UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

In Section 1557 of the Affordable Care Act, ("ACA"), Congress prohibited certain types of discrimination in health care. It did so by referencing four other statutes that prohibit discriminatory conduct against certain classes of individuals. Recognizing that transplanting these statutes to address discrimination in the health care setting might result in ambiguity best addressed by an agency knowledgeable in health law and policy, Congress authorized, but did not require, the United States Department of Health and Human Services, ("HHS") to elucidate its requirements by regulation. 42 U.S.C. § 18116(c).

On May 18, 2016, HHS initially promulgated a detailed regulation implementing Section 1557. *See* 81 Fed. Reg. 31,375, 31,376 (May 18, 2016) ("2016 Rule"). Lawsuits challenging some parts of that rule immediately followed its promulgation and a federal district court ultimately partially vacated the rule. But the partially vacated provisions involved novel constructions of terms in longstanding civil rights law, such as the definition of the term "sex." After a change in administrations, HHS questioned the wisdom of being at the forefront of litigation over the abstract definition of that term and of other constructions of Section 1557 that it found were not clearly consistent with the statute. HHS also determined that the 2016 Rule needlessly expanded upon the settled requirements of Title VI. By modifying the 2016 Rule, in part, to ensure consistency with longstanding Title VI guidance, HHS determined that it could save regulated entities billions of dollars in regulatory burdens without resulting in a discernable increase in discrimination. For those reasons and others, HHS initiated a new rulemaking proceeding and proposed a new rule making changes to the Section 1557 regulations.

On June 19, 2020, the Office of the Federal Register published HHS's Final Rule ("2020 Rule") along with a general statement of basis and purpose providing good reasons for the rule, as required by the Administrative Procedure Act ("APA"). Plaintiffs' arguments in support of their motion for summary judgment make clear that they disagree with HHS's policy decisions. But they provide no basis, because there is none, for this Court to vacate any part of the 2020 Rule. Such a result would be inappropriate in any case, but particularly so here, where Plaintiffs seek to

vacate the 2020 Rule's numerous policy changes from the 2016 Rule based on their generalized interest in the health and well-being of their residents in light of hypothetical future discrimination. While such an interest is no doubt an important one, it does not satisfy the standing requirements of Article III. Plaintiffs have provided a myriad of witness declarations purporting to establish that some residents fear future discrimination at the hands of third parties in light of abstract regulatory uncertainty, but because Plaintiffs "in the present case present no concrete evidence to substantiate their fears, [and] instead rest on mere conjecture about possible" future discrimination, they lack standing under Supreme Court precedent. *See Clapper v. Amnesty Int'l. USA*, 568 U.S. 398, 420 (2013). The Court should deny Plaintiffs' motion for summary judgment and grant summary judgment to Defendants.

BACKGROUND

Relevant statutory and regulatory background is set out in detail in Defendants' Memorandum of Law in Support of their Motion to Dismiss Plaintiffs' Complaint, *see* ECF No. 113 at 2-7. Given the posture of the case, Defendants summarize only the relevant procedural history here.

On June 19, 2020, the Office of the Federal Register published HHS's Final Rule implementing Section 1557 of the ACA. 85 Fed. Reg. 37,160 (June 19, 2020). The non-enjoined provisions of the rule went into effect on August 18, 2020. *Id.* Plaintiffs filed a Complaint ("Complaint" or "Compl.") on July 20, 2020, challenging many of the rule's provisions as violating the APA, 5 U.S.C. § 706(2)(A)-(C). Compl. ECF No. 1. On November 6, 2020, Defendants produced a copy of the Administrative Record to Plaintiffs' counsel and filed the certification and index for the Administrative Record. ECF No. 103. On November 19, 2020, this Court issued an Order Regulating Proceedings providing that "all motions shall be filed by December 2, 2020." ECF No. 106. On December 2, 2020, Plaintiffs moved for summary judgment on several of their claims, *see* ECF Nos. 108-09; and Defendants moved to dismiss the Complaint for lack of subject matter jurisdiction, *see* ECF Nos. 112-13.

ARGUMENT

I. Plaintiffs have Failed to Demonstrate Standing to Raise Any of their Claims

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. The "injury in fact" required by standing "must be 'concrete and particularized,' as well as 'actual or imminent.'" *Carney v. Adams*, 141 S. Ct. 493, 498 (2020) (citation omitted). "It cannot be 'conjectural or hypothetical.'" *Id.* (citation omitted). "[A] grievance that amounts to nothing more than an abstract and generalized harm to a citizen's interest in the proper application of the law does not count as an 'injury in fact.' And it consequently does not show standing." *Id.*

Defendants have moved to dismiss Plaintiffs' Complaint for lack of subject matter jurisdiction because Plaintiffs have failed to clearly allege facts demonstrating each element of standing at the pleading stage, as is their burden, and because their theory of standing is fatally flawed. *See* ECF No. 112, 113. Based on Plaintiffs' Complaint alone, this Court lacks subject matter jurisdiction over Plaintiffs' claims and should therefore grant Defendants' motion to dismiss and not consider Plaintiffs' motion for summary judgment. *United Transport Serv. Emp. Of Am., CIO, ex rel. Wash. v. Nat'l Mediation Bd.*, 179 F.2d 446, 453–54 (D.C. Cir. 1949).

Should the Court nonetheless proceed to consider Plaintiffs' summary judgment motion, their motion should be denied because Plaintiffs fail to establish facts demonstrating each element of standing. At the summary judgment stage, Plaintiffs can no longer rest on the allegations in their Complaint, but must set forth "by affidavit or other evidence 'specific facts'" that establish their standing with respect to each claim they raise. *Defenders of Wildlife*, 504 U.S. at 561.

Plaintiffs fail to establish standing for the same reasons discussed by the court in *Washington v. United States Dep't of Health & Human Servs.*, No C20-1105JLR, 2020 WL 5095467 (W.D. Wash. Aug. 28, 2020). Plaintiffs assert that their "standing here rests on different grounds and with more robust evidentiary support than was presented in that case, . . . and with the benefit of the full administrative record." ECF No. 109 at 13 n.9. But the only difference between the record in this case and in *Washington* is the number of witness declarations Plaintiffs have filed in support of their standing. *See* ECF No. 111. To be sure, Plaintiffs have established a sincere and deep commitment to "vindicating [a] general interest on behalf of the public," but "'no matter how sincere' or 'deeply committed'" Plaintiffs are to that goal, "to find standing based upon that kind of interest 'would significantly alter the allocation of power at the national level, with a shift away from a democratic form of government.'" *Carney*, 141 S. Ct. at 499 (citations omitted). Other than the quantity, there is no material difference between the witness declarations that the Plaintiff States have submitted in this case and those that the *Washington* court properly found insufficient to establish the type of concrete and particularized imminent injury that Supreme Court standing jurisprudence requires. *See* 2020 WL 5095467, at *6-*12; *see also Trump v. New York*, 141 S. Ct. 530, 534–36 (2020); *Carney*, 141 S. Ct. at 498–503; *Clapper*, 568 U.S. at 408–22; *Defenders of Wildlife*, 504 U.S. at 565; *City of Los Angeles v. Lyons*, 461 U.S. 95, 101–10 (1983); *Rizzo v. Goode*, 423 U.S. 362, 372 (1976); *O'Shea v. Littleton*, 414 U.S. 488, 495–96 (1972).

A. Threatened Injuries in Standing Law

"Although the mere threat of an injury might at first glance appear not to render a party 'aggrieved by agency action,' and may seem noncognizable in a judicial system given jurisdiction over only cases or controversies, the Supreme Court has accommodated allegations of threatened injury in two settings." *Wilderness Soc. v. Griles*, 824 F.2d 4, 11 (D.C. Cir. 1987). "The first setting involves cases in which the plaintiff alleges that governmental action will be taken directly against him." *Id*. "In all these cases involving claims of threatened injury emanating directly from governmental conduct, the Court has assessed the likelihood that the clash between the government

and the plaintiff will in fact occur." *Id*. A plaintiff may establish a sufficiently imminent injury in this setting "if the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014). If the plaintiff merely establishes "an objectively reasonable likelihood" of the future injury or a "not 'fanciful, paranoid, or otherwise unreasonable'" fear of the future injury, that "likelihood" is insufficient. *Clapper*, 568 U.S. at 407, 414 n.5, 416. In this case, Plaintiffs do not claim a threat of injury emanating directly from governmental conduct. *See* ECF No. 109 at 13-27.

"The other setting comprises cases in which the government acts directly against a third party, whose expected response in turn will injure the plaintiff." *Griles*, 824 F.2d at 11. "The standing question in these three-party[] cases frequently turns not on the existence of personal injury but rather on so-called causation issues, *i.e.*, whether the third party's decision is sufficiently dependent upon the governmental action that plaintiff's injury is 'fairly traceable' to that action and is 'likely to be redressed' by an order binding the government." *Id*. If a plaintiff establishes a concrete injury, but that injury stems from a third party's "not 'fanciful, paranoid, or otherwise unreasonable'" fears of the implications of government conduct, the plaintiff does "not establish injury that is fairly traceable" to the government. *Clapper*, 568 U.S. at 416, 417 n.7. "When personal injury *is* at issue in a three-party case, it usually depends on how likely it is that the third party's response to the challenged governmental action will injure the plaintiff *at all*." *Griles*, 824 F.2d at 12.

In this particular case, Plaintiffs' theory of standing is even further removed than the "other setting" described in *Griles*. In this case, the government has promulgated a regulation that governs the conduct of third parties (entities covered by Section 1557). Plaintiffs' purported injuries stem not only from their speculation that those third parties will change policies and procedures due to the new rule, but also from their speculation about the response of fourth parties—patients and insureds of those third parties. *See, e.g.*, ECF No. 109 at 23-25. Plaintiffs' purported injuries are nothing more than costs they speculate they might some day incur because of actions that they speculate covered entities might take as a result of the 2020 rule, which, they

further speculate, might affect patients or insureds in their states, whom they speculate might incur health implications that they speculate might trickle up to harm Plaintiff States. *See id.* (cost associated with uncompensated health care resulting from 2020 Rule). Alternatively, Plaintiffs provide proof of "costs they incurred [or plan to incur] in response to [these] speculative threat[s]." *See Clapper*, 568 U.S. at 416; ECF No. 15-21 (regulatory burdens and administrative costs addressing the rule's policy reversals and costs to enforce state civil rights protections for violations HHS purportedly will not address under section 1557). But it is well established that Plaintiffs may not rely on mere speculation—no matter how many declarations in support of that speculation they file—to establish an injury. *See, e.g.*, *Trump*, 141 S. Ct. at 535 (determining case was "riddled with contingencies and speculation that impede judicial review"). If Plaintiffs do establish injuries, but they are rooted in patients' or insureds' objectively reasonable fears of hypothetical future discrimination, those injuries are not fairly traceable to the challenged regulation, *see Clapper*, 568 U.S. at 417 n.7, even if the patients' or insureds' "fear is not 'fanciful, paranoid, or otherwise unreasonable,'" *id*. at 416. To be fairly traceable to the challenged regulation, the third (or fourth) parties' conduct cannot be based on fear, *see id*. at 416, 417 n.7, as "present fears are [often] less than horrible imaginings," *Ernst & Young v. Depositors Economic Protection Corp.*, 45 F.3d 530, 538 (1st Cir. 1995) (quoting Willliam Shakespeare, *Macbeth*, act 1 sc. iii, II. 133-34 (1605)). Fear alone is insufficient; Plaintiffs must "present . . . concrete evidence to substantiate their fears" and show that the alleged injury is imminent. *See Clapper*, 568 U.S. at 420; *see also Defs. of Wildlife*, 504 U.S. at 564; *Massachusetts v. U.S. Dep't of Health and Human Servs.*, 923 F.3d 209, 223 (1st Cir. 2019).

In *Defenders of Wildlife*, the Court criticized vague or conclusory assertions of future injury similar to those that the Plaintiffs present in this case. The Court said that the plaintiffs' filings were "simply not enough" because "'some day' intentions—without any description of concrete plans, or indeed even any specification of *when* the some day will be—do not support a finding of the 'actual or imminent' injury that our cases require." 504 U.S. at 564. Two justices dissented in *Defenders of Wildlife*, concluding that "a reasonable finder of fact could [have] conclude[d]

from the information in the affidavits and deposition testimony that either [plaintiff] will soon return to the project sites, thereby satisfying the 'actual or imminent' injury standard." *Id*. at 591. They explained that *Defenders of Wildlife* "differs from other cases," like this case, "in which the imminence of harm turned largely on the affirmative actions of third parties beyond the plaintiff's control." *Id*. at 592-93 (citing *Whitmore v. Arkansas*, 495 U.S. 149, 155–56 (1990); *Lyons*, 461 U.S. at 105; *Rizzo*, 423 U.S. at 372; *O'Shea*, 414 U.S. at 495–98; *Golden v. Zwickler*, 394 U.S. 103, 109 (1969)).

To be sure, "when the plaintiff is not himself the object of the government inaction or inaction he challenges, standing . . . is ordinarily 'substantially more difficult' to establish," but it "is not precluded," *Defs. of Wildlife*, 504 U.S. at 562 (quoting *Allen v. Wright*, 468 U.S. 737, 758 (1984)), provided that Plaintiffs "present . . . concrete evidence to substantiate their fears" of future imminent injury fairly traceable to the challenged government action, *Clapper*, 568 U.S. at 420. In cases that turn on the effect of government non-regulation of third parties, courts have found standing only when plaintiffs provide such "concrete evidence" that the third parties will take imminent action in light of their new regulatory freedom. *See, e.g.*, *Massachusetts v. U.S. Dep't of Health and Human Servs.*, 923 F.3d at 223 (quoting *Clapper*, 568 U.S. at 420); *see also California v. Azar*, 911 F.3d 558, 572–74 (9th Cir. 2018)). For example, in *Massachusetts v. HHS*, preexisting state law provided "that qualifying residents . . . who lose contraceptive coverage would then be covered by [the state]." 923 F.3d at 218. The plaintiff state challenged a regulation that "permitted employers with religious or moral objections to contraception to obtain exemptions from providing health insurance coverage to employers . . . for [certain] contraceptive care." *Id*. at 213. If employers took advantage of the exception, the costs of coverage would fall directly on the plaintiff state. Still, these facts alone were insufficient to establish standing without concrete evidence that specific Massachusetts employers were substantially likely to take advantage of the regulation's exemptions. The First Circuit held that the plaintiff established standing only by "demonstrat[ing] that it [was] highly likely that at least three [specific] employers in the Commonwealth . . . will use the expanded exemptions," and by "refer[ing] to data, which the

[Defendants did] not contest," showing that two of these entities employed a substantial number of people in the Commonwealth. *Id*. at 224. The First Circuit made clear that the inquiry needed to focus on women who would lose coverage based on the expanded exemptions, not women whose employers were denying contraceptive coverage "even before" the challenged exemption was implemented. *Id*. at 224 n.9.

Similarly, in *California v. Azar*, five plaintiff states challenged the same regulation at issue in *Massachusetts v. HHS*. *See* 911 F.3d at 567–68. Unlike the hypothetical discrimination at issue here, employers who had every intention of not providing residents with contraceptive coverage, like the Little Sisters of the Poor, intervened. Moreover, the Ninth Circuit based its conclusion that plaintiff had standing on concrete evidence that employers in plaintiff states would take advantage of the exemptions. *See id*. at 571–72. Specifically, the plaintiff states were able to show, on the record, "that between 31,700 and 120,000 women nationwide will lose some coverage," *id*. at 572, and "[t]he record . . . includes names of specific employers identified by the [regulatory impact analysis] as likely to use the expanded exemptions, including those operating in the plaintiff states like Hobby Lobby Stores, Inc.," *id*. at 572. As explained below, Plaintiffs fail to provide any such concrete evidence here.

Plaintiffs rely on *Department of Commerce v. New York*, 139 S. Ct. 2551, 2565-66 (2019), asserting that their injuries are predictable effects of unspecified parts—or all—of the 2020 Rule. *See* ECF No. 109 at 14. But that case did not involve the sort of speculation that Plaintiffs rely on here; the Court affirmed the trial court's finding that the concrete "evidence at trial established a sufficient likelihood" of imminent injury fairly traceable to the government's decision. *Commerce*, 139 S. Ct. at 2566. "The trial court's findings of fact that the Supreme Court confirmed included more than 25 pages of detailed findings specifically related to standing." *Washington*, 2020 WL 5095467, at *8 n.9 (addressing *New York v. United States Dep't of Commerce*, 351 F. Supp. 3d 502, 577-604 (S.D.N.Y. 2019)). And unlike this case, where HHS did "not 'admit' that discrimination will increase, or insurance coverage will decrease, as a result of the 2020 Rule,"

Washington, 2020 WL 5095467, at *9,[1] *see infra* at 21, in *Commerce*, the trial court found it "significant[] that [it was the agency's] *own* considered view" that "adoption of a citizenship question to the 2020 census will cause a significant net differential decline in self-response rates among noncitizen households." *Commerce*, 351 F. Supp. 3d at 578 (emphasis in original). "[S]everal persuasive Census Bureau analyses support[ed] this position, and no evidence in the record—from Defendants or otherwise—contradict[ed] it." *Id*. The Supreme Court also found this to be the most significant evidence supporting the predictability of the imminent injury resulting from the agency's action—explaining that "the District Court did not clearly err *in crediting the Census Bureau's [own] theory* that the discrepancy [in response rates] is likely attributable at least in part to noncitizens' reluctance to answer a citizenship question." *Commerce*, 139 S. Ct. at 2566 (emphasis added). As explained *infra*, in this case, Plaintiffs provide no concrete evidence of imminent concrete injury fairly traceable to any provision of the 2020 Rule.

Moreover, in *Commerce*, the plaintiff's injury was imminent in a manner not present here. In *Commerce*, the population count derived from the census was certainly impending in the subsequent year and the resultant injuries from a diminished population count—"los[ing] out on federal funds that are distributed on the basis of state population"—would follow directly thereafter. *See* 139 S. Ct. at 2565. The "specification of *when* the some day" that the injury would occur was plain, just like it was in *California v. Azar* and *Massachusetts v. HHS*. *See Defs. of Wildlife*, 504 U.S. at 564 (emphasis in original). In stark contrast, Plaintiffs fail to identify any policies or practices by any regulated entity that have changed or that any entity intends to change based on any provision of the 2020 Rule at any imminent time. Here, Plaintiffs assertion that hypothetical insurers and health care providers might some day engage in discrimination against hypothetical LGBT individuals or others in a manner that might trickle up to cause them harm is not enough. "Such 'some day'" speculation "without any description of concrete plans" does "not

[1] *See also Massachusetts v. U.S. Dep't of Health and Human Servs.*, 923 F.3d 209, 224-25 (1st Cir. 2019) (finding injury and traceability where the agency had already "done much of the legwork in establishing that there is a substantial risk that [specific employers]" would take specific action as a result of new regulation)

support a finding of the 'actual or imminent' injury that" is required. *See Defs. of Wildlife*, 504 U.S. at 564.

In any event, Plaintiffs' assertion that discrimination is predictable as a result of the 2020 Rule is simply wrong. For a number of reasons explained particularized to each of Plaintiffs' claims *infra*, Plaintiffs' predictions of future discrimination due to any of the provisions that they challenge are highly speculative. For example, several factors make it entirely unpredictable that insurers will effectuate widespread policy changes that harm Plaintiffs due to any provision in the 2020 Rule. Insurers must consider consumer demand and public relations concerns in addition to regulatory mandates when considering which insurance products to offer consumers. So, after considering these concerns, an insurer may not, for example, decide to drop all coverage of gender-affirming care—a prediction perhaps more plausible than Plaintiffs' as it accords with "application of basic economic logic," *see Connecticut v. Am. Elec. Power Co. Inc.*, 582 F.3d 309, 344 (2d Cir. 2009), *rev'd on other grounds*, 564 U.S. 410 (quoting *United Transp. Union v. ICC*, 891 F.2d 908, 912 n.7 (D.C. Cir. 1989)), while Plaintiffs' prediction—that insurers will ignore the implications of consumer demand—does not. The point is simply that Plaintiffs' suggestion that insurers will forgo covering gender-affirming care or discriminate in any manner is far from predictable. In any event, to establish standing, insurers must have modified their coverage *due to the 2020 Rule*, *see Massachusetts*, 923 F.3d at 222, 224 n.9, but the 2020 Rule "makes no changes to what has been the status quo since December 2016, when [HHS] was enjoined from enforcement of the gender identity provisions of the 2016 Rule; such provisions have now been vacated by a court. Any recent decrease in blanket exclusions for sex-reassignment coverage is therefore more [predictably] to be attributable to health insurance issuer or plan sponsor choice." 85 Fed. Reg. 37,160, 37,199 (June 19, 2020). These facts cast further doubt on the predictability of Plaintiffs' purported harms.

