

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

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

Case No. 1:20-cv-5583-AKH

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

Perhaps recognizing that, “[a]t present, this case is riddled with contingencies and speculation that impede judicial review,” *Trump v. New York*, 141 S. Ct. 530, 535 (2020), Plaintiffs invite this Court to adopt several novel theories of standing that disregard well-established standing law. First, they declare that they will incur costs associated with “educating the public about a new administrative rule.” ECF No. 128 at 6 (citation omitted); *see id.* at 5-9. Second, they declare that they will incur costs associated with enforcing state law. *See id.* at 9-14.

But standing requires concrete and particularized imminent injuries fairly traceable to each claim Plaintiffs seek to press and their alleged anticipated expenditures fall far short of this requirement. Indeed, granting Plaintiffs Article III standing to challenge federal regulations or statutes based on these types of injuries would effectively render standing a nullity.

Plaintiffs’ first theory is particularly expansive. If a plaintiff merely needs to anticipate incurring costs to educate the public about a new administrative rule, the New York Times, West, and Lexis would have standing to challenge any new statute or regulation before its effective date based on anticipated costs in reporting the change. Any special interest organization would have standing to challenge any policy it disagreed with based on anticipated costs that it no doubt would occur in educating, advocating, and lobbying. But that is not the law. *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972).

The same is true for Plaintiffs’ anticipated expenditures in enforcing state law. Under Plaintiffs’ reasoning, nothing would stop them from challenging any federal statute or regulation that they disagreed with and believed insufficiently regulates harms in their states. All Plaintiffs would have to do is pass their own laws—or provide declarations declaring they intend to pass their own laws—to address the conduct that they think the federal government should have addressed and then seek review of the federal action. That, too, is not the law. “[T]o find standing based upon [these] kind[s] of interest[s] ‘would significantly alter the allocation of power at the national level, with a shift away from a democratic form of government.’” *Carney v. Adams*, 141

S. Ct. 493, 499 (2020) (quoting *United States v. Richardson*, 418 U.S. 166, 188 (1974) (Powell, J., concurring)).

Plaintiffs “must demonstrate standing for each claim [they] seek[] to press,” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006) (citation omitted), but argue that their education-expense and enforcement-expense based theories effectively permit them to bypass that requirement entirely and assert that they will incur harms based on “the totality of the changes adopted by the 2020 Rule,” no matter what they might be, ECF No. 128 at 7. This reasoning should give the Court pause that something is awry.

Contrary to Plaintiffs’ theories, it is well-established that a plaintiff “cannot manufacture standing by choosing to make expenditures based on hypothetical future harm that is not” imminent. *Clapper v. Amnesty Intern. USA*, 568 U.S. 398, 402 (2013). Instead, Plaintiffs must allege imminent injury due to each challenged provision of the 2020 Rule with enough clarity to indicate that, later in the litigation, they will present “concrete evidence to substantiate their fears.” *See id.* at 420. Because they have not done so, this Court should dismiss Plaintiffs’ Complaint.

Even assuming Plaintiffs have established standing to press any claims, Plaintiffs have failed to overcome the strong presumption that the challenged regulation is not subject to abstract pre-enforcement review. Because many of their claims are not ripe for review, this Court should dismiss those claims until HHS crystalizes its policy in a manner that makes it clear that there is an actual dispute between HHS and Plaintiffs over underlying issues.

ARGUMENT

I. Plaintiffs Lack Standing to Raise Any of their Claims

To understand the extraordinary breadth of Plaintiff States' standing arguments, this Court need look no further than their own opposition brief.

a. Claims Related to HHS's Decision Not to Define "On the Basis of Sex" by Rule

1. *Increased Costs to State-Funded Health Care Programs*¹

Plaintiffs have failed to overcome Defendants' arguments that Plaintiffs lack standing to raise claims related to HHS's decision not to define "on the basis of sex" by rule based on their theory that the decision will cause covered entities to discriminate in a manner that harms residents of Plaintiff States and ultimately Plaintiff States themselves. *First*, Plaintiffs fail to meaningfully distinguish this case from *XY Planning Network, LLC v. SEC*, 963 F.3d 244 (2d Cir. 2020). Defendants previously explained that Plaintiffs have failed to allege the "fairly direct link" between the challenged regulation and increased costs that *XY Planning* requires. *See id.* at 252-53; ECF No. 113 at 11. Plaintiffs' only response is that "*XY Planning* addressed state plaintiffs' alleged standing resulting from a loss of tax revenue attributable to a challenged rule," while Plaintiffs here base their standing on purported "injuries resulting from public health costs and other financial injuries traceable to the 2020 Rule." ECF No. 128 at 16. But Plaintiffs do not even try to explain why this distinction matters. *See id.* In fact, there is no meaningful distinction between loss of future tax revenue and increased future cost to public health benefit programs, and, as such, *XY Planning* bars standing here. *See Commonwealth v. U.S. Dep't of Educ.*, 340 F. Supp. 3d 7, 17 (D.D.C. 2018) ("An increase in the payment of government benefits" is just "like a decrease in tax revenues.").

¹ The Complaint alleged and Defendants' Memorandum in Support of their Motion to Dismiss addressed speculative harms to Plaintiffs' public hospitals. *See* Compl. ¶ 253. Since Plaintiffs forfeited this claim at the summary judgment stage, Defendants need not address it here as it is ultimately moot. *See* ECF No. 130 at 20 n.5.

Second, Plaintiffs effectively concede that HHS’s decision not to define “on the basis of sex” by rule is unlikely to cause them imminent injuries in light of their arguments about the implications of *Bostock*. As Defendants explained, the Complaint made “no effort to explain why providers or insurers would be willing to risk revising their practices or policies to discriminate against LGBTQ individuals in light of the Supreme Court’s recent guidance in *Bostock* and the very arguments they make in this case” that “sex” must incorporate gender identity and sexual orientation discrimination. *See Washington v. U.S. Dep’t of Health and Human Servs.*, 2020 WL 5095467, at *8 (W.D. Wash. Aug. 28, 2020); ECF No. 113 at 13-14. Plaintiffs entirely fail to address this argument anywhere in their response brief, effectively conceding that they cannot establish an imminent concrete injury from HHS’s decision not to define “on the basis of sex” by rule. *See generally* ECF No. 128; *see also Zoulas v. N.Y.C. Dep’t of Educ.*, 400 F. Supp. 3d 25, 61 n.9 (S.D.N.Y. 2019) (quoting *Lipton v. Cty. of Orange, N.Y.*, 315 F. Supp. 2d 434, 446 (S.D.N.Y. 2004) (“This Court . . . will[] deem a claim abandoned when a plaintiff fails to respond to a defendant’s argument that the claim should be dismissed.”)).

Third, Defendants argued that the Plaintiff States’ own laws and regulations prohibiting the very discrimination that they believe the 2020 Rule will “invite” adds to the extraordinary speculation involved in asserting that the 2020 Rule will result in imminent harms to Plaintiffs’ residents in a manner that will trickle up to impose discernable costs on Plaintiff States’ state-funded health care programs. *See* ECF No. 113 at 14. Plaintiffs provide three responses to this argument, each of which fails. As an initial matter, they say that “as alleged in the Complaint, the Rule predicts that covered entities are likely to reduce protections in response to the Rule.” ECF No. 128 at 11 (citing Compl. ¶ 135).² Not only did HHS say no such thing, but the paragraphs of the Complaint that Plaintiffs cite do not allege this either. Paragraph 135 of the Complaint alleges that HHS said 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

² Plaintiffs also cite paragraphs 136 and 181 of the Complaint, involving allegations related to LEP individuals. Defendants will address these allegations *infra* note 11.

who would no longer receive those benefits after publication of this rule.” Compl. ¶ 135 (quoting 85 Fed. Reg. 37,225). The fact that HHS lacked data to analyze the impact of the 2020 Rule’s decision not to define “on the basis of sex” is not a “prediction” at all—let alone a “predict[ion] that covered entities are likely to reduce protections as a result of the rule.” See ECF No. 128 at 11. Furthermore, this statement is “in no way particular to the [Plaintiff States] or the particular [residents] on which [Plaintiffs] base[] [their] standing arguments.” See *Washington*, 2020 WL 5095467, at *9. To the contrary, HHS’s analysis speculated that the places least likely to see any changes in covered entities’ conduct would be in States with comprehensive state antidiscrimination protections like the Plaintiff States. See 85 Fed. Reg. at 37,237 (“some covered entities will avoid incurring training expenses . . . because several States,” like all of the Plaintiff States,³ “with large populations already” have comprehensive state antidiscrimination requirements implying no discernable change in governing law for covered entities in these states).⁴ What is more, part of the reason that HHS lacked data to analyze the effect of its decision not to define “on the basis of sex” by rule in areas outside of Plaintiff States with less comprehensive state laws is because it could not predict how courts would construe the meaning of the term in Title IX or Section 1557 in the future. See *id.*

Next, Plaintiffs say that “even though most of the Plaintiff States have prohibitions against health care discrimination, such protections are not necessarily identical to the Section 1557 protections eliminated by the Rule.”⁵ ECF No. 128 at 11 (citing Compl. ¶¶ 175, 248). But this

³ See Compl. ¶ 175 n.38.

⁴ “[A]s matters of public record, statements in the Federal Register can be examined in 12(b)(6) review” and on 12(b)(1) review, which more broadly permits the Court to examine matters outside the pleadings to ensure itself of jurisdiction. See *Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 n.6 (D.C. Cir. 1993).

