviewing a Rule 12(b)(1) motion to dismiss, a court “must accept as true all material factual allegations in the complaint, but [may] not [] draw inferences from the complaint favorable to plaintiffs.” *J.S. v. Attica Cent. Sch.*, 386 F.3d 107, 110 (2d Cir. 2004).

“When the Rule 12(b)(1) motion is facial, *i.e.*, based solely on the allegations of the complaint . . . and exhibits attached to it (collectively the “Pleading”), . . . [t]he task of the district court is to determine whether the Pleading ‘alleges facts that affirmatively and plausibly suggest that the plaintiff has standing to sue.’” *Carter v. HealthPort Technologies, LLC*, 822 F.3d 47, 56 (2d Cir. 2016) (quoting *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 145 (2d Cir. 2011)).

“The plausibility standard . . . asks for more than a sheer possibility that [the plaintiff might establish subject matter jurisdiction].” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). “Where a complaint pleads facts that are ‘merely consistent with’ [a plaintiff’s standing], it ‘stops short of the line between possibility and plausibility of entitlement to relief.’” *Id.* (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). “Neither conclusory assertions nor unfounded speculation can supply the necessary heft.” *Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 731 (1st Cir. 2016).

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

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) (citation omitted); *see also Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016). 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, they lack standing to advance any of their claims.

“Where, as here, a case is at the pleading stage, the plaintiffs must clearly allege facts demonstrating each element.” *Dubuisson v. Stonebridge Life Ins. Co.*, 887 F.3d 567, 573 (2d Cir. 2018) (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016), *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) (Souter, J.) (citation omitted); *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).

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

Plaintiffs’ theory of standing to challenge HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule is rooted in three alleged injuries it speculates may occur due to HHS’s decision: (1) additional “costs resulting from . . . harm [to] public health [that will occur] by reestablishing discriminatory barriers to care for particularly vulnerable segments of Plaintiffs’ populations,” Compl. ¶ 174; (2) increased administrative costs that the states speculate they might decide to incur or have incurred in order to notify residents about the requirements of applicable state and federal law, *id.*; and (3) costs Plaintiffs speculate they might incur if they decide to exercise their sovereign powers to initiate or ramp-up state antidiscrimination programs, *id.* As the court in *Washington v. HHS* correctly held, none of these theories comes close to plausibly alleging a concrete, particularized, and imminent injury fairly traceable to HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule that is likely to be redressed by a favorable decision by this court. *See Washington*, 2020 WL 5095467, at *6–*11.

1. *Increased Costs to State-Funded Health Care Programs and Public Hospitals*²

² Half of a paragraph in the Complaint alleges that Plaintiffs “have protectable interests in the health and well-being of adults and children who live in their states” and that the 2020 “Rule harms these interests.” Compl. ¶ 222. But it is well-established that “[a] State does not have standing as *parens patriae* to bring an action against the Federal Government.” *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982); *see also Gov’t of Manitoba v. Bernhardt*, 923 F.3d 173, 179–83 (D.C. Cir. 2019); *Michigan v. EPA*, 581 F.3d 524, 529 (7th Cir.

Plaintiffs “do not have Article III standing because they have failed to [plead] a direct link between” HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule and costs to their state-funded health care programs or public hospitals. *See XY Planning Network, LLC v. SEC*, 963 F.3d 244, 252 (2d Cir. 2020). In *XY Planning Network*, the Second Circuit recently clarified that, when a state seeks to invoke loss of future tax revenue as an injury to establish standing to challenge a federal regulation, “[a] ‘fairly direct link’ is required because” tax revenues are “driven by countless variables” and “the unavoidable repercussions of virtually all federal policies . . . suggest . . . that impairment of state tax revenues should not, in general, be recognized as sufficient injury in fact to support state standing.” *Id.* (quoting *Pennsylvania v. Kleppe*, 533 F.2d 668, 672 (D.C. Cir. 1976)). “An increase in the payment of government benefits,” including costs to state-funded health care programs and public hospitals, is just “like a decrease in tax revenues,” *Commonwealth v. U.S. Dep’t of Educ.*, 340 F. Supp. 3d 7, 17 (D.D.C. 2018)—it is “driven by countless variables” and, to provide a basis for standing, requires “a fairly direct link” between the challenged regulation and the increased costs, *see XY Planning Network*, 963 F.3d at 252–53 (citation omitted).

Here, Plaintiffs have not pleaded a direct link between HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule and Plaintiffs’ anticipated increased costs, “relying instead on a causal chain that is too attenuated and speculative to support standing.” *See id.* As discussed in further detail *infra*, Plaintiffs’ theory assumes that health care providers or insurers will change their policies or practices in response to the 2020 Rule’s lack of a definition of “sex” or “on the basis of sex,” and that HHS or courts will construe Section 1557’s plain meaning to exclude discrimination against a variety of classes of individuals. Accordingly, Plaintiffs “theory of injury rests too heavily on” speculation “concerning the long-term effects” of HHS’s decision not to

2009); *State ex rel. Sullivan v. Lujan*, 969 F.2d 877, 883 (10th Cir. 1992); *Nevada v. Burford*, 918 F.2d 854, 858 (9th Cir. 1990). Thus, any alleged injury to the plaintiff states’ citizens does not provide a basis for Plaintiffs’ standing.

define “sex” or “on the basis of sex” in the 2020 Rule on state health program costs to establish Article III standing. *XY Planning Network*, 963 F.3d at 253.

Even if *XY Planning Network* did not dispose of this alleged injury, other precedent would. “To establish Article III standing, an injury must be ‘concrete, particularized, and actual or imminent[,]’” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010)), “not conjectural or hypothetical,” *Friends of the Earth, Inc. v. Laidlaw Env’tl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000). Here, Plaintiffs do not allege actual increased costs to their state-funded health care programs and public hospitals, but instead indicate that HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule will set off a series of events that “will” ultimately result in costs “borne by Plaintiffs in the form of higher government-funded health care costs and increased costs of care for uninsured patients by public hospitals.” *See, e.g.,* Compl. ¶ 251. But these allegations do not plausibly allege *imminent* injury in light of the attenuated chain of inferences that would be necessary for the Court to conclude that they are anything but hypothetical.

“Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending.” *Clapper*, 568 U.S. at 409 (quoting *Lujan*, 504 U.S. at 565 n.2). Although a future injury need not be “literally certain,” there must at least be a “‘substantial risk’ that the harm will occur[.]” *Id.* at 414 n.5 (citation omitted). An “objectively reasonable likelihood” of injury is insufficient to meet Article III’s imminent injury requirement. *Id.* at 410 (determining that “the Second Circuit’s ‘objectively reasonable likelihood’ standard is inconsistent” with Article III’s requirements).

Just like the plaintiff state in *Washington v. HHS*, Plaintiffs here “base[] their [assertions] that the 2020 Rule will increase discrimination and decrease healthcare coverage [with resultant impacts on state health care programs and public hospitals], on assumptions about the impact that the 2020 Rule will have on” citizens in their states. *See Washington*, 2020 WL 5095467, at *7. For example, Plaintiffs assert that the 2020 “Rule purports to remove and reduce federal regulatory

protections for LGBTQ individuals, women and others seeking reproductive health care or with pregnancy-related conditions,” Compl. ¶ 223, and Plaintiffs characterize the 2020 Rule as “eliminating anti-discrimination protections,” *id.* ¶ 224. But the 2020 Rule does not define “sex” or “on the basis of sex” to exclude protections for any of these categories or the categories included in the 2016 Rule’s definition of “on the basis of sex.” *See* 85 Fed. Reg. at 37,244 (inserting 45 C.F.R. § 92.2). To the contrary, HHS “repeal[ed] the 2016 Rule’s definition of ‘on the basis of sex,’ but decline[d] to replace it with a new regulatory definition.” 85 Fed. Reg. at 37,178. “Instead, the final rule reverts to, and relies upon, the plain meaning of the term in the statute.” *Id.* And “to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court’s construction.” *Id.* at 37,168. Accordingly, nothing in the 2020 Rule stands in the way of a construction of “on the basis of sex” under Section 1557 that prohibits discrimination in the same manner as the 2016 Rule explicitly defined the phrase. HHS simply declines to take a position on this matter by rule and leaves development of the grounds of prohibited sex discrimination to case-by-case adjudication in an effort to avoid further litigation. Plaintiffs’ chain of inferences to find increased costs to their health care programs and public hospitals thus requires this Court to speculate that both courts and HHS, when adjudicating future claims of sex discrimination under Section 1557, will define “on the basis of sex” narrowly. And, indeed, if courts do adopt Plaintiffs’ reading of Title IX and Section 1557, HHS would be justified in following it. But “it is just not possible for a litigant to prove in advance that the judicial [or administrative] system will lead to any particular result.” *Clapper*, 568 U.S. at 413-14 (quoting *Whitmore v. Arkansas*, 495 U.S. 149 159–60 (1990)).