B. Injuries Stemming from the Fears of Plaintiffs' Residents are not Fairly Traceable to Any Provision of the 2020 Rule.

Plaintiffs largely ignore their obligation to "'demonstrate standing for each claim [they seek] to press.'" *See Mahon v. Ticor Title Ins. Co.*, 683 F.3d 59, 64 (2d Cir. 2012) (quoting *Daimler Chrysler Corp.*, 547 U.S. at 335 (2006)). "*[W]ith respect to each asserted claim*, '[a] plaintiff must always have suffered a distinct and palpable injury to [her]self.'" *Id.* (quoting *Gladstone Realtors v. Vill. of Bellwood*, 441 U.S. 91, 100 (1979)) (emphasis in original). Indeed, every court to have addressed a plaintiff's standing to raise numerous claims challenging distinct provisions within the 2020 Rule has recognized Plaintiffs' burden in this regard. *See Walker v. Azar*, No. 20-CV-2834 (FB) (SMB), 2020 WL 6363970, at *3 (E.D.N.Y. Oct. 29, 2020); *Whitman-Walker Clinic, Inc v. U.S. Dep't of Health and Human Servs.*, Civil Action No. 20-1630 (JEB), 2020 WL 5232076, at *9-*20 (D.D.C. Sept. 2, 2020); *Washington*, 2020 WL 5095467, at *6–*12. Nevertheless, throughout their standing arguments, Plaintiffs disregard this burden and entirely fail to particularize their analysis to any of the claims that they raise. *See* ECF No. 109 at 13-27. Instead, Plaintiffs repeatedly assert harms that are allegedly caused by the 2020 Rule as a whole. *See, e.g.*, ECF No. 109 at 23 ("the 2020 Rule will harm the public health"). Plaintiffs do not analyze with any degree of detail the likely implications of any of the actual changes that HHS made in the 2020 Rule because they recognize that doing so undermines their efforts to manufacture standing. *See id.* at 13-27. Indeed, Plaintiffs rely heavily on a purported expert witness, Jaclyn White Hughto, Phd, MPH, to support their standing, *see, e.g.*, ECF No. 109 at 17 n.15, 19 n.19, 22 n.31, 23 n. 33. But Ms. Hughto explains that "no empirical research, to [her] knowledge, has yet explored the impact of the 2020 Rule." ECF No. 111-37 at ¶ 44.

Plaintiffs appear to believe that they can bypass their obligation to establish imminent injuries that they allege are actually caused by HHS's changes in the 2020 Rule by instead relying on what their own residents—who are surely not familiar with the 2020 Rule—imagine the 2020 Rule might mean. *See* ECF No. 109 at 13-27. But it is well-established that injuries of this sort are "not . . . fairly traceable to [the government] because they are based on third parties' subjective

fear." *Clapper*, 568 U.S. at 417 n.7 (citing *Laird v. Tatum*, 408 U.S. 1, 10–14 (1972)); *see also Lyons*, 461 U.S. at 107 & n.8 (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 . . . injury that is relevant to the standing inquiry, not . . . subjective apprehensions."). Indeed, Ms. Hughto's declaration *admits* that any injuries to the public health are not traceable to actual implications of anything in 2020 Rule. Plaintiffs have "present[ed] no concrete evidence to substantiate their [residents'] fears." *See Clapper*, 568 U.S. at 420.

For example, Ms. Hughto states that in 2016, "a federal trial court judge in Texas issued a nationwide preliminary injunction prohibiting HHS from enforcing Section 1557 regulations that banned discrimination on the basis of gender identity and termination of pregnancy. Nearly three years later, on October 15, 2019, the judge issued a final judgment and opinion that vacated and remanded the parts of the regulation defining sex-based discrimination to include discrimination based on gender identity and termination of pregnancy." ECF No. 111-37 at ¶ 32. Nevertheless, she states that the decision was "not well known to many transgender people" in part because "media coverage of the case has been relatively limited." *Id*. ¶¶ 32-33. Accordingly, Ms. Hughto says that

> [i]t is my professional opinion that the numerous successful lawsuits that invoked Section 1557 on behalf of transgender victims of healthcare discrimination, together with a lack of awareness of the *Franciscan Alliance* preliminary injunction, led many transgender people to believe that they had continuous federal protections against discrimination in healthcare settings in the period between the 2016 Rule and the 2020 Rule. Just as believing that one's government deems you worthy of protections against discrimination in healthcare settings can yield health benefits for transgender people, perceiving that your government does not value your health and wellbeing can carry a number of adverse financial and health-related outcomes as discussed next.

Id. ¶ 34.

Throughout her declaration, Ms. Hughto asserts that the Plaintiff States will incur health-related costs not as a result of the *real* implications of the 2020 Rule, but instead due to patients' misconceptions about the state of the law before the 2020 Rule was issued and subjective fears of hypothetical future discrimination. *See, e.g.*, *id*. ¶¶ 58-62. Without a doubt, injury stemming from

third parties' subjective perceptions or apprehensions about the federal government's concern for their health that admittedly have no relationship to the objective realities of the actual implications of the challenged federal policies, *see id*. ¶ 34, cannot be fairly traceable to each of the provisions of the 2020 Rule challenged in this case, *see Clapper*, 568 U.S. at 417–18 (costs that "are simply the product of . . . fear[s]" are "insufficient to create standing"); *see also id*. at 417 n.7 (third party actions implicating plaintiffs "do not establish injury that is fairly traceable" to challenged statute "because they are based on third parties' subjective fear"). A plaintiff's standing cannot be premised on "imaginary" harms. *Kearns v. Cuomo*, 981 F.3d 200, 207 (2d Cir. 2020).

The 2020 Rule is especially unlikely to have real implications for Plaintiff States because of their own state laws and regulations explicitly prohibiting the very discrimination that they speculate or fear the 2020 Rule might prompt. *See* Compl. ¶ 175 n.38 (listing state statutes and regulations explicitly prohibiting discrimination by health providers). So Plaintiffs similarly invoke the fears of their residents in an effort to bypass this reality as well. According to Ms. Hughto, these state laws are irrelevant because "it is [her] professional opinion, that transgender individuals who are aware of the repeal of regulatory protections under the 2020 Rule and who are confused about the existence or extent of state protections are likely to believe that they have no legal recourse against healthcare discrimination" and about fifty-five percent of respondents to a survey in Massachusetts and Rhode Island—where state law explicitly prohibits gender identity discrimination—had no idea that those state laws existed. ECF No. 111-37 at ¶ 41.[2] But the Plaintiff States cannot invoke their own residents' lack of knowledge in an effort to show that they

[2] Ms. Hughto has not demonstrated with any degree of likelihood that there are individuals "who are aware of . . . the 2020 Rule" but who "are confused about the existence" of state law protections. *See* ECF No. 111-37 at ¶ 41. She does not indicate which of the respondents to the survey are more likely to be scanning the pages of the Federal Register for information about federal administrative actions, like the 2020 Rule. It seems more "predictable," *see Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2556 (2019), that there is a substantial overlap between the 55% of respondents who are uninformed about their states' laws prohibiting gender identity discrimination and those who are similarly uninformed about what rulemaking actions HHS takes, as well as substantial overlap between those who are informed about their protections regardless of whether they are under state law or under federal law.

are "'immediately in danger of sustaining some direct injury' *as a result of the challenged official conduct*" that is "both '*real* and immediate,' not 'conjectural' or 'hypothetical,'" *Lyons*, 461 U.S. at 102 (emphasis added) (quoting *Golden*, 394 U.S. at 103, 109-10). Any injury stemming from their citizens' lack of knowledge regarding state law is not fairly traceable to the challenged regulations. *See Clapper*, 568 U.S. at 417 n.7. Plaintiffs "in the present case present no concrete evidence to substantiate their fears, but instead rest upon mere conjecture about possible governmental actions," as well as conjecture about possible third-party covered entity actions and conjecture about fourth-party patient and insured actions. *See id*. at 420.

C. Plaintiffs Have not Demonstrated Standing to Raise Any of their Claims

1. Claims Related to the Repeal of the Regulatory Definition of "On the Basis of Sex" and Regulatory Provisions Defining Gender Identity Discrimination

(1) Plaintiffs Have Failed to Establish Imminent Increased Cost Associated with Uncompensated Health Care Resulting from HHS's Decision not to define "On the Basis of Sex" by Rule.

Plaintiffs claim that "the 2020 Rule will harm the public health by deterring individuals from seeking timely medical treatment, resulting in delayed or denied care and related economic costs." ECF No. 109 at 23. To the extent that they are discussing HHS's decision not to define "on the basis of sex" by rule, Plaintiffs fail to provide any evidence establishing a real imminent injury that is fairy traceable to this action. ECF No. 109 at 23-25.

Plaintiffs base their arguments that the 2020 Rule will increase discrimination and decrease healthcare coverage on speculation and conjecture about the impact the 2020 Rule will have on their residents. Plaintiffs submitted fifty-three exhibits, including forty-nine declarations, as part of their effort to manufacture standing. *See* ECF No. 111. Many of these declarations addressing the 2020 Rule's decision not to define "sex" or "on the basis of sex" assume that this portion of the 2020 Rule implies that protection from discrimination on the basis of sex in healthcare does not extend to LGBTQ people. ECF No. 111-2 at ¶ 15, 21; ECF No. 111-3 at ¶ 14; ECF No. 111-7 at ¶ 17. "But it is far from clear whether the 2020 Rule will, in fact, will have such an impact."

Washington, 2020 WL 5095467, at *7. "The text of the 2020 Rule prohibits discrimination on the grounds prohibited by Title IX." *Id*. "Thus, based on the text of the 2020 Rule, the 2020 Rule only provides that protection from discrimination on the basis of sex in healthcare does not extend to LGBTQ people . . . if Title IX also provides that protection from discrimination on the basis of sex in healthcare does not extend to LGBTQ people." *Id*.

Just like the plaintiff state in *Washington v. HHS*, Plaintiffs' exhibits all fixate "on HHS's language in the preamble which suggests that the term 'sex' as used in Title IX does not include gender identity and sexual orientation." *See Washington*, 2020 WL 5095467, at *7 n.8. *See, e.g.*, ECF No. 111-7 at ¶ 17. But there are "two problems with [Plaintiffs'] reliance on the preamble language." *Id*. First, "the preamble does not state that HHS's chosen interpretation of the term 'sex' will control application of the 2020 Rule. Instead, the preamble itself states that the 2020 Rule reverts to the plain language in Section 1557 and Title IX, . . . and explicitly concedes 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.'" *Id*. (quoting 85 Fed. Reg. at 37,168). "Thus, the language in the preamble acknowledges that Title IX caselaw will control the application of Section 1557, thereby rendering HHS's interpretation of the term 'sex' in the preamble less meaningful." *Id*. Indeed, as discussed *infra* at 51, when HHS proposed the 2020 Rule, HHS explained that it "decline[d] . . . to propose its own[] definition of 'sex' for purposes discrimination on the basis of sex in the regulation" because "of the likelihood that the Supreme Court will be addressing the issue in the near future." 84 Fed. Reg. 27,846, 27,856 & n.75 (June 14, 2019). "Second, and most importantly, the language in the preamble does not solve [Plaintiffs'] standing problems regarding the lack of concrete evidence that the 2020 Rule will have the impact on discrimination in [Plaintiffs' states] that [Plaintiffs] assume[] it will have." *See Washington*, 2020 WL 5095467, at *7 n.8.[3]

[3] One declarant asserts that HHS said in the preamble to the final rule "that covered entities are not required to process complaints alleging discrimination on the basis of gender identity." ECF No. 111-1 at ¶ 18 (citing 85 Fed. Reg. 37,236). HHS actually said that it did "not estimate a cost

Just like the plaintiff state in *Washington v. HHS*, Plaintiffs here "vehemently argue[] throughout [their] brief that the inevitable result of *Bostock* [*v. Clayton County*, 140 S. Ct. 1731 (2020)]—which was issued after HHS finalized the preamble language that [Plaintiffs] take[] issue with—is that 'on the basis of sex' under Section 1557 and Title IX must now be interpreted to include concepts like gender identity and sexual orientation." *See* 2020 WL 5095467, at *8. *See, e.g.*, ECF No. 109 at 37-39. "Ironically, however, [Plaintiffs'] argument about the impacts of *Bostock* harms [their] efforts to establish an injury in fact." *See Washington*, 2020 WL 5095467, at *8. 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." *See id.* "For purposes of standing, . . . the key point is that [Plaintiffs] make[] no effort to explain why providers or insurers would be willing to risk revising their practices or policies [due to the 2020 Rule] to discriminate against LGBTQ individuals in light of the Supreme Court's recent guidance in *Bostock* and the very arguments that [Plaintiffs] advance in this case." *See id.*; *see also* ECF No. 109 at 37-39.

Indeed what little factual evidence Plaintiffs offer refutes their suggestion that the 2020 Rule is likely to have discernable implications for LGBTQ individuals and their health, let alone that any such discrimination is "predictable." *See* ECF No. 109 at 26-27 (invoking *Commerce*, 139 S. Ct. at 2566). For example, Plaintiffs submit one declarant's analysis of "1,386 silver marketplace [insurance] plans from 176 insurers in the 36 states that use HealthCare.gov." ECF No. 111-49 at ¶ 10. The analysis found that only one lone insurer—Bright Health—decided to use "transgender-specific exclusions for 2021" in plans that did not use such exclusions in 2020. *Id.*

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savings concerning grievance procedures" from the 2020 Rule "because, as stated repeatedly elsewhere, the court order vacating the gender identity provisions of the 2016 Rule means that th[e 2020 Rule's] changes concerning gender identity will have no direct material economic impact." 85 Fed. Reg. at 37,236. And that analysis was conducted *before* the Supreme Court's opinion in *Bostock*. *See id.* HHS is unable to exempt covered entities from the requirements of the plain meaning of Section 1557.

¶ 11.[4] Plaintiffs' suggestion that insurers will forgo covering gender-affirming care is far from predictable.

Even assuming that Bright Health's policy change could plausibly have discernable impacts on Plaintiffs' costs associated with uncompensated health care, Plaintiffs provide nothing but speculation that Bright Health changed its policy as a result of the 2020 Rule. *Id.* ¶ 12. The declarant speculates that "[t]his trend,"—the lone insurer's purported change in policy—"has led [her] to conclude that at least some insurers are responding to the 2020 Final Rule by adopting categorical exclusions that were banned under the 2016 Final Rule." *Id.* There are several issues with Plaintiffs' attempt to establish standing to challenge HHS's decision not to define "on the basis of sex" based on Bright Health's policy change.

First, Plaintiffs fail to provide concrete evidence establishing the "substantial likelihood of the alleged causality" required. *See NRDC v. NHTSA*, 894 F.3d 95, 104–05 (2d Cir. 2018). "[T]he gender identity provisions of the 2016 Rule were preliminarily enjoined on a nationwide basis by a court from December 2016 until October 2019, when they were vacated entirely. As a result, the [2020 Rule] maintains the status quo with respect to gender identity under the enforcement of the Section 1557 rule." 85 Fed. Reg. at 37,238. If Bright Health has indeed made a policy change, Plaintiffs have offered no evidence establishing a substantial likelihood that the company has done so as a result of HHS's decision not to define "on the basis of sex" in the 2020 Rule. *See id.* To the contrary, it is just as likely, or more likely, that Bright Health decided to do so as a result of the federal district court's decision to vacate the inclusion of gender identity from the 2016 Rule's definition of "on the basis of sex." *See id.* Indeed, Plaintiffs offer no evidence whatsoever about how long it takes insurance companies to make policy changes, but the declarant does say that "[p]lan documents for the following calendar benefit year are available each fall to coincide with

[4] The declarant inflates this single insurer's decision, stating that the "number of insurers using transgender-specific exclusions for 2021 more than doubled from the prior year: from 5 insurers for 2020 plans to 13 insurers for 2021 plans." ECF No. 111-49 at ¶ 11. But in reality, these eight plans are just the same insurer—Bright Health—offering insurance coverage in eight different states, only two of which are Plaintiff States. *See Id.* at 13-14.

the annual open enrollment period, which typically runs from November 1 to December 15." ECF No. 111-49 at ¶ 8 n.7. So assuming that Bright Health made its 2021 policy change publically available in October 2020, Plaintiffs must assume that Bright Health was able to make all of these changes in a matter of four months—between HHS's release of the 2020 Rule and when Bright Health made its policy documents available. The more reasonable assumption is that Bright Health began working on a policy change long before the 2020 Rule, and its decision was made independently of it.

Second, even assuming that Bright Health changed its policy in reliance on its understanding of the 2020 Rule, "injury at the hands of [Bright Health] is insufficient by itself to establish a case or controversy in the context of this suit, for [Bright Health] is [not] a defendant." *Simon v. Eastern Kentucky Welfare Rights Organization*, 426 U.S. 26, 41 (1976). Even assuming that the 2020 Rule "'encouraged'" Bright Health to change its policy to deny gender-affirming care to Illinois and North Carolina citizens, and that vacating HHS's decision not to define "on the basis of sex" by rule would "'discourage'" Bright Health from maintaining that policy change, "it does not follow from the allegation and its corollary that [Bright Health's] denial of [gender affirming care] in fact results from" the 2020 Rule, "or that a court-ordered return by [HHS] to [its] previous policy would result in" Bright Health changing its policy as Plaintiffs desire. *See id.* at 42. "It is purely speculative whether" Bright Health's policy change "can be traced to [HHS's purported] 'encouragement' or instead results from decisions made by [Bright Health] without regard to" the 2020 Rule. *See id.* at 42–43. Indeed, two courts have preliminarily enjoined HHS's decision not to define "on the basis of sex" by rule, yet Plaintiffs' evidence of Bright Health's policy change post-dates those orders by several months. *See* ECF No. 111-49 (dated December 1, 2020). Plaintiffs' reliance on the policy change of a single insurer, followed by their decision to take HHS rather than Bright Health to court over that policy change, is evidence that Plaintiffs are not out to remedy any plausible actual injuries, but are instead motivated only by "their special interest in" LGBTQ rights. *See Simon*, 426 U.S. at 40. The Plaintiff States "may feel sincerely

and strongly that" HHS violated the APA in promulgating the 2020 Rule, "[b]ut that kind of interest does not create standing." *Carney*, 141 S. Ct. at 499.

Third, Plaintiffs' evidence establishes that it is not only speculative, but entirely unlikely, that fourth-party insurance consumers will act in a manner that will result in higher costs to the Plaintiffs associated with uncompensated care resulting from Bright Health's change in policy. Plaintiffs' own evidence suggests that consumers shopping for insurance on the Healhcare.gov silver marketplace have over one thousand plans from 176 insurers to choose from. ECF No. 111-49 at ¶ 10. So if one or two insurers decide that they will decline to offer gender conforming care to transgender individuals, for example, transgender individuals will likely opt for policies from the vast majority of insurers that do offer such coverage, resulting in no plausible implications for Plaintiff States health care costs. *See id*. Indeed, the Helathcare.gov website itself provides notice to transgender consumers that some "health plans are still using exclusions such as 'services related to sex change' or 'sex reassignment surgery' to deny coverage to transgender people for certain health care services," so that these consumers ensure that they find a plan that makes sense for them. *See* Healthcare.gov, Transgender health care, https://www.healthcare.gov/transgender-health-care/.

Plaintiffs assert that "[w]hen plans covered by the 2016 Rule but not subject to the 2020 Rule (and potentially not subject to state antidiscrimination laws) deny gender affirming care, some individuals will turn to state-funded care." ECF No. 109 at 24. But unlike, for example, *Massachusetts v. HHS*, where the Commonwealth of Massachusetts provided concrete evidence demonstrating that they serve as a "'secondary payer' for about 150,000 residents," meaning "that qualifying residents with employer-sponsored plans who lose contraceptive coverage would then be covered by MassHealth, and the Commonwealth would owe ten percent of the cost of contraceptive coverage paid by MassHealth," 923 F.3d at 218, the Plaintiff States provide no such evidence of any harm from Bright Health's policy change here. Plaintiffs merely assert repeatedly that they run programs like Medicaid and Children's Health Insurance Program (CHIP). *See* ECF No. 109 at 24 n.36 (and sources cited therein). But eligibility for these programs is limited to

certain classes of individuals and these programs reportedly provide "better coverage than anything" generally available "in the marketplace." *See* Consumer Reports, Is Medicaid good insurance? Yes (Dec. 17, 2013), https://www.consumerreports.org/cro/news/2013/12/is-medicaid-good-insurance/index.htm. So individuals who are eligible for Medicaid or CHIP are likely to take advantage of them as soon as they become eligible, not when hypothetical insurers "deny gender affirming care." *See* ECF No. 109 at 24. Plaintiffs note that Bright Health has made a policy change in Illinois and North Carolina, *see id.*, but they fail to provide any concrete evidence that this has had any discernable impact on enrollment in state-administered plans, as opposed to increasing enrollment in other available silver marketplace plans. *See id.*[5]

Ms. Hughto further suggests that "transgender individuals will also experience an increase in denied insurance claims for medically necessary procedures." ECF No. 111-37 at ¶ 37. But she supports that prediction with nothing more than "numerous studies conducted before the 2016 Rule [that] documented transgender people's experiences of being denied insurance coverage for medically necessary care." *Id.* And it is well established that "past wrongs do not in themselves amount to that real and immediate threat of [future] injury necessary to make out a case or controversy." *Lyons*, 461 U.S. at 103. In fact, if insurers have been denying fewer claims for medically necessary gender-conforming care, as Ms. Hughto's testimony suggests, there is every reason to believe that the trend will continue notwithstanding the 2020 Rule, since the 2020 Rule "makes no changes to what has been the status quo since December 2016, when [HHS] was enjoined from enforcement of the gender identity provisions of the 2016 Rule; such provisions have now been vacated by a court. Any recent decrease in blanket exclusions for [certain types of insurance] coverage is therefore more likely to be attributable to health insurance issuer or plan sponsor choice." 85 Fed. Reg. at 37,199.

[5] Plaintiffs' Complaint also alleged harms to their public hospitals, *see* Compl. ¶ 253, but having failed to make any argument related to costs to public hospitals in their brief and focusing only on their insurance plans, *see* ECF No. 109 at 23-26, Plaintiffs have waived any argument that the 2020 Rule will have cost implications for their hospitals.