⁵ Defendants dispute Plaintiffs’ characterization of HHS’s decision not to define “on the basis of sex” by rule as having “eliminated” protections that are provided by Section 1557. HHS lacks the authority to “eliminate” protections that Congress provided in Section 1557. Plaintiffs’ characterization elides an agency’s broad discretion to proceed by rulemaking or adjudication in construing a statute. *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). As HHS explained, just because the agency “does not adopt a position” on the scope of Section 1557 sex discrimination

statement is directly contradicted by the allegations of the Complaint cited in support. For example, the Complaint actually alleged that “[t]he 2016 Rule established comprehensive anti-discrimination protections in HHS’s Section 1557 implementing regulations *that have been coextensive with many state anti-discrimination protections.*” Compl. ¶ 175 (emphasis added).⁶ Because Plaintiffs bear the burden of proof and persuasion that this Court has subject matter jurisdiction, they, at a minimum, must identify any purported difference between their respective State’s anti-discrimination provisions and Section 1557 and explain how those differences establish an imminent injury fairly traceable to each provision of the 2020 Rule that they challenge. Plaintiffs have not met that burden.

Finally, Plaintiffs say “the States cannot impose the same remedies as HHS, which can suspend or terminate federal financial assistance for violations of its regulations.” ECF No. 128 at 11. But common sense dictates that whether insurers or healthcare providers subject to state law in Plaintiff States will imminently discriminate against fourth parties in a manner causing imminent costs to the Plaintiffs’ programs does not turn on the remedies available to HHS; it turns on the implications of violating State law, which Plaintiffs do not even begin to discuss. Without concrete evidence or any explanation to the contrary, the presumption in a standing analysis like this one is that regulated entities will comply with state law. So, at a minimum, Plaintiffs have failed to meet their burden of persuasion on this matter.

Fourth, Defendants explained that Plaintiffs’ arguments must be disposed of in light of *Simon v. E. Kentucky Welfare Rights Organization*, 426 U.S. 26 (1976). *See* ECF No. 113 at 15-16. *Simon* prohibits Plaintiffs from establishing standing based on the very type of arguments—purported government “encouragement” of third-party conduct—that Plaintiffs advance in this case. Because Plaintiffs fail to address or distinguish *Simon* in their response, the Court should dismiss their Complaint accordingly. *See Lipton*, 315 F. Supp. 2d at 446.

by rule, “it does not mean that OCR could not consider [any such] claims of discrimination.” 84 Fed. Reg. at 27,870 n.159.

⁶ Defendants have reviewed paragraph 248, which Plaintiffs also cite in support of their statement, *see* ECF No. 128 at 11, and cannot fathom how it has any relevance. *See* Compl. ¶ 248.

Fifth, Defendants explained that it is well-established that confusion or uncertainty stemming from ambiguities in laws or regulations is not an injury that can form the basis of Article III standing. ECF No. 113 at 16-17. Permitting plaintiffs who are generally confused about the requirements of a statute or a regulation to come to federal court just to resolve that abstract confusion would entirely undermine Article III's purpose of avoiding advisory opinions; any advisory opinion reduces uncertainty about ambiguity in the law. Plaintiffs concede that confusion does not permit a plaintiff access to federal court. ECF No. 128 at 31-32. But Plaintiffs appear to believe they can nonetheless invoke this Court's jurisdiction based on their independent decision to incur costs to mitigate the purported confusion by explaining the requirements of *state* law. Yet these transitive standing arguments have been squarely rejected by the Supreme Court. *See Clapper*, 568 U.S. at 417 n.7. If generalized confusion and uncertainty is not sufficient to support standing to sue the federal government, common sense dictates that a State's independent decision to incur costs to minimize any confusion or uncertainty does "not establish an injury that is fairly traceable to the" federal government defendant because it is based on the State's perception of and desire to address third parties' confusion as to the requirements of state law. *See id.*; *see also Habeas Corpus Resource Ctr. v. DOJ*, 816 F.3d 1241, 1251 (9th Cir. 2016).

Sixth, Plaintiffs fail to distinguish *Clapper*. Plaintiffs say that "[i]t is unreasonable to assume, as Defendants urge . . . , that newly exempted insurers will *never* deny or limit coverage to an individual on a discriminatory basis."⁷ ECF No. 128 at 21-22. Defendants have never urged that it is implausible that some covered entity *might* engage in conduct some day that it would not have engaged in had HHS decided to maintain the 2016 Rule's definition of "sex" as partially vacated by a federal district court. Indeed, Plaintiffs' Complaint alleges that HHS lacked the data necessary to draw concrete conclusions about some implications of the 2020 Rule. Compl.¶ 135. But Plaintiffs' burden in establishing an *imminent* injury is much greater than asserting that it is reasonable to assume that some entity might some day engage in conduct that might trickle up to

⁷ Again, HHS disputes Plaintiffs' characterization of its decision not to define "on the basis of sex" by rule as an exemption. *See supra* n.5.

harm the States due to HHS's decision not to define "on the basis of sex" by rule. In *Clapper*, the Supreme Court held that the plaintiffs could not "establish injury in fact because there is an objectively reasonable likelihood" of future injury in light of a new statute. 568 U.S. at 402. Plaintiffs have failed to explain why the same reasoning is not applicable here. "Such 'some day'" allegations—"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." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 565 (1992). To find standing based on Plaintiffs' concern that somebody might discriminate some day would entirely undermine Article III's requirement that the federal courts are reserved for actual cases or controversies. When Plaintiffs are able to identify an *imminent*—not a "some day"—concrete injury, "the scope of the controversy [will be] reduced to manageable proportions, and its factual components [can be] fleshed out." *Lujan v. Nat'l Wildlife Fed.*, 497 U.S. 871, 891 (1990).

Plaintiffs also try to distinguish *Clapper* by claiming that they "are not asserting standing based on their own 'subjective apprehensions,' . . . but on the substantial likelihood that they will suffer injuries to their proprietary and quasi-sovereign interests, based, in part, on the predictable fear and confusion of their residents, providers, and regulated entities traceable to the Rule." ECF No. 128 at 28. But that injury is indistinguishable from the injury alleged by the plaintiff Amnesty International USA in *Clapper*. Amnesty International claimed that it too would incur costs based on not only its own subjective apprehensions, but the substantial likelihood that it would suffer injuries in the form of increased costs because "third parties might be disinclined to speak with them due to surveillance." *See* 568 U.S. at 417 n.7. The Supreme Court explained that "[t]o the extent that such assertions are based on anything other than conjecture, . . . they do not establish injury that is fairly traceable to" the challenged statute "because they are based on third parties' subjective fear of surveillance." *Id.* Just as Plaintiffs here assert injuries stemming from the fear and confusion of third parties, so too did the plaintiff in *Clapper*. *Id.* Plaintiffs have not presented a basis for undermining the requirement that they present "concrete evidence to substantiate their fears"—whether the fears are theirs alone or also shared by their residents. *See id.* at 420.

Seventh, Plaintiffs fail to meaningfully address redressability. ECF No. 18-20. Plaintiffs assume for the sake of argument the indisputable fact that “vacatur of the 2020 Rule would not restore the phrases ‘gender identity’ and ‘termination of pregnancy’ struck from the 2016 Rule by [a federal] district court.” ECF No. 128 at 27 (citation omitted). “[T]he restored definition would once again enumerate [only] discrimination based on ‘pregnancy, false pregnancy, or recovery therefrom, childbirth or related medical conditions, [and] sex stereotyping’ as forms of prohibited discrimination on the basis of sex.” *Id.* (citation omitted). But Defendants explained that the force of all of Plaintiffs’ allegations of harm in the Complaint are rooted in hypothetical future LGBTQ discrimination, not these other types of discrimination. *See generally* Compl. Plaintiffs say that resurrecting the partially-vacated definition would “reduce the States’ harms incurred in responding to confusion by residents and regulated entities caused by the definition’s rescission.” ECF No. 128 at 27. Even assuming that addressing regulatory uncertainty is a legally cognizable injury or an injury fairly traceable to the federal Defendants—which it is not, *see Habeas Corpus Resource Ctr.*, 816 F.3d at 1251—Plaintiffs fail to establish how a rule that defines “on the basis of sex” to include only some, but not all, of the types of discrimination that they claim sex discrimination encompasses is less confusing than no definition at all (which could encompass all the types of discrimination covered by Section 1557 itself). *See* ECF No. 128 at 27.

2. *Increased Education and Enforcement Costs*

Plaintiffs explain that they have decided to incur costs educating their residents about the requirements of state law and intend to incur future enforcement costs once HHS’s decision not to define “sex” by rule is in effect. *See* ECF No. 128 at 5-14. But as described *supra* at 3-8, Plaintiffs have offered nothing but speculation that HHS’s decision not to define “on the basis of sex” by rule will lead to any *real* harms. And it is well-established that Plaintiffs “cannot manufacture standing by choosing to make expenditures” or asserting that they will take enforcement actions in the future “based on hypothetical future harm” when they have not established that real future harm is imminent. *See Clapper*, 568 U.S. at 402. Indeed, a closer look at some of Plaintiffs’

arguments addressing these purported injuries reveals that they cannot form the basis of Article III standing.

- i. *Plaintiffs' Intentions to Make Expenditures to Educate the Public About State Law Once HHS's Decision Not to Define "On the Basis of Sex" by Rule is Effective Does Not Represent A Legally Cognizable Injury Fairly Traceable to the Decision or to Any Provision of the 2020 Rule*

The Court must reject Plaintiffs' baseless efforts to bypass Article III's requirement that Plaintiffs suffer a concrete and particularized imminent injury fairly traceable to the challenged provisions of the 2020 Rule by doing no more than planning to incur costs in "educating the public about a new administrative rule." ECF No. 128 at 6 (citation omitted). Plaintiffs purported interest in educating their residents and regulated entities about the 2020 Rule "can hardly be called personalized to the" Plaintiff States. *See In re U.S. Catholic Conference (USCC)*, 885 F.2d 1020, 1026 (2d Cir. 1989). It "could be asserted by any member of the public who disagrees with the views of [HHS]" and decides to incur costs to educate the public about the new rule. *See id.* "Affording standing on th[is] basis would lack a limiting principle, and would effectively give standing to any spectator who" expresses an intent to incur costs educating the public about impending federal administrative action. *See id.* at 1030. Under Plaintiffs' erroneous theory, the New York Times would have standing to challenge any rule any agency promulgates because of the costs it might anticipate incurring in reporting about the rule if it goes into effect. West and Lexis would have standing to challenge any regulation issued by any agency based on the costs they would incur in printing supplements to their annotated codes and shipping them to law libraries should any rule go into effect.

