IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Plaintiffs' challenge to the Revised Rule is firmly rooted in the multitude of harms the Revised Rule has caused and continues to cause plaintiffs, their patients, their members, and the LGBTQ communities they serve. Vacatur of the Revised Rule would remedy, in whole or in part, these ongoing, concrete harms.

In granting plaintiffs' motion for preliminary relief, in part, the Court found that plaintiffs have standing to raise and are likely to succeed on their claims that HHS's Revised Rule arbitrarily and capriciously eliminated "sex stereotyping" from the 2016 Final Rule's definition of discrimination "on the basis of sex" and improperly incorporated Title IX's exemption of certain religious organizations from the statute's nondiscrimination mandate. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-01630-JEB, 2020 WL 5232076, at *1 (D.D.C. Sept. 2, 2020) (ECF No. 56). Plaintiffs demonstrate here that they also have standing to challenge the Revised Rule's narrowing of covered entities under Section 1557, the elimination of protections against associational discrimination, the elimination of sex discrimination in unrelated regulations, and the elimination of enforcement mechanisms. Defendants' ripeness arguments and arguments for dismissal under Rule 12(b)(6) also are without merit.

HHS promulgated the 2016 Final Rule to provide guidance concerning and clarify the scope of the nondiscrimination protections in Section 1557 of the Affordable Care Act ("ACA"), 42 U.S.C. § 18116. HHS believed such guidance and clarity would "promote understanding of and compliance with Section 1557 by covered entities and the ability of individuals to assert and protect their rights under the law." Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 31,444 (May 18, 2016) (formerly 45 C.F.R. pt. 92) (the "2016 Final Rule").

The Revised Rule upends this guidance and clarification, specifically carving out LGBTQ people and people with limited English proficiency ("LEP") from regulatory protections under Section 1557. By eliminating numerous nondiscrimination provisions, narrowing the scope of Section 1557, and adopting interpretations of Section 1557 that are contrary to law, the Revised

Rule erodes Section 1557's protections, burdens access to health care in violation of Section 1554, and creates confusion about the scope of Section 1557's nondiscrimination protections.

Defendants now attempt to defend the Revised Rule and the elimination of these protections by claiming they are merely hewing to the statutory text and courts will determine the scope of protections. Not only does the Revised Rule set forth the agency's clear and unequivocal views regarding Section 1557's scope, but the Court's ruling on plaintiffs' motion for preliminary relief forecloses defendants' argument. As the Court recognized, the crux of plaintiffs' challenge to the Revised Rule is that HHS was not writing on a blank slate. HHS changed positions and repealed provisions that offered clarity about rights under Section 1557 and how to protect them. In eliminating these protections, HHS was required to provide a reasoned explanation for its policy changes grounded in the data and evidence before the agency and the truth.

Plaintiffs' complaint sufficiently alleges that HHS acted arbitrarily and capriciously in adopting the Revised Rule. Plaintiffs allege the Revised Rule runs counter to the evidence before the agency, HHS disregarded material facts and evidence, and HHS failed to supply reasoned explanations for its policy changes from the 2016 Final Rule. Plaintiffs also allege HHS failed to consider important aspects of the issues, including harm to LGBTQ patients and people with LEP, and failed to account properly for the costs and benefits of the Revised Rule.

In addition, the Revised Rule is contrary to law. It violates Section 1554 of the ACA because, in direct contravention of the statute, it creates unreasonable barriers to obtaining health care and impedes timely access. Further, multiple provisions of the Revised Rule conflict with the statutory language and purpose of Section 1557 and other statutes.

Defendants' motion to dismiss should be denied. Indeed, dismissal would be premature with respect to many of plaintiffs' claims because defendants have refused to produce the administrative record. The law is well established that judicial review under the arbitrary and capricious standard obligates the court to examine the administrative record to ensure the agency had factual support for its decisions. Without the administrative record, neither plaintiffs nor the

Court can test and evaluate fully HHS's proffered justifications for its policy changes, the reasonableness of its explanations, and whether the record evidence supports the agency's actions.

ARGUMENT

I. THE COURT HAS SUBJECT MATTER JURISDICTION OVER EACH OF PLAINTIFFS' CLAIMS.

To establish the Court's subject matter jurisdiction, plaintiffs bear the burden of demonstrating the three elements of standing – injury-in-fact, causation, and redressability – but at the pleading stage, "general factual allegations of injury resulting from the defendant's conduct may suffice." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Plaintiffs "need only allege facts that demonstrate a realistic danger of . . . sustaining a direct injury." *Nat'l Cmty. Reinvestment Coal. v. Nat'l Credit Union Admin.*, 290 F. Supp. 2d 124, 131-32 (D.D.C. 2003) (quotations omitted). Courts "presum[e] that general allegations embrace those specific facts that are necessary to support the claim." *Lujan*, 504 U.S. at 561 (quotation omitted). In assessing the facts necessary to confirm jurisdiction, the court is "free to consider relevant materials outside the pleadings." *Nat'l Cmty. Reinvestment Coal.*, 290 F. Supp. 2d at 131.