Contrary to Plaintiffs' assertions, HHS never "conceded" that any change in the 2020 "Rule will cause the States to bear increased health care costs." ECF No. 109 at 25. HHS actually concluded that it "is uncertain as to the total number of covered entities that will change their policies and grievance processes" as a result of the 2020 Rule. 85 Fed. Reg. at 37,225. Plaintiffs misquote a part of the preamble where HHS explained that it "lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits after publication of this rule—nor data to estimate how many of those individuals may experience the workplace and health-related negative consequences that many commenters contend will result from [the 2020] Rule." *Id*. *See* ECF No. 109 at 25. HHS also explained that it "lacks data to estimate what greater public health costs, cost-shifting and expenses may result from entities changing their nondiscrimination policies and procedures after promulgation of this rule." 85 Fed. Reg. at 37,225. *See* ECF No. 109 at 25. HHS's lack of data does not represent a concession that these costs will occur or that the 2020 Rule would have any implications for the Plaintiff States themselves. Part of the reason HHS lacked this data is because HHS could not predict how courts would construe the plain meaning of "sex" under Title IX. *See supra* at 14-16. HHS actually concluded that "it believes" that the 2020 Rule's "effects will be minimal, again, due to the fact that the gender identity provisions were vacated from the 2016 Rule by the *Franciscan Alliance* court before this rulemaking was finalized." 85 Fed. Reg. at 37,225. Nothing about anything that HHS said, "which was in no way particular to [Plaintiffs] or the particular [residents] on which [Plaintiffs] base[] [their] standing arguments, . . . measure[s] 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.

The Plaintiff States' "general lack of evidence that the 2020 Rule will create an injury in fact is also exacerbated by the impact that" their own laws "could have on providers and insurers." *See id*. at *10. *See* Coml. ¶ 175 n.38. Some of Plaintiffs' declarants point out that some subset of consumers might be insured by plans not subject to their laws, *see, e.g.*, ECF No. 111-25 at ¶ 8,

but Plaintiffs provide no "concrete evidence about potential providers or insurers who might revise policies or practices in response to the 2020 Rule" falling into this group. *See Washington*, 2020 WL 5095467 at *9; *see also Clapper*, 568 U.S. at 420 (stressing the need for "concrete evidence to substantiate [Plaintiff'] fears" of future harm"). Plaintiffs' declarants merely assert, for example, that "New Yorkers who are in plans that are not subject to state anti-discrimination law . . . *may* lose protections contained in HHS's former Section 1557 regulations," ECF No. 111-25 at ¶ 8 (emphasis added), but that kind of "mere conjecture about possible [insurer] actions" is insufficient to establish standing," *Clapper*, 568 U.S. at 420.

Plaintiff States have also "present[ed] no concrete evidence to substantiate their fears" of future harm related to "termination of pregnancy", "but instead rest on mere conjecture." *See id*. For example, one declarant *admits* that the 2020 Rule's coverage of "complaints related to pregnancy status and particularly termination of pregnancy is not entirely clear." ECF No. 111-2 at ¶ 15. Indeed, HHS explained that "[a]lthough th[e 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 [the Office for Civil Rights ("OCR")] could not consider such claims of discrimination." 84 Fed. Reg. at 27,870 n.159. The same logic is true of any complainant alleging any type of sex discrimination claim. *See id.*

(2) Plaintiffs' Intentions to Incur Administrative Costs or Costs to Enforce Their Own Laws are Not Fairly Traceable to HHS's Decision not to Define "On the Basis of Sex."

Plaintiffs assert that they plan to incur administrative costs "issuing guidance and directives confirming that their state agencies will . . . (1) investigate discrimination in health care by a broad range of entities, including private insurance companies providing employer-based plans; (2) investigate complaints alleging discrimination on the basis of gender identity, sexual orientation, and pregnancy status; and (3) continue to require language access and interpretive services." ECF No. 109 at 16. They also assert that they plan to incur costs to enforce their own state antidiscrimination laws. ECF No. 109 at 18-21. But as described *supra* at 14-22, Plaintiffs have offered nothing but mere speculation that HHS's decision not to define "on the basis of sex" by

rule will lead to any *real* harms. They have only raised all kinds of speculation, conjecture, and fear that the decision *might* lead third party covered entities to change their policies or practices which *might* lead fourth-party patients and insureds to take different actions. *See supra id*. It is well-established that Plaintiffs "cannot manufacture standing by choosing to make expenditures based on hypothetical future harm" when they have not establish that real future harm is imminent. *See Clapper*, 568 U.S. at 402. Plaintiffs' "contention that they have standing because they" plan to incur "certain costs as a reasonable reaction to a risk of harm is unavailing—because the harm respondents seek to avoid" has not been "prov[en with] concrete facts showing that [HHS]'s actual action has caused [any] substantial risk of harm." *See id*. 414 n.5, 416.

Plaintiff States do "not point to any provision in the 2020 Rule that requires [them] to incur administrative costs to inform their citizens about changes in the 2020 Rule" or to enforce their own laws in different ways, "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 administrative costs as a result of the changed regulations." *Id*. "This is not the law," *id*., because "to find standing based upon that kind of" self-inflected cost would "'permit general oversight of the elected branches of government by a nonrepresentative, and in large measure insulated, judicial branch,'" *Carney*, 141 S. Ct. at 499 (quoting *United States v. Richardson*, 418 U.S. 166, 188 (1974) (Powell, J., concurring)). Plaintiffs simply may not substitute a failure to provide concrete evidence of real harm fairly traceable to HHS's decision not to define "on the basis of sex" by rule with their own decisions to incur costs while the new Rule is in effect.

In any event, Plaintiffs' arguments suffer from additional flaws. For example, Plaintiffs provide no support for their assertion that they "will now be the sole governmental authorities accepting and investigating claims of health care discrimination by all types of health care entities" as a result of HHS's decision not to define "on the basis of sex" by rule. ECF No. 109 at 19. HHS

explained that "[a]lthough th[e 2020 Rule] does not adopt a position on whether discrimination on [certain bases] 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. As Defendants explained in support of their motion to dismiss, the extent to which HHS will enforce individual complaints of discrimination in light of the new rule is simply not ripe for review—Plaintiffs have not shown that HHS has failed to adjudicate any particular claim of sex discrimination in light of the 2020 Rule and any suggestions regarding how HHS might enforce Section 1557 in the future in light of the 2020 Rule are purely speculative. *See* ECF No. 113 at 36-44.

Plaintiffs also have not shown that any enforcement costs would be redressed by a decision of this Court vacating HHS's decision to remove the 2016 Rule's already partially vacated definition of "on the basis of sex". Plaintiffs confuse HHS's decision to promulgate the 2020 Rule, which they challenge, with HHS's enforcement priorities, which are not subject to judicial review. *See Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985). HHS is not under any obligation to enforce all of its rules at all times against any arguable violation notwithstanding HHS's limited resources and enforcement priorities. *See id*. (discussing "the many variables involved" and factors considered when agencies make enforcement decisions).[6]

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

[6] OCR's limited resources allow for very few civil rights resolution agreements—the agency's 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/for-providers/compliance-enforcement/agreements/index.html (last visited Jan. 4, 2021). 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.

accordance with Plaintiffs' enforcement priorities. Whether, how, and to what extent HHS would 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.

Additionally, a close examination of Plaintiffs' "evidence" in support of some of these costs shows just how Plaintiffs rely on layer upon layer of speculation. For example, one declarant's statement that Plaintiffs cite in support of their contention that "States must ensure that providers and insurers in their jurisdictions understand their continuing nondiscrimination obligations under state law," *see* ECF No. 109 at 16 & n.11, says:

> the Rule eliminates the prohibition against discrimination on the basis of gender identity as it relates to marketing and benefit plan design, in qualified health plans, and in essential health benefits. As a result, in reliance on this Rule, but in violation of state law, unscrupulous insurers, or their agents, could attempt to discriminate in their marketing by using sexual orientation as a basis to refuse to market or advertise in areas with a larger LGBTQ+ community, or argue that they are providing essential health benefits even if they discriminate based upon sexual orientation or gender identity, to the detriment of this community's health. Past discriminatory efforts during the early years of the AIDS epidemic stand as a stark warning of these potential harms.

ECF No. 111-1 at ¶ 11. The first sentence appears to "presume[] that the 2020 Rule does not extend protection against discrimination to LGBTQ individuals," but 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." *See Washington*, 2020 WL 5095467, at *8. Neither this declarant, the Plaintiffs' other declarants, nor Plaintiffs' briefing make any "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 [they] advance[] in this case." *See id.*

In addition, it facially absurd speculation to suggest that "unscrupulous insurers … could attempt to discriminate" "in violation of state law", ECF No. 111-1 at ¶ 11; it makes no sense to assume that insurers would violate state law in light of a new federal regulation. Moreover, even assuming that sex discrimination does not encompass gender identity discrimination, the declarant's assertions that insurers "*could* attempt to discriminate," *id.* "without any description of concrete plans, or indeed even any specification of *when* the some day will be—do not support a finding of the 'actual or imminent' injury that [Supreme Court] cases require." *Defs. of Wildlife*, 504 U.S. at 564. The declarant's assertion does not overcome the "usual reluctance to endorse standing theories that rest on speculation about the decisions of independent actors." *Clapper*, 568 U.S. at 414.

Finally, to the extent that "[p]ast discriminatory efforts during the early years of the AIDS epidemic" has any relevance to the 2020 Rule whatsoever, it is well established that "past wrongs do not in themselves amount to that real and immediate threat of injury necessary to make out a case or controversy." *Lyons*, 461 U.S. at 103.

In light of the mere speculation that the 2020 Rule will cause any discernable actual harm at all, Plaintiffs cannot nonetheless manufacture standing by "incur[ing] costs issuing guidance and directives confirming that their state agencies will" enforce their own laws. *See* ECF No. 109 at 16. This is precisely the theory of standing that was rejected in *Clapper*, where the Court explained that Plaintiffs "cannot manufacture standing by choosing to make expenditures based on hypothetical future harm." 568 U.S. at 402. To the extent these costs can be considered an "injury" at all, they are "not fairly traceable to the Government's purported activities." *See Washington*, 2020 WL 5095467, at *11 (quoting *Clapper*, 568 U.S. at 418).

2. Claims Related to the 2020 Rule's Construction of the Scope of the term "Health Program or Activity."

Plaintiffs raise claims that HHS violated the APA when construing the term "health program or activity." *See* ECF No. 109 at 28-34 (citation omitted). Plaintiffs' efforts to establish standing to raise these claims suffer from many of the same deficiencies as described above.

Plaintiffs assert that "complainants alleging discrimination . . . against entities that were covered by OCR's prior interpretation of Section 1557, but are no longer covered under the Rule, will need to file their complaints with [state regulators] instead of with OCR." *See, e,g,*, ECF No. 111-32 at ¶ 14. But Plaintiffs assume, "without evidence, 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." *See Washington*, 2020 WL 5095467, at *12. "[T]hese speculative allegations are insufficient to confer standing . . . to challenge the 2020 Rule's construction of the scope of covered entities." *See id*.

Indeed, as discussed *supra* at 16-20, Plaintiffs provide evidence of only one single insurer—Bright Health—that *might* have changed a policy because of the 2020 Rule. But Plaintiffs cannot plausibly establish standing to challenge HHS's definition of "health program or activity" based on arguable imminent injury from Bright Health's policy change in Illinois and North Carolina. In addition to speculation that Bright Health's policy change will actually mean that these States will incur any costs, as discussed *supra* at 19-20, Plaintiffs only describe changes to Bright Health silver marketplace plans offered "in the individual market in states that use Healthcare.gov." *See* ECF No. 111-49 at ¶ 7. But "[t]hese plans remain subject to [the 2020 Rule] because they are sold on the Exchanges established under Title I of the ACA (see § 92.3(a)(3) of this final rule)." 85 Fed. Reg. at 37,170; *see also infra* note 9. Thus, Bright Health's change in policy is not plausibly fairly traceable to HHS's new construction of the term "health program or activity" in Section 1557.

What is more, Plaintiffs provide nothing but speculation that consumers facing discrimination would be more likely to file a complaint with OCR instead of state regulators. *See, e.g.*, ECF No. 111-32 at ¶ 14. So even assuming that a health insurer no longer subject to Section 1557 might change a policy in violation of state law, it is merely conjecture that the states will see any more complaints than they do right now as a result.

3. Claims Related to the 2020 Rule's Construction of the Scope of Federal Entities Covered by Section 1557

Plaintiffs raise claims that HHS violated the APA when construing the term "any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)," in a manner that results in a narrower scope of federal government entities subject to Section 1557. *See* ECF No. 109 at 34-36 (citation omitted. Plaintiffs do not clearly raise any arguments supporting their standing to raise this claim. *See id*. at 15-27. In any event, any effort to establish standing to raise this claim would suffers from many of the same deficiencies as described above. Plaintiffs "present no concrete evidence to substantiate their fears," *see Clapper*, 568 U.S. at 420, of any imminent discrimination against anyone by any federal entity as a result of the 2020 Rule's changes, *see* ECF No. 111. 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 State. Moreover, it is implausible that Plaintiff States could reasonably incur costs related to enforcing state laws against any federal entity because of the Supremacy Clause. *See McCulloch v. Maryland*, 17 U.S. 316 (1819).

4. Claims Related to the 2020 Rule's Conforming Modifications to other HHS Regulations

Plaintiffs raise claims that HHS violated the APA when making conforming amendments to other HHS regulations. *See* ECF No. 109 at 40-41. Plaintiffs' standing to raise these claims suffers from many of the same deficiencies as described above. Plaintiffs do not clearly raise any arguments supporting their standing to raise these claims. *See id*. at 15-27. And Plaintiffs appear to present no evidence whatsoever in support of any injury fairly traceable to these conforming amendments. *See* ECF No. 111.

5. Claims Related to HHS's Construction of Section 1557 to Prohibit Conduct in the Health Care Setting only Insofar as Prohibited by the System of Civil Rights Statutes it Incorporates

Plaintiffs raise claims that HHS violated the APA when promulgating a provision of the 2020 Rule, 45 C.F.R. §92.6(b), prohibiting conduct in the health care setting only insofar as

prohibited by the system of civil rights statutes that Section 1557 incorporates. *See* ECF No. 109 at 41-42, 67-70. The Plaintiff States lack standing to challenge this provision "for many of the same reasons that [they] lack[] standing to challenge HHS's decision not to define 'on the basis of sex.'" *See Washington*, 2020 WL 5095467, at *11.

Plaintiffs present declarations stating that "the Rule's broad religious and abortion exemptions *could* additionally impact reproductive care access." *See* ECF No 111-3 at ¶ 14 (emphasis added); *see also* ECF No. 111-35 at ¶ 6 ("the Rule's blanket religious and abortion exemptions *could* further impact reproductive care for women.") (emphasis added). "That kind of off-handed speculation . . . does not measure up to the kind of detailed . . . analysis about the expected impact of an agency regulation that courts have relied on to find standing." *See Washington*, 2020 WL 5095467, at *9. Plaintiffs "present no concrete evidence to substantiate their fears, but instead rest on mere conjecture about possible" thirty-party "actions." *See Clapper*, 568 U.S. at 420.

In addition, Plaintiffs do not explain how any plausible injury could be fairly traceable to this provision as opposed to the underlying applicable statutory right, when the regulation merely incorporates *applicable* statutory exemptions. By its explicit terms, § 92.6(b) only applies "[i]nsofar as the application of any requirement under" its regulations would violate anything in the statutes incorporated by reference into Section 1557. *See* 85 Fed. Reg. at 37,245 (§ 92.6(b)). Thus, as HHS explained, HHS "is already bound by statute to implement Title IX and Section 1557 consistent with those statutes and with RFRA, [and HHS] does not attribute its compliance with those statutes to be attributable to th[e 2020 R]ule." 85 Fed. Reg. at 37,239. In other words, this provision does little more than state the obvious—that HHS's regulations may not overcome any applicable statutory exemption or right. *See* 85 Fed. Reg. at 37,235 (§ 92.6(b)). At a minimum, Plaintiffs' claims are not ripe for review without any analysis of a concrete application of this provision. *See* ECF No. 113 at 36-41.

6. Claims Related to the 2020 Rule's "Meaningful Access" Standard for Limited English Proficient Individuals

Plaintiffs raise claims that HHS violated the APA in modifying its regulations governing access to health programs and activities by individuals with limited English proficiency ("LEP"). *See* ECF No. 109 at 60-67. Plaintiffs' standing to raise these claims suffers from many of the same deficiencies as described above.

Plaintiffs note that HHS acknowledged that its changes to the notice and taglines requirement "*may* impose costs, such as decreasing access to, and utilization of, healthcare for non-English speakers by reducing their awareness of available translation services." ECF No. 109 at 25 (quoting 85 Fed. Reg. at 37,232) (emphasis added). But this "kind of off-handed speculation—which was in no way particular to [Plaintiff States] or the particular [citizens] 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." *See Washington*, 2020 WL 5095467. Indeed, HHS actually relied on evidence that "the 2016 Rule's requirements did not appreciably increase the use of translation services." *See* 85 Fed. Reg. at 37,233. HHS cited one report that "indicated that utilization of translation services did not appreciably rise after the 2016 Rule's imposition of notice and taglines requirements." *Id*. So it stands to reason that removing those requirements would have little discernable impact on anyone, let alone anyone that would end up causing harms to the Plaintiff States. *See id*.

Again, Plaintiffs' fears about the implications of HHS's decision to modify the "Meaningful Access" standard for LEP individuals appear to rest upon a misunderstanding of the nature of the agency action at issue. For example, a declarant representing the Virginia Department of Medical Assistant Services says that the state agency "plans to continue to provide notice of nondiscrimination and language taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to Medicaid programs and services." ECF No. 111-32 at ¶ 10. But the 2020 Rule does not eliminate requirements that covered entities provide meaningful

access to their programs and activities by LEP persons. To the contrary, as discussed *infra* at 71-79, HHS decided that it was sufficient to incorporate meaningful access standards from longstanding Title VI guidance. Thus, covered entities must continue to provide notice and taglines or any other action that constitutes a "reasonable step[] to ensure meaningful access to" their health programs or activities "by limited English proficient individuals." 85 Fed. Reg. at 37,245 (§ 92.101(a)). With respect to LEP, the 2020 Rule, among other things, removed the requirement that covered entities provide certain notice 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. *See* 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 a discernable increase in discrimination. *See id*. Plaintiffs present no concrete evidence substantiating their fears of harm in light of HHS's actual changes to LEP requirements in the 2020 Rule. *See* ECF No. 111. Indeed, one New York State regulatory official stated that an unspecified number of entities have decided to remove an unspecified number of taglines in response to the 2020 Rule, but the declarant does not even provide any concrete evidence that those taglines might have been needed to prevent discernable discrimination in New York. *See* ECF No. 111-25 ¶¶ 15-16.

D. Plaintiffs May Not Invoke *Parens Patriae* Interests Against the Federal Government

Plaintiffs also assert standing based on their *parens patriae* interests in the health and well-being of their residents. *See* ECF No. 109 at 21-22. 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. 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)).

To be sure, as Plaintiffs point out, a State may sometimes bring an action against the federal government to assert its own quasi-sovereign interests. *See* ECF No. 109 at 21-22 (citing *Massachusetts v. EPA*, 549 U.S. 497, 520 n.17 (2007)). But "there is a critical difference between allowing a State 'to protect her citizens from the operation of federal statutes' (which is what [standing doctrine] prohibits) and allowing a State to assert its rights under federal law (which it has standing to do)." *Massachusetts*, 549 U.S. at 520 n.17. In *Massachusetts v. EPA*, the Supreme Court found a state had standing to sue the federal government by invoking its quasi-sovereign interest in "preserv[ing] its sovereign territory," not its quasi-sovereign interest in protecting its citizens. *Id*. at 519. But Plaintiffs assert the latter interest here. Plaintiffs admit that their interest in suing the federal government here is to protect the health and well-being of their own residents, *see* ECF No. 109 at 21, which is exactly the type of claim to "protect [their] citizens from the operation of federal" actions that the Court in *Massachusetts v. EPA* reaffirmed as prohibited. *See Massachusetts*, 549 U.S. at 520 n.17. "While the State, under some circumstances, may sue in [its quasi-sovereign] capacity for the protection of its citizens . . ., it is no part of its duty or power to enforce [its citizens'] rights in respect of their relations with the Federal Government. In that field it is the United States, and not the State, which represents them as *parens patriae*." *Alfred L. Snapp & Son*, 458 U.S. at 610 n.16 (quoting *Massachusetts v. Mellon*, 262 U.S. 447, 485-76 (1923)).

II. Plaintiffs have Failed to Overcome the Strong Presumption that an Agency's Regulation is not Subject to an Abstract Pre-Enforcement Challenge

Plaintiffs allege "that violation of the law is rampant within" HHS's 2020 rulemaking. *See Lujan v. Nat'l Wildlife Fed.*, 497 U.S. 871, 891 (1990). *See generally* ECF No. 109 (challenging an extraordinary number of the 2020 Rule's changes to the code of federal regulations). But Plaintiffs "cannot seek *wholesale* improvement of this program by court decree, rather than in the offices of [HHS] or the halls of Congress, where programmatic improvements are normally made." *Lujan*, 497 U.S. at 891. "[A] regulation is not ordinarily considered the type of agency action 'ripe' for judicial review under the APA until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action

applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him." *Id*.