If the plaintiffs in *Clapper* could not "manufacture standing by choosing to make expenditures based on hypothetical future harm that [wa]s not certainly impending," *see Clapper*, 568 U.S. at 402, the Plaintiff States cannot manufacture standing by choosing to make expenditures based not even on hypothetical future harm but merely to effectuate an interest in educating the public. "[T]o 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.'" *Carmey*,

141 S. Ct. at 499 (quoting *Richardson*, 418 U.S. at 188) (Powell, J., concurring)). Courts must “be ever mindful of the contradictions that would arise if a democracy were to permit general oversight of the elected branches of government by a nonrepresentative, and in large measure insulated, judicial branch.” *Id.* (citation omitted).

Plaintiffs fail to identify a single appellate decision supporting their theory. Appellate courts to have considered the issue have found that the Supreme Court’s “refusal to serve as a forum for generalized grievances,” see *Lance v Coffman*, 549 U.S. 437, 439 (2007), would be upended by finding standing based on a mere interest in educating the public about the fact that the government made a certain decision. For example, in *Food & Water Watch, Inc v. Vilsack*, 808 F.3d 905 (D.C. Cir. 2015), an advocacy group challenged USDA poultry inspection system regulations. The group claimed that if the rule went into effect the group “would have to increase the resources that it spends on educating the general public and its members that [the new rules] do not allow for the inspection of poultry product prescribed by the” Poultry Products Inspection Act. *Id.* at 920. “Additionally,” the group asserted that it “will spend time and money on increasing its efforts to educate members of the public that just because a poultry product has a USDA inspection legend does not mean that it is not adulterated and is wholesome.” *Id.* The court found that the group “alleged no more than an abstract injury to its interests that is insufficient to support standing.” *Id.* at 921.

Similarly, in *Keep Chicago Livable v. City of Chicago*, 913 F.3d 618 (7th Cir. 2019), a group challenged the constitutionality of a Chicago ordinance governing home sharing. The plaintiff was “a non-profit organization that focuses on educating home-sharing hosts.” *Id.* at 621. The group’s standing theory was “that the alleged uncertainty around the Ordinance’s constitutionality burdens the organization’s education and advocacy mission.” *Id.* at 624. Specifically, the organization’s efforts in “educating and advising hosts and putative hosts as to their proper rights and duties under the new law” would be hindered. *Id.* “But nowhere [did] the organization allege that it own[ed] or rent[ed] property or otherwise engage[d] in activity regulated

or protected by the Ordinance.” *Id.* These “allegations in the original and amended complaints f[e]ll short of establishing standing.” *Id.*

In *Habeas Corpus Resource Ctr. v. DOJ*, 816 F.3d 1241 (9th Cir. 2016), groups providing legal representation to capital defendants challenged DOJ regulations implementing a statute permitting “fast tracking” of federal habeas cases for certain capital prisoners. The groups contended “that they had standing to challenge the Final Regulations because the Final Regulations are vague, and th[ey] must advise and assist their death-sentenced clients without knowing, in advance, whether the Attorney General” would take certain actions indicating that the statute would “therefore apply to their clients’ federal habeas cases.” *Id.* at 1249. Just as it may be reasonable for the Plaintiff States to incur certain administrative costs to advise their residents and regulated entities about state law in light of perceived uncertainty created by HHS’s decisions in the 2020 Rule, in *Habeas Corpus Resource Center*, the Court noted that “it may be eminently reasonable for the [plaintiffs] to take measures to prevent or mitigate the harm their clients may face due to the possible future application of [the statute] to their federal habeas cases.” *See id.* at 1251. But taking those measures did not confer standing on the *Habeas Corpus Resource Center* plaintiffs. *Id.* “[E]ven if their clients face[d] a ‘certainly impending’ harm from ‘confusion’ caused by the [challenged regulations, the groups] ha[d] given [the court] no reason to believe that they can parlay such harm into an injury of their own.” *Id.*

Plaintiffs assert that their anticipated education costs “must be incurred in response to the totality of the changes by the 2020 Rule.” ECF No. 128 at 7. But “the 2020 Rule does not regulate [Plaintiffs’] conduct, force [Plaintiffs] to change [their] policies or practices, or impact [Plaintiffs’] law[s]. To the contrary, the 2020 Rule specifically states that it shall not be construed to ‘supersede State laws.’” *Washington*, 2020 WL 5095467, at *11. Plaintiffs continue to fail to identify anything in the 2020 Rule that requires them to incur any education costs.

To be sure, as Plaintiffs point out, the 2020 Rule did suggest that “*covered entities* will face ‘additional costs’ ‘regarding training and revision of policies and procedures.’” ECF No. 128 at 8 (emphasis added) (quoting 85 Fed. Reg. at 37,163). But even assuming that these training costs

would be sufficient to confer standing on a covered entity to challenge the 2020 Rule, Plaintiffs do not allege increased administrative costs in their role as *covered entities*. See ECF No. 128.⁸ They allege decisions to incur costs stemming from their purported obligations arising under their own state laws to educate the public about state law. See *Washington*, 2020 WL 5095467, at *11. HHS was addressing potential training costs that might affect *covered entities*—*i.e.*, the entities that are themselves the “object of the action (or forgone action) at issue.” See *Defenders of Wildlife*, 504 U.S. at 562. Specifically, HHS “estimated that 275,002 covered entities would train their employees on the rule’s requirements in general.” 85 Fed. Reg. at 37,236. As covered entities are the regulated entities directly affected by and responsible for complying with the 2020 Rule, HHS considered the training costs that they might incur in making their staffs aware of the 2020 Rule’s changes. See *id.* But Plaintiff State Agencies’ purported costs are not fairly traceable to the 2020 Rule because they stem not from the 2020 Rule but from the obligations that state law imposes on those agencies. HHS is not responsible for the content of state law. See, *e.g.*, ECF No. 128 at 8 (quoting Compl. ¶ 200) (explaining that “Minnesota’s Department of Human Rights” feels itself obligated “to ensure that the public understands they remain protected by state law”).

What is more, HHS’s analysis assumed that “some covered entities will avoid incurring training expenses . . . because several States,” like all of the Plaintiff States,⁹ “with large populations already” have comprehensive state antidiscrimination requirements implying no discernable change in law for the covered entities in these states. See 85 Fed. Reg. at 37,237. In light of HHS’s anticipation that nothing would change in Plaintiff States, it is hard to understand why the States are deciding to spend additional resources on education activities. See *Clapper*,

⁸ The fact that some Plaintiff States may operate covered entities is immaterial. Not only have the Plaintiff States failed to clearly allege an injury based on their operation of covered entities, HHS’s analysis presumed that covered entities operating in States with comprehensive state antidiscrimination laws—like all of the Plaintiff States, see Compl. ¶ 175 n.38—“will avoid incurring training expenses” in light of the low likelihood that the rule would result in material changes in governing law for covered entities in those states, see 85 Fed. Reg. at 37,237.

⁹ See Compl. ¶ 175 n.38.

568 U.S. at 402 (Plaintiffs “cannot manufacture standing by choosing to make expenditures based on hypothetical future harm that is not certainly impending”).

ii. Plaintiffs’ Intentions to Take Enforcement Actions Under State Law at some Undefined Future Time After HHS’s Decision not to Define “On the Basis of Sex” Becomes Effective Does Not Represent A Legally Cognizable Injury Fairly Traceable to HHS’s Decision or Any Provision of the 2020 Rule

As Defendants explained, “[a]lthough it may well be prudent on [a state’s] part to incur [enforcement] costs to” ensure compliance by regulated entities with a state’s own antidiscrimination laws, Plaintiffs “do[] not point to any provision in the 2020 Rule that requires [them] to incur those costs beyond the general fact that the 2020 Rule is a new agency regulation that includes differences from the 2016 Rule.” *See Washington*, 2020 WL 5095467, at *10; *see also* ECF No. 113 at 24. So the costs Plaintiffs incur to enforce their respective state laws are derived from their independent state laws and enforcement priorities, not from any challenged federal action. Plaintiffs counter that they “can[not] simply ignore civil rights violations” because “the Complaint plausibly alleges that many of the Plaintiffs are required to investigate meritorious complaints of health care discrimination and lack discretion to ‘decide’ not to incur increased investigation and enforcement costs.” ECF No. 128 at 9. Leaving aside the fact that Plaintiffs never establish the imminence of any change in policies or practices by any regulated entities in their states that they would have to incur enforcement costs to counteract, Plaintiffs ignore the fact that Plaintiffs’ purported “requirements” to investigate meritorious complaints of health care discrimination are self-imposed. For example, Plaintiffs point out that “[t]he California Department of Fair Employment and Housing does not have discretion to decline to process complaints within its jurisdiction, so any increase in complaints necessarily increases its workload.” *Id.* at 9-10 (quoting ¶ 215). But the California Department of Fair Employment and Housing is an arm of Plaintiff State of California. So assuming that it is obligated to process complaints, any such obligation would arise from state law—a state law that Plaintiff State of California itself wrote. Plaintiffs cannot create their own purported obligation and then seriously assert that their hands are tied in the matter. Plaintiffs do not point to anything in the 2020 Rule

that creates any obligation for states to maintain any particular antidiscrimination law or to enforce them in any particular way. “Affording standing on th[is] basis would lack a limiting principle, and would effectively give standing to any spectator [State] who” expresses an intent to incur increased enforcement costs to remediate a public policy issue in its borders any time that Congress passes a new statute or an agency promulgates a new regulation. *See U.S. Catholic Conference*, 885 F.2d at 1030. Indeed, Plaintiffs’ theory is so expansive that even if a new federal statute or regulation proscribed *more* conduct than was previously proscribed at the federal level, a state could always assert this theory of standing to address purported imminent injuries from future harms that an even-more encompassing federal action could or would have addressed. This is not the law; “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 (quoting *Richardson*, 418 U.S. at 188).