In fact, the Second Circuit has instructed that courts must “accept[] plaintiffs’ allegations as true and assum[e] they would be successful on the merits . . . for purposes of [a] threshold jurisdictional analysis[.]” *Dubuisson*, 887 F.3d at 574. And Plaintiffs claim that the “Supreme Court’s holding in *Bostock v. Clayton County* [applies to Section 1557 and provides] that the plain meaning of sex discrimination encompasses discrimination based on an individual’s sexual

orientation and gender identity.” Compl. ¶ 260. Presuming, solely for the sake of argument, that *Bostock* controls precisely as the Plaintiffs allege, there would be no reason to vacate the 2020 Rule, because “the final rule reverts to, and relies upon, the plain meaning of the term [‘sex’] in the statute.” 85 Fed. Reg. at 37,178. As the *Washington v. HHS* court correctly explained:

[i]ronically, . . . Washington’s argument about the impact of *Bostock* harms [its] efforts to establish an injury in fact. Washington’s evidence in support of its claim that it will suffer an injury in fact once the 2020 Rule is implemented presumes that the 2020 Rule does not extend protection against discrimination to LGBTQ individuals. . . . Yet, if Washington is 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. . . . For purposes of standing, . . . the key point is that Washington makes no effort to explain why providers or insurers would be willing to risk revising their practices or policies to discriminate against LGBTQ individuals in light of the Supreme Court’s recent guidance in *Bostock* and the very arguments that Washington advances in this case.

2020 WL 5095467, at *8.

Another reason that the Complaint fails to plausibly allege that HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule is substantially likely to invite discrimination in Plaintiffs’ states in a manner that trickles up to impose costs on Plaintiffs’ health care programs and public hospitals is that the Complaint alleges that their own state laws and regulations explicitly prohibit the very discrimination that they claim the Rule will “invite” in their jurisdictions. *See* Compl. ¶ 175 n.38 (listing state statutes and regulations explicitly prohibiting discrimination by health providers). It makes no sense to presume that third-party health providers are substantially likely to ignore governing state antidiscrimination law in light of the 2020 Rule’s decision not to define “on the basis of sex.” And that is especially true where HHS explained in the preamble to the 2020 Rule that “[s]tates and localities do indeed manifest a range of different views on what specific protections should be accorded to the categories of sexual orientation and gender identity in civil rights law” and HHS decided that “it is appropriate *not* to preempt States’ diverse views on these topics without a clear mandate to do so.” 85 Fed. Reg. at 37,182.

Yet another reason that Plaintiffs can only speculate as to the cost implication of HHS's decision not to define "sex" in the 2020 Rule on their future health care spending budgets and public hospitals is that Plaintiffs "assume away the potential [cost up] sides" of [the 2020 Rule] on their health provision services. *See XY Planning Network, LLC*, 963 F.3d at 253. "The definition of 'recipient' of Federal financial assistance in the civil rights laws referenced in Section 1557 does not contain geographic limitations, and includes . . . States and political subdivisions." 81 Fed. Reg. at 31,380. Accordingly, many of the Plaintiffs' health programs and activities are covered entities under Section 1557. *See id.* So even assuming that the 2020 Rule *does* end up imposing less liability on health providers—a speculative proposition itself—the 2020 Rule might lower, not increase, the costs of operating Plaintiffs' health programs. State health care programs or activities may incur less liability or penalties in the form of withheld federal financial assistance from the instances of discrimination occurring within public hospitals and other state public health services. *See id.* at 54,192 ("[T]he enforcement mechanisms provided for and available under the civil rights laws referenced in Section 1557 include suspension of, termination of, or refusal to grant or continue Federal financial assistance.").

The Complaint does not identify a single third-party provider or insurer that has engaged in discrimination or plans to discriminate against anyone in light of the 2020 Rule. But even if Plaintiffs had identified such a provider or insurer, any resulting injury would be caused *not* by the 2020 Rule, but instead by those third-party entities. To establish standing, "there must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly . . . trac[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'" *Lujan*, 504 U.S. at 560 (quoting *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976)). In *Simon v. E. Kentucky Welfare Rights Organization*, for example, the Supreme Court held that advocacy organizations lacked standing to challenge an IRS regulation they believed would induce hospitals to deny services because "injury at the hands of a hospital is insufficient by itself to establish a case or controversy [where] no hospital is a defendant." *See* 426 U.S. at 41; *see also Branton v. FCC*, 993 F.2d 906, 910–11

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

Just like in *Simon*, Plaintiffs here do not allege that the government will injure them by refusing to provide medical services. Instead, Plaintiffs claim that various components of the 2020 Rule may lead healthcare providers to deny services to certain patients, which will then impose downstream costs on the plaintiff states. *See, e.g.*, Compl. ¶ 177 (discussing “the Rule’s effective invitation to health providers and insurers to discriminate against vulnerable groups”); *id.* ¶ 212 (“the Rule will invite discrimination and confusion within the regulated community”). *id.* ¶ 213 (“the Rule threatens to induce covered entities to roll back or reduce certain protections they previously understood to be required by the law”); *id.* ¶ 226 (alleging that the 2020 Rule “embolden[s] discrimination”). But as discussed, *supra*, Plaintiffs claim that the plain meaning of Section 1557 includes a prohibition on discrimination based on gender identity, sexual orientation, and other categories. And if that is the case, HHS’s decision to rely on the plain meaning of the term “sex” in the 2020 Rule establishes no barrier whatsoever to Plaintiffs’ bringing complaints against entities that engage in those classes of discrimination. This Court should reject Plaintiffs’ invitation to resolve those questions abstractly in the absence of a concrete case or controversy involving alleged actual or imminent discrimination by an actual third-party covered entity against an actual fourth-party patient.

Perhaps recognizing the speculative nature of the chain of inferences that would be required to find imminent concrete injury, the Complaint instead sometimes focuses on “confusion” or “fear of discrimination” that purportedly stems from the 2020 Rule and will supposedly result in imminent injuries. *See, e.g.*, Compl. ¶ 232 (“As a result of the Rule and related confusion and fear of discrimination, LGBTQ individuals who do seek care may avoid disclosing their sexual orientation or transgender status to their health care providers.”). But it is well established that confusion or uncertainty stemming from ambiguity in a law or regulation cannot be an injury that forms the basis of Article III standing. *See New England Power Generators Ass’n v. FERC*, 707

F.3d 364, 369 (D.C. Cir. 2013) (“It would be a strange thing indeed if uncertainty were a sufficiently certain harm to constitute an injury in fact.”); *City & Cnty. of San Francisco v. Whitaker*, 357 F. Supp. 3d 931, 944 (N.D. Cal. 2018) (explaining that “regulatory uncertainty alone does not” establish “cognizable injury” for purpose of Article III standing); *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.”). If the opposite were true, standing doctrine would fail to achieve its purpose of avoiding advisory opinions because every judicial opinion would resolve generalized uncertainty and confusion over the status of the law and anybody confused about obligations under an ambiguous statute would have standing to bring suit for an advisory opinion as to the statute’s requirements from the very moment Congress passes it. *See Spokeo*, 136 S. Ct. at 1548–49 (discussing importance of the “concreteness” requirement).