In this case, most of the actions challenged by Plaintiffs are rules of general applicability that establish standards governing the conduct of third-parties. Importantly, each of these challenged provisions involves broad standards whose precise implications on those third parties cannot be fully realized until either HHS brings enforcement action in response to case-by-case complaints or until private parties bring claims against covered entities under Section 1557 in the courts. Plaintiffs' claims are not ripe for review absent a concrete allegation that someone has violated Section 1557. *See* ECF No. 113 at 36-44.

III. The 2020 Rule Reasonably Construes Section 1557

The Second Circuit "evaluate[s] challenges to an agency's interpretation of a statute that it administers within the two-step *Chevron* deference framework." *Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 507 (2d Cir. 2017). "At *Chevron* Step One, [courts] ask 'whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *Id*. (quoting *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-43 (1984)). "If the statutory language is 'silent or ambiguous,' however, [courts] proceed to *Chevron* Step Two, where 'the question for the court is whether the agency's answer is based on a permissible construction of the statute' at issue." *Id*. (quoting *Chevron*, 467 U.S. at 843). "For [courts] to decide for [themselves] what in fact is the preferable route for addressing the substantive problem at hand would be directly contrary to this constitutional scheme." *Id*. "No matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has stayed within the bounds of its statutory authority*." *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 297 (2013) (emphasis in original).

A. HHS's Definition of the Scope of Entities Covered by Section 1557 is a Substantively Permissible Construction of Section 1557

1. HHS Permissibly Construed "Health Program or Activity" Consistently with the Civil Rights Restoration Act of 1987

As Plaintiffs acknowledge, "Section 1557, by its plain statutory terms, applies to 'any health program or activity, any part of which is receiving Federal financial assistance.'" ECF No. 109 at 29 (quoting 42 U.S.C. § 18116(a)). The term "health program or activity," however, is not defined by the ACA. The ACA is silent as to its precise reach, including whether its reach extends to health insurers. *See* ECF No. 109 at 29-30. But the term "program or activity" is a term of art that has a long history in the civil rights law context that Plaintiffs entirely ignore. *See id.*

In support of their reading that Section 1557 unambiguously applies to health insurers, Plaintiffs rely on little more than *Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 954-55 (9th Cir. 2020). *See* ECF No. 109 at 29-30. To be sure, in *Schmitt*, the Ninth Circuit addressed a class of insureds' claims that their insurer violated Section 1557. 965 F.3d at 951–60. But *Schmitt* was decided when the 2016 Rule was effective. *See id.* "A court's prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982 (2005). And the Second Circuit will not regard even its own prior interpretation of a statute that is explicitly "based on the 'plain meaning' of [the statute's] term[s]" as holding that the statutory phrase is unambiguous for purposes of *Chevron*. *See Catskill*, 846 F.3d at 510-511. *Schmitt* did not conclude that Section 1557 unambiguously applies to health insurers. *See* 965 F.3d at 948, 945-55; *see also Catskill*, 846 F.3d at 510-11. Indeed, the *Schmitt* court relied on the 2016 Rule—the effective rule at the time—in construing Section 1557. 965 F.3d at 954-55, 957 (citing Nondiscrimination in Health Programs and Act, 81 Fed. Reg. at 31,376).[7]

[7] Plaintiffs also cite *Tovar v. Essentia Health*, 857 F.3d 771, 779 (8th Cir. 2017) to support their assertion that "federal courts have consistently interpreted Section 1557 . . . to apply to health

If Congress unambiguously intended to subject all health insurers receiving federal financial assistance to Section 1557's antidiscrimination requirements, Congress would have said so clearly and explicitly in the text of Section 1557. That is exactly what Congress did when regulating health insurers throughout the rest of the ACA, a statute that, as Plaintiffs point out, addresses the "policies and practices of health insurers" and "expand[s] coverage in the individual health insurance market." ECF No. 109 at 30-31 (citations omitted). *See, e.g.*, 42 U.S.C. § 300gg-91. In light of Congress's explicit regulation of health insurers throughout the ACA, the absence of health insurers among entities receiving federal financial assistance upon which Section 1557 clearly and explicitly imposes its antidiscrimination mandate is conspicuous. For example, Plaintiffs point out that 42 U.S.C. § 18113—inserted by the ACA—defines "'health care entity' to include 'a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.'" ECF No. 109 at 33. But Congress did not extend Section 1557 to any "health care entity" as defined in § 18113; Congress extended Section 1557 to certain "health program[s] or activit[ies]." *See* 42 U.S.C. § 18116(a). And the term "health care entity" as defined in § 18113(b) applies only "[i]n th[at] section." § 18813(b).

Plaintiffs point out, correctly, that Section 1557 prohibits discrimination by any "health program or activity, any part of which is receiving Federal financial assistance, including . . . *contracts of insurance*." 42 U.S.C. § 18116(a) (emphasis added). *See* ECF No. 109 at 30 (discussing insurance contracts language). But if Congress unambiguously intended to subject all health insurers receiving federal financial assistance to Section 1557's antidiscrimination mandate, this was a strange way to so. Congress plainly listed "contracts of insurance" along with "credits"

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insurers." ECF No. 109 at 30. But the *Tovar* court did not go even as far as *Schmitt*. It simply determined that the district court erred in dismissing the plaintiff's "ACA claim under Rule 12(b)(1) for lack of Article III standing" and remanded to the district court for further proceedings. 857 F.3d at 779. Notably, the "parties agree[d] that the Office for Civil Rights' regulations interpreting § 1557 deserve[d] *Chevron* deference" and the regulations in effect at the time, the 2016 Rule, construed Section 1557 to extend to health insurers. *See id.* at 779–80 (Benton, J., concurring).

and "subsidies" as examples of "Federal financial assistance" not as a type of "health program or activity." *See id*. As HHS explained:

> Commenters are correct that Section 1557 includes 'contracts of insurance' as a type of Federal financial assistance. [HHS] agrees that health programs or activities that receive contracts of insurance from the Federal government are covered entities under Section 1557. But this does not mean that health insurers, as such, are health programs or activities.

85 Fed. Reg. at 37,172.

In sum, Plaintiffs have raised nothing that "speak[s] to the issue before" the Court—whether Section 1557 prohibits discrimination by health insurers—"with the 'high level of clarity' necessary to resolve the textual ambiguity . . . at *Chevron* Step One." *Catskill*, 846 F.3d at 515 (quoting *Cohen v. JP Morgan Chase & Co.*, 498 F.3d 111, 120 (2d Cir. 2007)).

In light of the statute's ambiguity on this score, Plaintiffs turn to an elaborate *Chevron* step two argument. *See* ECF No. 109 at 30-34. But *Chevron* step two "is not a high bar for [HHS] to clear." *Illinois Pub. Telecomms. Ass'n v. FCC*, 752 F.3d 1018, 1024 (D.C. Cir. 2014) (Kavanaugh, J.). An agency construction would violate *Chevron* step two "if it were picked out of a hat, or arrived at with no explanation," not because, in Plaintiffs' view, it is unwise or unnecessary. *See Catskill*, 846 F.3d at 521; *see also Batterton v. Francis*, 432 U.S. 416, 428 (1977) (explaining that agencies may not "adopt a regulation that bears no relationship to any recognized concept of" term at issue). In this case, HHS provided a reasoned explanation for its decision to construe the term "health program or activity" to "encompass[] all of the operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance as described in [§ 92.39(a)(1)]" and to exclude from its scope "an entity principally or otherwise engaged in the business of providing health insurance." 85 Fed. Reg. at 37,244-45 (§ 92.3(b)-(c)); *id*. at 37,169-74; *see also* 84 Fed. Reg. at 27,850.

"[I]t is generally presumed that Congress is . . . knowledgeable about existing laws pertinent to later-enacted legislation" and "familiar with previous interpretations of specific statutory language." *United States v. Bonanno Organized Crime Family of La Cosa Nostra*, 879

F.2d 20, 25 (2d Cir. 1989). In Section 1557, Congress did not write on a blank slate, but instead incorporated the grounds of discrimination prohibited by several other civil rights laws. *See* 42 U.S.C. § 18116(a). In much the same way, Congress consciously chose a term of art from the civil rights law context—the specific language "health program or activity"—when defining the scope of Section 1557's application. Title IX has long prohibited sex "discrimination under any education *program or activity* receiving Federal financial assistance," 20 U.S.C. § 1681(a) (emphasis added), and Section 504 of the Rehabilitation Act has long prohibited disability "discrimination under any *program or activity* receiving Federal financial assistance," 29 U.S.C. § 794(a) (emphasis added). HHS reasonably looked to the meaning of these terms in discerning Congress's intent in using the same language in Section 1557.

In two companion cases issued in 1984, the Supreme Court construed the term "program or activity" in Title IX and Section 504 of the Rehabilitation Act. *See Consolidated Rail Corp. v. Darrone*, 465 U.S. 624 (1984) (Rehabilitation Act § 504); *Grove City College v. Bell*, 465 U.S. 555 (1984) (Title IX). Congress, however, disagreed with the Supreme Court's construction of the term and three years later passed the Civil Rights Restoration Act of 1987, Pub. L. No. 100-259, 102 Stat. 28 (1988) ("CRRA"), "'to overturn the Supreme Court's 1984 decision in *Grove City College v. Bell*' and, by extension, *Consolidated Rail Corporation*." *McMullen v. Wakulla Cty. Bd. of Cty. Comm'rs.*, 650 F. App'x 703, 705 (11th Cir. 2016) (quoting S. Rep. No. 100-64, at 2 (1988)).

The CRRA provides an "interpretation of 'program or activity'" for each of the statutes incorporated by reference into Section 1557. *See* Pub. L. No. 100-259 § 3 (Title IX); § 4 (Rehabilitation Act § 504); § 5 (Age Discrimination Act of 1975); § 6 (Title VI of the Civil Rights Act of 1964). Specifically, the CRRA defines "program or activity" to encompass all operations of regulated entities only when they are "principally engaged in the business of providing

education, health care, housing, social services, or parks and recreation." *See, e.g.*, 20 U.S.C. § 1687(3)(A)(ii) (Title IX).[8]

Accordingly, "with respect to the health sector," the CRRA applies "'program or activity' to cover all of the operations of an entity only when that entity is 'principally engaged in the business of providing . . . health care . . . .'" 85 Fed. Reg. at 37,171 (quoting CRRA § 3(a) (adding § 908(3)(A)(ii) to Title IX of the Education Amendments of 1972)). In the 2020 Rule, HHS reasonably looked to this definition to discern the meaning of "health program or activity" in Section 1557. *See* 85 Fed. Reg. at 37,244-45 (§ 92.3); *see also Mozilla Corp. v. FCC*, 940 F.3d 1, 25 (D.C. Cir. 2019) (agency interpretation reasonable where consistent with another regulatory regime interpreting "nearly verbatim" statutory text rationally related to the statute at issue); *Bonanno*, 879 F.2d at 25; *Blitz v. Donovan*, 740 F.2d 1241, 1245 (D.C. Cir. 1984) (Agency could "presume that Congress was aware that the pivotal word[s] . . . had been construed in similar contexts as a term of art.").

Faced with this critical statutory context, Plaintiffs disregard it entirely and simply assert that "[a] health insurer plainly qualifies as a health program." ECF No. 109 at 29; *see also id* at 33 (arguing that the CRRA "neither defines 'health care' nor suggests that being 'principally engaged in the business of providing health care' excludes health insurance companies"). To be sure, health insurance is an important tool in ensuring patients receive health care. But the CRRA defines "program or activity" with respect to the health sector as being engaged in "health care."

[8] Plaintiffs point out that the CRRA defines "program or activity" to "mean *all* of the operations" of several enumerated entities "any part of which is extended Federal financial assistance." *E.g.*, 20 U.S.C. § 1687. *See* ECF No. 109 at 32. But Plaintiffs' reading leaves out the CRRA's interpretation of the scope of private corporations and organizations it covers. *See, e.g.*, 20 U.S.C. § 1687(3)(A). Read in full, the CRRA defines a program or activity to apply to "*all* the operations of . . . an entire corporation, partnership, or other private organization . . . (i) if assistance is extended to such corporation, partnership, private organization, or sole proprietorship, *as a whole*; or (ii) *which is principally engaged in* the business of providing education, *health care*, housing, social services, or parks and recreation . . . any part of which is extended Federal financial assistance." *Id*. (emphasis added). So, if an organization is not extended federal financial assistance "as a whole" it must be "principally engaged in the business of providing . . . health care" in order for it to be a "program or activity." *Id*.

See, e.g., CRRA § 3(a). Just as one would not say one's homeowner's insurance provides lodging, HHS reasonably concluded that health insurance is not "health care." *See* 85 Fed. Reg. at 37,244-45 (§ 92.3(c)). HHS's construction is permissible.

Plaintiffs make policy arguments in an effort to undermine HHS's construction of the term "health program or activity." For example, Plaintiffs say that their construction, unlike HHS's, would "reduce barriers to health care." ECF No. 109 at 31. But it is well-established that Plaintiffs cannot rely on their own policy justifications for their preferred interpretation of the statute, even if in light of a purported "goal" of the statute. *See Catskill*, 846 F.3d at 520 ("Although the Rule may or may not be the best or most faithful interpretation of the Act in light of its paramount goal . . . it is supported by several valid arguments—interpretive, theoretical, and practical. And the [agency's] interpretation of the Act as reflected in the Rule seems to us to be precisely the kind of policymaking decision that *Chevron* is designed to protect from overtly intrusive judicial review."). Of course, if Congress wanted to reduce barriers to health care by including health insurers within the scope of Section 1557, it could have said so.

Plaintiffs remarkably claim that HHS's interpretation is invalid at step two because it is "unnecessary." *See* ECF No. 109 at 31 ("HHS's incorporation of the CRRA . . . is, in any event, unnecessary"); *see also id*. at 32 ("Incorporation of the CRRA is unnecessary . . ."). But Plaintiffs cite no case for the proposition that only a "necessary" construction of a statute, whatever that means, is valid under *Chevron*. Such interpretive reasoning would entirely undermine *Chevron*. The question at *Chevron* step two, is not whether, in the view of the Court, the agency's construction was necessary or not, it "is 'whether the agency's answer to the interpretive question is based on a permissible construction of the statute.'" *Catskill*, 846 F.3d at 520 (quoting *Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 54 (2011)). An interpretation is only "necessary" if Congress "directly addressed the precise question at issue" at *Chevron* step one. 467 U.S. at 843. For example, in *Chevron* itself, "the statutory definition of the term 'source' [was] sufficiently flexible to cover either a plantwide definition, a narrower definition covering each unit within a plant, or a dual definition that could apply to both the entire 'bubble' and its

components." *Id*. at 859. The agency chose one of those definitions, but obviously, in light of the other permissible readings, the agency's wasn't "necessary." *See id*. Like here, no single construction is "necessary" in light of other permissible constructions. This Court must reject Plaintiffs' efforts to wage "in a judicial forum a specific policy battle which they ultimately lost in the agency." *See id*. at 864.[9]

2. HHS Reasonably Construed the Scope of Federal Entities Covered by Section 1557

Plaintiffs argue that the 2020 Rule impermissibly "exclude[s] from Section 1557's scope all health programs and activities administered by HHS *except* for those administered under Title I of the ACA." ECF No. 109 at 35. The 2020 Rule defines Section 1557 to extent to "[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]" as well as programs or activities "administered by [HHS] under Title I of the [ACA]" or programs or activities "administered by any entity established under such Title." 85 Fed. Reg. at 37,244 (§ 92.3(a)).

Contrary to Plaintiffs' contention, the language HHS selected represents the most reasonable construction of Section 1557, which provides that antidiscrimination protections apply to "any health program or activity, any part of which is receiving Federal financial assistance, . . . [and] any program or activity that is administered by an Executive Agency or any entity established under this title [*sc.*, Title I]." 42 U.S.C. § 18116(a). If the second category were read piecemeal, as Plaintiffs argue, *see* ECF No. 109 at 35-36, Section 1557 would apply to "any program or activity that is administered by an Executive Agency"—*i.e. all federal action*, regardless of its connection to healthcare or HHS (as well as to any program or activity that is administered by any entity established under Title I). Clearly, Congress did not intend to have HHS regulate non-healthcare-related discrimination in programs administered by other agencies. If Congress had

[9] Certain health insurance products remain subject to Section 1557 under HHS's construction of Section 1557 in the 2020 Rule. For example, a Qualified Health Plan "would be covered by the rule because it is a program or activity administered by an entity established under Title I (i.e., an Exchange), pursuant to § 92.3(a)(3)." 85 Fed. Reg. at 37,174.

wanted to subject *all* federal activity to Section 1557's restrictions, it would have said so clearly rather than burying such an expansive provision within the ACA, which everywhere else deals exclusively with healthcare; it also, presumably, would not have given HHS express authority to adopt implementing regulations if the statute were meant to govern other agencies. *See* 42 U.S.C. § 18116. "Congress . . . does not alter the fundamental details of a regulatory scheme," let alone the sum total of federal activity, "in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001). Thus, Section 1557 necessarily must be read in context.

To avoid an improperly expansive reading of the provision, HHS construed Section 1557 to mean "[a]ny health program or activity, any part of which is receiving Federal financial assistance . . . provided by the Department," "[a]ny program or activity administered *by the Department under Title I of the Patient Protection and Affordable Care Act*," and "[a]ny program or activity administered by any entity established under such Title." 85 Fed. Reg. at 37,244 (42 C.F.R. § 92.3(a)) (emphasis added). Plaintiffs complain that such a construction is "in contravention of the text and statutory purpose of Section 1557." ECF No. 109 at 35. But even the 2016 Rule—which Plaintiffs defend, *see id*.—"acknowledged implicitly what the Department now states more clearly: The grammar of the relevant sentence in the Section 1557 statutory text concerning limits to its scope is less clear than it could have been." 85 Fed. Reg. at 37,170. To address that ambiguity, the prior rule applied Section 1557 to "every *health* program or activity administered *by the Department*; and every *health* program or activity administered by a Title I entity." 81 Fed. Reg. at 31,466 (45 C.F.R. § 92.2(a)) (emphasis added). While such a construction avoided applying Section 1557 to *all* federal programs and activities, which Plaintiffs seemingly agree would be impermissible, *see* ECF No. 109 at 35 n.42, it required injecting the word "health" into the relevant portion of the text, even though Congress had not included the word in the clause. *See* 85 Fed. Reg. at 37,170. In the 2020 Rule, HHS instead chose to rely upon the limitation already in the text—that is, Title I programs and activities. *See id.* That approach is a reasonable construction of the statute that warrants deference. *See Chevron*, 467 U.S. at 844.

Plaintiffs' argument that the 2020 Rule's interpretation renders part of the statute superfluous, ECF No. 109 at 36, is erroneous. Plaintiffs point out that "under the rule of last antecedent, a limiting phrase must be read as 'modifying only the term immediately preceding it, *unless a contrary intention is apparent*.'" *Id*. (emphasis added) (quoting *Hedges v Obama*, 724 F.3d 170, 192 n.134 (2d Cir. 2013)). But Defendants have already explained that reading these provisions piecemeal would render the section applicable to all programs or activities of all federal executive agencies, and "[i]t is implausible that Congress meant the Act to operate in this manner." *See King v. Burwell*, 576 U.S. 473, 494 (2015). So the statute is ambiguous, *see id*. at 492, and under subsection (c), Congress explicitly intended HHS, if it chooses, to resolve the ambiguity, *see City of Arlington*, 569 U.S. at 296 (quoting *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 740–41 (1996)) ("*Chevron* is rooted in a background presumption of congressional intent: namely, that 'Congress, when it left ambiguity in a statute' administered by an agency, 'understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows."). Congress did not intend to defer to Plaintiffs' unsupported assertion that it actually "intended . . . to refer to health programs and activities" even though that is not what Congress stated. ECF No. 109 at 35 n.42. A contrary intention—deference to the agency's permissible construction—is indeed apparent. *See Hedges*, 724 F.3d at 192 n.134.

B. HHS's Decision not to Define "On the Basis of Sex" by Rule is not an Agency Interpretation of a Statute at All; This Action Cannot Plausibly Conflict with Section 1557

HHS's Decision not to Define "On the Basis of Sex"

Remarkably, Plaintiffs contend that HHS's decision to "decline[] . . . to propose its own[] definition of 'sex' for purposes of discrimination on the basis of sex in the regulation," 84 Fed. Reg. at 27,857, is substantively invalid "because it conflicts with Section 1557's statutory prohibition on discrimination 'on the basis of sex,'" ECF No. 109 at 36. Plaintiffs' argument makes little sense; by declining to include a definition of "on the basis of sex" in the 2020 Rule, the Rule "relies upon[] the plain meaning of the term in the statute," 85 Fed. Reg. at 37,178.

Because Plaintiffs cannot plausibly support the extraordinary claim that a rule that hews to the text of the statute it implements is contrary to that statute, they make no actual argument that the rule itself is not in accordance with Section 1557. *See* ECF No. 109 at 36-39. Instead, they focus only on HHS's *reasoning* in support of its decision to repeal the 2016 Rule's definition. *See, e.g.*, ECF No. 109 at 37 (arguing that the "2020 Rule's removal of the prior regulation's definition of discrimination 'on the basis of sex' *was based solely on HHS's misconception that* . . ."); *id.* at 39 (arguing that HHS's decision not to define "on the basis of sex" by rule is invalid because it was "*based on HHS's legally erroneous position that* . . .").