In any event, Defendants also explained that *Diamond v. Charles* prevents Plaintiffs from invoking their “interests in enforcement” of Section 1557 by HHS as a basis of standing to seek vacatur of any part of the 2020 Rule and resurrection of any part of the 2016 Rule. 476 U.S. 54, 63 (1986). *See* ECF No. 113 at 25. Plaintiffs cannot “compel [HHS] to enforce [its Section 1557 regulations] . . . because ‘a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.’” *Diamond*, 476 U.S. at 63 (quoting *Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973)). *See* ECF No. 113 at 25. Because Plaintiffs can only speculate as to how HHS will enforce its Section 1557 regulations in the future, Plaintiffs cannot rely on an interest in HHS enforcement to establish standing.¹⁰ Plaintiffs’ response is little more than a

¹⁰ Plaintiffs pull out several regulatory provisions and point to provisions in OCR’s “Case Resolution Manual for Civil Rights Investigations” indicating that OCR will investigate complaints. *See* ECF No. 128 at 12. Plaintiffs miss the point. OCR is committed to the legal resolution of complaints within its jurisdiction. But Defendants explained that OCR has discretion in complaint management in light of the agency’s limited resources. *See* ECF No. 25 n.4. As the Supreme Court explained in *Heckler v. Chaney*, in managing requests for enforcement action, an “agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency’s overall policies, and, indeed,

mischaracterization of the facts of *Diamond*. ECF No. 128 at 14. Specifically, Plaintiffs characterize *Diamond* as “simply” holding “that a pediatrician’s general interests in enforcing an abortion statute ‘as a doctor, a father, and a protector of the unborn’ did not give him standing to defend it, as the doctor alleged no financial impact resulting from the statute.” *Id.* (quoting *Diamond*, 476 U.S. at 65-66). But *Diamond*’s holding was not so limited.

The Court in *Diamond* actually explained that “Doctor Diamond,” who was attempting to defend an Illinois law criminalizing abortion under certain circumstances against attack from appellees—physicians who faced prosecution under the law—could not “equate his position with that of appellees, the physicians who instituted th[e] suit.” 476 U.S. at 64. “Appellees . . . had standing to bring suit against the state officials who were charged with enforcing the Abortion Law because appellees faced possible criminal prosecution.” *Id.* “The conflict between state officials empowered to enforce a law and private parties subject to prosecution under the law is a classic ‘case’ or ‘controversy’ within the meaning of Art. III.” *Id.*; see also *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 164-67 (2014). Here, Plaintiffs do not argue that they are challenging the 2020 Rule based on an interest in avoiding prosecution under Section 1557.

The Court went on to explain that “[t]he conflict presented by *Diamond* is different. Were the Abortion Law to be held to be constitutional, *Diamond* could not compel the State to enforce it against appellees because ‘a private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.’” *Diamond*, 476 U.S. at 64 (quoting *Linda R.S.*, 40 U.S. at 619). In this case, Plaintiffs have not meaningfully explained how they are in a different position from Doctor *Diamond*. To be sure, Doctor *Diamond* may have been little more than “a doctor, a

whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing.” 470 U.S. 821, 831 (1985). Nothing Plaintiffs cite is to the contrary. Indeed, OCR’s “Case Resolution Manual for Civil Rights Investigations,” which is not legally binding on HHS, see *Aulenback, Inc. v. FHA*, 103 F.3d 156, 166-69 (D.C. Cir. 1997), and was written before Congress enacted Section 1557, emphasizes that a “[s]trategic use of resources is critical not only to the success of individual investigators but also to OCR regional offices, which must consider all cases on the regional docket when allocating OCR’s key resource: staff time,” ECF No. 129-3 at 7.

father, and a protector of the unborn,” *see id.* at 66, while the Plaintiffs are States. But Congress gave the States no role whatsoever in enforcing Section 1557, like Doctor Diamond’s role in enforcing the Illinois Abortion Law. So for Section 1557 purposes Plaintiff States and Doctor Diamond are similarly situated bystanders. Just like Doctor Diamond, were this Court to vacate any part of the 2020 Rule and resuscitate any part of the 2016 Rule, the Plaintiff States “could not compel” HHS “to enforce it against” those entities that they fear will engage in hypothetical future discrimination. *See id.*

The Court did indicate that an entity enduring “a direct financial impact” from a statute or regulation may have standing to challenge it. *Id.* at 65. But Defendants have already explained that Plaintiffs do not allege a direct financial impact from HHS’s decision not to define “on the basis of sex,” but instead rest their claims of harm upon conjecture about possible third-party covered entity actions followed by further speculation about fourth-party patient and insured actions. *See supra* at 3-8; *see also* ECF No. 130 at 5-6. It is precisely because the numerous links in the chain between HHS’s decision not to define “on the basis of sex” by rule and Plaintiff’s indirect purported financial injuries are so “riddled with contingencies and speculation,” *see Trump*, 141 S. Ct. at 535, that Plaintiffs instead try to invoke these education-based and intention-to-enforce-state-law based injuries. As to the latter, *Diamond* clarifies that such an interest in HHS’s expected enforcement of Section 1557 regulations cannot form the basis of Plaintiffs’ standing. 476 U.S. at 64. And in general, Plaintiffs may not “manufacture standing by choosing to make expenditures based on hypothetical future harm that is not” imminent. *Clapper*, 568 U.S. at 402.

Plaintiffs assert that “[f]or standing purposes, it suffices that the States plausibly allege that they will likely receive, and need to process and investigate, discrimination complaints that previously could have been referred to and handled by HHS but—under [HHS’s decision not to define “on the basis of sex” by rule]—cannot be.” ECF No. 128 at 13. That is not so. *See supra* at 14-17. But even assuming that this theory suffices for standing purposes, Plaintiffs fail to

address the fact that HHS’s decision not to define “on the basis of sex” by rule does not mean it will not accept any subset of sex discrimination complaints. 84 Fed. Reg. at 27,870 n.159.

b. 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

Defendants explained that Plaintiffs failed to establish an imminent injury fairly traceable to HHS’s decision to promulgate a provision of the 2020 Rule, 45 C.F.R. § 92.6(b)—a provision prohibiting conduct in the health care setting only insofar as prohibited by the system of civil rights statutes that Section 1557 incorporates, *see* 85 Fed. Reg. at 37,245 (45 C.F.R. § 92.6(b))—for many of the same reasons that Plaintiffs failed to establish standing to challenge HHS’s decision not to define “on the basis of sex” by rule. *See* 85 Fed. Reg. at 37,245.

As Defendants explained, Plaintiffs alleged nothing more than abstract regulatory confusion and uncertainty as a result of the 2020 Rule, which is insufficient for standing or to demonstrate an imminent injury resulting from the rule. ECF No. 113 at 26-27. In response, Plaintiffs effectively concede that they have not alleged any concrete or particularized injuries stemming from this change by abandoning any purported harms to their health benefit programs and instead relying on their intent to incur education and enforcement costs, *see* ECF No. 128 at 32, which, are insufficient for standing, *see supra* at 10-18.

Plaintiffs assert that they “will incur additional costs . . . remediating additional allegations of discrimination by entities subject to federal regulatory exemptions that would have otherwise been accepted and investigated by OCR,” ECF No. 128 at 32-33, but provide no clearly alleged facts indicating that any covered entity in their states is planning on utilizing this provision to change their policies. *See Massachusetts v. HHS*, 923 F.3d 209, 223 (1st Cir. 2019). To be sure, the *Massachusetts* court explained that “a plaintiff need not demonstrate that it is literally certain that the harms they identify will come about.” ECF No. 128 at 33 (quoting *Massachusetts*, 923 F.3d at 222, 225). But that does not imply that Plaintiffs can rely on speculation that harms might come about some day to satisfy the imminence requirement. The *Massachusetts* court made that statement while explaining that once the “Commonwealth established that there is a substantial

risk that *some* women in Massachusetts will lose coverage due to the regulations” by providing evidence that “it is highly likely that at least three [specific] employers in the Commonwealth with self-insured health plans . . . will use the expanded exemptions,” the precise identities of the women were not important. *See* 923 F.3d at 223. Plaintiffs are entirely incorrect to assert that “Defendants fail to distinguish *Massachusetts*.” ECF No. 128 at 33. It is Plaintiffs that fail to address *Massachusetts*’ distinctions.

Remarkably, Plaintiffs *admit* that they are trying to invoke standing based on nothing more than their residents’ subjective “fear of encountering discrimination” even though Plaintiffs do not substantiate that fear by concretely connecting anything in the 2020 Rule to any identifiable imminent injury at the hands of a covered entity. ECF No. 128 at 33. Instead of explaining that they intend to provide “concrete evidence to substantiate their fears,” *Clapper*, 568 U.S. at 420, Plaintiffs admit that their “standing to challenge the religious and abortion exemptions does not hinge on the possibility of third-party religiously affiliated providers *actually* discriminating against LGBTQ patients,” ECF No. 128 at 33. As Defendants have explained in opposing Plaintiffs’ Motion for Summary Judgment, *see* ECF No. 130 at 11-14, Plaintiffs’ hypothetical-threat theory is foreign to Article III’s requirements; “[i]t is the *reality* of the threat of . . . injury that is relevant to the standing inquiry, not [anyone’s] subjective apprehensions,” *City of Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983) (emphasis in original). If Plaintiffs are injured by little more than the implications of “nonparanoid fear” of third-parties, “they do not establish injury that is fairly traceable to the [challenged regulations], because they are based on third parties’ subjective fears.” *Clapper*, 568 U.S. at 416, 417 n.7.