A. Plaintiffs Have Standing to Challenge the Revised Rule's Narrowing of Covered Entities Under Section 1557.

Defendants argue plaintiffs do not have standing to challenge the Revised Rule's narrowing of covered entities subject to Section 1557 because they claim plaintiffs have failed to allege an injury "particularized to any of the named plaintiff[s]." (ECF No. 57-1 at 19.) Defendants are mistaken. Plaintiffs' allegations provide a predictable, common sense, and record-based link between the Revised Rule and their injuries. It is a "predictable effect of Government action on the decisions of third parties," *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019), that the Revised Rule's narrowing of covered entities likely will cause previously-covered insurers and providers to discriminate against LGBTQ people and others.

i. The health care provider plaintiffs have organizational standing based on economic injury.

Plaintiffs' complaint specifically alleges the economic injuries the health care provider plaintiffs will suffer as a result of the Revised Rule's narrowing of covered entities under Section

1557. Plaintiffs allege it will "result in a reduction in coverage and access to medically necessary health care for transgender and gender nonconforming patients" and this "[i]ncreased discrimination by health insurance plans will harm plaintiffs and the patients and individuals whom they serve." (Compl. ¶¶ 215, 216.) Specifically, "Plaintiffs that provide health care services will face increased costs because many private and public plans will refuse to cover medically necessary procedures" and "Plaintiffs, in turn, will be forced to either cover the costs of these medically necessary procedures, or turn away LGBTQ patients who need these services but cannot afford to pay for them out of pocket." (*Id.* ¶ 216.)

Additional record evidence makes the injuries even clearer. For example, plaintiff Whitman-Walker "has large numbers of patients who require gender affirming care, including hormone therapy and affirming, supportive mental health services." (ECF No. 29-3 (Shafi Decl.) ¶ 35.) Its CEO Naseema Shafi has explained that the "narrowing of covered entities under Section 1557 will result in discrimination against LGBTQ patients, who already face disproportionate barriers to accessing appropriate care" (*id.* ¶ 28), and to "the extent that the Revised Rule results in insurance plans and insurance companies reducing their coverage of such therapies, Whitman-Walker itself – as well as [its] patients – will be directly harmed by reduced reimbursements." (*Id.* ¶¶ 28, 35.) The Court has recognized this type of economic injury as sufficient to confer standing. *See Whitman-Walker*, 2020 WL 5232076, at *16.

In addition, because the health care provider plaintiffs provide care even when their patients cannot afford to pay for care—whether because they are uninsured or underinsured—and because the health care provider plaintiffs have limited financial resources, plaintiffs reasonably expect the Revised Rule's exemption of insurance companies will cause them to provide additional unfunded care. (Compl. ¶ 216; *see also* ECF No. 29-8 (Cummings Decl.) ¶ 7 ("Given our commitment to serve all clients regardless of their ability to pay, the Revised Rule's removal of insurance coverage and nondiscrimination requirements will cause the Center to be flooded with more clients and create significant financial strains on the Center."); ECF No. 29-3 (Shafi Decl.) ¶¶ 34, 40 (noting the Revised Rule "increases the costs we must incur in order to provide our

patients with adequate health care, as well as by the likelihood that more people will turn to Whitman-Walker to fill gaps in care and assistance caused by the Revised Rule")).

Moreover, by narrowing the scope of covered entities, defendants have sought to make previously unlawful conduct permissible. Under the 2016 Final Rule, health insurance companies could not discriminate on the basis of sex, including discrimination based on gender identity, transgender status, and sex stereotypes. But under the 2020 Revised Rule, because they are no longer subject to these prohibitions on discrimination, health insurance companies do not (defendants argue) need to comply with Section 1557's prohibition on sex discrimination. Thus, the "injurious private conduct" that "was illegal under the 2016 Rule" is now "made permissible by the 2020 Rule," which is sufficient to meet the causation and redressability prongs of the standing inquiry. *Whitman-Walker*, 2020 WL 5232076, at *17.

That plaintiffs have standing to challenge the narrowing of covered entities makes sense, as "what matters is not the length of the chain of causation, but rather the plausibility of the links that comprise the chain." *California v. Ross*, 358 F. Supp. 3d 965, 1006 (N.D. Cal. 2019) (cleaned up). It should be "immaterial to the Court's analysis whether the causal chain between the Final Rule and Plaintiffs' injury consists of few or many causal links—so long as both chains are equally plausible." *New York v. Scalia*, 464 F. Supp. 3d 528, 543 (S.D.N.Y. 2020).