To be sure, the APA permits courts to "insist that an agency . . . articulate a satisfactory explanation for its action.'" *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (quoting *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). But courts do so when evaluating whether an agency action must be set aside because it "is 'arbitrary' or 'capricious,'" *see id.* (quoting 5 U.S.C. § 706(2)(A)), not when evaluating whether the challenged action is substantively contrary to the statute it implements, *cf. Catskill*, 846 F.3d at 521–24 (reprimanding district court for "incorporating the *State Farm* standard into its *Chevron* Step Two analysis"). Plaintiffs also bring an arbitrary and capricious claim in support of their challenge to HHS's decision not to define "on the basis of sex" by rule, *see* ECF No. 109 at 40-41, and that claim is so indistinguishable from their erroneous contrary-to-law claim that in making it Plaintiffs do little more than refer back to their contrary-to-law arguments, *see* ECF No. 109 at 40.

Even the *Whitman-Walker* court, which erroneously held, in a preliminary posture, that HHS's decision not to define "on the basis of sex" by rule was arbitrary and capricious, recognized this distinction. *See* 2020 WL 5232076, at *27. The *Whitman Walker* court explained that it did "'not hold that the agency decision here was substantively invalid[;]' . . . [n]othing prevents HHS from . . . issu[ing] a regulation that parrots Section 1557's prohibition on sex discrimination." *Id.* (quoting *Commerce*, 139 S. Ct. at 2576).

Plaintiffs provide lengthy argument that Title IX's prohibition on sex discrimination, incorporated into Section 1557, includes a *per se* prohibition on discrimination based on transgender status because "*Bostock* makes clear that discrimination based on transgender status is *per se* sex discrimination." *See* ECF No. 109 at 37-39. But Plaintiffs fail to explain why that makes the action that they challenge—HHS's decision to "decline[] . . . to propose its own[] definition of 'sex' for purposes of discrimination on the basis of sex in the regulation," 84 Fed. Reg. at 27,857—contrary to Section 1557. HHS's decision not to further define "on the basis of sex" by rule and instead to rely on Section 1557's plain text cannot plausibly be contrary to that statute.

HHS's Decision not to Include Specific Prohibitions on Certain Conduct in the 2020 Rule

Plaintiffs also contend that HHS's decision to remove provisions detailing how entities might discriminate on the basis of sex from the Code of Federal Regulations is contrary to Section 1557. *See* ECF No. 109 at 36 (claiming that the 2020 Rule's removal of former §§ 92.206, 92.207 "is contrary to law because it conflicts with Section 1557's statutory prohibition on discrimination 'on the basis of sex'"). But this claim fails for similar reasons as Plaintiffs' claim that HHS's decision not to define "on the basis of sex" by rule is contrary to Section 1557. Indeed, Plaintiffs provide no support for their argument that HHS's decision not to define the outer contours of sex discrimination by rule is contrary to Section 1557. *See id*. at 36-39. They point to nothing in Section 1557 or elsewhere *requiring* the agency to define the outer contours of what Section 1557 prohibits by rule. *See id*. To the contrary, Section 1557(c) provides that HHS "may" implement the statute by rule and "the usual presumption" is that "'may' confers discretion, while 'shall' imposes an obligation to act." *See Int'l Union, United Auto., Aerospace and Agr. Implement Workers of Am., UAW v. Dole*, 919 F.2d 753, 756 (D.C. Cir. 1990). Plaintiffs cannot point to anything in the text of the 2020 Rule itself that is contrary to their view of Section 1557 because there is nothing in the rule itself that *authorizes* entities regulated by Section 1557 to engage in any of the conduct that Plaintiffs fear. HHS merely removed detailed standards for complying with Section 1557 from the Code of Federal Regulations.

Plaintiffs provide nothing supporting their argument that HHS's decision to remove sections 92.206 and 92.207 is contrary to law other than to attack the agency's *explanation* for doing so—amalgamated with their arguments disagreeing with the agency's reasons for deciding not to define "on the basis of sex" by rule. *See* ECF No. 109 at 36-39. But these are not claims that the agency's decision is contrary to Section 1557; these are arbitrary or capricious claims disguised as contrary to Section 1557 claims and must fail for the same reasons Defendants have explained. *See supra* at 43-44. Defendants refute Plaintiffs' arguments that HHS's decision to remove these provisions from the Code of Federal Regulations is arbitrary or capricious *infra* at 50-67.

C. HHS's Conforming Changes to Related Regulations Are Not Contrary to Law

Plaintiffs claim that HHS's decision to make conforming amendments to regulations governing CMS-funded managed care programs is contrary to law, but they fail to identify how. First, Plaintiffs' arguments fail to address anything in the new 2020 Rule that they challenge as being contrary to law but again point to HHS's *reasoning* for making the change. *See* ECF No. 19 at 40 (arguing that conforming changes to CMS regulations are contrary to law because of their purported "motivat[ion]" derived from the agency's explanation). But for the reasons explained *supra* at 43-44, this is not a challenge to the action itself, but at most a challenge to the reasonableness of HHS's explanation for the change.

Plaintiffs also argue that "the eliminated" provisions "were not added to the CMS regulations pursuant to Section 1557, nor were they adopted to comply with Section 1557," without explaining what bearing that has on whether they are in accordance with law. *See* ECF No. 109 at 40. Plaintiffs point out that prior regulations governing CMS-funded managed care programs prohibiting discrimination on the basis of gender identity and sexual orientation were promulgated "pursuant to HHS's authority under Section 1902 of the Social Security Act to provide methods of administration 'necessary for the proper and efficient operation' of CMS programs." *Id*. at 40 (quoting 42 U.S.C. § 1396A(a)(4)).

To the extent Plaintiffs are arguing that HHS's decision to make conforming amendments to the CMS regulations is outside the scope of HHS's authority, that claim must be analyzed under the *Chevron* framework. At *Chevron* step one, courts ask "whether Congress has directly spoken to the precise question at issue." 467 U.S. at 842. Here, HHS acted under its authority to determine "methods of administration 'necessary for the proper and efficient operation' of CMS programs." *See* ECF No. 109 at 40 (quoting 42 U.S.C. § 1396A(a)(4)). Nothing in that language forecloses HHS's authority to implement changes to the CMS regulations that conform to HHS's Section 1557 regulations. To the contrary, Congress used just the type of "illustrative terms . . . intended to enlarge, rather than to confine, the scope of the agency's power." *Chevron*, 467 U.S. at 862. Nor do the Plaintiffs make any argument that it is substantively impermissible under this language, at *Chevron* step two, to return CMS regulations to the way they were written only a few years ago. HHS explained that it permissibly "deem[ed] it appropriate to pursue a more uniform practice concerning nondiscrimination categories across programs and activities to which Section 1557 applies," because many entities subject to these other regulations are also subject to Section 1557. 85 Fed. Reg. at 37,219. Plaintiffs may well believe that the prior "regulations were warranted," ECF No. 109 at 40, but it is well established that they may not "now wag[e] in a judicial forum a specific policy battle which they ultimately lost in the agency," *Chevron*, 467 U.S. at 864.

Plaintiffs argue that the conforming amendments "violate HHS's own obligation under Section 1557 to administer its health programs and activities in a nondiscriminatory manner." ECF No. 109 at 41. But this argument is based on a faulty premise—namely, that the amendments "authorize managed care programs regulated by those CMS regulations to discriminate based on sexual orientation or gender identity." *Id*. Tellingly, Plaintiffs again point to nothing in the conforming amendments "authorizing" any type of discrimination. These amendments continue to prohibit discrimination on the basis of sex, which is exactly what Section 1557 prohibits. Accordingly, the amendments cannot violate Section 1557.

D. HHS'S Construction of Section 1557 to Prohibit Conduct in the Health Care Setting only Insofar as Prohibited by the System of Civil Rights Statutes it Incorporates is Substantively Reasonable

The 2020 Rule provides that "[i]nsofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by" Title IX, "such application shall not be imposed or required." 85 Fed. Reg. 37,245 (45 C.F.R § 92.6(b)). Without support, Plaintiffs claim that HHS's promulgation of this provision is in excess of HHS's statutory authority. *See* ECF No. 109 at 41-42.

A statute's "'generic reference' to an existing statute 'is a recognized mode of incorporating one statute or system of statutes into another, and serves to bring into the latter all that is fairly covered by the reference'" *Schmitt*, 965 F.3d at 952 (quoting *Panama R.R. v. Johnson*, 264 U.S. 375, 391–92 (1924)). HHS's incorporation of Title IX's religious exemption and abortion neutrality principle is a reasonable construction of what is fairly covered by Section 1557's incorporation of Title IX, in light of 20 U.S.C. § 1681(a)(3), and the Civil Rights Restoration Act of 1987, 20 U.S.C. § 1687. And Congress explicitly granted HHS authority to implement Section 1557 by rule. *See* 42 U.S.C. § 18116(c).

Section 1557 prohibits discrimination "on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.)." 42 U.S.C. § 18116(a). The term "ground," in this context, is ambiguous. *See Schmitt*, 965 F.3d at 953 (explaining that Section 1557 is "ambiguous" with respect to the extent to which it incorporates the same causal standard from the Rehabilitation Act). Although it may be reasonable to define "ground" in Section 1557 as Plaintiffs appear to prefer—limited only to the protected characteristic identified in Title IX (in this case "sex"),[10] the plain meaning of the term is broader. "Ground," in this context, is defined

[10] In *Schmitt*, before the effective date of the 2020 Rule, the Ninth Circuit found that a "ground" for discrimination "is not typically understood to encompass the legal elements necessary to establish a discrimination claim," like the causal standard that was at issue in that case, but "simply the protected classification at issue." 965 F.3d at 953. But because it was not at issue, *Schmitt* did not consider whether Section 1557 incorporates and prohibits sex discrimination that is not prohibited by Title IX, like conduct falling within the scope of 20 U.S.C. § 1681(a)(3). And *Schmitt* did not consider the deference given to HHS's regulatory construction in light of HHS's authority to implement Section 1557 by rule under 42 U.S.C. § 18116(c), nor did *Schmitt* indicate

as "[a] circumstance on which a[] . . . claim is founded, or which has given rise to an action, procedure, or mental feeling." *Ground*, Oxford English Dictionary (3d ed. 2020); *see also Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (explaining that Federal Rule of Civil Procedure 8 requires a plaintiff "to provide the 'grounds' of his 'entitlement to relief'"). Section 1557 thereby prohibits only conduct involving sex discrimination in the health care setting on which a claim may be founded, or which may give rise to an action, under Title IX. And Title IX, in turn, excludes from the circumstances on which a claim can be founded, any "application" that "would not be consistent with the religious tenets of" an organization that controls a covered institution. *See* 20 U.S.C. § 1681(a)(3). Title IX also excludes from the circumstances on which a claim can be founded any application which would "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." 20 U.S.C. § 1688. As HHS explained, "Section 1557 incorporates the statutory scope of Title IX, so it is appropriate for this rule to incorporate the Title IX statutory language concerning religious institutions and abortion neutrality." 85 Fed. Reg. at 37,207-08. Plaintiffs' argument that Section 1557 unambiguously prohibits discrimination on the basis of sex even if that conduct would not be prohibited under Title IX is totally divorced from the plain text of Section 1557, which incorporates no more than the grounds of discrimination that are prohibited by Title IX. *See* ECF No. 109 at 41-42.

HHS's incorporation of the scope of Title IX's rights and protections is simultaneously a reasonable construction of the term "program or activity" in Section 1557. Section 1557 applies to certain health "program[s] or activit[ies]." 42 U.S.C. § 18116(a). As explained, *supra* at 37-38, although the scope of this term is ambiguous, Congress was likely familiar with it when it enacted the ACA because it is a term of art in the civil rights law context. The Civil Rights

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that its construction follows from the unambiguous language in Section 1557. *See Brand X Internet Servs.*, 545 U.S. at 982 (2005) ("A court's prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statue and thus leaves no room for agency discretion.").

Restoration Act of 1987, defines "program or activity" for the purposes of the statutes incorporated into Section 1557, including Title VI, Section 504 of the Rehabilitation Act, the Age Act, and Title IX. *See* 20 U.S.C. § 1687. Specifically, it defines "the term 'program or activity' and 'program' [to] mean all of the operations of" several enumerated entities "any part of which is extended Federal financial assistance, except that such term does not include any operation of an entity which is controlled by a religious organization if the application of [Title IX] of this title to such operation would not be consistent with the religious tenets of such organization." *Id*. So it was reasonable for HHS to conclude that the very same term used in another civil rights context, Section 1557, should be defined to exclude this conduct from its reach. *See id*.

In sum, the provision of the 2020 Rule providing that "[i]nsofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections by" provided by Title IX, "such application shall not be imposed or required," 85 Fed. Reg. 37,245 (§ 92.6(b)), represents a reasonable construction of both the "ground[s]" of discrimination under Title IX incorporated by referenced into Section 1557 and of the scope of the term "program or activity" in Section 1557. *See* 20 U.S.C. §§ 1681(a)(3), 1687, 1688.

IV. HHS Engaged in Reasoned Decisionmaking When Promulgating the Challenged Provisions of the 2020 Rule

"The Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, which sets forth the full extent of judicial authority to review executive agency actions for procedural correctness, . . . permits . . . the setting aside of agency action that is 'arbitrary' or 'capricious.'" *Fox Television*, 556 U.S. at 513. Under "this 'narrow' standard of review," an agency must "'examine the relevant data and articulate a satisfactory explanation for its action.'" *Id*. (quoting *State Farm*, 463 U.S. at 43). "'[A] court is not to substitute its judgment for that of the agency, . . . and should 'uphold a decision of less than ideal clarity if the agency's path may be reasonably discerned.'" *Id*. (citations omitted). When an agency changes policies, it "need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is

permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *Id*. at 515. And it is doubtful that this Court may "reverse[] an executive agency, not for violating" Supreme Court "cases, but for failure to discuss them adequately." *Id*. at 526.

In cases brought under the APA, review of the challenged agency action is based on the administrative record rather than extra-record material. *See, e.g.*, *Nat. Res. Def. Council, Inc. v. U.S. Dep't of Agric.*, 613 F.3d 76, 83–84 (2d Cir. 2010). There are no factual disputes for the court to resolve, and "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973); *see also Just Bagels Mfg., Inc. v. Mayorkas*, 900 F. Supp. 2d 363, 372 n.2 (S.D.N.Y. 2012) (cases based on the review of an administrative record "present[] only a question of law").

A. HHS Reasonably Decided Not to Define "On the Basis of Sex" by Rule

HHS had good reasons satisfying the requirements of *Fox Television* for repealing the 2016 Rule's definition of "on the basis of sex" and declining to replace it with a new definition. *See* 556 U.S. at 517–28.

First, HHS explained that its policy change was based on a value judgment rejecting the prior policy as inappropriately placing HHS in the driver's seat in defining the outer boundaries of the meaning of broadly applicable civil rights statutory terms, outside of the agency's core competency. As HHS explained, it believed that the prior administration's effort to interpret "Section 1557, through Title IX, to prohibit gender identity discrimination was a relatively novel legal theory when [HHS] adopted the [2016] Rule." 84 Fed. Reg. 27,853. HHS explained that "a large volume of district court opinions ha[d] been inconsistent on the issue" and "[a]ppellate courts have also been split over the legal question whether discrimination on the basis gender identity is prohibited by Title VII." *Id*. at 27,855 (and cases cited therein). So HHS determined it was a better policy to "rel[y] upon . . . the plain meaning of the term in the statute," 85 Fed. Reg. at 37,178, which would permit HHS to interpret the scope of sex discrimination consistently with

how courts rule on that issue, *see id*. at 37,168 ("[T]o 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.").

Second, and relatedly, HHS explained that its policy change is based on a value judgment of the importance of issuing regulations that the agency can be confident are consistent with the authorizing statute. By not defining "on the basis of sex" by rule, HHS's Section 1557 regulations could not plausibly be inconsistent with the plain meaning of the term "sex" in Section 1557, which could not as definitively be said of any agency-created definition of the term, let alone the agency's prior definition. *See* 84 Fed. Reg. at 27,853, 27,855-57. The Supreme Court has held that "an agency may justify its policy choice by explaining why that policy 'is more consistent with statutory language' than alternative policies.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 175 (2007)). So too here. *See* 84 Fed. Reg. at 27,853, 27,855-57. Few regulations can be more consistent with the statutory language of the authorizing statute than a regulation that relies on nothing more than the statutory language itself. *See id*.

Third, HHS recognized that the Supreme Court had granted certiorari in a case determining the scope of the meaning of the term "sex" in Title VII, and crafted the 2020 Rule in a manner that accounts for the possibility that the Supreme Court's decision might have had implications for the scope of the meaning of the term "sex" in Title IX and Section 1557. *See* 84 Fed. Reg. at 27,856 & n.75. HHS explained that "[b]ecause of the likelihood that the Supreme Court will be addressing the issue in the near future, [HHS] declines, at this time, to propose its own[] definition of 'sex' for purposes of discrimination on the basis of sex in the regulation." *Id*. at 27,857. Instead, the Rule "relies upon . . . the plain meaning of the term in the statute." 85 Fed. Reg. at 37,178; *see also id*. at 37,168.

Finally, HHS explained that, by not taking a position on the scope of the term "sex" by rule, HHS also made "changes [that] . . . may minimize litigation risk." 84 Fed. Reg. at 27,849. HHS relied on its experience defending HHS's prior definition of "on the basis of sex" which

resulted in "lawsuits and court orders blocking enforcement of significant parts of the Final Rule for over two years." *Id.* By "declin[ing] . . . to propose its own[] definition of 'sex' for purposes of discrimination on the basis of sex in the regulation," *id*. at 27,857, HHS could "minimize litigation risk," *id*. at 27,849, because the agency would not be taking a position in either direction on this subject by rule; the agency could instead await judicial guidance as to the scope of the plain meaning of the term "sex" and then follow that guidance accordingly in its administration of Section 1557 on a case-by-case basis. *See id*.; *see also id.* at 27,857 (declining to propose its own definition of 'sex' for purposes of discrimination on the basis of sex in the regulation). Resolving complaints of discrimination on a case-by-case basis permits HHS to address allegations of discrimination without opining on the *per se* scope of Section 1557 in an abstract rule of generally applicability and future effect. *See id*. at 27,870 n.159. And resources not used on litigation defending a regulatory definition could be used for other matters, like investigating actual claims of discrimination by health programs and activities. *See id*. at 27,849.

In sum, at the time of HHS's decision, the agency "could rationally decide it needed to step away from its old regime," which explicitly defined 'on the basis of sex' and had been the subject of long-standing litigation, and replace that regime with one that could flexibly apply regardless of how courts interpret the scope of Title IX or Section 1557. *See Fox Television*, 556 U.S. at 518.

a. Plaintiffs' Arguments that HHS Entirely Failed to Take Bostock *Into Account Display A Lack of Understanding of the Historical Setting Within Which the Agency Action Took Place and the Nature of the Agency Action Under Review*.

Plaintiffs argue that the Rule is "arbitrary and capricious because HHS failed to consider *Bostock*'s application to Section 1557." ECF No. 109 at 44-46; *see also id*. at 36-39. But that is simply not true. HHS *did* consider the possibility that *Bostock* might have implications for the meaning of "sex" in Section 1557. *See* 84 Fed. Reg. at 27,857 & n.75. For that very reason, HHS "decline[d] . . . to propose its own[] definition of 'sex' for purposes of discrimination on the basis of sex in the regulation." 84 Fed. Reg. at 27,857; *see also id*. at 27,857 n.75. Instead, the Rule "relies upon . . . the plain meaning of the term in the statute." 85 Fed. Reg. at 37,178; *see also id.* at 37,168 ("Moreover, to the extent that a Supreme Court decision is applicable in interpreting the

meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court's construction."). Plaintiffs thus cannot fairly say that HHS "*entirely failed* to consider [this] important aspect of the problem." *See State Farm*, 463 U.S. at 43 (emphasis added); *see also New York v. Dep't of Justice*, 951 F.3d 84, 122 (2d Cir. 2020) ("While agency action may be overturned if the agency 'entirely failed to consider an important aspect of the problem' at issue . . . a court will not 'lightly' reach that conclusion.") (citations omitted).

To the extent Plaintiffs are arguing that HHS failed to consider the *outcome* of the Supreme Court's decision in *Bostock*, that argument "displays a lack of understanding of the historical setting within which the agency action took place and of the nature of the [action] itself." *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). The agency decision under review in this case was made *before* the Supreme Court's opinion was issued. As the Supreme Court has explained:

> Administrative consideration of evidence always creates a gap between the time the record is closed and the time the administrative decision is promulgated and we might add, the time that the decision is judicially reviewed. If upon the coming down of the order litigants might demand rehearings as a matter of law because some new circumstance has arisen, some new trend has been observed, or some new fact discovered, there would be little hope that the administrative process could ever be consummated in an order that would not be subject to reopening.

Id. (quoting *ICC v. Jersey City*, 322 U.S. 503, 514 (1944)).

HHS issued the proposed rule on June 14, 2019, opening the administrative record to comments for sixty days—ending on August 13, 2019. 84 Fed. Reg. 27,846, 27,846 (June 14, 2019). HHS "received 194,845 comments in response to the proposed rule during the comment period," which took HHS nearly a year to diligently consider before the Secretary signed off on the Final Rule on May 20, 2020. *See* 85 Fed. Reg. at 37,164, 27,348. So it is no surprise that "the Supreme Court's *Bostock* decision," which was not issued until June 15, 2020, is "absent from the administrative record." ECF No. 109 at 44.