Plaintiffs’ fear of discrimination theory of injury is that, even if an individual would not be able to establish standing to challenge the 2020 Rule based only on that person’s own fear of possible future discrimination by health providers, *see City of Los Angeles v. Lyons*, 461 U.S. 95, 107 & n.8 (1983) (holding that fear of police misconduct, even when grounded in past injury, is not enough to demonstrate imminent threat: “It is the *reality* of the threat of repeated injury that is relevant to the standing inquiry, not the plaintiff’s subjective apprehensions.”), Plaintiffs can do so based on their speculation that the fears of those individuals will ultimately trickle up to cause increased costs to Plaintiffs’ health programs. *See, e.g.,* Compl. ¶¶ 224, 251 (“By increasing the likelihood that . . . individuals . . . will hesitate to seek care because they fear discrimination, the Rule” will delay care resulting “in higher medical costs later. Some of those costs will be borne by Plaintiffs in the form of higher government-funded health care costs and increased care for uninsured patients by public hospitals”). But the Supreme Court has already held that injuries stemming not from a defendant’s actions but from fear by third parties about the uncertain impacts of a defendant’s actions on other third-parties are “not . . . fairly traceable to [the defendant] because they are based on third parties’ subjective fear.” *Clapper*, 568 U.S. at 417 n.7 (citing

Laird v. Tatum, 407 U.S. 1, 10-14 (1972)). Indeed, Plaintiffs’ “fear of discrimination”-based theory of standing is no different from the theory that was squarely rejected in *Clapper*. See *id.* at 416 (rejecting the Second Circuit’s determination that “respondents [could] establish standing by asserting that they suffer present costs and burdens that are based on a fear of surveillance, so long as that fear is not ‘fanciful, paranoid, or otherwise unreasonable.’”) (quoting *Amnesty Int’l USA v. Clapper*, 638 F.3d 118, 134 (2d Cir. 2011)). As Judge Raggi explained in an opinion ultimately validated by the Supreme Court, had Plaintiffs’ theory of standing “only occurred to the plaintiff in *City of Los Angeles v. Lyons*, 461 U.S. 95 [], he presumably could have avoided the need to show an actual or imminent risk of being subjected to the challenged police chokehold procedure simply by moving from Los Angeles to Glendale, and then claiming that the actual injury of his moving costs was ‘fairly traceable’ to a not-irrational fear of a procedure to which he, after all, had already been subjected.” *Amnesty Int’l USA v. Clapper*, 667 F.3d 163, 180 (2d Cir. 2011) (Raggi, J., dissenting). But that is not the law. See *Clapper*, 568 U.S. at 416 (“[Plaintiffs] cannot manufacture standing merely by inflicting harm on themselves based on fears of hypothetical future harm that is not certainly impending. . . . Any ongoing injuries that respondents are suffering are not fairly traceable to [the challenged statute.]”); *id.* at 417 n.7 (“[A]ssert[ions]” of harm “due to a fear” by third parties “do not establish injury that is fairly traceable to [the challenged statute] because they are based on third parties’ subjective fear.”).

Plaintiffs also cannot establish redressability based on this theory of injury. Plaintiffs’ speculative increased costs purportedly stem from their belief that HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule would “reduce federal regulatory protections for LGBTQ individuals, women and others seeking reproductive health care or with pregnancy related conditions.” Compl. ¶ 223. Plaintiffs complain that “the Rule eliminates the 2016 Rule’s express protections against sex discrimination based on gender identity and sex stereotyping.” *Id.* ¶ 226. And they complain that the 2020 Rule “serves to further stigmatize abortion and may embolden providers to deny abortion care (potentially including contraception).” See *id.* ¶¶ 233, 234.

But there is no available remedy for reviving the 2016 Rule’s explicit definition of “sex” as including discrimination on the basis of “gender identity” or “termination of pregnancy” because these two provisions were vacated from the 2016 Rule by another court. *See Franciscan Alliance Order* at ECF p. 3 (“[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 Alliance*, 414 F. Supp. 3d at 945. Vacating the challenged 2020 Rule would thus leave Plaintiffs with the non-vacated portions of the 2016 Rule and Section 1557 itself, neither of which includes the definition of sex Plaintiffs prefer.

To be sure, *Franciscan Alliance* did not vacate 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 purportedly bypass redressability concerns in granting preliminary relief. *See Whitman-Walker Clinic, Inc. v. U.S. Dep’t of Health and Human Servs.*, --- 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).³ But these decisions fail to explain why the 2020 Rule in any way affects coverage of discrimination based on “sex stereotyping.” Nowhere in the preamble explaining the basis of the 2020 Rule did HHS purport to claim that discrimination on the basis of sex under Title IX or Section 1557 does not encompass sex stereotyping as a general theory of liability. 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. Thus, to the extent that courts have held that Title IX’s prohibition encompasses sex stereotyping, there is no reason to believe that HHS or courts will construe Section 1557 to exclude sex stereotyping

³ In *Bostock*, the Court did not rely on a sex-stereotyping theory to recognize gender identity or sexual orientation coverage under Title VII. *See Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1739, 1743 (2020). It is therefore doubly premature to argue that any failure to explicitly include sex stereotyping in the rule harms Plaintiffs.

claims in light of HHS's decision to decline to explicitly define "on the basis of sex" by rule to include that type of claim.

In addition to addressing gender identity discrimination, Plaintiffs would like this Court to direct HHS to promulgate a rule that explicitly defines discrimination "on the basis of sex" to include sexual orientation discrimination. *See, e.g.*, Compl. ¶ 212 ("By wrongfully suggesting that sexual orientation . . . [is] outside Section 1557's scope, the Rule will invite discrimination and confusion within the regulated community."). But the only remedy available to this Court is to vacate the 2020 Rule's repeal of the 2016 Rule's explicit definition, thereby reviving the non-vacated parts of the 2016 Rule. *See, e.g., New York v. DHS*, 969 F.3d 42, 87 (2d Cir. 2020) ("[C]ourts have long held that when an agency action is found unlawful under the APA, 'the ordinary result is that the rules are vacated.'" (quoting *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998)), *petition for cert. filed*, No. 20-449 (U.S. Oct. 8, 2020); *Palisades Gen. Hosp., Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) (explaining that in APA cases district courts have "jurisdiction only to vacate the [agency's] decision" and have "no jurisdiction to order specific relief") (quoting *Cty. Of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999)). And the 2016 Rule *did not define "on the basis of sex" to include sexual orientation discrimination*. *See* 81 Fed. Reg. at 31,467; *see also id.* at 31,390 ("OCR has decided not to resolve in [the 2016] rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination under Section 1557."). So vacating the 2020 Rule's repeal of the 2016 rule's definition of "on the basis of sex" would not result in a rule that explicitly defines "on the basis of sex" to include sexual orientation discrimination.

In sum, speculation that the states will endure increased costs to their health programs or public hospitals because yet-to-be-identified third-party providers may deny service to hypothetical patients at some point in the future, which may then impose downstream costs on the plaintiff states, 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.

2. *Administrative Costs*

Plaintiffs also allege that HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule “has already required, or will require, Plaintiffs to incur costs by issuing new or revised guidance, regulations, or legislation clarifying distinct state standards and specifying that more stringent state law standards governing anti-discrimination in health care continue to apply.” Compl. ¶ 177. But, as the *Washington v. HHS* court correctly determined, Plaintiffs’ decision to incur these administrative costs is “not fairly traceable to HHS or the 2020 Rule.” *Washington*, 2020 WL 5095467, at *11. To establish standing, Plaintiffs must show that “there is ‘a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court.’” *Oneida Indian Nation v. U.S. Dep’t of the Interior*, 789 F. App’x 271, 274 (2d Cir. 2019) (quoting *Lujan*, 504 U.S. at 560-61).