Indeed, Plaintiffs say that “the Complaint plausibly alleges that there is a ‘substantial risk’ that health care consumers will perceive that the 2020 Rule’s religious and abortion exemptions will increase the likelihood that they will be denied care for discriminatory reasons, thereby leading to increased expenditures within Plaintiffs’ public health care programs.” ECF No. 128 at 34. But even assuming the Complaint did plausibly make those allegations, they would be entirely irrelevant to Plaintiffs’ standing to challenge any provision of the 2020 Rule because Plaintiffs’

standing cannot turn on a *risk* that “health care consumers *will perceive* that the 2020 Rule” will lead to any result, *see id.*, without “concrete evidence to substantiate” those perceptions and demonstrate that future harm will imminently and actually occur, *see Clapper*, 568 U.S. at 420. Plaintiffs provide no indication that their residents’ perceptions are based on anything but conjecture. *See Massachusetts*, 923 F.3d at 223 (citation omitted) (“The imminence concept, while far reaching, is bounded by its Article III purpose: to ensure that the alleged injury is not too speculative.”) (cleaned up).

Plaintiffs claim that the “administrative record is replete with comments observing the likelihood that religiously affiliated providers will use the new exemptions to deny care.” ECF No. 128 at 34 n.11. But Plaintiffs “must seek relief for an injury that affects [them] in a ‘personal and individual way,’” *Hollingsworth v. Perry*, 570 U.S. 693, 705 (2013) (citation omitted), and Plaintiffs provide no argument or analysis indicating that anything in the comments is “particular to [Plaintiff States] or the particular [residents] on which [Plaintiffs] base[] their standing arguments,” *Washington*, 2020 WL 5095467, at *9. Indeed, Plaintiffs, who provide no analysis of these comments whatsoever, fail even to assert that any of them have provided concrete evidence of any imminent policy change due to the challenged regulation. Moreover, Plaintiffs can only speculate that any cited commenter will make an imminent policy change in their states in light of their own state antidiscrimination laws, which lack religious or abortion exemptions. *See Compl.* ¶ 175 n.38.

Plaintiffs seek refuge from Article III’s requirements in *New York v. U.S. Dep’t of Commerce*, 351 F. Supp. 3d 502, 576 (S.D.N.Y. 2019). *See* ECF No. 128 at 35. But for the reasons Defendants explained in opposing Plaintiffs’ motion for summary judgment, they cannot. *See* ECF No. 130 at 8-10.

Plaintiffs say that “[v]acatur of the 2020 Rule, which will restore provisions of the 2016 Rule, will fully redress Plaintiffs’ injuries caused by the newly created religious and abortion exemptions.” ECF No. 128 at 35. But that seems unlikely as they admit that their injuries do not stem from anything in the 2020 Rule but instead stem from third-parties’ subjective “fear of

encountering discrimination when seeking care” and things that “health care consumers will perceive that the 2020 Rule” does notwithstanding what real impact the Rule actually has on the covered entities it regulates. *See id.* at 33-34. Indeed, according to Plaintiffs’ “expert,” “the majority of transgender individuals” that fear future discrimination may very well be “unaware of” any orders stemming from litigation over Section 1557’s implementing regulations. *See* ECF No. 111-37 at ¶¶ 32-34. Plaintiffs cannot rely on speculation about “the unfettered choices made by independent actors not before the court.” *See Defs. of Wildlife*, 504 U.S. at 562 (citation omitted).

Even assuming Plaintiffs were asserting actual imminent injuries from Title IX’s religious and abortion exemptions, Plaintiffs cannot establish redressability as the plain text of the challenged provision incorporates Title IX’s rights or protections only “[i]nsofar as the application of any requirement under [the 2020 Rule] would violate, department from, or contradict definitions, exemptions affirmative rights, or protections provided by [Title IX].” 85 Fed. Reg. at 37,245 (45 C.F.R. § 92.6(b)). In other words, any injury would be attributable to Congress’s decision to place a statutory exemption in Title IX, not anything in HHS’s regulations. *See id.*; *see also id.* at 37,239 (“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.”). Vacating § 92.6(b) would not result in removing Title IX’s exemptions from the United States Code. Accordingly, it would not affect any hypothetical entity’s decision to invoke that statutory exemption if charged with discrimination in violation of Title IX as incorporated into Section 1557.

c. Claims Related to HHS’s Construction of the Scope of the term “Health Program or Activity”

Defendants explained that Plaintiffs’ allegations of injury from HHS’s construction of the scope of the term “health program or activity” is “riddled with contingencies and speculation that impede judicial review.” *See Trump*, 141 S. Ct. at 535; *see also* ECF No. 113 at 21-22. Plaintiffs lack standing to challenge HHS’s construction of the scope of the term “health program or activity” for many of the same reasons they lack standing to challenge HHS’s decision not to define “on the

basis of sex” by rule. *See supra* at 3-18. The fact remains that Plaintiffs have not identified any insurer or entity in their states that has changed its policy or practice due to HHS’s new construction of the scope of the term “health program or activity.” Plaintiffs argue that if, at some unspecified time in the future, such a change does occur, and a hypothetical resident who would have complained to OCR now complains to Plaintiff States, Plaintiffs will have standing because of the costs incurred to investigate that complaint. *See* ECF No. 113 at 22. But this scenario relies on speculation about future discrimination because Plaintiffs have failed to identify any change by any entity that might arguably have been made due to the 2020 Rule.

Assuming Plaintiffs could overcome their lack of clear allegations of imminent discrimination by any insurer, the claim also relies on additional speculation—namely, speculation about what a future hypothetical victim of discrimination by a hypothetical insurer might have done but for the 2020 Rule’s decision to define the scope of “health program or activity” to exclude certain insurers. According to Plaintiffs, this hypothetical victim knows about the existence of the state’s antidiscrimination regulatory program. So it may well be that the hypothetical victim would have always preferred to file his complaint with the state program. Alternatively, the hypothetical victim may not seek the assistance of the state at all, but may seek to remedy the hypothetical discriminatory conduct by filing an action directly in court.

Plaintiffs also assert harms to their public benefit programs from hypothetical future discrimination by entities not subject to state discrimination laws, but these harms are speculative for the same reasons. ECF No. 128 at 23.

Plaintiffs assert that they suffer an injury “[r]egardless of how any individual insurer responds to the 2020 Rule’s changes to the definition of covered entity.” ECF No. 128 at 23. But that makes no sense. If no insurer implements a discriminatory policy due to any regulatory change in the 2020 Rule, then there can be no future claims of discrimination that give rise to all of Plaintiffs’ purported some-day injuries due to the 2020 Rule. Even assuming that an insurer might some day take such an action, the point is that Plaintiffs have failed to allege the imminence of that action, which is required to establish a case or controversy within the meaning of Article III.

See supra at 8. The proper time to resolve Plaintiffs' claims is when they can establish that such harm is imminent. Plaintiffs say that "[i]f a state enforcement agency in any one of the Plaintiff States receives even one complaint against an insurer that would have previously gone to HHS, . . . Plaintiffs have standing." ECF No. 128 at 22. The key word here is "if." *See id.* Without concrete evidence that any individual insurer will imminently respond to the 2020 Rule's changes in some way that creates a victim of discrimination who decides to complain to the states and alternatively would have complained to HHS, Plaintiffs can only speculate that they will endure imminent injury due to the challenged regulation.

Plaintiffs claim that "[t]his Court is not being asked, as *Washington* suggests, to assume 'that entities who are no longer subject to Section 1557 will freely engage in discrimination against LGBTQ individuals.'" ECF No. 128 at 22 (quoting *Washington*, 2020 WL 5095667, at *12). But Plaintiffs would have to demonstrate that kind of free engagement in discrimination in order to establish the type of substantial risk of predictable future harm needed to satisfy Article III's imminent injury requirement. It is precisely this type of anticipated and predicable widespread noncompliance with the census by noncitizens in light of the Census Bureau's proposed policy that permitted the plaintiffs to have standing in *Dep't of Commerce v. New York*, 139 S. Ct. 2551 (2019). Plaintiffs admit that such free engagement in discrimination is far from predictable. *See* ECF No. 128 at 22. As such, Plaintiffs' injuries are not imminent unless and until they can demonstrate that "*any* of the States' residents [will] experience[e imminent] discrimination by" a covered entity by presenting concrete evidence that at least one entity intends to change its policy because of the 2020 Rule, and, in turn, by establishing concrete harms to the Plaintiff States from that change. *See id.*; e.g., *Massachusetts*, 923 F.3d at 223.

As Defendants explained, *Diamond* also presents a barrier to Plaintiffs' standing to challenge the 2020 Rule based on their interests in HHS's enforcement of complaints filed with OCR. *See* ECF No. 113 at 30-31. Plaintiffs say that they "do not seek a remedy compelling HHS to take any specific enforcement action." ECF No. 128 at 24. But neither did Doctor Diamond. Both Plaintiff States and plaintiff Doctor Diamond attempted to defend the existence of a code

based on their interest in enforcement of the code by an independent government. *See* 476 U.S. 64. Even if this Court vacates the 2020 Rule and resurrects any part of the 2016 Rule that Plaintiffs want, Plaintiffs' increased-enforcement-cost-based injuries rely on speculation about the manner in which HHS would process complaints under the resurrected rule. *See id.*

d. Claims Related to HHS's Construction of the Scope of Federal Entities Covered by Section 1557

Defendants explained that the Complaint is devoid of the type of clear allegations in support of standing to raise Plaintiffs' claims related to the scope of federal entities covered by Section 1557. ECF No. 113 at 29. In response, Plaintiffs assert that this change "will drastically impact the ability of victims of discrimination to obtain relief" that will ultimately trickle up to harm Plaintiffs' public health and public benefits programs. ECF No. 128 at 23-24. But Plaintiffs fail to cite a single allegation in their Complaint or any of the myriad declarations they filed to support this theory of standing. *See id.* Plaintiffs cannot rely on allegations in their brief alone. Accordingly, they have failed to "clearly allege facts demonstrating each element" of standing to press claims related to HHS's decision on this matter. *See Spokeo, Inc. v. Robbins*, 136 S.Ct. 1540, 1547 (2016) (quoting *Warth v. Seldin*, 422 U.S. at 490, 518 (1975)).