Contrary to Plaintiffs' characterization, HHS hardly "published the rule anyway" after purportedly determining that "*Bostock* ultimately contradicted [the agency's] . . . position." ECF No. 109 at 45. As Plaintiffs acknowledge, *see* Compl. ¶ 84, by the time the "new circumstance" of the Supreme Court's opinion "ha[d] arisen," *see Vt. Yankee*, 435 U.S. at 555 (quoting *Jersey City*, 322 U.S. at 514), the record had already been closed, the Rule had already been publically posted on HHS's website, and the Rule had been sent to the Office of the Federal Register to be prepared for publication. *See* Compl. ¶ 84 (acknowledging that HHS "issued . . . the 2020 Rule on June 12, 2020" and "[t]hree days later, on June 15, 2020, the Supreme Court issued the *Bostock* decision"); *see also Washington*, 2020 WL 5095467, at *4 ("On June 15—three days after HHS filed the 2020 Rule . . . the United States Supreme Court issued a decision that interpreted 'sex' discrimination under Title VII."); *see also id.* at *3 n.5 ("Although the 2020 Rule was published in the Federal Register on June 19, 2020, the Rule was finalized within HHS on May 20, 2020, and was filed on June 12, 2020."). And by "declin[ing] . . . to propose its own, definition of 'sex' for purposes of discrimination on the basis of sex in the regulation," HHS had crafted a rule that would be valid no matter the outcome of *Bostock*. *See* 84 Fed. Reg. at 27,857

To be sure, ensuring that HHS "articule[d] a satisfactory explanation for its action," *State Farm*, 463 U.S. at 43, depends in part on the nature of the action itself, *see Vt. Yankee*, 435 U.S. at 553 (holding that courts must consider "the nature of" the action). HHS did not address its views about the plain meaning of "on the basis of sex" by promulgating a rule defining that term to *exclude* sexual orientation, gender identity, or sex stereotyping discrimination even though it knew that a Supreme Court decision on a related issue was impending. *See* 84 Fed. Reg. at 27,857. Instead, HHS declined to include a definition of "on the basis of sex" in the 2020 Rule, *see id.*; the Rule "relies upon . . . the plain meaning of the term in the statute," 85 Fed. Reg. at 37,178. So even if this Court accepts Plaintiffs' invitation to engage in "Monday morning quarterbacking," *see Vt. Yankee*, 435 U.S. at 547, and determines that one aspect of the agency's *explanation* for doing so is erroneous in light of the post hoc outcome in *Bostock*, any error is harmless because the preamble makes clear that the Rule would not conflict with whatever decision the Court

reached: "Moreover, to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court's construction." *Id.* at 37,168. *See* 5 U.S.C. § 706 ("due account shall be taken of the rule of prejudicial error" in judicial review"); *see also Shinseki v. Sanders*, 556 U.S. 396, 406 (2009) (citation omitted) ("the APA's reference to 'prejudicial error' is intended to 'sum up in succinct fashion the harmless error rule"). HHS's decision *not* to place its pre-*Bostock* views on the meaning of "on the basis of sex" into the text of the regulation itself but instead to rely on the plain text of the statute reflects how HHS *did* craft the language at issue to accommodate any plausible ramification of any Supreme Court case on the matter. Because, as HHS recognized, the Rule's language may be interpreted in conformity with *Bostock*, it was neither arbitrary nor capricious for HHS to decide against including a definition for "on the basis of sex" throughout the regulations amended by the agency.

b. HHS Provided Good Reason for Repealing §§ 92.206, 92.207(b)(3)-(5) of the 2016 Rule and Believes that the 2020 Rule is Better Without Those Provisions

As explained *supra* at 50-52, HHS provided a number of good reasons for deciding not to define "on the basis of sex" by rule, in contrast to the prior policy, which explicitly provided a definition by rule. Accordingly, HHS also repealed former §§ 92.206, 92.207(b)(3)-(5), which were inconsistent with HHS's decision not take a position by rule on the application of "sex" to gender identity discrimination. *See* 85 Fed. Reg. at 37,177-92. Plaintiffs have failed to explain why this decision was irrational, especially in light of the timeframe in which HHS's decision was made. *See Market St. Ry. Co. v. Railroad Commission of State of Cal.*, 324 U.S. 548, 557 (1945) (judicial "review considers only whether the order was valid when and as made").

As the Rule "relies upon . . . the plain meaning of the term in the statute," 85 Fed. Reg. at 37,178; *see also id.* at 37,168, to the extent "sex" discrimination incorporates gender identity discrimination, Section 1557 continues to prohibit covered entities from conduct that actually injures patients as a result of gender identity discrimination.

Moreover, contrary to Plaintiffs' argument, HHS's rationales for removing these provisions were not limited to its reasons, as discussed *supra* at 50-52, for not taking a position on the proper scope of the meaning of "sex" in Title IX or Section 1557 by rule. *See* ECF No. 109 at 46 (purporting that HHS had "no other rationale" for deleting the former §§ 92.206 and 92.207(b)(3)). Former § 92.206, for example, required that covered entities "treat individuals consistent with their gender identity." 81 Fed. Reg. at 31,471 (§ 92.206). But HHS was concerned about the ambiguous scope of this language, *see* 85 Fed. Reg. at 37,185, so it explained that it was "repeal[ing] a mandate that was, at least, ambiguous and confusing," *id*. at 37,187. Even assuming that sex discrimination encompasses gender identity discrimination, "reasonable distinctions on the basis of sex, as the biological binary of male and female, may, and often must, 'play a part of the decisionmaking process'—especially in the field of health services" requiring health care providers to sometimes treat individuals consistent with their sex assigned at birth—not necessarily gender identity. *Id*. at 37,185. For example, HHS explained that a covered entity must be permitted to "warn[] females that heart-attack symptoms are likely to be quite different than those a man may experience" or "advise[] women that certain medications tend to affect women differently than men," even if this requires covered entities to treat individuals inconsistently with their gender identity as required under the former § 92.206. *Id*. In the Title VII context, the Supreme Court has explained that the law "does not set forth 'a general civility code for the American workplace.'" *Burlington Northern & Sante Fe Railway Co. v. White*, 548 U.S. 53, 68 (2006) (quoting *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 80 (1998)). So "the term 'discriminate against' refers to 'distinctions or differences in treatment that injure protected individuals.'" *Bostock*, 140 S. Ct. at 1753 (quoting *Burlington N.*, 548 U.S. at 59). Here, HHS reasonably explained why it was eliminating an explicit requirement that could be construed to prohibit medically necessary conduct and did not on its face appear to require that the

discrimination be actually injurious to or to materially affect the individual. *See* 85 Fed. Reg. at 37,185.[11]

c. HHS Did Not Entirely Fail to Consider the Principles Underlying Several Other Cases Plaintiffs Cite

Plaintiffs claim that HHS "failed to grapple meaningfully with the overwhelming weight of prior case law holding that discrimination against transgender and gender nonconforming people is a form of unlawful sex stereotyping prohibited by federal sex discrimination laws." ECF No. 109 at 47. But Plaintiffs provide no explanation of how exactly HHS was supposed to "grapple" with these cases at the time of HHS's decision, other than agreeing with Plaintiffs' views of them. *See id.* To the contrary, HHS extensively and explicitly considered those cases in responding to comments. *See* 85 Fed. Reg. at 37,184-85. Indeed, the Supreme Court has explained that it has never "before reversed an executive agency, not for violating [its] cases, but for failure to discuss them adequately," *Fox Television*, 556 U.S. at 536, because the question is whether the agency "*entirely failed* to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43 (emphasis added); *see also New York v. U.S. Dep't of Educ.*, --- F. Supp. 3d ---, ---, 2020 WL 4581595, at *10 (S.D.N.Y. Aug. 9, 2020) ("A court will not lightly reach the conclusion that an agency action should be overturned as arbitrary and capricious because the agency entirely failed to consider an important part of the problem.") (citation omitted). Plaintiffs effectively acknowledge that HHS considered these cases; accordingly, HHS did not entirely fail to consider this aspect of the problem. *See id.* By inviting this Court to go beyond ensuring that HHS considered these cases, Plaintiffs invite the Court to "itself weigh the evidence [and] substitute its judgment for that of the agency," which it may not do. *See Constitution Pipeline Company, LLC v. N.Y. State Dep't of Environmental Conservation*, 868 F.3d 87, 102 (2d Cir. 2017) (quoting *Islander East Pipeline Co. v. McCarthy*, 525 F.3d 141, 150 (2d Cir. 2008)). Thus, Plaintiffs' efforts to have this Court re-weigh the reasons for and against HHS's decision must be rejected.

[11] HHS also had independent reasons for deciding to remove the explicit requirements under former § 92.207, which Plaintiffs confusingly challenge in two separate sections of their brief, so Defendants address these reasons *infra* at 58-63.

Even assuming that Plaintiffs have established an arbitrary or capricious claim on this basis, which they have not, Plaintiffs have not established prejudicial error in light of the fact that the 2020 Rule's mere decision to remove a regulatory definition of the term "on the basis of sex" means only that the plain meaning of the term "sex" in the statute governs. So nothing in the 2020 Rule forecloses a reading of Section 1557 relying on any of the case law that Plaintiffs cite. *See* 5 U.S.C. § 706 ("due account shall be taken of the rule of prejudicial error" in judicial review"); *see also Shinseki*, 556 U.S. at 406 (citation omitted) ("the APA's reference to 'prejudicial error' is intended to 'sum up in succinct fashion the harmless error rule").

1. HHS Reasonably Removed Former § 92.207 from the Code of Federal Regulations

Former § 92.207(b)(3) provided that a covered entity may not "[d]eny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for any health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available." And former § 92.207(b)(4) prohibited covered entities from "[h]aving or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition." As the *Whitman-Walker* court correctly explained, "HHS expressly confronted its prior policy regarding prohibitions on categorical coverage exclusions and delivered a sufficiently reasoned explanation for its new position. In promulgating the 2020 Rule, the agency consulted scientific studies, government reviews, and comments from a host of medical professionals regarding treatment for gender dysphoria." *Whitman-Walker*, 2020 WL 5232076, at *30. HHS found "that 'the medical community is divided on many issues related to gender identity, including the value of various 'gender-affirming' treatments for gender dysphoria (especially for minors).'" *Id*. (quoting 85 Fed. Reg. at 37,187). And "[t]hat division counseled against a blanket prohibition on categorical coverage exclusions of gender-affirming care." *Id*. "[E]liminating the prohibition would enable providers and insurers

'to use their best medical judgment' when delivering and covering care, as informed by 'ongoing medical debate and study' regarding gender-affirming treatment." *Id*. (quoting 85 Fed. Reg. at 37,187). HHS more-than-adequately "examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id*. at *29 (quoting *State Farm*, 463 U.S. at 43).

Plaintiffs claim that HHS "failed to give any weight to the prevailing medical consensus that gender-affirming surgical and medical treatments for gender dysphoria, including those recognized by the World Professional Association of Transgender Health's *Standards for Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* (7th Version 2012) (WPATH Standards of Care)." ECF No. 109 at 48. But Plaintiffs' failure-to-give-weight argument "displays a lack of understanding of the . . . nature of the" 2020 Rule itself. *See Vt. Yankee*, 435 U.S. at 553 The 2020 Rule did not *prohibit* covered entities from providing gender-affirming surgical and medical treatments for gender dysphoria. It "enable[d] providers and insurers 'to use their best medical judgment' when delivering and covering care, as informed by 'ongoing medical debate and study' regarding gender-affirming treatment." *Whitman-Walker*, 2020 WL 5232076 at *30 (quoting 85 Fed. Reg. at 37,187). So if there is indeed a medical consensus consistent with the WPATH Standards of Care, as Plaintiffs purport, the 2020 Rule will have little or no discernable effect on gender-affirming surgical and medical treatments for gender dysphoria. *See* ECF No. 109 at 48.

Plaintiffs' failure-to-give-weight-to-the-WPATH-Standards-of-Care argument also appears to "misconceive[] . . . the scope of the agency's statutory responsibility" under the APA and the scope of review under the "arbitrary and capricious" standard. *See Vt. Yankee*, 435 U.S. at 553; *see also Fox Television*, 556 U.S. at 513–16; *State Farm*, 463 U.S. at 43. An "agency must examine the relevant data and articulate a satisfactory explanation for its action" and cannot "entirely fail[] to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. Here, HHS explicitly addressed the WPATH standards, and explained that "[s]ome medical clinicians criticized" them "for coming to policy conclusions without adequate clinical evidence and

recommending treatments that are still experimental." 85 Fed. Reg. at 37,197. And other "commenters disputed the conclusions of [these] medical professional associations, . . . stating that they had mischaracterized the medical data, and that life-altering transition interventions are not medically necessary, effective, or safe." *Id*. at 37,198. HHS explained that it shared these concerns. *Id*.

To be sure, an agency cannot offer "an explanation for its decision that runs counter to the evidence before" it, *State Farm*, 463 U.S. at 43, but the Court may not "itself weigh the evidence [and] substitute its judgment for that of the agency," *see Constitution Pipeline Company*, 868 F.3d 102 (citation omitted). And HHS relied on substantial evidence in support of its agreement with commenters that the WPATH standards came "to policy conclusions without adequate clinical evidence and recommending treatments that are still experimental." 85 Fed. Reg. at 37,197 & n.232; *see* AR 01445306-646, 01446350-61; 01445795, 01446362-71. These policy disagreements in the medical world over the WPATH Standards of Care support HHS's determination "that the 2016 Rule's prohibition on categorical coverage exclusions 'inappropriately interfered with the ethical and medical judgment of health professionals." ECF No. 109 at 48 (quoting 85 Fed. Reg. at 37,187).[12]

Plaintiffs assert that HHS did "not explain how allowing insurers to maintain categorical coverage exclusions for services deemed medically necessary to treat gender dysphoria, while covering identical services for other needs, can be justified." ECF No. 109 at 49. But HHS explained that it agreed with "clinicians [who] stated that current care for gender dysphoria includes accommodation counseling [and] the 'wait and see' approach, . . . because dysphoria, particularly in children, has [] high rates of resolving without other interventions." 85 Fed. Reg. at 37,197-98. Plaintiffs appear not to recognize that it may be reasonable for an insurer to disagree with one medical provider's determination of medical necessity.

[12] Plaintiffs summarily dismiss some studies as "irrelevant" because they address "childhood gender dysphoria." ECF No. 109 at 48-49. But the 2016 Rule's prohibition on categorical coverage exclusions did not exclude children from its scope. *See* 81 Fed. Reg. at 31,471-72 (former § 92.207).

Plaintiffs complain that a certain 2011 study on LGBT health care that existed in the administrative record supporting the 2016 Rule was absent from the administrative record for the 2020 Rule, but provide no support for the proposition that an agency is required to import wholesale administrative records from prior agency proceedings in support of a new agency action. ECF No. 109 at 50. Nor do Plaintiffs argue that HHS entirely failed to consider the problem addressed in the 2011 study. To be sure, HHS considered the 2016 rulemaking in promulgating the 2020 Rule, *see* AR 02267081-232, but the 2020 Rule was not based on the administrative record from the rulemaking proceeding that developed the 2016 Rule; it "was based on an entirely new record," *Ark Initiative v. Tidewell*, 816 F.3d 119, 130 (D.C. Cir. 2016). And in any event, Plaintiffs explicitly waived any challenge to the contents of the administrative record at this Court's status conference dated November 19, 2020.

The purpose of notice and comment is to develop an administrative record that tests the reasonableness of the proposed rule. *See Int'l Union, United Mine Workers of Am. v. Mine Safety and Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) ("Notice [and comment] requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties the opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.") Plaintiffs were free to submit the 2011 study for HHS's consideration when commenting on the 2020 proposed rule, but did not.[13] Nor do Plaintiffs contend that any

[13] The Plaintiff States are frequent and sophisticated participants in rulemaking proceedings that were well aware that by undertaking notice and comment rulemaking, HHS opened the administrative record to Plaintiffs and the public to place before the agency any materials Plaintiffs wanted HHS to consider before finalizing the 2020 Rule. Indeed, Plaintiffs placed an extraordinary number of studies and reports in the administrative record for HHS's consideration in the rulemaking proceeding. *See* AR-00146072-77 ("ACOG Committee Opinion" titled "The Limits of Conscientious Refusal in Reproductive Medicine"); AR-00146078-86 (study titled "The Implications of Unintended Pregnancies for Mental Health in Later Life"); AR-00146087-96 (Study titled "Women's Mental Health and Well-being 5 years After Receiving or Being Denied an Abortion"); AR-00146097-136 (Report titled "Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers"); AR-00146137-41 (article titled "Side Effects, Physical Health Consequences, and Mortality Associated with Abortion and Birth after an

other commenter submitted the study for HHS's consideration. Accordingly, they have waived any complaint that the administrative record excludes a study that they failed to present to the agency for its consideration in the rulemaking proceeding. *See United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952) ("Simple fairness to those who are engaged in the tasks of administration, and to litigants, requires as a general rule that courts should not topple over administrative decisions unless the administrative body has not only erred but has erred against objection made at the time appropriate under its practice."); *see also Vt. Yankee*, 435 U.S. at 553 (explaining that it is "incumbent upon" Plaintiffs to "structure their participation so that it is

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Unwanted Pregnancy"); AR-00146142-256 (chapter from book titled "Clinical Preventative Services for Women: Closing the Gaps"); AR-00146257-63 (study titled "Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States"); AR-00146264-71 (study titled "Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children"); AR-00146272-79 (study titled "Comparison of Health, Development, Maternal Bonding, and Poverty Among Children Born After Denial of Abortion vs After Pregnancies Subsequent to an Abortion"); AR-00146280-31 (report titled "The Economic Effects of Abortion Access: A Review of the Evidence"); AR-00146316-43 (report titled "When Health Care Isn't Caring"); AR-00146344-78 (talking points titled "Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S."); AR-00146379-680 ("The Report of the 2015 U.S. Transgender Survey"); AR-00146681-87 ("Health Care Disparities Among Lesbian, Gay, Bisexual, and Transgender Youth: A Literature Review"); AR-00146688-90 (NJ State Press Release titled "Murphy Administration Works to End the AIDS Epidemic in New Jersey"); AR-00146691-93 (data from U.S. Census Bureau); AR-00146694-753 (report titled "Language Services Action Kit Interpreter Services in Health Care Settings for People with [LEP]"); AR-00146754-61 ("ASPRE Research Brief" titled "The [ACA] and Asian Americans and Pacific Islanders"); AR-00146762-810 ("HHS Action Plan to Reduce Racial and Ethnic Health Disparities"); AR-00146811-20 (article titled "Disability Discrimination in Health Care"); AR-00146821-52 (U.S. Census data regarding "Americans With Disabilities"); AR-00146853-959 (2015 comments of the National Health Law Program on the 2016 Rule); AR-001467960-76 (report titled "Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care"); AR-001467977-89 (report titled "How Many Adults Identify as Transgender in the United States?"); AR-00146990-7006 (Cal. Dep't of Insurance "Health Insurance and ASO Health Covered Lives Report"); AR-00147007-30 (report titled "Enrollment Trends"); AR-00147031-263 ("Employer Health Benefits 2018 Annual Survey"); AR-00147264-71 (article regarding "Health Care Costs"); AR-0014272-86 (Cal. Dep't of Insurance "Economic Impact Assessment" regarding "Gender Nondiscrimination in Health Insurance"). *Cf. Vt. Yankee*, 435 U.S. at 553–54 ("[A]dministrative proceedings should not be a game or a forum to engage in unjustified obstructionism by making cryptic and obscure references to matters that 'ought to be' considered and then, after failing to bring the matter to the agency's attention, seeking to have the agency's determination vacated on the ground that the agency failed to consider matters 'forcefully presented.'")

meaningful, so that it alerts the agency to [their] position and contentions"); *Cal. Communities Against Toxics v. EPA*, 928 F.3d 1041, 1049 (D.C. Cir. 2019); *Universal Health Servs. v. Thompson*, 363 F.3d 1013, 1019 (9th Cir. 2004) ("[A] party's failure to make an argument before the administrative agency in comments on a proposed rule bar[s] it from raising that argument on judicial review."); *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 394 (D.C. Cir. 1973).

Even assuming that HHS erred, which it did not, Plaintiffs have not demonstrated how any error would be prejudicial. *See* 5 U.S.C. § 706 ("due account shall be taken of the rule of prejudicial error" in judicial review"). "[T]he burden of showing that an error is harmful normally falls upon the party attacking the agency's determination." *Shinseki*, 556 U.S. at 409. HHS's silence in the 2020 Rule as to whether categorical exclusions violate Section 1557 does not mean that a categorical exclusion does not violate Section 1557. Indeed, Plaintiffs cite a federal district court opinion from Wisconsin concluding that a categorical coverage exclusion violated Section 1557. *See* ECF No. 109 at 49 (quoting *Flack v. Wis. Dep't of Health Servs.*, 328 F. Supp. 931, 950 (W.D. Wis. 2018)). But the case upon which Plaintiffs rely did not defer to an HHS construction of Section 1557. *See Flack*, 328 F. Supp. at 948–51. In fact, the *Flack* court made no mention of HHS regulations whatsoever and at the time the relevant provisions were preliminarily enjoined nationwide. *See id*. So *Flack* indicates that nothing about the 2020 Rule, which does nothing to affect the plain meaning of sex discrimination prohibited by Section 1557, would have any "substantial bearing on [Plaintiffs'] ultimate rights" to bring claims against covered entities that they believe violate Section 1557 on behalf of their residents, just like the *Flack* plaintiffs. *See Market St. Ry. Co.*, 324 U.S. at 562; *see also Flack*, 328 F. Supp. at 948–51.