For example, the Complaint alleges that New York “amend[ed] the State’s insurance regulations to prohibit discrimination based on an insured’s or prospective insured’s actual or perceived sexual orientation, gender identity or expression, or transgender status” and New York State’s financial regulator “also issued a Circular Letter on June 28, 2020, to remind regulated entities of New York’s non-discrimination protections based on sexual orientation, gender identity or expression, and transgender status and the requirements pertaining to preventative care and screenings.” Compl. ¶ 183. As another example, the Complaint alleges that Colorado’s Division of Insurance “updated its website to address LGBTQ resources (including distinguishing between state and federal rights and protections).” *Id.* ¶ 189.

As the *Washington v. HHS* court explained however, “[t]he problem with [these] argument[s] is that these administrative costs are voluntary, ‘self-inflicted’ costs that [the Plaintiffs] impose[] based on [their] desire to inform [their citizens] of changes in federal law.” 2020 WL 5095467, at *10 (quoting *Clapper*, 568 U.S. at 418). Plaintiffs do not point to any part

of the 2020 Rule that requires states to incur these costs to inform their citizens about changes in the 2020 Rule. “[I]f states could establish standing based solely on administrative costs incurred because of a change in agency regulation, then a state could manufacture standing any time it wanted to challenge an agency regulation by expressing a desire to incur administrative costs as a result of the changed regulations. This is not the law.” *Id.*; *see also Clapper*, 568 U.S. at 416 (“[R]espondents cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm. . . . If the law were otherwise, an enterprising plaintiff would be able to secure a lower standard for Article III standing simply by making an expenditure based on a nonparanoid fear.”). Plaintiffs’ costs for “iss[ing] guidance[] and engag[ing] in public education campaigns” to notify their citizens and the entities that they regulate about the requirements of state law, *see* Compl. ¶ 174, may or may not be prudently incurred costs, but they are entirely separate from the 2020 Rule—entities subject to state law must follow state law. The “principle that ignorance of the law is no defense applies whether the law be a statute or a duly promulgated and published regulation”—and there is no exception when a third party’s negligent ignorance of state law might be premised on some federal action. *See United States v. Int’l Minerals & Chemicals Corp.*, 402 U.S. 558, 563 (1971).

The fact that Plaintiffs’ alleged administrative costs stem from the states’ desire to implement their own antidiscrimination laws and policies and not from HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule is underscored by the fact that the Complaint alleges that Plaintiffs have chosen to “train staff, issue guidance, and engage in public education campaigns” related to their decisions to implement their own regulations making “it unlawful to deny coverage or otherwise discriminate on the basis of gender identity [and] sexual orientation.” Compl. ¶¶ 174-75. But as discussed *supra*, neither the 2016 Rule nor the 2020 Rule explicitly defined “on the basis of sex” to cover discrimination on the basis of sexual orientation. *See supra* at 19-20. And gender identity discrimination had been vacated from the 2016 Rule’s definition of “on the basis of sex” by a court back in October 2019. *See Franciscan Alliance*, 414 F. Supp. 3d at 947. Thus, Plaintiffs’ decisions to govern by implementing their own antidiscrimination laws

that may or may not be more protective of their citizens than federal law stems from the wishes of the citizens in those states who desire that their state government implement those policies, not from HHS's decision not to define "sex" or "on the basis of sex" in the 2020 Rule.

What is more, many Plaintiffs allege that they have already incurred these administrative costs. *See, e.g.*, Compl. ¶¶ 183-84 (alleging that New York State incurred administrative costs in June 2020 when implementing their own antidiscrimination laws). But an already-incurred cost "is not an injury that can be redressed through the prospective . . . relief sought in this action." *See Knife Rights, Inc. v. Vance*, 802 F.3d 377, 388 (2d Cir. 2015).

3. *Costs from Enforcing State Antidiscrimination Programs Administered by Plaintiffs*

Finally, Plaintiffs allege that HHS's decision not to define "sex" or "on the basis of sex" in the 2020 Rule will cause them to incur future costs associated with enforcing their own antidiscrimination programs. But this theory also suffers from many of the same flaws as Plaintiffs' other theories.

The Complaint premises this theory on the following reasoning: (1) the Supreme Court's decision on *Bostock* means that Section 1557's sex discrimination prohibition also prohibits "discrimination based on transgender status and sexual orientation," (2) "by flouting *Bostock* and other case law, the [2020] Rule's [decision not to define 'sex' or 'on the basis of sex'] will demand that such complaints [will] be filed with state agencies instead of [HHS]," which, in turn (3) "expose[s] state and local enforcement agencies to continuing enforcement costs from individuals seeking relief from discrimination." Compl. ¶¶ 210-11. But, as discussed *supra*, 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*, 2020 WL 5095467, at *8. So it is far from clear that this parade of horrors is substantially likely to occur at all.

The theory also is premised on the idea that "the Rule will invite discrimination and confusion within the regulated community" within Plaintiffs' jurisdictions and "Plaintiffs and their

enforcement agencies will bear the burden of this.” Compl. ¶ 212; *see also id.* at ¶ 213 (“[T]he Rule threatens to induce covered entities to roll back or reduce certain protections that they previously understood to be required by the law” and associated impacts “will now fall entirely to state and local enforcement agencies and the courts.”). But even assuming that “inviting” discrimination by third parties can ever form the basis of standing, *see Simon*, 426 U.S. at 42, Plaintiffs cannot plausibly argue that the 2020 Rule is substantially likely to invite discrimination in their states because their own state laws and regulations explicitly prohibit the very discrimination that they claim the Rule will “invite” in their jurisdictions. *See* Compl. ¶ 175 n.38 (listing state statutes and regulations explicitly prohibiting discrimination by health providers). It makes no sense to presume that third-party health providers are substantially likely to ignore governing state antidiscrimination law in light of the 2020 Rule’s decision not to define “on the basis of sex.” And that is especially true where HHS explained in the preamble to the 2020 Rule that “[s]tates and localities do indeed manifest a range of different views on what specific protections should be accorded to the categories of sexual orientation and gender identity in civil rights law” and HHS decided that “it is appropriate not to preempt States’ diverse views on these topics without a clear mandate from Congress to do so.” 85 Fed. Reg. at 37,182.

Even assuming that Plaintiffs have alleged a plausible imminent injury in the form of costs that they expect to incur by increasing enforcement of their own antidiscrimination laws, these costs are not fairly traceable to HHS’s decision not to define “sex” or “on the basis of sex” in the 2020 Rule for the same reasons that their administrative costs are not fairly traceable the 2020 Rule. “Although it may well be prudent on [a state’s] part to incur [enforcement] costs to [enforce its own antidiscrimination laws, Plaintiffs] do[] not point to any provision in the 2020 Rule that requires [them] to incur those costs beyond the general fact that the 2020 Rule is a new agency regulation that includes differences from the 2016 Rule.” *See Washington*, 2020 WL 5095467, at *10. “[I]f states could establish standing based solely on administrative costs incurred because of a change in agency regulation, then a state could manufacture standing any time it wanted to challenge an agency regulation by expressing a desire to incur [enforcement] costs as a result of

the changed regulations. This is not the law.” *See id.*; *see also Clapper*, 568 U.S. at 416. Plaintiffs do not need the Court to vacate the 2020 Rule to avoid incurring increased enforcement costs, they “merely need[] to decide not to incur such costs.” *See Washington*, 2020 WL 5095467, at *11.