How health insurance companies that are exempt from Section 1557's requirements under the Revised Rule will behave in response to the Rule is not a matter of mere speculation. There is concrete evidence. Not only do defendants "admit[] that some insurers will not maintain coverage consistent with the 2016 Rule's requirements," *Whitman-Walker*, 2020 WL 5232076, at *16 (citing 85 Fed. Reg. at 37,181), but recent data confirms plaintiffs' allegations. First, a review of health insurance plans for the year 2021 showed for the first time since the ACA was enacted, "a significant increase relative to prior years" of plans containing categorical exclusions for coverage of gender affirming health care. *See* Out2Enroll, *Summary of Findings: 2021 Marketplace Plan Compliance with Section 1557* (Nov. 2020), at 1, https://perma.cc/6W53-9YGH. The authors of the review "suspect[] this doubling in the number of insurers that are using such exclusions is

related to the Trump administration's recent efforts to roll back explicit nondiscrimination protections in regulations to implement Section 1557 of the Affordable Care Act." *Id.* Second, insurers already are relying on the Revised Rule's narrowing of covered entities to justify their deviation from Section 1557's nondiscrimination requirements. *See, e.g.*, Br. in Supp. of Defs.' Mot. for J. on the Pleadings on Count III, *T.S. v. Heart of Cardon, LLC*, No. 1:20-cv-01699-TWP-TAB (S.D. Ind. filed Oct. 20, 2020) (ECF No. 37), at 6; Br. of Appellant, *Kadel v. North Carolina. State Health Plan*, No. 20-1409 (4th Cir. filed July 30, 2020) (Doc. No. 27), at 21 (arguing the "restrictions of § 1557 do not, as of the latest interpretation from HHS, apply to the State Health Plan at all"). Here, there clearly is more than a "substantial . . . probability" of injury," *Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010), to establish standing.

ii. Plaintiffs' patients, members, and patrons will suffer discrimination that was previously impermissible under the 2016 Final Rule.

The narrowed scope of Section 1557 exempts entities from Section 1557's nondiscrimination requirements, harming plaintiffs' patients, members, and patrons.

a) Patients of the health care provider plaintiffs

The Court has recognized that the "health-provider Plaintiffs . . . have standing to assert the . . . rights of third-party LGBTQ patients." *Whitman-Walker*, 2020 WL 5232076, at *22; *see also City & Cnty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1011 (N.D. Cal. 2019). Here, the narrowing of covered entities harms plaintiffs' patients because it will "increase discrimination against LGBTQ patients." (ECF No. 29-8 (Cummings Decl.) ¶ 31.) This harm is not speculative. Rather, it "presents a grave threat to the health and wellbeing of the patient population that [the LA LGBT Center] serve[s]." (*Id.* ¶ 33.) The Chief Health Officer of Whitman-Walker declared, "Discrimination by health insurance providers against transgender individuals is yet another barrier to care that my patients and the patients whose care I oversee frequently experience." (ECF No. 29-4 (Henn Decl.) ¶ 22.) Given that insurers already are attempting to justify their discriminatory practices based on the Revised Rule's narrowing of the scope of covered entities under Section 1557, increased discrimination against LGBTQ people is not merely a predictable outcome of the Revised Rule, it is the *actual* outcome of the Revised Rule.

One example of how the Revised Rule's narrowing of covered entities affects the patients of the health care provider plaintiffs involves Medicaid. The Revised Rule exempts Medicaid programs from Section 1557's nondiscrimination requirements because: 1) Medicaid is an insurer that defendants do not consider to be "principally engaged in the business of providing healthcare" under the Revised Rule, 85 Fed. Reg. at 37,244-45; and alternatively, 2) the Revised Rule exempts federal health programs and activities that HHS administers, other than those established under Title I of the ACA. *See* 85 Fed. Reg. at 37,244. Whitman-Walker provides care not only to transgender patients who live in Washington, DC, but also to transgender patients who live in other jurisdictions, like West Virginia. (ECF No. 29-3 (Shafi Decl.) ¶ 4.) Whitman-Walker continuously encounters "patients whose insurance – including Medicaid plans, Medicare, and private insurance plans – denies coverage of surgical procedures [and] hormone therapies that are medically indicated and vital to patient health and well-being." (ECF No. 29-4 (Henn Decl.) ¶ 22.) Whitman-Walker's West Virginia transgender patients enrolled in Medicaid are unable to obtain coverage for gender affirming care because the State's Medicaid program excludes coverage for "[s]ex transformation procedures and hormone therapy for sex transformation procedures." *See* Aetna Better Health of West Virginia, *2019-2020 Member Handbook*, at 31, https://perma.cc/5WBA-4BSH; UniCare Health Plan of West Virginia, Inc., *Member Handbook – Mountain Health Trust West Virginia Health Bridge*, at 61, https://perma.cc/2W6D-Q6BW. The same is true for other forms of health insurance. For example, Whitman-Walker's West Virginia transgender patients who are state employees also are unable to obtain coverage for gender affirming care because the health plan for West Virginia state employees excludes coverage for "[s]urgical or pharmaceutical treatments associated with gender dysphoria or any physical, psychiatric, or psychological examinations, testing, treatments or services provided or performed in preparation for, or as a result of, sex transformation surgery." West Virginia Pub. Emp. Ins. Agency, *Summary Plan Description – PPB Plans A, B & D Plan Year 2021*, at 81, https://perma.cc/9YSU-WRVT.