In any event, the allegations Plaintiffs make in their brief are in no way "particularized"—they do not describe how any Plaintiff State is affected "in a personal and individual way" by HHS's construction of the scope of federal entities covered by Section 1557. *Spokeo*, 136 S. Ct. at 1548 (quoting *Defs. of Wildlife*, 504 U.S. at 560 n.1). For example, Plaintiffs claim injuries stemming from hypothetical future discrimination by the "Indian Health Service" but provide no facts indicating that the Indian Health Service operates a facility in each Plaintiff State, much less explain how any such discrimination is imminently likely to occur. *See* ECF No. 128 at 23. Their assertions are "in no way particular to [Plaintiffs] or the particular [residents] on which [Plaintiff States] base[] their standing arguments." *See Washington*, 2020 WL 5095467, at *9.

Plaintiffs also fail to address Defendants' contention that the fact that federal government entities may not discriminate on the basis of sex as a result of the equal protection principles

embodied in the Fifth Amendment adds to the speculation regarding any plausible impact of this change on any Plaintiff. *See* ECF No. 128 at 24. To the extent that Plaintiffs are arguing that federal entities do not comply with the Fifth Amendment’s equal protection principles because individuals seeking to enforce it must file private lawsuits, they provide no basis to support their assertion that the federal government would willfully violate the Constitution because it is unlikely to be enforced. It is Plaintiffs, not Defendants, who bear the burden of establishing an actual or imminent nonspeculative concrete and particularized injury for each claim they seek to press.

e. Claims Related to HHS’s Construction of the Legal Standards for Enforcement of Section 1557 and HHS’s Decision Not to Take a Position by Rule Regarding Section 1557 Associational Discrimination

Defendants explained that Plaintiffs did not clearly allege facts in their Complaint supporting their standing to press the Complaint’s claims related to (1) HHS’s decision not to take a position by rule with respect to whether Section 1557 affords individuals a private right of action or compensatory damages, (2) HHS’s regulatory construction of Section 1557 requiring claims to be brought under each incorporated statute’s enforcement mechanisms, and (3) HHS’s decision not to take a position by rule as to Section 1557’s coverage of discrimination on the basis of association. ECF No. 113 at 31-32. Plaintiffs admit in a footnote that “the Complaint does not allege *specific* injuries arising from those discrete provisions.” ECF No. 128 at 7 n.3. But Plaintiffs’ burden is to “clearly allege facts,” *see Spokeo*, 136 S. Ct. at 1547 (citation omitted), “demonstrat[ing] standing for each claim [they seek] to press,” *DaimlerChrysler Corp.*, 547 U.S. at 352. Accordingly, Plaintiffs have failed in their burden and these claims must be dismissed for lack of standing.

Plaintiffs attempt to rely on their abstract interest in educating the public and others about the changes in federal law, *see* ECF No. 128 at 7 n.3, but as Defendants have explained, *see supra* at 10-14, this type of “injury,” with no limiting principle, has no place establishing standing in an Article III court. It is neither “concrete,” “particularized.,” *see Spokeo*, 136 S. Ct. at 1548-50, nor fairly traceable to anything in the 2020 Rule.

f. Claims Related to the 2020 Rule’s “Meaningful Access” Standard for Limited English Proficient Individuals and its Modifications to the Notice and Taglines Requirements

Defendants explained that Plaintiffs failed to clearly allege facts demonstrating standing to press claims related to the 2020 Rule’s “meaningful access” standard for limited English proficient individuals. *See* ECF No. 113 at 32-34. In response, Plaintiffs make many of the same errors that they have made throughout their brief. *See* ECF No. 128 at 36-38. Plaintiffs rely on their plan to educate the public about these changes, *see id.* at 36, which as explained *supra* at 10-14, cannot form the basis for standing. Plaintiffs also say that they will “expend public health resources to address the increased health disparities faced by LEP individuals,” without addressing the fact that they can only speculate as to whether any such discrimination against LEP individuals will occur. *See id.*¹¹ Plaintiffs focus on HHS’s explanation in the preamble to the 2016 Rule justifying the 2016 Rule’s requirements, *see id.* at 36-37, but do not clearly allege or explain how HHS’s modifications to the 2016 Rule’s standards in the 2020 Rule—which do not eliminate meaningful access requirements—will result in nonspeculative harm.¹²

¹¹ Plaintiffs claim that “the Rule predicts that covered entities are likely to reduce protections in response to the Rule.” ECF No. 128 at 11 (citing Compl. ¶¶ 136, 181). But the cited “predictions” are actually HHS’s own speculation that its changes to LEP meaningful access requirements “*may* impose costs, such as decreasing access to . . . healthcare by non-English speakers,” Compl. ¶ 136 (quoting 85 Fed. Reg. at 37,232) (emphasis added), or speculation that, as a result, “some unknown subset of th[e] LEP] population *may* suffer remediable grievances, but will not complain to OCR,” Compl. ¶ 181 (quoting 85 Fed. Reg. at 27,883) (emphasis added). “That kind of off-handed speculation—which was in no way particular to [Plaintiffs] or the particular [residents] on which [Plaintiffs] base[] their standing arguments, . . . does not measure up to the kind of detailed agency analysis about the expected impact of an agency regulation that courts have relied on to find standing.” *Washington*, 2020 WL 5095667, at *9.

¹² Plaintiffs state that “[n]umerous commenters warned that the 2020 Rule would likely ‘result in a number of LEP individuals being unable to access healthcare, and will contribute to discrimination and to healthcare disparities.’” ECF No. 128 at 37 n.12. But Plaintiffs, who bear the burden of demonstrating standing, make no effort to analyze what these commenters said nor provide any indication that these commenters provide concrete evidence that would substantiate fears of future harm that would be acceptable in an Article III court, as opposed to fear and conjecture alone. *See Clapper*, 568 U.S. at 420 (“[R]espondents in the present case present no concrete evidence to substantiate their fears, but instead rest on mere conjecture about possible governmental actions.”).

Plaintiffs claim that if this Court vacated the 2020 Rule, it would redress their abstract injury of intending to educate the public about the 2020 Rule. *See id.* at 38. Even assuming this injury could establish standing, which it cannot, Plaintiffs have never established why they would not have a similar desire to educate the public about this Court’s opinion vacating the 2020 Rule.

g. Claims Related to HHS’s Decision to Remove Detailed Standards for Complying with Section 1557’s Requirements as Applied to Gender-Identity Discrimination from the Regulations

Defendants explained that Plaintiffs failed to clearly allege facts demonstrating standing to press claims related to the 2020 Rule’s decision to remove from the Code of Federal Regulations detailed standards for compliance with Section 1557 related to gender-identity discrimination. *See* ECF No. 113 at 34-35. Plaintiffs say that the basis of their standing to challenge these changes is “virtually identical to those providing standing to challenge of the elimination of other protections for transgender people in the Rule and the Rule’s exclusion of many insurance companies from the Rule’s scope.” ECF No. 128 at 29. Assuming Plaintiffs can incorporate wholesale those justifications to support standing to press these claims, Plaintiffs fail to establish standing because they failed to establish standing to press those claims. *See supra* at 3-18, 21-25.

Plaintiffs explain that the “elimination of th[ese] provisions allows insurers to deny *all* treatment for gender dysphoria, regardless of medical necessity.” ECF No. 128 at 30. But Plaintiffs elsewhere have argued that “the prevailing medical *consensus* is that gender-affirming surgical and medical treatments for gender dysphoria . . . are safe, effective, and when clinically indicated, medically necessary.” ECF No. 109 at 48. If such a consensus exists, Plaintiffs fail to explain why they will endure an imminent harm resulting from the elimination of this provision. *See id.* At a minimum, Plaintiffs must provide “concrete evidence to substantiate their fears” of harm from these changes, which they have not. *See Clapper*, 568 U.S. at 420.

h. Claims Related to HHS’s Conforming Amendments to Related Regulations

Defendants explained that the Complaint is devoid of any allegations—let alone clear ones—explaining how any Plaintiff has suffered an injury caused by these changes in the 2020 Rule. *See* ECF No. 113 at 35-36. Plaintiffs fail to respond to this argument at all, other than noting

within their arguments purporting to establish standing to challenge HHS’s decision not to define “on the basis of sex” by rule, that they “also challenge so-called ‘conforming amendments’ to other HHS regulations.” ECF No. 128 at 25. But these changes affect different programs and regulate different entities than the Section 1557 regulations. Accordingly, Plaintiffs cannot incorporate wholesale their arguments that they have standing to challenge a different regulation. As Plaintiffs have cited no allegations in their Complaint addressing any alleged harms from *these* regulatory changes, Plaintiffs have forfeited any claim to standing to challenge these provisions by failing to reply to Defendants’ arguments.

i. Plaintiffs May Not Invoke *Parens Patriae* Interests in the Health and Well Being of their Residents that are Shared with the Federal Government Defendants in a Suit Against Federal Government