Plaintiffs also have not shown that any enforcement costs would be redressed by a decision by this Court vacating HHS’s decision to remove the 2016 Rule’s definition of “on the basis of sex” from the Code of Federal Regulations. A close examination of Plaintiffs’ allegations indicates that they confuse HHS’s decision to promulgate the 2020 Rule with its enforcement policies. For example, Plaintiffs say that “[w]ith HHS’s abdication of its enforcement obligations through the Rule, the burden of holding these entities accountable for maintaining nondiscriminatory policies or practices, or making discriminatory coverage determinations on these bases, will now fall entirely to state and local enforcement agencies and the courts.” Compl. ¶ 213. But HHS is not under an “obligation” to enforce all of its rules at all times against any arguable violator notwithstanding HHS’s limited resources and other enforcement priorities. *See Heckler v. Chaney*, 470 U.S. 821, 831–32 (1985) (discussing “the many variables involved” and factors considered when agencies make enforcement decisions).⁴

In *Diamond v. Charles*, the Supreme Court held that a person’s “interests in enforcement” of a law is an insufficient basis for establishing that person’s standing to defend the law’s existence from attack; the person “could not compel the State to enforce [the law] . . . because ‘a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.’” 476 U.S. 54, 64 (1986) (quoting *Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973)). For precisely the same reasons, Plaintiffs cannot establish standing premised on anticipated enforcement costs that are rooted in speculation that HHS will not enforce antidiscrimination provisions in accordance with Plaintiffs’ enforcement priorities. Whether, how, and to what extent HHS would

⁴ OCR’s limited resources allow for very few civil rights resolution agreements—the agency primary enforcement tool—each year to enforce all of its civil rights statutes. Settlements are publically available on OCR’s website. *See* <https://www.hhs.gov/civil-rights/providers/compliance-enforcement/agreements/index.html>. So it is pure speculation to say that HHS would enforce any particular provision of any regulation in one of Plaintiffs’ particular jurisdictions regardless of what the rule says or means.

enforce the 2016 Rule, as partially vacated by the *Franciscan Alliance* court, if this Court were to vacate HHS's decision not to define "on the basis of sex" in the 2020 Rule, is entirely speculative. Accordingly, Plaintiffs' interests in HHS's enforcement policies cannot be redressed by an order of this Court vacating any part of the 2020 Rule.

(2) *Incorporation of Title IX's Exemptions*

The Complaint alleges that, "[b]y unlawfully incorporating Title IX's blanket religious exemption and abortion exception, . . . the 2020 Rule will create confusion about the scope of protections against these forms of discrimination under federal law." Compl. ¶ 233. "In turn, the Rule *may* prevent or discourage women and other individuals seeking reproductive health care from accessing that care." *Id.* (emphasis added). And "[a] blanket religious exemption *could* result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care." *Id.* ¶ 235 (emphasis added) (quoting 81 Fed. Reg. at 31,380). The Complaint speculates that these possible impacts could then trickle up to have implications for Plaintiffs in the form of "higher government-funded health care costs and increased costs of care for uninsured patients by public hospitals." *Id.* ¶ 251. But for many of the same reasons that Plaintiffs have not established the imminence of similar injuries allegedly stemming from HHS's decision not to define "sex" or "on the basis of sex" in the 2020 Rule, they also have not established an imminent injury stemming from the 2020 Rule's incorporation of Title IX's religious and abortion exceptions. *See XY Planning*, 963 F.3d at 252.

First, the Complaint pleads confusion about the scope of protections arising from the 2020 Rule's explicit incorporation of Title IX's exemptions. Compl. ¶ 233. But it is well established that confusion or uncertainty stemming from ambiguity in a law or regulation cannot be an injury that forms the basis of Article III standing. *See supra* at 16-17; *New England Power Generators Ass'n*, 707 F.3d at 369 ("It would be a strange thing indeed if uncertainty were a sufficiently certain harm to constitute an injury in fact."); *City & Cnty. of San Francisco*, 357 F. Supp. 3d at 944 (explaining that "regulatory uncertainty alone does not" establish "cognizable injury" for purpose of Article III standing); *Gerber Products Co.*, 254 F. Supp. 3d at 81 ("[U]ncertainties that arise

from regulatory decisions are not the kind of concrete and particularized injuries sufficient to establish an injury in fact.”).

Second, the Complaint’s use of “speculative and conclusive language like” “may” and “could” to allege harms to public health that it believes will occur, *see* Compl. ¶¶ 233, 235, are conclusory allegations that are insufficient to establish an actual, imminent injury, *see Conference of State Bank Supervisors v. Office of Comptroller of Currency*, 313 F. Supp. 3d 285, 296–97 (D.D.C. 2018). Moreover, the allegations in the Complaint are based entirely on the assumption “that healthcare providers or health insurers will refuse to provide services if the 2020 Rule’s religious [or abortion] exemption goes into effect.” *Washington*, 2020 WL 5095467, at *11. Courts that have permitted states to challenge a health care regulatory coverage exemption based on purported impacts of the exemption on state health care benefits have required “concrete evidence” that the exemption will be used—specific institutions or entities that for some reason are “highly likely” to use the exemption. *See Massachusetts v. HHS*, 923 F.3d 209, 223–24 (1st Cir. 2019) (determining that state had standing to challenge a regulation establishing a conscience exemption to employer contraceptive coverage requirement based on implications for state’s benefit programs because the state plaintiff “demonstrated that it is highly likely that at least three [specific] employers in the Commonwealth . . . that [were] exempt from state regulation . . . will use the expanded exemptions”); *see also California v. Azar*, 911 F.3d 558, 572 (9th Cir. 2018) (determining that states had standing to challenge a regulatory conscience exemption to employer contraceptive coverage requirement based on implications for states’ benefit programs because the state plaintiffs could set forth “names of specific employers . . . likely to use the expanded exemptions, including those operating in the plaintiff states like Hobby Lobby Stores, Inc.”). Without setting forth any concrete particularized allegations that health providers or insurers will take advantage of the 2020 Rule’s explicit incorporation of Title IX’s exemptions to reduce specific types of coverage, and that any such reductions will impose costs on the states, Plaintiffs fail to “clearly allege facts demonstrating” a concrete and particularized imminent injury, as opposed to a conjectural or speculative one. *See Spokeo*, 136 S. Ct. at 1547 (quoting *Warth v.*

Seldin, 422 U.S. 490, 518 (1975)); *see also Whitman-Walker*, 2020 WL 5232076, at *18 (“Simply asserting, without any elaboration, that individuals will experience discrimination . . . does not ‘suffice to demonstrate the substantial probability’ that discrimination will actually occur as required to establish standing.”) (quoting *Chamber of Commerce v. EPA*, 642 F.3d 192, 201 (D.C. Cir. 2011)).⁵

Clear allegations establishing the concrete chain of inferences between the 2020 Rule’s explicit incorporation of Title IX’s exemptions and imminent harms in the form of increased costs for Plaintiffs’ health benefit programs are especially important here because the Complaint alleges that the Plaintiff States each have their own applicable antidiscrimination statutes and regulations that do not include religious or abortion exemptions. Compl. ¶ 175 n.38. The Complaint does not allege that there are any gaps in coverage for their own statutes and regulations, and there is no reason to believe that health providers or insurers will simply ignore state law in light of a federal religious or abortion exemption to federal regulatory requirements. Accordingly, these Plaintiff States cannot plausibly establish an imminent injury to their health benefit programs in light of their own statutes and regulations prohibiting discrimination.