The denial of coverage for gender-affirming care to the patients of the health care provider plaintiffs is injurious conduct, *i.e.*, discrimination, that the Revised Rule has made permissible by excluding Medicaid programs and other insurance programs from the scope of covered entities. These patients have no recourse with HHS's Office of Civil Rights ("OCR") even though they may suffer the health and economic consequences of being denied coverage. In addition, plaintiffs' patients will have to pay out of pocket for this coverage or delay it.

b) Members of the TransLatin@ Coalition

Plaintiffs' complaint specifically alleges that the TransLatin@ Coalition is "assert[ing] claims on behalf of its transgender and gender nonconforming members." (Compl. ¶ 34.) In ruling on plaintiffs' motion for preliminary relief, the Court acknowledged that TransLatin@ Coalition members "who rely on public-health-insurance coverage through Medicaid – which also would no longer enjoy Section 1557's protections – allege that they will suffer discrimination." *Whitman-Walker*, 2020 WL 5232076, at *18 (citing ECF No. 29-7 (Inurritegui-Lint Decl.) ¶¶ 56-58; ECF No. 29-6 (Salcedo Decl.) ¶¶ 38-39). The Court, however, did not credit these allegations as sufficient to establish standing because in its view, "[s]imply asserting, without any elaboration, that individuals will experience discrimination at the hands of Title I programs and health insurers" is insufficient to demonstrate standing because it failed to show an imminent injury. *Id.* But the imminence requirement is met "if the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper v. Amnesty Int'l, USA*, 568 U.S. 398, 409, 414 n.5 (2013)). "Either a certainly impending harm *or* substantial risk of harm suffices." *Massachusetts* v. *U.S. Dep't of Health & Human Servs.*, 923 F.3d 209, 222 (1st Cir. 2019).

A regulation that deems permissible conduct that would have been considered unlawful under a prior version of the rule, however, is sufficient to confer standing. *See Whitman-Walker*, 2020 WL 5232076, at *17. The loss of legal nondiscrimination protections also is sufficient to confer standing. *See Walker v. Pierce*, 665 F. Supp. 831, 836 (N.D. Cal. 1987). Under the 2016 Final Rule, health insurers and *all* HHS health programs or activities were subject to Section

1557's nondiscrimination protections, thus protecting LGBTQ people from discrimination on the basis of sex by health insurers and HHS health programs and activities. By narrowing the scope of covered entities under Section 1557, the Revised Rule eliminates the right to be free from discrimination on the basis of sex by health insurers and HHS health programs or activities other than those established under Title I of the ACA. The invasion of this legally protected interest is sufficient to confer standing. *See Linda R.S. v. Richard D.*, 410 U.S. 614, 617 (1973).

And there is more than a substantial risk of injury to the TransLatin@ Coalition's members. Kellan Valentín Pedroza presents one example. Kellan is an individual member of the TransLatin@ Coalition living in Puerto Rico. (Valentín Pedroza Decl. ¶¶ 1, 3.) Kellan is transgender and nonbinary.[1] (*Id.* ¶ 1.) Kellan receives his health coverage through Puerto Rico's Medicaid program. (*Id.* ¶ 4.) Although Kellan has been diagnosed with gender dysphoria and desires and needs gender affirming surgery, Kellan is unable to obtain such care because Puerto Rico's Medicaid program excludes from coverage "[p]rocedures for sex changes, including hospitalizations and complications." (*Id.* ¶¶ 5-8.) Kellan's story and harms are representative of the experiences of the TransLatin@ Coalition members who rely on public-health-insurance coverage through Medicaid. (*See* ECF No. 29-6 (Salcedo Decl.) ¶¶ 38–39; ECF No. 29-7 (Inurritegui-Lint Decl.) ¶ 57.) The TransLatin@ Coalition "is composed of thousands of transgender and gender nonconforming Latinx individual members across the United States, including in states and territories without any state-level protections from discrimination on the basis of sexual orientation, gender identity, or transgender status," like Arizona and Georgia. (ECF No. 29-6 (Salcedo Decl.) ¶¶ 6, 50.) Arizona and Georgia explicitly exclude coverage of gender-affirming care from their Medicaid programs. *See* Christy Mallory and William Tentindo, *Medicaid Coverage for Gender-Affirming Care* (Oct. 2019), https://perma.cc/KF2J-4TRS.

The Revised Rule purports to eliminate Kellan's right to nondiscrimination as applied to Puerto Rico's Medicaid program, as well as his ability to rely on HHS OCR, which can no longer

[1] As a nonbinary individual, Kellan's gender identity is neither exclusively male nor exclusively female. Kellan goes by both male ("él" or "he," in English) and female ("ella" or "she") pronouns.

enforce Section 1557's prohibition on sex discrimination against Puerto Rico's Medicaid program. This policy change deprives Kellan of not only a legal protection, but also an avenue to relief. And again, it will cause these members to absorb out-of-pocket costs *if* they have the resources (ECF No. 29-7 (Inurritegui-Lint Decl.) ¶ 50), or in Kellan's case, delay medically necessary health care.