As Defendants have explained, it is well-established that States cannot invoke in a suit against the United States the same *parens patriae* interests in state residents that are also residents of the United States and for whom the United States has the same *parens patriae* interest. ECF No. 113 at 10 n.2; ECF No. 130 at 31-32. Plaintiffs argue that this Court should disregard the Supreme Court’s clear conclusions on this issue because one case Defendants cited “has never been applied in this Circuit to bar *parens patriae* suits” and “[i]n the Second Circuit, states have regularly been found to have *parens patriae* standing to sue federal agencies.” ECF No. 128 at 17. But Plaintiffs cite only one Second Circuit opinion in support of that claim, which *predates* the Supreme Court’s exposition. *See id.* Moreover, *XY Planning* raises considerable doubt that such an expansive basis for standing remains viable in the Second Circuit. *See* 963 F.3d at 252-53. If States may not invoke indirect impairments of their state tax revenues as a basis for standing because “the unavoidable economic repercussions of virtually all federal policies suggest to us that impairment of state tax revenues should not, in general, be recognized as sufficient injury in fact to support state standing,” *id.* (quoting *Pennsylvania v. Kleppe*, 533 F.2d 668, 672 (D.C. Cir. 1976)), it makes little sense that the Second Circuit would accept a theory of standing that is inconsistent with Supreme Court precedent and would invite even more challenges to “virtually all federal policies,” *see id.*

j. Plaintiffs Have Not Meaningfully Distinguished *Washington v. HHS*

Contrary to Plaintiffs' assertion, Defendants do not "insist that States lack standing to contest the 2020 Rule because a district court in . . . Washington . . . found that Washington State lacked standing" to challenge the 2020 Rule's provisions. *See* ECF No. 128 at 18. Defendants have asked the Court to review the *reasons* stated by that court, which apply with equal measure to Plaintiffs' claims here. The *Washington* opinion represents a straightforward application of the governing standing law to a state plaintiff that is indistinguishable from Plaintiffs here. *See* 2020 WL 5095467.

Contrary to Plaintiffs' assertions, Defendants are not arguing that States like Plaintiffs or Washington "could *never* . . . establish standing." *See* ECF No. 128 at 18. In fact, throughout Defendants' briefing, Defendants acknowledge that a non-covered entity plaintiff may be able to establish standing to challenge a provision of the 2020 Rule if it could demonstrate a concrete and particularized legally cognizable imminent injury at the hands of a covered entity due to the provision of the 2020 Rule. To be sure, the *Washington* court explained, consistent with applicable Supreme Court precedent, that "Washington failed to adduce sufficient evidence to establish injury resulting from the" challenged provisions of the Rule. *See id.* The *Washington* court's opinion is entirely consistent with governing precedent prohibiting plaintiffs from presenting only fears about what the implications of challenged federal policy might be in support of standing to challenge the policy; instead plaintiffs must provide "concrete evidence [that] substantiates [those] fears." *See Clapper*, 568 U.S. at 420. Plaintiffs here, like the *Washington* plaintiff, do not allege facts supporting the existence of any such evidence; they instead rest entirely on "mere conjecture" about hypothetical future harms. *See id.*

Plaintiffs try to seek refuge from this requirement by invoking liberal pleading standards. *See* ECF No. 128 at 18. As an initial matter, this argument is moot. Plaintiffs have already moved for summary judgment and "present no concrete evidence to substantiate their fears" just like the *Washington* plaintiff. *See Clapper*, 568 U.S. at 420. In any event, Plaintiffs are wrong to suggest that they can rely on the conclusory allegations of future harm that they have provided in their

Complaint. *See* ECF No. 128 at 18. At the pleading stage, Plaintiffs must provide allegations that substantiate how they will actually be harmed by the provisions of the 2020 Rule that they challenge and that they intend to back up with “concrete evidence” at the summary judgment stage. *See Clapper*, 568 U.S. at 420. Without any such substantive allegations, Plaintiffs fail to meet the requirement that they “‘clearly allege facts demonstrating’ each element” of standing. *See Spokeo*, 136 S. Ct. at 1547 (quoting *Warth*, 422 U.S. at 518). Plaintiffs have failed to plead “factual content that allows the court to draw the reasonable inference,” *see Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), that they will be able to provide “concrete evidence to substantiate their fears” of imminent injury later in the litigation, *see Clapper*, 568 U.S. at 420. (In fact, that is exactly what they failed to do when they moved for summary judgment. *See* ECF No. 130.)

II. Plaintiffs’ Claims are not Ripe for Review

Plaintiffs fail to establish that their claims are fit for review. Plaintiffs complain that “Defendants repeatedly characterize Plaintiffs’ alleged harms as ‘hypothetical,’” ECF No. 128 at 39, but Plaintiffs fail to raise a single concrete instance of discrimination that has occurred due to HHS’s decision not to define “on the basis of sex” by rule, nor have they explained why any purported instances of discrimination can no longer be remedied in court or by filing a complaint with HHS. It is Plaintiffs’ failure to allege these facts that make their injuries hypothetical.

Plaintiffs say that they “challenge a final agency rule, not a future enforcement action.” *Id.* But that is exactly the problem. Plaintiffs cannot establish prematurely that neither courts nor HHS will enforce Section 1557 differently in light of HHS’s decision not to define “on the basis of sex” by rule. That is why “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 [a covered entity’s] situation in a fashion that” harms Plaintiff States. *See Nat’l Wildlife Fed.*, 497 U.S. at 891.

Plaintiffs say that “LGBTQ individuals, women, and LEP individuals will reasonably understand HHS’s [regulatory changes] to strip them of legal protections, increase the likelihood

of discrimination by health providers and insurers, and deny them the ability to seek administrative relief from HHS.” ECF No. 128 at 40. But HHS can be held accountable only for the actions it actually took, not for what individuals “reasonably understand.” *See id.*; *see also Clapper*, 568 U.S. at 416 (holding that the government cannot be responsible for “not ‘fanciful, paranoid, or otherwise unreasonable’” fears of the implications of government policy). And the reality is that HHS’s decision not to define “on the basis of sex’ by rule does not proscribe any of these individuals from seeking administrative relief from HHS if they believe they have been subject to discrimination prohibited by Section 1557. *See, e.g.*, 84 Fed. Reg. at 27,870 n.159.

Plaintiffs are wrong to say that Defendants’ arguments “would mean that any decision to eliminate regulatory protections and not replace them would be insulated from judicial review.” ECF No. 128 at 40. Ripeness doctrine insulates from judicial review generalized regulatory standards unless and until the regulation directly and actually affects the “primary conduct” of a regulated entity. *See Toilet Goods Ass’n, Inc. v. Gardner*, 387 U.S. 158, 164 (1967); *see also Nat’l Wildlife Fed.*, 497 U.S. at 891; *Sprint Corp. v. FCC*, 331 F.3d 952, 956 (D.C. Cir. 2003). The cases Plaintiffs cite involved clear, direct, and immediate effects. For example, in *Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 38 (1983), the agency permitted cars to be manufactured without passive restraint seat belts as soon as the rule became effective. The agency did not replace the rule with a generalized standard that might someday be interpreted to require passive restraints. *See id.*

Plaintiffs’ comparison to *Nat’l Ass’n of Home Builders v. U.S. Army Corp of Engineers*, 417 F.3d 1272 (D.C. Cir. 2005), is similarly inapt. *See* ECF No. 128 at 40. In that case, the Army Corps of Engineers had made significant modifications to Clean Water Act Permits that would require plaintiffs’ members—home builders—to obtain individual permits for conduct previously covered by general national permits. *Id.* at 1276-77. The challenged action thus required the plaintiff entities directly regulated by the agency to “adjust their conduct immediately.” *Id.* at 1283. “[I]n the absence of judicial review the appellants are left with [two] choices,” (1) “modify their projects to conform to the [new general permit] thresholds and conditions (as the Corp

contemplates they will do) or” (2) “refrain from building until they can secure individual permits.” *Id.* at 1284. The agency’s conduct therefore “affect[ed] the appellants’ activities in a ‘direct and immediate’ way.” *Id.* In stark contrast, Plaintiffs here continue to point to nothing in the 2020 Rule requiring them to take any action at all.

Most importantly, Plaintiffs are wrong to assert that the 2020 Rule “did not, as HHS contends, simply ‘decline’ to define ‘on the basis of sex.’” ECF No. 128 at 40. As HHS explicitly explained, it “repeal[ed] the definition of ‘on the basis of sex’ that had been adopted in its [2016] Section 1557 Final Rule. Because of the likelihood that the Supreme Court will be addressing the issue in the near future, [HHS] decline[d], at th[e] time, 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.

Instead of explaining why their claims—all premised on the erroneous belief that HHS defined “sex” by rule to exclude gender identity discrimination or other types of discrimination—are ripe for review, Plaintiffs switch to arguing the merits of their APA claims. ECF No. 128 at 40, 41. But this Court must assure itself that Plaintiffs’ claims are ripe before moving to the merits. *See, e.g., Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998); *Bronx Household of Faith v. N.Y.C. Bd. of Educ.*, 492 F.3d 89, 91 (2d Cir. 2007) (per curiam); *Sprint Corp.*, 331 F.3d at 956-57 (concluding that challenge to agency action as being arbitrary and capricious unripe for judicial review).

Nor are Plaintiffs correct to suggest that the timeline here—the fact that HHS is not “promulgating Section 1557 regulations for the first time”—is determinative. ECF No. 128 at 40. *Cf. Sprint Corp.*, 331 F.3d at 957 (“[W]here the agency has replaced a prohibition or right with a discretionary process *and applied its new process*, the court has held that a challenge to the agency’s decision is ripe for judicial review.”) (emphasis added). Instead, “[t]he fundamental purpose of ripeness doctrine” governs. *See id.* That purpose “is ‘to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and to protect the agencies from judicial interference until an administrative decision has been formalized and its effect felt in a concrete way by the challenging

parties.” *Id.* (quoting *Nat’l Park Hospitality v. Dep’t of the Interior*, 538 U.S. 803 (2003)); see also *Habeas Corpus Resource Ctr.*, 816 F.3d at 1252-54. Here, the court must discern for itself whether there is a likelihood that even without its involvement, HHS (or courts) will construe Section 1557 and the 2020 Rule in adjudication in the precise way that Plaintiffs believe it should be construed by rule, ultimately rendering Plaintiffs’ APA claims moot.