(3) *Scope of 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) [a]ny program or activity administered by [HHS] under Title I of the [ACA]; or (3) [a]ny program or activity administered by any entity established under such Title.” *Id.* at 37,244 (codified at § 92.3(a)); *see also id.* at 37,169. HHS changed this definition

⁵ In *Whitman-Walker*, the Court preliminarily found that at least one plaintiff had standing to challenge the 2020 Rule’s explicit incorporation of Title IX’s religious exemption. But the Court’s decision was erroneous because it was not premised on any substantial likelihood that any provider would “*actually* discriminat[e] against LGBTQ, but rather on patients’ genuine *fear* of encountering discrimination when seeking care from such institutions.” 2020 WL 5232076, at *15 (emphasis in original). And, as explained *supra* at 17-18, that precise theory has been squarely rejected by the Supreme Court in *Clapper*.

“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. Comp. ¶¶ 86(b), 99-104, 259.

The Complaint’s allegations in support of Plaintiffs’ standing to challenge HHS’s construction of the scope of entities covered by the 2020 Rule suffer from similar deficiencies as those described *supra*. See Compl. ¶¶ 209-10, 248-50. Plaintiffs’ allegations assume “that entities who are no longer subject to Section 1557 as a result of the 2020 Rule will freely engage in discrimination against LGBTQ individuals, which will result in increased . . . enforcement costs[] and public health costs.” *Washington*, 2020 WL 5095467, at *12 (internal citations omitted); see Compl. ¶ 209-10 (enforcement costs); *id.* ¶ 248-50 (public health costs). But such assumptions are insufficient to establish standing. The 2020 Rule makes two modifications to the scope of entities covered by Section 1557: (1) the scope of federal entities covered by Section 1557 and (2) the scope of the term “health program or activity.” Plaintiffs must have standing to challenge both. See *DaimlerChrysler Corp.*, 547 U.S. at 352.

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. See Compl. ¶ 86(b) (“exclud[ing] HHS programs not established under the ACA”).⁶ But the 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. And the fact that federal government entities may not discriminate on the basis of sex as a result of the Equal Protection Clause only adds to the speculation regarding any plausible impact of this change on any Plaintiff.

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.” Compl. ¶ 86(b). The Complaint

⁶ The Complaint suggests that the 2020 Rule’s revised definition of “health program or activity” impacts the number of HHS programs covered by Section 1557. Compl. ¶ 86(b). Actually, the Rule modifies the scope of federal entities covered by Section 1557 as a result of its construction of the following language in 42 U.S.C. § 18116(a): “any program or activity that is administered by an Executive Agency or any entity established under this title [*sc.*, Title I of the ACA].” See 85 Fed. Reg. at 37,170.

alleges that Plaintiffs will be injured by HHS's construction of the scope of covered entities because, again, they claim that HHS's revised definition of this term will increase their enforcement costs and public health costs. *Id.* ¶ 209-10 (enforcement costs); *id.* ¶ 248-50 (public health costs).

But all of these allegations are insufficient because they “rest on speculation about the decisions of independent actors.” *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 or other unclear classes of individuals. And the Complaint includes no allegations indicating that any health insurer intends to change its coverage because of the 2020 Rule—much less any insurer providing coverage in Plaintiffs' jurisdictions. Because Plaintiffs have not provided any “specific [allegation] that a third-party provider or insurer plan[s] to discriminate against or limit its healthcare coverage for LGBTQ individuals” as a result of the 2020 Rule, they have not established standing. *See Washington*, 2020 WL 5095467, at *8 (holding that similar allegations of standing by a state challenging the 2020 Rule were insufficient). “Simply asserting, without any elaboration that individuals will experience discrimination at the hands of . . . health insurers does not ‘suffice to demonstrate the substantial probability’ that discrimination will actually occur as required to establish standing.” *Whitman-Walker*, 2020 WL 5232076, at *18 (quoting *Chamber of Commerce*, 642 F.3d at 201); *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”); *Azar*, 911 F.3d at 572 (determining standing could be premised on the likely actions of third parties based on “names of specific employers identified” as likely to take the action and reasons supporting that conclusion specific to those entities).

Finally, Plaintiffs' alleged injuries in support of standing to challenge the 2020 Rule's construction of the term “health program or activity” also runs headlong into *Diamond v. Charles*. Plaintiffs allege that “the Rule limits the scope . . . of OCR's federal enforcement against discrimination,” and thus, “individuals who previously would have sought assistance from OCR

will be forced to seek assistance from state agencies or bring private lawsuits.” Compl. ¶ 209; *see also id.* ¶ 210 (“an individual who is subject to race discrimination by a health insurance company offering an employer-sponsored plan will have no recourse with OCR. Whereas HHS should bear the primary responsibility of enforcing discrimination prohibitions in all forms against health care entities, the Department’s refusal to do so will expose state and local enforcement agencies to continuing enforcement costs from individuals seeking relief from discrimination.”). Because “a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another,” the Plaintiffs “could not compel [HHS] to enforce [the 2016 Rule] against” insurers. *Diamond*, 476 U.S. at 64. Thus, any injury is not redressable.

(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 Complaint claims that this change violates the APA because it is arbitrary and capricious. Compl. ¶¶ 86(e), 122-24. The Complaint also alleges that HHS’s decision not to take a position with respect to whether Section 1557 affords litigants a private right of action or compensatory damages violates the APA. *Id.* ¶ 123. But the Complaint is utterly devoid of any allegations—let alone clear ones—explaining how any Plaintiff has suffered an injury caused by these aspect of the 2020 Rule. Plaintiffs thus lack standing to challenge it.

It is implausible that Plaintiffs could establish a nonspeculative impending injury with respect to HHS’s decision not to take a position one way or the other by rule on whether a private right of action or compensatory damages is available for Section 1557 litigants. 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. A concrete injury would have to be premised

on a future court’s decision that private rights of action and compensatory damages are unavailable to Section 1557 plaintiffs because, in the absence of a regulation to afford any degree of deference, the court could conclude for itself that private rights of action and compensatory damages are unavailable under Section 1557. But “[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in [a] case” in that manner. *Clapper*, 568 U.S. at 413–14 (quoting *Whitmore*, 495 U.S. at 159–60). And 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*, 2020 WL 5095467, at *8. As another court explained in holding that plaintiffs lacked standing to raise similar claims, “[t]he proper context for quarrels surrounding the legal standard[s] for Section 1557 claims would be an actual lawsuit bringing such a claim.” *Whitman-Walker*, 2020 WL 5232076, at *20.

(5) *Discrimination on the basis of association*

The Complaint includes a claim that the 2020 Rule violates the APA because HHS “reversed its position” that “associational discrimination is a form of prohibited discrimination” under Section 1557 “without a reasonable explanation or sufficient justification.” Compl. ¶ 123. But the Complaint does not include any allegations of standing to challenge this aspect of the 2020 Rule. Plaintiffs thus lack standing to challenge it.

(6) *Notice and Taglines*

The Complaint includes allegations that the 2020 Rule’s modifications to notice and taglines requirements “will require Plaintiffs to invest resources to inform LEP individuals of their rights to obtain language services and to file complaints when they are denied those services or otherwise face discrimination by health care providers or insurers.” Compl. ¶ 181; *see also id.* ¶ 185 (California “may also engage in a multi-lingual campaign to educate LEP Californians about their rights due to the Rule’s removal of notice and tagline requirements and other language assistance requirements”) ¶ 201 (New Jersey “will need to work proactively with the NJDOH

Health Systems branch, hospital associations, and primary care associations to ensure patients with LEP have options and the same standard access to health care”).