These injuries are redressable. An order restoring the 2016 Final Rule's definition of covered entities would redress the injuries of the TransLatin@ Coalition members. *See Whitman-Walker*, 2020 WL 5232076, at *17.

c) Members of health professional association plaintiffs

Members of the health professional association plaintiffs suffer similar injuries to the patients of the health care provider plaintiffs and the TransLatin@ Coalition's members. For example, as a result of the narrowing of covered entities, they lose the protections against discrimination by health insurers and HHS health programs and activities they had under the 2016 Final Rule. (*See, e.g.*, ECF No. 29-12 (Vargas Decl.) ¶¶ 16-21, 26; ECF No. 29-13 (Harker Decl.) ¶¶ 11-22.) Dr. Deborah Fabian, an individual member of GLMA who works for the Indian Health Service (IHS), is one example of a member who has lost these protections. (ECF No. 29-14 (Fabian Decl.) ¶¶ 5, 19-21. Under the Revised Rule, IHS is no longer a covered entity under Section 1557 because it is a federal health program not administered by HHS under Title I of the ACA. *See* 85 Fed. Reg. at 37,244. Dr. Fabian thus no longer has the legal protections that were explicitly recognized and provided for under the 2016 Final Rule. Loss of legal protections emanating from a federal statute is sufficient to confer Article III standing. *See Walker*, 665 F. Supp. at 836.

iii. Plaintiffs will be injured because the narrowing of covered entities hampers their ability to advocate for their patients and patrons.

In ruling on plaintiffs' motion for preliminary relief, the Court acknowledged plaintiffs' assertion that the Revised Rule hampers their abilities to advocate for their patients and patrons because health insurers now are purportedly exempt from the nondiscrimination requirements of Section 1557. *See Whitman-Walker*, 2020 WL 5232076, at *19. But the Court observed that plaintiff Bradbury-Sullivan LGBT Center did not "explain how it has or will 'use[ ] its resources

to counteract that harm' — specifically, its alleged diminished ability to advocate on behalf of patients to insurers." *Id.* Plaintiff Bradbury-Sullivan LGBT Center, however, did provide an explanation. Adrian Shanker, the Executive Director of the Bradbury-Sullivan LGBT Center, explained that as a result of the inevitable increase in denials of care and discrimination that will follow from the Revised Rule, the Center (1) may need to hire an additional case-manager (ECF No. 29-11 (Shanker Decl.) ¶ 18); (2) will experience an increased demand for its time and resources by patrons (*id.* ¶ 26); (3) will need to develop new resources and training materials from scratch (*id.*); (4) will have to initiate many other new services, including, but not limited to, education and community outreach programs (*id.* ¶ 24); and (5) may be required to redirect additional staff and resources from providing its own services to assisting patrons. (*Id.* ¶ 29.) The same holds true for other plaintiffs, like Whitman-Walker, LA LGBT Center, and the TransLatin@ Coalition. (*See* ECF No. 29-3 (Shafi Decl.) ¶ 37; ECF No. 29-8 (Cummings Decl.) ¶ 26; ECF No. 29-6 (Salcedo Decl.) ¶¶ 53-54; ECF No. 29-7 (Inurritegui-Lint Decl.) ¶¶ 66-67.)

Plaintiffs' advocacy involves both direct advocacy with health insurers over their discriminatory exclusions as well as the filing of complaints before HHS OCR. (*See* ECF No. 29-11 (Shanker Decl.) ¶ 8; ECF No. 29-3 (Shafi Decl.) ¶ 26; Nelson Decl. ¶ 7.) Because the narrowing of covered entities exempts health insurers from Section 1557's nondiscrimination requirements, plaintiffs will be denied the main tool to pressure health insurers not to discriminate and a key avenue to obtain redress for their clients.

If the Court vacates the Revised Rule, however, plaintiffs would be able to continue to rely on the 2016 Final Rule's definition of covered entities, as well as OCR's enforcement, and not suffer an increased demand in their services.

B. Plaintiffs Have Standing to Challenge the Revised Rule's Elimination of Protections Against Associational Discrimination and Sex Discrimination in Unrelated Regulations.

This Court has squarely held that plaintiffs have standing to challenge HHS's removal of explicit protections for LGBTQ people seeking health care from the definition of sex discrimination prohibited under the statute. *See Whitman-Walker*, 2020 WL 5232076, at *12-15.

Defendants' repeated attempts to portray the Revised Rule as simply hewing to the statutory text and not taking a position on the scope of protections that Section 1557 provides cannot overcome the injury created by the Revised Rule's removal of explicit regulatory protections. The Court's injunction redresses those injuries temporarily. Vacatur of the Rule would redress them permanently. *See id.* at *8.