2. HHS Did Not Rely on Factual Findings that Contradict those Which Underlay its Prior Policy When Promulgating the 2020 Rule

"Although an 'agency need not always provide a more detailed justification than would suffice for a new policy created on a blank slate,' 'sometimes it must.'" *New York v. HHS*, 414 F. Supp. 3d 475, 547 (S.D.N.Y. 2019) (quoting *Fox Television*, 556 U.S. at 515). A more detailed justification may be required "when (1) the 'new policy rests upon factual findings that contradict

those which underlay its prior policy' or (2) 'its prior policy has engendered serious reliance interests.'" *Id*. (quoting *Fox Television*, 556 U.S. at 55).

Plaintiffs try to invoke the first exception, *see* ECF No. 109 at 51, but that circumstance is not present here. HHS "did not rely on new facts, but rather on a reevaluation of which policy would be better in light of the facts." *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1038 (D.C. Cir. 2012). Just like in *Fox Television* and *Brand X*, HHS's decision not to define "on the basis of sex" by rule was based on different value, policy, and legal judgments which can be freely changed, not some redetermination that some fact previously found to be true no longer is. *See Fox Television*, 556 U.S. at 519 ("[T]he fact that an agency had a prior stance does not alone prevent it from changing its views."); *Brand X*, 545 U.S. at 981 (agency "must consider varying interpretations and the wisdom of its policy on a continuing basis, for example, in response to . . . a change in administrations").

Plaintiffs' reliance on *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1284–85 (D.C. Cir. 2019), is misplaced. *See* ECF No. 109 at 51. In *United Steel*, an agency administered a statute "subject to a unique limitation: 'no mandatory health or safety standard shall reduce the protection afforded miners by an existing mandatory health or safety standard'" (the no-less-protection standard). *Id*. at 1281 (quoting 30 U.S.C. § 811(a)(9)). In 2017, the agency "adopted a new standard for workplace examinations: 'a competent person designed by the operator shall examine each working place at least once each shift *before minors begin work* in that place, for conditions that may adversely affect safety or health.'" *Id*. at 1282 (quoting 30 C.F.R. § 56.18002(a)(2017)). In 2018, the agency amended those requirements, replacing them with the requirement that "a competent person must 'examine each working place at least once each shift before work begins *or as miners begin work in that place* for conditions that may adversely affect safety or health.'" *Id*. (quoting 30. C.F.R. § 56.18002(a)). The 2017 rule was promulgated after a finding "that 'if the examination is performed after miners begin work, miners may be exposed to conditions that may adversely affect their safety and health.'" *Id*. at 1284 (citation omitted). But in promulgating the 2018 rule, the agency found that under the new standard "adverse conditions

will be 'identified and miner notification provided before miners are potentially exposed to the conditions,'" *id*. at 1283, which could "not be reconciled with the factual findings that [the agency] made in support of the 2017 Standard," *id*. at 1284.

Here, Plaintiffs point to no "unique limitation" like that in the statute administered in *United Steel*, *id*. at 1281, requiring a factual finding that any new rule implementing Section 1557 must result in less discrimination than a prior rule notwithstanding any other cost or policy consideration or the scope of the plain meaning of discrimination prohibited by Section 1557 itself. *See* ECF No. 109 at 51-53. Indeed, Section 1557(c) simply states that HHS "may" promulgate regulations implementing the section. Nor have Plaintiffs identified any factual finding made by HHS in promulgating the 2020 Rule that contradicts any finding Plaintiffs identify supporting the 2016 Rule. *See* ECF No. 109 at 51.

Plaintiffs assert that "evidence of systemic insurance discrimination against transgender people" that commenters provided to HHS was not "considered by HHS in" promulgating the 2020 Rule. ECF No. 109 at 52 & n. 53. But that is not true. HHS considered all of the comments in promulgating the Rule,[14] but as discussed *supra* at 50-52, HHS's decision was not premised on the quantity of purported 'systemic insurance discrimination against transgender people,' but was instead premised on interests—such as maintaining rules that HHS could be confident are interpreted consistently with the plain meaning of the statute and not maintaining rules that include definitions of broadly-applicable-civil-rights-law terminology that would likely be subject to substantial litigation—that HHS determined to outweigh any arguable harm to interests in preventing the discrimination that the statute might but does not clearly prohibit. And HHS's decision was also premised on its understanding of the nature of its action—that by not defining the term "sex" by rule, HHS's action could only have implications on the scope of systemic

[14] As discussed *infra* at 67-71, HHS explicitly addressed the individual and public health harms that could result from HHS's decision to remove the gender-identity provisions of the definition of "on the basis of sex" from the Code of Federal Regulations.

discrimination against transgender people in the health care context if courts determine that transgender discrimination is not covered by the plain meaning of "sex" discrimination.

To be sure, a more detailed justification for policy change might be required if a "prior policy has engendered serious reliance interests." *New York*, 414 F. Supp. 3d at 547 (quoting *Fox Television*, 556 U.S. at 515). But HHS explained that there could be little or no reliance interests on the 2016 Rule's gender-identity provisions: "[B]ecause the gender identity provisions of the 2016 Rule have been vacated prior to this rule being finalized, it is even less likely than at the time of the proposed rule that this final rule will lead to changes in policies or procedures concerning gender identity." 85 Fed. Reg. at 37,225. Plaintiffs take issue with the fact that HHS explained that it "lack[ed] data to estimate what greater public health costs, cost-shifting, and expenses may result from entities changing their nondiscrimination policies and procedures after promulgation of [the 2020] Rule." *Id*. *See* ECF No. 109 at 52-53. But Plaintiffs point to nothing in the administrative record indicating that this determination is unsupported. *See id*. at 52-53; *see also State Farm*, 463 U.S. at 52 ("It is not infrequent that the available data does not settle a regulatory issue and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion."); *American Public Commc'ns Council v. FCC*, 215 F.3d 51, 56 (D.C. Cir. 2000) (courts "cannot require an agency to enter precise predictive judgments on all questions as to which neither its staff nor interested commenters have been able to supply certainty"). The fact that some commenters may have provided HHS with information about systemic discrimination against transgender people, *see id*. at 52 n.53, does not undermine this statement in any way because it is not the type of data the agency would need to make accurate estimates about implications on aggregate public health costs, etc. In any event, Plaintiffs mischaracterize HHS's statement, which was considering the impact of the 2020 Rule on transgender communities. *See* 85 Fed. Reg. at 37,225. In context, HHS was explaining why it had every reason to believe that public health costs, cost-shifting, and expenses resulting from the 2020 Rule's removal of gender-identity-related provisions "will be minimal [because] the gender

identity provisions were vacated from the 2016 Rule by the *Franciscan Alliance* court before th[e] rulemaking was finalized." *Id*.

3. HHS Did Not Entirely Fail to Consider any Important Aspects of the Problem; HHS Reasonably Determined that Little or No Discernable Individual and Public Health Harms Could Result from its Decision not to Define "On the Basis of Sex" in the 2020 Rule or the Removal of Other Provisions Specific to Gender Identity Discrimination

"Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. Contrary to Plaintiffs' argument, *see* ECF No. 109 at 53, HHS did not entirely fail to consider harms to affected groups and public health stemming from HHS's decision not to define "on the basis of sex" or its decision to remove gender-identity-related provisions from the Code of Federal Regulations.

Many commenters expressed concern that "the proposed rule would lead covered entities to remove protections from transgender individuals in their policies or procedures." 85 Fed. Reg. at 37,225. But HHS did not fail to consider this issue. To the contrary, HHS reasonably explained that it disagreed. *See id*. HHS explained that

> [i]n December 2016, the *Franciscan Alliance* court preliminarily enjoined the gender identity provisions of the 2016 Rule on a nationwide basis, and more recently the court vacated those provisions. Consequently, this final rule's revisions to the provisions addressing gender identity do not change cover entities' obligations. Therefore, even though some entities may have changed their policies or procedures at the outset of the 2016 Rule, [HHS] concludes that because the gender identity provisions of the 2016 Rule have been vacated prior to this rule being finalized, it is even less likely than at the time of the proposed rule that this final rule will lead to changes in policies and procedures concerning gender identity. In addition, as explained above, the 2016 Rule did not include language prohibiting discrimination on the basis of sexual orientation status standing alone as a form of sex discrimination. [HHS] therefore does not anticipate any material change to covered entities' policies concerning sexual orientation as a result of this final rule.

Id.

Plaintiffs' arguments that HHS entirely failed to consider this issue depend on assertions that HHS never made. *See* ECF No. 109 at 54. Plaintiffs claim that HHS "predicts that 50 percent of covered entities will revert their policies . . . and cease accepting and handling internal

grievances based on gender identity and sex stereotyping." ECF No. 109 at 54. But HHS did not say that. HHS actually said that it "does not estimate a cost savings concerning grievance procedures. This is because, as stated repeatedly elsewhere, the court order vacating the gender identity provisions of the 2016 Rule means that this final rule's changes concerning gender identity will have no direct material economic impact." 85 Fed. Reg. at 37,236. HHS also explained that sex stereotyping claims "were already authorized by the Supreme Court's longstanding interpretation of sex stereotyping," so the agency did not anticipate a change in grievance procedures concerning sex stereotyping discrimination stemming from HHS's decision not to define "on the basis of sex" by rule. *Id*.

In an attempt to undermine the reasonableness of HHS's response to concerns that the Rule will impact the transgender community, Plaintiffs criticize HHS's explicit consideration of concerns raised by commenters. ECF No. 109 at 55. Plaintiffs claim that HHS's determination "that denials of health care are 'rare' and 'based largely on unsubstantiated hypothetical scenarios'" is "contrary to HHS's prior factual findings" from 2016. ECF No. 109 at 55. But Plaintiffs fail to disclose that HHS also explained that the cited instances reported are largely "not recent," 85 Fed. Reg. at 37,192, which is not contrary to HHS's old factual findings at all. Indeed, Plaintiffs point to little more than old data from an entirely different administrative record—the record supporting the 2016 Rule—such as a 2010 survey, despite rapid cultural change on this issue. *See* ECF No. 109 at 54-55. In any event, Plaintiffs cannot demonstrate that any of this indicates that HHS has entirely failed to consider any important aspect of the problem, nor can they demonstrate prejudice in light of HHS's determinations, discussed above, that HHS's decision not to define "on the basis of sex" by rule cannot plausibly have a discernable impact on LGBTQ discrimination because the relevant provisions were vacated prior to the 2020 Rule being finalized.

Plaintiffs point out that the "administrative record for the 2020 Rule reflects examples of transgender individuals being subjected to denial of treatment and coverage for health care, categorical coverage exclusions for gender-conforming health treatments, and inappropriate and humiliating comments for being transgender." ECF No. 109 at 56-59. But none of these examples

undermine HHS's explicit consideration of the implications of the removal of the definition of "on the basis of sex" and gender-identity-related provisions from the Code of Federal Regulations in the 2020 Rule or HHS's determination that it is implausible that the 2020 Rule could have a material effect on the transgender community in light of the fact that the relevant provisions of the prior rule had been enjoined and vacated. *See id*. And the same is true for the "termination of pregnancy provisions" of the 2016 Rule, *see* ECF No. 109 at 57 (citation omitted), which were preliminarily enjoined and ultimately vacated before HHS issued the 2020 Rule.

Perhaps recognizing the faulty nature of their argument, Plaintiffs only briefly complain that HHS "refuses to calculate costs that would result from adopting Title IX's religious exemption." ECF No. 109 at 57. But what Plaintiffs apparently do not recognize is that the 2020 Rule does not "adopt" a religious exemption that does not already exist. The Rule merely clarifies what Section 1557 already says: it prohibits no more than the grounds of discrimination that would be prohibited under the incorporated statutes. *See* 85 Fed. Reg. 37,253 (§ 92.6(b)) (providing that "[i]nsofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections by" Title IX, "such application shall not be imposed or required"). Accordingly, HHS reasonably explained that

> [t]he Title IX statute already includes certain exemptions concerning religious groups, and RFRA protects certain exercises of religion from substantial burdens. . . . As [HHS] is already bound by statute to implement Title IX and Section 1557 consistent with those statutes and with RFRA, [HHS] does not attribute its compliance with those statutes to be attributable to this final rule. Economic impacts due to compliance with Title IX and RFRA would be attributable, not to this final rule, but to those statutes themselves, and are not relevant.

Id. at 37,239.

Plaintiffs assert that HHS did not consider or weigh public health costs and related harms to state and local governments. *See* ECF No. 109 at 58-59. But Plaintiffs do not explain why they would have impacts stemming from the 2020 Rule when, as just explained, HHS reasonably determined that there are no discernable impacts stemming from the provisions of the 2020 Rule

that Plaintiffs discuss on pages 53-58 of their memorandum.[15] Unable to meaningfully respond to the reality that the gender-identity provisions were already vacated from the Code of Federal Regulations, Plaintiffs incorrectly assert that "HHS merely asserted that the States are unlikely to see an increase in complaints from transgender people because it had not enforced the gender identity provisions of the 2016 Rule due to the *Franciscan Alliance* injunction." ECF No. 109 at 59. But this statement inaccurately characterizes the status quo at the time HHS issued the 2020 Rule as though HHS decided, in its discretion, not to enforce the 2016 Rule. To the contrary, "the *Franciscan Alliance* court preliminarily enjoined the gender identity provisions of the 2016 Rule on a nationwide basis, and more recently the court vacated those provisions." 85 Fed. Reg. at 37,225. Because the relevant provisions of the 2020 Rule had been vacated, they did not exist in the Code of Federal Regulations at the time HHS issued the 2020 Rule. Plaintiffs' efforts to distort the agency action at issue into something else entirely in an effort to undermine the rule must be rejected. They say "HHS did not otherwise attempt to consider the public health effects of its continued non-enforcement of these provisions." ECF No. 109 at 59. But in addition to the issues described above, HHS's purported enforcement policy is not the agency action at issue. Instead, in issuing the 2020 Rule, HHS made changes to the Code of Federal Regulations, and the APA required HHS not to entirely fail to consider any important aspect of any relevant problems associated with *that* action.

Plaintiffs point out that "after *Bostock*, HHS is obligated to enforce Section 1557's sex discrimination protections on behalf of individuals alleging discrimination based on transgender status and sexual orientation." ECF No. 109 at 59. With the caveat that HHS has prosecutorial

[15] Plaintiffs claim that HHS's "only" response to their comments about the impact of the final rule on state and local governments is that HHS "'must follow the text of the ACA.'" ECF No. 109 at 59 (quoting 85 Fed. Reg. at 37,169). That is not so. Plaintiffs cherry-pick the first sentence of a paragraph. The final sentence of the paragraph provides that HHS's "specific reasoning in interpreting Section 1557's scope of coverage follows" throughout the rest of the entire preamble to the 2020 Rule. 85 Fed. Reg. at 37,169. In other words, each change that HHS made in the 2020 Rule is distinct and has different implications (or lack of implications). Accordingly, HHS considered and responded to commenters' concerns (including Plaintiffs' comments) about changes in the 2020 Rule on a provision-by-provision basis. *See id.*

discretion in light of its limited resources—so it does not necessarily have any such "obligation," *see Heckler*, 470 U.S. at 831–32—HHS has never disputed that *Bostock* might have implications for the meaning and scope of Section 1557. *See* 84 Fed. Reg. at 27,857 & n.75. But neither that abstract issue nor any other development in the law since HHS issued the 2020 Rule are before the Court. Instead, as addressed *supra*, the issue is whether HHS's decision not to define "on the basis of sex" by rule was arbitrary and capricious in light of the rulemaking proceeding as a whole, considering not just the date that the regulation was promulgated but also the nature of the agency's decision, the time the record was closed, the time the decision was made, and the time the decision was issued to the public. *See Vt. Yankee*, 435 U.S. at 533 (citing *Jersey City*, 322 U.S. at 514)). It was not, for the reasons discussed above.

B. HHS Provided a Myriad of Good Reasons for Modifying the "Meaningful Access for Individuals with Limited English Proficiency" Provisions of the Section 1557 Regulations

HHS has provided several "good reasons" for replacing the "Meaningful Access for Individuals with Limited English Proficiency" Regulations formally codified at 45 C.F.R. § 92.201 with the new provisions promulgated at § 92.101(a)-(b). *See Fox Television*, 556 U.S. at 515–16.

First, the new provisions are more consistent with Section 1557 than the old ones. Section 1557 does not explicitly prohibit discrimination against individuals with limited English proficiency ("LEP"). *See* 42 U.S.C. § 18116(a). Instead, Section 1557 prohibits certain conduct "on the ground prohibited under title VI of the Civil Rights Act of 1964." *Id*. *See* 85 Fed. Reg. at 37,210. And Title VI, in turn, prohibits discrimination on the basis of national origin, among other things. 42 U.S.C. § 2000d. Agencies may effectuate Title VI by promulgating regulations. *Id*. § 2000d-1.

The Supreme Court, in *Lau v. Nichols*, 414 U.S. 563 (1974), held that Title VI prohibits conduct that has a disproportionate effect on LEP persons because such conduct constitutes national-origin discrimination. In *Lau*, a San Francisco school district that had a significant number of non-English speaking students of Chinese origin was required to take reasonable steps

to provide them with a meaningful opportunity to participate in federally funded educational programs. *See id*.

Executive Order 13166 directs each Federal agency that extends assistance subject to the requirements of Title VI to publish guidance for its respective recipients clarifying the obligation to ensure meaningful access to their programs and activities by LEP persons consistent with Title VI. *See* 65 Fed. Reg. 50,121 (Aug. 16, 2000). Accordingly, DOJ published guidance in compliance with Executive Order 13166 in 2002. *See* 67 Fed. Reg. 41,455 (June 18, 2002). And in 2003, HHS published guidance in compliance with Executive Order 13166 using the DOJ Guidance as a model. 68 Fed. Reg. 47,311 (Aug. 8, 2003). The 2003 guidance required "[r]ecpients . . . to take reasonable steps to ensure meaningful access to their programs and activities by LEP persons." *Id*. at 47,314. The guidance also set forth a four-factor balancing test: "(1) The number or proportion of LEP persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the program to people's lives; and (4) the resources available to the grantee/recipient and costs." *Id*.; *see also* 67 Fed. Reg. at 41,459.

Such was the state of Title VI's LEP requirements when Congress passed the ACA, including Section 1557, incorporating those requirements for application in the health care setting. And "it is generally presumed that Congress is . . . knowledgeable about existing laws pertinent to later-enacted legislation" and "familiar with previous interpretations of specific statutory language." *Bonanno*, 879 F.2d at 25; *see also Hall v. United States Dep't of Ag.*, --- F.3d ---, --- 2020 WL 7777888, at *9-*10 (9th Cir. Dec. 31, 2020) (presuming that Congress was "aware of an agency's interpretation of a statute" in agency guidance); *Mozilla*, 940 F.3d at 25-26 (agency interpretation reasonable when relying on previous interpretations of a consent degree from which it appears Congress derived statutory language). So HHS incorporated "DOJ's longstanding LEP guidance (under Executive order 13166), and HHS's corresponding LEP guidance from 2003," because adopting "the Title VI standard requiring reasonable steps to ensure meaningful access"

is more consistent with Section 1557's incorporation of Title VI's requirements, *see* 85 Fed. Reg. 37,210. HHS's decision to do so was reasonable because "an agency may justify its policy choice by explaining why that policy 'is more consistent with statutory language' than alternative policies." *Encino Motorcars*, 136 S. Ct. at 2117 (quoting *Long Island Care at Home*, 551 U.S. at 175).

Second, HHS explained that the new standards are more administrable than the old standards. HHS's Office for Civil Rights administers both Section 1557 and Title VI to both the health programs and the human services programs falling under the Department of Health and Human Services umbrella. But under the 2016 Rule, HHS had to administer two different LEP standards depending on whether a health program or a human service program was at issue, even though Section 1557 incorporates Title VI's standards. HHS explained that "[a]dopting th[e new] language would apply the same standard to both health and human services programs within the Department," improving administrability. 85 Fed. Reg. at 37,210. "Administrability is important" and a good reason for policy change. *See City of Portland v. United States*, 969 F.3d 1020, 1038 (9th Cir. 2020); *see also Mayo Found.*, 562 U.S. at 59 (concluding that agency "reasonably concluded that its [new] rule would 'improve administrability'") (citation omitted).

Third, HHS explained that the new rule, incorporating longstanding Title VI standards, is less confusing than the 2016 Rule's standards. "Title VI enforcement mechanisms are broadly known to the regulated community, and the HHS LEP Guidance has been effective in helping covered entities comply with the statute and implementing regulation." 85 Fed. Reg. at 37,210. HHS found this regulatory certainty to be valuable, and a good reason for policy change. *See id*. In contrast, HHS determined the 2016 Rule's requirements to be facially confusing. *Id*. For example, HHS explained that the 2016 Rule "could potentially be interpreted to require a covered entity to provide language assistance services to every LEP individual it comes into contact with." *Id*.

Fourth, HHS explained that the 2020 standards provide a better balance of "the relevant factors in ensuring nondiscrimination on the basis of national origin." *Id.* Specifically, HHS found

the longstanding Title VI LEP standards to strike an appropriate "balance that ensures meaningful access by LEP individuals to critical services while not imposing undue burdens on small business, small local governments, or small nonprofits." *Id.*; *see Chevron*, 467 U.S. at 845 (quoting *United States v. Shimer*, 367 U.S. 374, 382 (1961)) ("If [the] choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, [courts] should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.").