Plaintiffs fail to distinguish *Aulenback*, 130 F.3d at 167. They say that unlike *Aulenback*, the preamble to the 2020 Rule “clearly explains HHS’s interpretation of Section 1557.” ECF No. 128 at 41. Of course, the *Aulenback* plaintiffs claimed that the challenged policy manual provided an interpretation of a statute the agency implemented, 49 U.S.C. § 521(b)(5)(A). See 103 F.3d at 159, 164. Plaintiffs provide no basis for their statement that the preamble to the 2020 Rule more “clearly explains” an interpretation of the statute than the policy manual at issue in *Aulenback*. Indeed, unlike the policy manual at issue in *Aulenback*, HHS’s preamble was qualified: “the elimination of a regulatory definition of [a] term would not preclude application of the [Supreme Court’s] construction.” 85 Fed. Reg. at 37,168. The reason that the *Aulenback* plaintiffs could not establish ripeness based on the interpretation alone—whether in a preamble or a policy manual—is that, like here, “petitioners fail[ed] to show on the record before the court that [the agency] ha[d] purported to take an enforcement action based on the Manual’s definition” of the statutory term. 103 F.3d at 167. In other words, an interpretation is not ripe for review unless it appears in a binding rule or has been established by case-by-case adjudication. See *id.*

Plaintiffs also try to distinguish *Aulenback* by claiming that here “there is an administrative record on which to assess whether HHS complied with the APA and whether the 2020 Rule is lawful.” ECF No. 128 at 41. But Plaintiffs provide no reason to believe that there would not have likewise been an administrative record supporting the agency’s creation of the Manual at issue in *Aulenback*.

Plaintiffs say that “Defendants have still not taken a consistent position on whether *Bostock* controls the definition of ‘on the basis of sex’ in the 2020 Rule,” but point to nothing demonstrating inconsistency *period*, let alone anything in the record subject to review. See ECF No. 128 at 41.

Plaintiffs apparently find it hard to believe that HHS has decided to construe Section 1557's prohibition on sex discrimination through adjudication of specific complaints, as opposed to abstractly in a rule of general application and future effect. But that is exactly what HHS explained it was doing, *see* 84 Fed. Reg. at 27,857 (“Because 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.”), and it is entirely permissible for an agency to take this approach, *see NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974); *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947); *see also Williams-Yulee v. Florida Bar*, 575 U.S. 433, 499 (2015) (even under strict scrutiny, the government “need not address all aspects of a problem in one fell swoop”).

As previously explained, *see* ECF No. 130 at 52-55, Plaintiffs’ statement that “*Bostock* was decided before the HHS Rule was published” is highly misleading, *see* ECF No. 128 at 42. As Plaintiffs acknowledge, *see* Compl. ¶ 84, by the time the Supreme Court issued its decision in *Bostock*, the decision at issue in this case had already been made; by that time, the administrative record had been closed, the 2020 Rule had been issued publically on HHS’s website, and the 2020 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.”); *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.”).

Plaintiffs say that “[i]f HHS believed *Bostock* could control and LGBTQ claims would need to be adjudicated on a case-by-case basis, the agency could have stated as much in the preamble.” ECF No. 128 at 42. Of course, that is *precisely* what HHS said. 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.” 84 Fed. Reg. at 27,857. HHS also explained that even though its pre-*Bostock* views as to the meaning of that term aligned with the position of the United States in *Bostock*, “to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court’s construction.” 85 Fed. Reg. at 37,168. In other words, contrary to Plaintiffs’ unsupported assertions, HHS intentionally acted with *Bostock* in mind, reasonably ensuring that it could have valid regulations in place to adjudicate sex discrimination complaints no matter what the Supreme Court decided in *Bostock* or future cases. *See id.*

Plaintiffs note that HHS’s pre-*Bostock* discussion included statements that were consistent with the United States’ litigating position in that case but entirely ignore the greater context discussed *supra* at 32, *see* ECF No. 42. These statements alone are not a final agency action. Ripeness doctrine was designed precisely to prevent premature judicial review of non-binding (and qualified) agency statements like those Plaintiffs cite. The Court must respect “the agency’s interest in crystalizing its policy before that policy is subjected to judicial review.” *Connecticut v. Duncan*, 612 F.3d 107, 114 (2d Cir. 2010) (quoting *Nevada v. Dep’t of Energy*, 457 F.3d 78, 84 (D.C. Cir. 2006)).

As Defendants have explained, Plaintiffs’ injuries—based on regulatory uncertainty and “fear”—are insufficient for standing, let alone the more stringent hardship prong of the ripeness analysis. ECF No. 113 at 42; *see Habeas Corpus Resource Ctr.*, 816 F.3d at 1249-50. Plaintiffs’ contention that they will suffer the type of immediate and direct substantial impact required for the hardship prong is far off the mark. *See* ECF No. 128 at 43. Indeed, earlier in their brief they struggle to explain how they believe they have an “identifiable trifle” of injury because they hypothesize that one of the numerous Plaintiff States might receive “one complaint” of discrimination “against an insurer.” ECF No. 128 at 22. Even assuming Plaintiffs have established standing, which they have not, Plaintiffs’ novel “injuries” based on layers of speculation could not plausibly form the basis of hardship, which requires the court to consider both the “degree” and

the “nature of the regulation’s present effect on those seeking relief.” *See Toilet Goods*, 387 U.S. at 164.

Like in *Reno v. Catholic Social Servics, Inc.*, 509 U.S. 43, 58–59 (1993), HHS’s decision not to define “on the basis of sex” by rule “imposes no penalties for violating any newly imposed restriction” on any Plaintiff. *See id.* at 58. And the hardships imposed on the plaintiffs and the social service organization from awaiting further administrative action in *Catholic Social Services*, which were insufficient to establish ripeness, were quite similar to those Plaintiffs describe here. *See id.* at 79 (Stevens, J., dissenting) (explaining that regulations unripe for review required plaintiffs to live in “fear . . . afraid to seek help when their rights are violated, when they are victimized by criminals . . . or when they become ill”).

As Defendants explained, these same ripeness principles govern Plaintiffs’ power to bring pre-enforcement challenges to other provisions of the 2020 Rule that replace standards from an earlier rule with new standards (or the statutory language) that may ultimately be applied against covered entities in a manner preventing the very discrimination that Plaintiffs fear and will purportedly trickle up to cause them harm. *See* ECF No. 113 at 43-44. As Plaintiffs appear to recognize that “the same analysis applies,” *see* ECF No. 128 at 41 n.14, the Court should also find that these provisions are not ripe for review until it becomes clear that they are construed in a manner that has caused Plaintiffs harm.

CONCLUSION

For the foregoing reasons, this Court should grant Defendants’ motion to dismiss the Complaint in its entirety.¹³

¹³ In Defendants’ Opposition to Plaintiffs’ Motion for Summary Judgment, Defendants analyzed a Declaration by Katie Keith and an attached Out2Enroll 2021 Marketplace Plan Report, ECF No. 111-49. *See* ECF No. 130 at 16-18. The declarant stated 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 ¶ 11. As Defendants explained, the declarant and the Out2Enroll 2021 Report inflate the total number of insurers reportedly imposing transgender-related exclusions by counting insurers multiple times if they offer insurance policies in different states. *See* ECF No. 111-49; ECF No. 130 at 17 n.4. Because Bright Health is listed eight times in the 2021 Report’s data, *see* ECF No. 111-49 at 13-14, Defendants inferred

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Respectfully submitted,

JOHN V. COGHLAN
Deputy Assistant Attorney General
Federal Programs Branch

MICHELLE R. BENNETT
Assistant Director
Federal Programs Branch

/s/ Liam C. Holland
LIAM C. HOLLAND
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, D.C. 20530
(202) 514-4964
Liam.C.Holland@usdoj.gov

Attorneys for Defendants

that Bright Health alone was responsible for the purported jump from five insurers to thirteen. *See* ECF No. 111-49 ¶ 11.

After addressing this evidence in another case, Defendants now realize that the picture is more complicated, and take this opportunity to correct the record. Out2Enroll reported five insurers having “broad” transgender-related exclusions for 2020 Silver Marketplace Plans: AdventHealth, Health First Health Plans, Medical Mutual, Sendero Health Plan, and Common Ground. *See* Out2Enroll Summary of Findings, 2020 Marketplace Plan Compliance with Section 1557, <https://out2enroll.org/out2enroll/wp-content/uploads/2019/11/Report-on-Trans-Exclusions-in-2020-Marketplace-Plans-2.pdf> (“2020 Out2Enroll Report”). For 2021 Plans, Out2Enroll reports only four insurers imposing such exclusions: Bright Health, United Healthcare, Alliant, and MercyCare. *See* ECF No. 111-49 at 13-14. So the number of insurers with such exclusions has reportedly *decreased*, not increased. *See id.* But contrary to Defendants’ erroneous representation, Bright Health is not the only insurer that is listed as having “broad exclusions” for 2021 and did not in 2020. *See* ECF No. 130 at 16-18. Nevertheless, many insurers, like Advent Health and Health First, which reportedly imposed transgender related exclusions for 2020 Plans, are reported to provide that coverage for 2021. *See* ECF No. 111-49 at 13. Although all four of the insurers reportedly imposing “broad exclusions” for 2021 Plans were not listed as having “broad exclusions” in 2020 Plans, *see* 2020 Out2Enroll Report at 4-5, the 2020 Out2Enroll Report also does not clearly indicate what any of these insurers’ transgender-related policies were in 2020. The 2020 Out2Enroll Report lists Bright Health as “silent” while listing Alliant and MercyCare as “unavailable.” United Healthcare is nowhere to be found in the report at all. Defendants do not believe that this has a substantial impact on the arguments they made in their brief.