First, Plaintiffs have not established an imminent injury “in light of the attenuated chain of inferences necessary to find harm.” *Clapper*, 568 U.S. at 414 n.5. Plaintiffs appear to believe that the 2020 Rule will impact LEP individual third-parties because “HHS admits that ‘an unknown number of persons are likely not aware of their right to file complaints with OCR and some unknown subset of this population may suffer remediable grievances, but will not complain to OCR absent notices informing them of the process.’” Compl. ¶ 181 (quoting 84 Fed. Reg. at 27,883). But Plaintiffs’ allegation—supported by nothing more than HHS’s own speculation that some people “may” suffer remediable grievances might be unaware of the grievance process—cannot form the basis of concrete injury because it is unsupported by anything other than HHS’s own speculation. *See id.*; *see also id.* ¶¶ 241-47. “The 2020 Rule . . . does not ‘admit,’” *Washington*, 2020 WL 5095467, at *9, that LEP individuals *will* suffer remediable grievances but will not complain to OCR absent notices informing them of the process—just that it “may,” *see* 84 Fed. Reg. at 27,883. “That kind of off-handed speculation—which was in no way particular to [any Plaintiff State or the particular citizens of Plaintiff States] on which [Plaintiffs] base[their] standing arguments . . . does not measure up to the kind of detailed agency analysis about the expected impact of an agency regulation that courts have relied on to find standing.” *Washington*, 2020 WL 5095467, at *9.

Indeed, a closer look at precisely what HHS did in revising the notice and tagline requirements in the 2020 Rule reveals that Plaintiffs can only speculate that LEP populations will be unaware of their rights under federal law in Plaintiff States. HHS “retain[ed] many of the 2016 Rule’s provisions related to access for LEP individuals.” 85 Fed. Reg. at 37,209. And many changes were just technical ones. For example, HHS removed two definitions “but the 2019 NPRM expressed [HHS’s] commitment to interpreting those terms naturally and consistently with the 2016 Rule.” *Id.* As Plaintiffs acknowledge in their Complaint, HHS did not eliminate the 2016 Rule’s language access requirements leaving nothing in their place. *See* Compl. ¶ 108. Instead,

the 2020 Rule’s main change with respect to LEP requirements was to remove the inflexible requirement for covered entities to provide certain notices and taglines in the top fifteen languages spoken in each state regardless of the size of the state or the demographics of a covered entities’ subscribers. Accordingly, for example, “the 2016 Rule required health insurance issuers . . . in Wyoming . . . to provide translation notices in Gujarati and Navajo” in numerous communications “to account for approximately 40 Gujarati speakers and 39 Navajo speakers.” 85 Fed. Reg. at 37,233. The flexibility allowed in the 2020 Rule permits more innovative approaches to cost-effectively serving these populations without resulting in discrimination. Nevertheless, the Plaintiffs speculate that the new rule *will* result in reduced access to programs or activities without citing any covered entity’s changes to any policy or program that appears likely to result in a substantial risk that any such reduced access is imminent.

What is more, the rulemaking record supports the conclusion that the 2016 Rule did not, in fact, actually result in LEP individuals becoming aware of their rights and filing grievances. For example, one commenter “stated that since the implementation of the 2016 Rule, it has not experienced significant changes in its member demographics or languages spoken, and has not seen any notable increases in requests for translation services.” 85 Fed. Reg. at 37,232; *see also id.* (“commenters stated they did not see a significant increase in requests after the 2016 Rule required notices and taglines, but instead experienced relatively flat demand”). An “objectively reasonable likelihood” of harm to LEP populations that will trickle up to somehow cause harm to the states is insufficient for Article III standing, *Clapper*, 568 U.S. at 410, and Plaintiffs cannot even make that showing.

Second, for the same reasons discussed *supra* at 20-25, Plaintiffs administrative costs and enforcement costs that they decide to incur now that the 2020 Rule is in effect are self-generated and are accordingly, not fairly traceable to the 2020 Rule.

(7) Flexibility in Treatment of Gender Dysphoria and Repeal of Specific Prohibitions on Discriminatory Treatment

The 2020 Rule repeals provisions of the 2016 Rule which prohibited the flexible treatment of gender dysphoria. *See* 85 Fed. Reg. at 37,198. The Complaint challenges this decision and the elimination of other “specific prohibitions on discriminatory treatment” as violating the APA, seeking to reinstate the 2016 provisions. *See* Compl. ¶ 86(a)(2). But the Complaint fails to allege any facts, let alone “clearly allege[d] facts demonstrating” a concrete injury to Plaintiffs stemming from this change. *See Spokeo*, 136 S. Ct. at 1547. And any effort by Plaintiffs to bend their abstract and generalized allegations of injury to challenge this modification as well would face similar barriers as described *supra*. For example, even under the 2016 Rule, “[n]othing in th[e] section” Plaintiffs seek to revive “[was] intended to determine, or restrict, a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.” 81 Fed. Reg. at 31,472 (inserting 45 C.F.R. § 92.207). The rule simply required “a nondiscriminatory process to determine whether a particular health service is medically necessary or otherwise meets applicable coverage requirements.” *Id.* at 31,437. But if Plaintiffs are “correct that *Bostock* means that Title IX and Section 1557 must incorporate protection for gender identity . . . discrimination, . . . [f]or purposes of standing . . . [Plaintiffs provide no allegations indicating] why providers or insurers would be willing to risk revising their practices or policies to discriminate against LGBTQ individuals in light of the Supreme Court’s recent guidance in *Bostock* and the very arguments [Plaintiffs] advance[] in this case,” as well as their own state antidiscrimination laws. *Washington*, 2020 WL 5095467, at *8. Accordingly, Plaintiffs lack standing to challenge these provisions and seek this relief.

(8) *Conforming Amendments to Related Regulations*

The Complaint claims that conforming amendments the agency made to related regulations are contrary to law and arbitrary and capricious. Comp. ¶¶ 125-27. But the 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 Complaint takes aim, this case should be dismissed in its entirety for lack of subject matter jurisdiction.

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,” *id.* at 37,178, consistent with Section 1557(c)⁷ and black letter law permitting agencies discretion to decline to proceed by rulemaking, *see NLRB v. Bell Aerospace Co.*, 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 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.

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

⁷ Section 1557(c) provides that HHS “may”—not must—“promulgate regulations to implement this section.”

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 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)); see also *N.Y. Civil Liberties Union v. Grandeau*, 528 F.3d 122, 131 (2d Cir. 2008) (explaining that the issue is “whether the alleged policy at this stage is sufficiently definite and clear to permit sound review by [the] Court”).

“To determine whether a challenge to administrative action is ripe for judicial review, [courts] proceed with a two-step inquiry, ‘requiring [them] to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.’” *Grandeau*, 528 F.3d at 131-32 (quoting *Abbott Labs.*, 387 U.S. at 149). 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.”); *S. C. Elec. & Gas Co. v. ICC*, 734 F.2d 1541, 1545 (D.C. Cir. 1984) (determining agency policy not ripe for review where one “portion of the test is not met”).

Fitness of the Issues for Decision. Plaintiffs’ invitation to litigate the meaning of “on the basis of sex” in Section 1557 abstractly and without reference to an actual case of discrimination just because the Supreme Court issued a decision interpreting the term in the Title VII context 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) (pre-

enforcement review unripe where claim is *not* “sufficiently fleshed out to allow the court to see the concrete effects and implications of its decision”) (quoting *Chamber of Commerce v. Reich*, 57 F.3d 1099, 1100 (D.C. Cir. 1995)).

“The fitness analysis is concerned with whether the issues sought to be adjudicated are contingent on future events or may never occur at all.” *Grandeau*, 528 F.3d at 132 (quoting *Simmonds*, 326 F.3d 351, 359 (2d Cir. 2003)). For example, the Second Circuit has “deemed unripe a challenge to a proposed policy change in Medicare administration,” explaining “that plaintiffs’ challenge was ‘directed at possibilities and proposals only, not at a concrete plan which has been formally promulgated and brought into operation.’” *Id.* (quoting *Isaacs v. Bowen*, 865 F.2d 468, 477 (2d Cir. 1989)). Even when “there can be no question that [a] regulation—promulgated in a formal manner after notice and evaluation of submitted comments”—is the subject of litigation, and the issue plaintiffs raise “presents a purely legal question,” the “legal issue as presently framed [may] not [be] appropriate for judicial resolution,” *Toilet Goods Ass’n v. Gardner*, 387 U.S. 158, 162–63 (1967), “where the agency retains considerable discretion to apply the new rule on a case-by-case basis,” *Sprint Corp. v. FCC*, 331 F.3d 952, 956 (D.C. Cir. 2003).