Finally, HHS found that incorporating the longstanding Title VI LEP standards into the 2020 Rule "would conform to the other Federal agencies that follow DOJ's LEP Guidance, consistent with its civil-rights coordinating authority." 85 Fed. Reg. at 37,210. As DOJ explained in that guidance, "[c]onsistency among Departments of the Federal government is particularly important. Inconsistency or contradictory guidance could confuse recipients of Federal funds and needlessly increase costs without rendering the meaningful access for LEP persons that [Title VI standards are] designed to address." 67 Fed. Reg. at 41,457-58.

In sum, HHS provided abundant "good reasons" for its new policy and explained that the "agency *believes* it to be better" than the old one, which meets *Fox Televisions*'s reasonableness requirement. 556 U.S. at 516. "[T]he fact that [HHS] had a prior stance does not alone prevent it from changing its view or create a higher hurdle for doing so." *Id*. at 519. Plaintiffs nonetheless make several arguments that HHS's decision is arbitrary or capricious. None are valid.

1. Plaintiffs do not Demonstrate that HHS Failed to Adequately Justify its "Meaningful Access" Provision Modifications

First, Plaintiffs complain that HHS's desire "to ensure consistency between Section 1557 and Title VI enforcement" is "inconsistent with HHS's earlier determination that the 2016 Rule compiled with and codified the federal LEP guidance in the context of the ACA" even though it "is based on no new factual findings." ECF No. 109 at 61. When "a new policy rests upon factual findings that contract those which underlay its prior policy," an agency might need to "provide a more detailed justification than what would suffice for a new policy created on a blank slate." *Fox*

Television, 556 U.S. at 515. But HHS's new policy does not rest upon factual findings contradicting those underpinning the 2016 Rule. HHS "did not rely on new facts, but rather on a reevaluation of which policy would be better in light of the facts." *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1038 (D.C. Cir. 2012). Just like in *Fox Television* and *Brand X*, HHS's decision to bring the Section 1557 LEP requirements in line with the Title VI standards was based on different value, policy, and legal judgments which can be freely changed, not some redetermination that some fact previously found to be true no longer is. *See Fox Television*, 556 U.S. at 519 ("[T]he fact that an agency had a prior stance does not alone prevent it from changing its views."); *Brand X*, 545 U.S. at 981 (agency "must consider varying interpretations and the wisdom of its policy on a continuing basis, for example, in response to . . . a change in administrations"). As explained, *supra* at 71-74, HHS had several reasons for conforming Section 1557's meaningful access requirements with the longstanding requirements under Title VI. And HHS's determination that the 2016 Rule's LEP provisions were inconsistent with the longstanding Title VI guidance is not a "factual finding." It was a conclusion drawn by comparing the plain text of the relevant provisions of the 2016 Rule with the plain text of the longstanding Title VI meaningful access guidance. *See* 85 Fed. Reg. at 37,210 ("[T]he 2016 Rule impose a stringent requirement on covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served or likely to be encountered."). "[E]ven in the absence of evidence, the agency's . . . judgment" about the facial differences between the 2016 Rule's requirements and the longstanding Title VI guidance "makes entire sense." *See Fox Television*, 556 U.S. at 521. "The law simply does not require any heightened scrutiny of an agency change in position." *Investment Co. Institute v. U.S. Commodity Futures Trading Comm'n*, 891 F. Supp. 2d 162, 194 (D.D.C. 2012).

In addition, Plaintiffs cannot rationally argue that the 2020 Rule, which incorporates verbatim a standard from longstanding Title VI LEP guidance, has "erode[d] Section 1557's protections for LEP individuals" and at the same time assert that "the 2016 Rule [merely] complied with and codified the federal LEP guidance in the context of the ACA." *See* ECF No. 109 at 60-

61. If the 2016 Rule merely codified the federal LEP guidance in the context of the ACA, it is even more clear that Plaintiffs could not plausibly have standing to challenge the 2020 Rule's changes to the meaningful access requirements, which simply codify verbatim longstanding Title VI federal LEP guidance for application in the context of the ACA.

Second, Plaintiffs inappropriately complain about the wisdom of HHS's new standards, stating that they "are a poor fit for Section 1557." ECF No. 109 at 61-62. But the Court is limited to considering whether HHS has "examine[d] the relevant data and [has] articulate[d] a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43. "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Id*. In any event, Plaintiffs' assertion that the "2020 Rule . . . prioritize[s] administrative costs without regard to meaningful access" is clearly erroneous. *See* ECF No. 109 at 62. "Cost is not the primary factor in the four-factor analysis" in the 2020 Rule; "no single factor is determinative. The four-factor analysis does not supersede the right to meaningful access but rather helps determine when an entity has taken reasonable steps to secure that right." 85 Fed. Reg. at 37,212. By its plain terms, the 2020 Rule's meaningful access provisions provide that "[a]ny entity operating or administering a health program or activity subject to this part shall take reasonable steps to ensure meaningful access to such programs or activities by [LEP] individuals." 85 Fed. Reg. at 37,245 (§ 92.101(a)). And HHS explained that under the 2020 Rule's meaningful access provisions—identical to longstanding Title VI meaningful access requirements—HHS's "LEP Guidance will help covered entities assess their programs using the four factors to ensure meaningful access to their programs by individuals with LEP." 85 Fed. Reg. at 37,210. HHS also explained that the 2020 Rule "fully retains all protections offered by Section 1557, and it does not shift any focus from an individual's right to the covered entity's programs or activities. It ensures that covered entities do not use their programs or activities to discriminate on the basis of any individual's national origin, which includes (under *Lau*'s disparate impact analysis)," 85 Fed. Reg. at 37,211, requiring those entities to "take reasonable steps to provide meaningful access to LEP individuals," *id*. at 37,245 (45 C.F.R. § 92.101(a)). Plaintiffs' characterization of the standards

that the federal government has had in place for twenty years for implementing Title VI's requirement that federally funded programs and activities ensure meaningful access by LEP persons as "without regard to meaningful access" is unfounded. *See* ECF No. 109 at 62.

2. HHS Complied with the APA's Requirements in Promulgating the 2020 Rule's "Meaningful Access for Individuals with Limited English Proficiency" Provisions

Yet again, Plaintiffs return to a straw man, trying to characterize HHS's change of policy as resting "upon factual findings that contradict those which underlay its prior policy." *Fox Television*, 556 U.S. at 515. *See* ECF No. 109 at 63-64. But Plaintiffs own briefing demonstrates that the new rule is not based on contrary factual findings, but instead on a "reevaluation of which policy would be better in light of the facts." *Nat'l Ass'n of Home Builders*, 682 F.3d at 1038. Plaintiffs do not point to a single "factual finding" that was contradicted in the 2020 Rule. To the contrary, HHS simply determined that utilizing the longstanding Title VI requirements for meaningful access for LEP persons sufficiently addressed the problem in this area, as it does in the Title VI arena (on which Section 1557 is based), especially in light of the additional value of consistency. *See* 85 Fed. Reg. at 37,210. *See supra* at 71-74.

Plaintiffs again criticize HHS for not addressing studies that they admit are not even in the administrative record. *See* ECF No. 109 at 63-64. But the issue is whether HHS's "changes in current policy . . . are . . . justified by [this] rulemaking record." *State Farm*, 463 U.S. at 42. To be sure, HHS considered the 2016 rulemaking in promulgating the 2020 Rule, *see* AR 02267081-232, but the 2020 Rule was not based on the administrative record from the rulemaking proceeding that developed the 2016 Rule; it "was based on an entirely new record," *Tidewell*, 816 F.3d at 130. And Plaintiffs explicitly waived any challenge to the contents of the administrative record at this Court's status conference dated November 19, 2020. If these studies are not part of the administrative record, it is because no commenter submitted them to HHS for its consideration after it proposed the 2020 Rule. This claim is meritless for the same reasons explained *supra* at 61 in the context of HHS's decision not to define "on the basis of sex" by rule.

Plaintiffs argue that HHS failed to consider numerous comments asserting that HHS's decision to utilize longstanding Title VI standards for ensuring meaningful access to health programs or activities by individuals with LEP might have implications for LEP persons' ability to access health care. *See* ECF No. 109 at 64-66. But Plaintiffs' own briefing shows that HHS did consider these comments. *See id*. HHS "acknolwedge[d] the potential of reduced awareness of the availability of language services by LEP individuals by the changes made in [the 2020 R]ule, or downstream effects on malpractice claims due to less awareness." 85 Fed. Reg. at 37,235. But HHS determined that those potential harms would be mitigated by the fact that the 2020 Rule "continues to provide protections for LEP individuals and commits [HHS] to enforcement of Section 1557." *Id*. So any plausible "negative effects predicted by some commenters may be mitigated by the continued commitment to enforcement of Section 1557." *Id*. HHS recognized the importance of adopting a test that "ensures meaningful access by LEP individuals to critical services." *Id*. at 37,210. But HHS determined it was also appropriate to account for the benefits of consistency with the longstanding standards implementing Title VI, which consider whether there is an "undue[] burden on small businesses, small local governments, or small nonprofits." *See id*. *Cf. Michigan v. EPA*, 576 U.S. 743, 759 (2015) (explaining the importance for agencies to "consider costs—including, mostly importantly, cost of compliance—before deciding whether regulation is appropriate and necessary").

In any event, HHS also highlighted the fact-specific nature of the new requirement in determining that commenters' fears about far-reaching implications were misplaced. HHS explained that because compliance by covered entities using the "four-factor analysis" is evaluated "on a case-by-case basis," the "fact-dependent nature of Title VI makes it impossible to make pronouncements" about the likely implications for access to health care "without all the relevant facts" of a particular scenario. *See* 85 Fed. Reg. at 37,212.

Plaintiffs' assertion that an agency needs to provide "factual support" for its determination that the 2016 Rule's requirements were facially confusing is unsupported. *See* ECF No. 109 at 65. The Supreme Court has explained that a "regulation . . . just means what it means—and [a] court

must give it effect, as [a] court would any law." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019). HHS's determination that the 2016 Rule's requirements—which do not match longstanding Title VI guidance—is "confusing" stems from reading the plain text of that rule, as the public and courts must do when determining what an agency regulation requires. *See id*. Plaintiffs fail to explain why a robust record is required in order to justify HHS's determination that a comparison of the facial legal requirements of the 2016 Rule's plain text and longstanding Title VI guidance reveals a mismatch between their requirements. *See* 85 Fed. Reg. at 37,210 (explaining that HHS's decision was based on how the 2016 Rule's plain language "could potentially be interpreted").

Finally, Plaintiffs' assertion that the administrative record provides no factual support for HHS's determination that the prior standards were "unnecessary" to ensure meaningful access to health programs or activities by LEP individuals is both flawed and erroneous. *See* ECF No. 109 at 65. It is flawed because whether a policy is "necessary" or "appropriate" to achieve a certain goal involves a value judgment by the policy making agency, not a factual finding. *Cf. Michigan*, 576 U.S. at 751-57; *see also Brand X*, 545 U.S. at 981 ("the agency must consider varying interpretations and the wisdom of its policy on a continuing basis"). Here, Plaintiffs do not dispute that the administrative record included significant comments indicating that the 2016 Rule imposed undue burdens on covered entities. For example, commenters explained that "under the 2016 Rule, providers are required to physically post the information at their facilities, on their websites, and in any 'significant' publications and communications." 85 Fed. Reg. at 37,210. "This example underscored that the term 'significant' ha[d] never been defined by [HHS], which ha[d] resulted in providers using taglines notices in nearly every document provided to patients." *Id*. "This practice was described as administratively burdensome and counterproductive, because patients already receive numerous notices mandated by [HHS]." *Id*. This is one example of how the 2016 Rule's requirements were unnecessary and confusing. HHS was permitted to balance these interests that weigh against the value of the 2016 Rule when considering the costs and benefits of replacing the 2016 Rule's meaningful access for LEP provisions with those that have long existed (and successfully protected LEP persons) in Title VI guidance.

C. HHS's Construction of Section 1557 to Prohibit Conduct in the Health Care Setting only Insofar as Prohibited by the System of Civil Rights Statutes it Incorporates With Somewhat Greater Clarity than the 2016 Rule was Procedurally Reasonable

The 2020 Rule provides that "[i]nsofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections" provided by Title IX, "such application shall not be imposed or required." 85 Fed. Reg. at 37,245 (§ 92.6(b)). Plaintiffs cannot succeed on their claim that HHS failed to provide a reasoned explanation for including this provision in the 2020 Rule. *See* ECF No. 109 at 67-70. HHS acknowledged that it was changing positions and proffered "good reasons" for its new policy, which is all that the APA requires. *Fox Television*, 556 U.S. at 515. Specifically, HHS explained that its previous exclusion of the Title IX religious exemption was not based on the best reading of the statute, that the exclusion had made the rule vulnerable to legal attack (and had already led to an injunction), and that expressly incorporating religious exemptions would better protect the rights of religious objectors.

HHS determined that its previous refusal to incorporate Title IX's religious exemption was based on a flawed reading of Title IX. "[A]n agency may justify its policy choice by explaining why that policy 'is more consistent with statutory language' than alternative policies." *Encino Motorcars*, 136 S. Ct. at 2127 (2016) (quoting *Long Island Care at Home*, 551 U.S. at 175). Plaintiffs contend that HHS failed to consider that Title IX's exemption is inappropriate in the healthcare setting because Title IX's exemption "specifically apply to educational institutions." ECF No. 109 at 67. But HHS explained why it disagreed with that argument. 85 Fed. Reg. at 37,207.[16] By its own terms, Title IX applies to "any education program or activity receiving

[16] Plaintiffs have also waived this argument by failing to raise it before the agency. "[A] party's failure to make an argument before the administrative agency in comments on a proposed rule bar[s] it from raising that argument on judicial review." *Universal Health Servs.*, 363 F.3d at 1019; *see also id*. at 1020 (citing cases from "every other circuit to have addressed the issue"). "[T]here is a near absolute bar on raising new issues—factual or legal—on appeal in the administrative context." *Nat'l Wildlife Fed. v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002). Nowhere in Plaintiffs' comments do they criticize § 92.6(b), as proposed, on this basis. *See* AR-00146049-

Federal financial assistance," 20 U.S.C. § 1681(a), and Title IX has long been understood to apply outside of core educational institutions. Indeed, Title IX defines a "program or activity" under § 1681(a) to include "all of the operations" of "an entire corporation, partnership, or other private organization" that "is principally engaged in the business of providing education, *health care*, housing, social services, or parks and recreation." 20 U.S.C. § 1687(3)(A)(ii) (emphasis added). That provision shows that Title IX's presence in healthcare settings was expressly anticipated. And the history of Title IX's application shows the same. The Third Circuit, for example, recently held that Title IX applied to a medical resident's claim against the private teaching hospital at which she was employed, which was affiliated with a university and administered the program at least in part for the purpose of educating residents. *Doe v. Mercy Catholic Med. Ctr.*, 850 F.3d 545, 558 (3d Cir. 2017). In sum, HHS considered Plaintiffs' argument about the supposed limitation of Title IX to education institutions, and HHS determined in its sound judgment that Plaintiffs' argument was mistaken.

Similarly, HHS determined in its sound judgment that Section 1557 had to be applied consonant with RFRA. 85 Fed. Reg. at 37,207. "RFRA specifies that it 'applies to all Federal law, and the implementation of that law, whether statutory or otherwise,'" and "[t]he ACA does not explicitly exempt RFRA." *Little Sisters of the Poor Saints Peter and Paul Home v. Pa.*, 140 S. Ct. 2367, 2383 (July 8, 2020) (quoting 42 U.S.C. § 2000bb-3(a)). HHS therefore determined that it was appropriate to state that Section 1557 will be implemented consistent with RFRA, which is a sufficiently good reason for a change in an agency's position.

Another good reason offered by HHS was that the exclusion of religious exemptions had caused the 2016 Rule to be vacated in part in *Franciscan Alliance*. 85 Fed. Reg. at 37,207. The Supreme Court has recognized that agencies may legitimately consider past court decisions regarding the need for religious exemptions when crafting regulations. When the Supreme Court

71. Nor have Plaintiffs pointed to any comments making this argument. Accordingly, it is waived and Plaintiffs may not now raise it for the first time on judicial review.

recently upheld the conscience exemptions to the contraceptive mandate, the Court noted that its own past decisions "all but instructed the Departments to consider RFRA going forward." *Little Sisters of the Poor*, 140 S. Ct. at 2383. It was, the Court held, "hard to see how the Departments could promulgate rules consistent with these decisions if they did not overtly consider these entities' rights under RFRA." *Id.* Indeed, the Court opined that failing to consider the Court's instruction would make the regulation "susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem." *Id.* at 2384. The same is true here—the 2016 Rule had been vacated for failing to provide religious exemptions, and it was not unreasonable for HHS to take that into account in providing religious exemptions for the new rule.

Another good reason offered for the rule was the desire to "protect . . . providers' medical judgment and their consciences." 85 Fed. Reg. at 37,206. The protection of religious beliefs and the rights of conscience more generally is widely recognized as a legitimate government objective. For example, the Supreme Court has repeatedly upheld the propriety of religious exemptions from constitutional challenge, stating that "lifting a regulation that burdens the exercise of religion" is a "proper purpose" of government action. *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 338 (1987). And Congress has repeatedly demonstrated through legislation that accommodation of religion is an important and legitimate goal of the government—for example, it has passed wide-ranging protections for religious liberty, such as RFRA and RLUIPA, and has also explicitly created religious exemptions in many individual statutes, such as the religious exemptions to Title VII and Title IX. Protecting the religious beliefs of people otherwise burdened by government regulation is a sufficient reason to justify HHS's change here.

Plaintiffs also contend that HHS entirely failed to consider "harms to individuals who will be denied health treatments, services, and insurance coverage *because of* these provisions, particularly those for whom religiously-affiliated medical providers are the only available options, and attendant public health costs." ECF No. 109 at 67 (emphasis added). But HHS considered

comments like those that Plaintiffs identify. *See* 85 Fed. Reg. at 37,239. HHS considered comments indicating that the agency "should conduct a cost-benefit analysis specifically on the impact of adopting Title IX's religious exemptions." *Id*. But HHS explained that there could not plausibly be any harms to individuals or other costs *because of* the new § 92.6(b) since the 2020 Rule does not create any new religious or abortion exemption. *See id*. Instead, the new § 92.6(b) simply "affirms that [HHS] will only enforce Section 1557 consistent with the statutory provisions of Title IX" that Section 1557 incorporates. *Id*. Again, the 2020 Rule merely provides that Section 1557 does not apply "[i]nsofar as the application of the [antidiscrimination] requirement" under Title IX "would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections" provided by Title IX. 85 Fed. Reg. 37,245 (§ 92.6(b)). Plaintiffs have not explained how HHS entirely failed to consider any important part of the problem in light of this restrained and common sense policy. *See id*.

HHS also addressed this issue by discussing the evidence it received from healthcare providers that showed a widespread practice among religious institutions of adhering to nondiscrimination principles and seeking only narrow exemptions from providing particular types of services due to sincere religious objections. 85 Fed. Reg. at 37,206. HHS reasonably concluded that accommodating conscience objections is a legitimate goal that should have been more clearly emphasized than in the 2016 Rule, and that including religious exemptions is unlikely to lead to widespread diminishing of healthcare options for individuals.

V. The Court Should Consider Remand without Vacatur if it Determines that HHS Erred in Violation of the APA; The 2020 Rule's Provisions are Severable

If this Court finds that any provision of the 2020 Rule is "potentially lawful but insufficiently or inappropriately explained," which it is not, the Court should remand without vacating the problematic aspect of the 2020 Rule to the extent that "'there is at least a serious possibility that the agency will be able to substantiate its decision' given an opportunity to do so, and . . . vacating would be 'disruptive.'" *Radio-Television News Directors Ass'n v. FCC*, 184 F.3d 872, 888 (D.C. Cir. 1999) (quoting *Allied-Signal, Inc v. NRC*, 988 F.2d 146, 151 (D.C. Cir. 1993)).

Here, vacating any provision of the 2020 Rule would result in resurrecting a regulation that has itself been partially vacated and could accordingly lead to confusing results. *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, Inc. v. Azar*, 414 F. Supp. 3d 928, 945 (N.D. Tex. 2019). The Court should avoid this disruptive scenario by carefully considering whether remand without vacatur might be the appropriate remedy, if it concludes that the agency erred in any way (which it did not).

Should the Court determine that vacatur of any portion of the 2020 Rule is necessary, the Court should sever and vacate only the offending portion. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988). There is a "strong presumption of severability." *Barr v. Am. Ass'n of Political Consultants, Inc.*, 140 S. Ct. 2335, 2350 (2020). And here, HHS made its intention that the provisions of the 2020 Rule are severable explicit. *See* 85 Fed. Reg. 37,245 (45 C.F.R. § 92.3(d)).

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs' motion for summary judgment and grant summary judgment for Defendants.[17]

[17] The Second Circuit has "sanctioned a sua sponte award by the court of summary judgment to a non-moving party where it appeared from the papers, affidavits and other proofs submitted by the parties that there were no disputed issues of material fact and that judgment for the non-moving party would be appropriate as a matter of law." *Lowenschuss v. Kane*, 520 F.2d 255, 261 (2d Cir. 1975); *see also Jackson v. Nassau Cty Bd. of Sup'rs*, 818 F. Supp. 509, 535–36 (E.D.N.Y. 1993) ("The weight of authority is that summary judgment may be rendered in favor of the opposing party even though that party has made no formal cross-motion under Rule 56."). A *g*rant of summary judgment to Defendants is especially appropriate here as this is an APA case where there can be no dispute of fact for trial; "[s]ummary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). If Plaintiffs have failed to meet their burden of demonstrating that Defendants violated the APA, the Court should accordingly enter summary judgment for Defendants.

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Respectfully submitted,

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