For the same reasons, defendants' challenge to the Court's subject matter jurisdiction over plaintiffs' claims concerning the Revised Rule's repeal of provisions relating to discrimination based on association and the elimination of gender identity and sexual orientation protections in unrelated regulations also fails. These claims are part of plaintiffs' challenge to the Revised Rule's unlawful removal of protections for LGBTQ patients. (*See* Compl. ¶¶ 100-101, 148-158.) Although plaintiffs must prove standing to challenge every component of the Revised Rule, *Whitman-Walker*, 2020 WL 5232076, at *8, these components cannot be viewed in isolation. Courts "must read a regulation as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into an harmonious whole." *In re Grand Jury Investigation*, 315 F. Supp. 3d 602, 633 (D.D.C. 2018), *aff'd*, 916 F.3d 1047 (D.C. Cir. 2019) (cleaned up). Plaintiffs have standing to bring these claims for the same reasons they have standing to challenge the elimination of the 2016 Final Rule's definition of sex discrimination.

The Revised Rule's elimination of provisions relating to associational discrimination is another rollback of protections for LGBTQ people against discrimination on the basis of sex. (*See* Compl. ¶¶ 100-101.) Essentially, the Rule removes protections against discrimination based on being associated with someone of a particular sex, which is one of the ways courts have recognized that sex-based discrimination manifests against LGBTQ people. *See Zarda v. Altitude Express, Inc.*, 883 F.3d 100, 124 (2d Cir. 2018) (sexual orientation discrimination is sex discrimination in part because "in most contexts where an employer discriminates based on sexual orientation, the employer's decision is predicated on opposition to romantic association between particular sexes"); *Bostock v. Clayton Cty., Georgia*, 140 S. Ct. 1731, 1746 (2020) (an employer who discriminates against lesbians or gay men "intentionally penalizes men for being attracted to men

and women for being attracted to women. . . . Any way you slice it, the employer intentionally refuses to hire applicants in part because of the affected individuals' sex."). In removing this provision, the Revised Rule restates HHS's position that LGBTQ people are not included within Section 1557's protections. Plaintiffs' standing to challenge this repeal is tied to their patients' credible fear of sexual orientation discrimination. (*See* ECF No. 29-3 (Shafi Decl.) ¶¶ 17-19, 21, 34-39; ECF No. 29-4 (Henn Decl.) ¶¶ 9, 10, 16; ECF No. 29-5 (Pumphrey Decl.) ¶¶ 10, 13-14; ECF No. 29-10 (Carpenter Decl.) ¶¶ 9, 15; ECF No. 29-8 (Cummings Decl.) ¶ 22.)

Defendants' repeal of sexual orientation and gender identity protections from unrelated regulations likewise was part of defendants' efforts to foreclose protections for LGBTQ patients. (See Compl. ¶¶ 148-158.) The Revised Rule eliminates protections for LGBTQ patients in regulations related to Medicaid State Plans, Programs for All-Inclusive Care for the Elderly (PACE), and ACA state health insurance exchanges and plans. *See* 85 Fed. Reg. at 37,218-22, 37,243. Defendants excised these prohibitions based on their desire to "conform" the regulations to the Revised Rule. 85 Fed. Reg. at 37,243. The Revised Rule's removal of explicit protections from these regulations creates the same harms this Court already has held plaintiffs have standing to challenge – namely, the financial and operational injuries to plaintiffs from increased access of their services resulting from patients' and members' fear of discrimination. *Whitman-Walker*, 2020 WL 5232076, at *10-11. For example, the removal of explicit prohibitions against sexual orientation and gender identity discrimination from the Centers for Medicare and Medicaid Services regulations directly affects the TransLatin@ Coalition given the high number of its members who rely on Medicare or Medicaid for their care. (ECF No. 29-6 (Salcedo Decl.) ¶¶ 38-39; ECF No. 29-7 (Inurritegui-Lint Decl.) ¶¶ 56-58.) Other patients of plaintiffs also rely on Medicare or Medicaid, and with the elimination of explicit recognition of sexual orientation and gender identity protections, the fear and experience of denials will increase the burdens on plaintiffs' services. (*See* ECF No. 29-3 (Shafi Decl.) ¶¶ 10, 24, 27-29; *see also* Valentín Pedroza Decl. ¶¶ 4, 8, 10.) Plaintiffs thus have standing to challenge the Revised Rule's unreasonable elimination of explicit protections against sex discrimination in unrelated regulations.

C. Plaintiffs Have Standing to Challenge the Revised Rule's Elimination of Enforcement Mechanisms.

Plaintiffs have standing to challenge the Revised Rule's elimination of the unitary legal standard for enforcing violations of Section 1557 and the provisions recognizing a private right of action and compensatory damages (collectively, "enforcement mechanisms"). Defendants' attempt to portray the Revised Rule as silence on the appropriate interpretation of the statute (*see* ECF No. 57-1 at 7-8) ignores the ramifications of the Revised Rule's revocation of avenues for redress that the 2016 Final Rule announced clearly and explicitly.