In this case, Plaintiffs’ own complaint recognizes that the 2020 Rule merely “remove[d] gender identity, sex stereotyping, and pregnancy-related conditions as forms of *expressly* prohibited sex discrimination.” Compl. ¶ 89 (emphasis added). “Even where there is no express [regulatory] statement” providing that sex discrimination under Section 1557 includes the classes of discrimination Plaintiffs think it should include, their inclusion “may be implied.” *Cf. Ass’n of Int’l Auto Mfrs. v. Abrams*, 84 F.3d 602, 607 (2d Cir. 1996). “In a future decision” adjudicating the meaning of Section 1557 and the 2020 Rule, Plaintiffs’ “concerns might well be addressed, and [HHS] as a result might never apply [the 2020 Rule] in a manner that will harm [Plaintiffs].” *Sprint Corp.*, 331 F.3d at 957.

In absence of any explicit policy in the 2020 Rule to attack, Plaintiffs challenge *the preamble* to the 2020 Rule, complaining that HHS “repeat[ed] scores of times throughout the

Rule’s preamble [HHS’s] . . . position that discrimination ‘on the basis of sex’ does not include discrimination against transgender people.” Compl. ¶ 86(a). Even if this language represented the totality of HHS’s understanding of its rule’s application to gender identity discrimination claims, “language in the preamble of a regulation is not controlling over the regulation itself.” *Halo v. Yale Health Plan, Dir. Of Benefits & Records Yale Univ.*, 819 F.3d 42, 52–53 (2d Cir. 2016) (quoting *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999)).

In any event, this language is *not* the totality of HHS’s understanding of the rule’s application to gender identity discrimination claims. The preamble language 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. Accordingly, “[P]laintiffs’ challenge” is “‘directed at possibilities and proposals only, not at a concrete plan which has been formally promulgated and brought into operation.’” *Grandeau*, 528 F.3d at 132 (quoting *Isaacs*, 865 F.2d at 477). In other words, HHS never promulgated their pre-*Bostock* views about the scope of sex discrimination claims *in the language of the rule itself*. The agency simply replaced the prior definition with the language of the statute to permit claims to be addressed on a case-by-case basis as relevant caselaw continues to develop. In no way does the 2020 Rule prohibit construing sex discrimination to encompass whatever its plain meaning encompasses.

In light of *Bostock*, “further administrative action is needed to clarify the agency’s position,” making the issues unfit for judicial resolution at this stage. *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”).

Similarly, with respect to sex stereotyping, Plaintiffs attack the legality of HHS’s decision to remove its explicit inclusion in a definition of “on the basis of sex,” *see, e.g.*, Compl. ¶ 86(a), but do not even try to allege that HHS’s decision to rely on the plain meaning of the term in the statute represents an abandonment of sex stereotyping claims. And for good reason: nowhere in the preamble did HHS assert 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 Complaint also accurately alleges that the 2020 Rule removes “pregnancy-related conditions” from “express” inclusion in a definition of discrimination on the basis of sex covered by Section 1557. *See* Compl. ¶ 86(a). But similarly, any claim related to this allegation is not ripe unless and until a concrete case is presented for adjudication—that is, until HHS takes a position as to the extent to which pregnancy-related discrimination is covered by Section 1557. As HHS explained, although 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. Plaintiffs fail to account for black letter law permitting agencies discretion to proceed by rulemaking or adjudication. *See supra*, at 35-36. This Court should decline Plaintiffs’ invitation to entangle itself in abstract disagreements over administration policies just because Plaintiffs would prefer guidance now.

If concrete cases establish 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”). Plaintiffs’ claims that HHS failed to engage in reasoned decision-making by failing to consider *Bostock* are entirely irrelevant if concrete cases establish that the plain meaning of Section 1557 covers sex stereotyping, sexual orientation discrimination, gender identity discrimination, and termination of pregnancy discrimination. Compl. ¶ 86; *see Texas*, 523 U.S. at 301 (“The operation of the statute is better grasped when viewed in light of a particular application.”); *Sprint Corp.*, 331 F.3d at 956 (determining that “question of whether an agency decision is arbitrary and capricious” is not ripe for review). The case that Plaintiffs bring “is, at this stage, largely hypothetical, and such cases are seldom fit for federal judicial review.” *Ernst & Young v. Depositors Econ. Prot. Corp.*, 45 F.3d 530, 538 (1st Cir. 1995). For these reasons, resolution of the meaning of “on the basis of sex” in Section 1557 (and thus the 2020 Rule, which merely hews to the text of 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 Legal Found. v. EPA*, 325 F.3d 281, 284 (D.C. Cir. 2003) (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.

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. *See Toilet Goods Ass’n*, 387 U.S. at 164; *Grandeau*, 528 F.3d at 131 (determining case not to be ripe for review even if standing could be established through “increase[d] administrative burden and [an] infringe[ment] [on plaintiff’s] First Amendment rights”); *Simmonds*, 326 F.3d at 358, 360–61 (determining injury sufficient to meet constitutional standing requirements but insufficient for hardship prong of ripeness analysis); *In re Combustion Equip. Assocs., Inc.*, 838 F.2d 35, 39 (2d Cir. 1988) (“the presence of some possible harm from delaying litigation does not automatically render a dispute ripe . . . if the possible harm is outweighed by other factors”). “[F]or the test of ripeness . . . [hardship is] the *degree and nature* of the regulation’s present effect on those seeking relief.” *Toilet Goods Ass’n*, 387 U.S. at 164 (emphasis added).

Plaintiffs allege little more than abstract confusion, uncertainty, and “fear” purportedly stemming from HHS’s decision in the 2020 Rule not to define “on the basis of sex” and that they might decide to incur administrative or enforcement costs or the confusion might trickle up to have some impact on their health care programs. *See, e.g.*, Compl. ¶ 232. But “mere uncertainty” does not “constitute[] a hardship for purposes of the ripeness analysis.” *See Nat’l Park Hosp. Ass’n v. Dep’t of Interior*, 538 U.S. 803, 811 (2003); *see also Toilet Goods Ass’n*, 387 U.S. 158. And similarly, “fear” about what a regulation might mean for the future is insufficient. *See Ernst & Young*, 45 F.3d at 538 (quoting William Shakespeare, *Macbeth*, act I, sc. iii, II. 133-35 (1605)) (explaining that “present fears are often less than horrible imaginings” and concluding that they are insufficient to establish hardship in the ripeness analysis); *In re Combustion Equip.*, 838 F.2d at 39 (determining that hardship insufficient for ripeness analysis “[w]ithout attempting to belittle [plaintiff’s] fears”).

Plaintiffs provide no allegations whatsoever that the 2020 Rule has actually affected the “primary conduct” of any regulated entity at all. *See Toilet Goods Ass’n*, 387 U.S. at 164 (“This is not a situation in which primary conduct” of a regulated party “is affected.”). They have not explained how “the impact of the administrative action could be said to be felt immediately *by those subject to it* in conducting their day-to-day affairs.” *Id.* (emphasis added). 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” through adjudication or litigation under Section 1557. *See 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.*

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; HHS’s decision not to include provisions barring associational discrimination by rule, and HHS’s decision to provide for meaningful access to health programs or activities for LEP persons through a generalized standard instead of inflexible mandates. 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. 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. And application of HHS’s flexible language access standard to covered entities in Plaintiffs’

jurisdictions might result in no discernible difference between the actual impact of the 2016 requirements and the 2020 Rule. Plaintiffs do not allege sufficiently weighty hardship from awaiting concrete instances of discrimination before filing a complaint in court or before HHS requiring a construction of Section 1557. Mere 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.

CONCLUSION

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

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