The Court previously characterized plaintiffs' theory of standing for these challenges as "murky." *Whitman-Walker*, 2020 WL 5232076, at *19. Plaintiffs clarify that their theory of standing is the organizational harm plaintiffs the TransLatin@ Coalition, LA LGBT Center, and Whitman-Walker will experience based on the additional resources they must devote to community education programs to support their members and patients as they navigate and address experiences with discrimination. (*See, e.g.*, ECF No. 29-6 (Salcedo Decl.) ¶¶ 42, 53-54; ECF No. 29-7 (Inurritegui-Lint Decl.) ¶¶ 36, 66-67; ECF No. 29-8 (Cummings Decl.) ¶¶ 12-14, 16; Nelson Decl. ¶¶ 7-9.) Darrel Cummings, the Chief of Staff of the LA LGBT Center, explained the Center will be forced to spend additional resources educating its clients and staff about their rights and available remedies because of the chaos sown by the Revised Rule's removal of the unitary legal standard, which "creates an additional barrier for clients to seek justice for the harms they experience, let alone finding a successful remedy for the harms." (ECF No. 29-8 (Cummings Decl.) ¶ 12.) The Center also will have "to divert resources away from other programming to conduct informational sessions about the Revised Rule to answer patients' and staff members' questions about how the Rule will affect them." (*Id.* ¶ 26.) Amy Nelson, the Director of Legal Services at Whitman-Walker, explains that the elimination of these enforcement mechanisms "restricts the administrative complaint process in ways that narrow its likelihood to address our clients' discrimination and harassment, requiring our staff to undertake additional educational efforts to provide our clients and WWH staff with information about the scope of protections, ways to seek relief, and remedies available to combat the discrimination they face." (Nelson Decl. ¶ 7.)

The elimination of the enforcement mechanisms will cause particular harm to the TransLatin@ Coalition. Serving and advocating for the needs of people with intersectional identities is central to its mission, recognizing the unique experiences and challenges of people who are both transgender and Latinx. (ECF No. 29-6 (Salcedo Decl.) ¶ 5.) The work of the Coalition and its members targets the increased marginalization of people who face discrimination because of the multiple aspects of who they are – their race, national origin, immigration status, HIV status, sexual orientation, *and* transgender status – including in health care. (ECF No. 29-6 (Salcedo Decl.) ¶¶ 30-31, 37; ECF No. 29-7 (Inurritegui-Lint Decl.) ¶¶ 11, 16, 24, 39.) This work includes educating and training TransLatin@s about their rights regarding equal access to health care (ECF No. 29-6 (Salcedo Decl.) ¶¶ 2, 7, Ex. B at 41), and making referrals for legal support. (ECF No. 29-7 (Inurritegui-Lint Decl.) ¶ 13.) Like the organizational plaintiff in *Action Alliance of Senior Citizens of Greater Philadelphia v. Heckler*, 789 F.2d 931, 937-38 (D.C. Cir. 1986), "the challenged regulations deny the [Coalition] access to information and avenues of redress they wish to use in their routine information-dispensing, counseling, and referral activities."

The same is true for Whitman-Walker, whose legal services arm provides legal advice and representation to patients on a wide range of health-related issues, and more broadly to LGBTQ people and people living with HIV in the larger Washington DC metropolitan area. (Nelson Decl. ¶ 2.) All but one of the clients they represented on health care discrimination issues in the last year were transgender and approximately half also identified as a racial minority, living with HIV, or a non-U.S. citizen. (*Id.* ¶ 3.) As a result of the Revised Rule, the Whitman-Walker legal team already has increased its educational outreach to clients and to staff "to clarify the protections that remain available under Section 1557, including the path forward for those clients who experience discrimination because of multiple aspects of their identities." (*Id.* ¶ 9.) Whitman-Walker's Director of Legal Services specifically noted that the Revised Rule's disavowal of the unitary standard "will make these claims even more difficult to pursue and require still more time and resources from our legal team and from our clients, who do not have time and resources to spare." (*Id.*)

Although defendants are correct that the Revised Rule cannot eliminate avenues for relief authorized by Section 1557 (ECF No. 57-1 at 18), the Revised Rule's repudiation of these standards and remedies has a direct impact on the educational and advising efforts plaintiffs must undertake to ensure their members or patients are able to pursue and enforce their rights. *See Mass. Fair Hous. Ctr. v. U.S. Dep't of Hous. & Urban Dev.*, No. 20-cv-11765, 2020 WL 6390143, at *5 (D. Mass. Oct. 25, 2020). The Revised Rule's newly splintered approach to discrimination claims depending on which aspect of a person's identity was the root of the discrimination and the agency's reversal on the availability of routes to court and remedies require additional educational efforts by plaintiffs so their members are not misled into not asserting their legal rights. (Compl. ¶ 118; ECF No. 29-8 (Cummings Decl.) ¶¶ 12-14; Nelson Decl. ¶¶ 8-9.) Thus, this aspect of the Rule "might increase the number of people in need of counseling . . . [and] reduce[ ] the effectiveness of any given level of [the Coalition's] outreach efforts." *Fair Emp't Council of Greater Wash., Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268, 1276 (D.C. Cir. 1994). Plaintiffs' expenditure of resources for "additional education of and outreach to" their patients and members "beyond those normally expended" is the type of "concrete and demonstrable injury to [their] activities" to establish standing. *District of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 41 (D.D.C. 2020). Because this harm is directly traceable to the Revised Rule and would be redressed by vacating these provisions and reverting to the enforcement mechanisms recognized in the 2016 Final Rule, it is sufficient to establish plaintiffs' standing.

Additionally, the TransLatin@ Coalition can assert standing on behalf of its members and Whitman-Walker can assert standing on behalf of its patients and clients to challenge the Revised Rule's revocation of the enforcement mechanisms. *See Sierra Club v. Fed. Energy Reg. Comm'n*, 827 F.3d 59, 65 (D.C. Cir. 2016); *S. Poverty Law Ctr. v. U.S. Dep't of Homeland Sec.*, No. 18-cv-760, 2020 WL 3265533, at *13 (D.D.C. June 17, 2020) (citing *Caplin & Drysdale, Chartered v. United States*, 491 U.S. 617, 623 n.3 (1989)). Although the Court previously did not consider future discrimination to be sufficiently imminent to establish injury-in-fact, *Whitman-Walker*, 2020 WL 5232076, at *20, the injury from the Revised Rule's elimination of these enforcement

mechanisms does not flow from the future actions of would-be discriminators, but from the Revised Rule's deprivation of a means of redress.

The Revised Rule makes it more difficult to bring discrimination claims under Section 1557, especially claims of intersectional discrimination, particularly before the HHS OCR. (Compl. ¶¶ 16, 210, 230-31.) As Ms. Lint noted, "This change will have a particularly harmful effect because discrimination based on sexual orientation, gender identity, transgender status, national origin, disability, and LEP status does not occur in an identity vacuum." (ECF No. 29-7 (Inurritegui-Lint Decl.) ¶ 52; *see also* ECF No. 29-6 (Salcedo Decl.) ¶ 37.) Subjecting intersectional discrimination claims to different standards, enforcement mechanisms, and remedies based on which aspects of a person's identity is at issue effectively deprives victims of such discrimination of a means of seeking redress, an injury more than sufficient to establish standing. *See United States v. Facebook, Inc.*, 456 F. Supp. 3d 105, 111 (D.D.C. 2020) (courts have found standing where a plaintiff's "injury was grounded in the loss of a means of *seeking* redress"). And of course, not every person has the resources to challenge discrimination in court, making reliance on *administrative* avenues for redress common *and* necessary. (*See* Nelson Decl. ¶¶ 5, 9.) The Revised Rule eliminates such administrative avenues. Accordingly, the Revised Rule's revocation of the enforcement mechanisms "may raise the cost and difficulty of contesting a denial of services," *Action All.*, 789 F.2d at 937, resulting in harm to plaintiffs' members, patients, and clients.

II. PLAINTIFFS' CLAIMS ARE RIPE.

Despite stating they are not seeking dismissal of plaintiffs' challenge to the Revised Rule's elimination of "sex stereotyping" from the definition of "on the basis of sex" given the Court's ruling that plaintiffs are likely to succeed on this claim (ECF No. 57-1 at 1), defendants nevertheless argue this challenge is not ripe because HHS did not "purport to claim that discrimination on the basis of sex under Title IX do[e]s not encompass sex stereotyping." (*Id.* at 23.) The Court's ruling on plaintiffs' motion for preliminary relief – finding not only that plaintiffs had stated a viable claim that HHS acted arbitrarily and capriciously in removing this language

from the rule but were likely to prevail – plainly forecloses this argument.

The Court specifically rejected the argument on which defendants' new "ripeness" challenge rests – *i.e.*, that HHS could not have acted arbitrarily and capriciously in repealing the definition from the 2016 Final Rule because it merely replaces the definition "by hewing to the text of Section 1557." (*Id.* at 20.) As the Court already recognized, however, defendants' insistence that the Revised Rule merely "regurgitates the plain, unobjectionable text of Section 1557" misses the point. *Whitman-Walker*, 2020 WL 5232076, at *26. Plaintiffs' challenge to defendants' elimination of the definition of "on the basis of sex" is based on the agency's change in position and its decision to repeal a prior regulatory position for which it must provide a reasoned explanation. *Id.* Defendants cannot escape the Court's assessment of the reasonableness of HHS's explanation for *why* it made the change "by simply asserting that 'the elimination of a regulatory definition of [a statutory] term would not preclude application of the [Supreme] Court's construction' of that term's meaning." *Id.* (quoting 85 Fed. Reg. at 37,168). The Court "remains obligated to 'examin[e] the reasons' underlying HHS's action." *Id.* (quoting *Judulang v. Holder*, 565 U.S. 42, 53 (2011)).

Defendants' ripeness arguments thus are without merit. Plaintiffs do not challenge an uncertain, abstract, or speculative event, as defendants suggest. (ECF No. 57-1 at 20.) They challenge an already promulgated regulation and final agency action that has caused and will continue to cause harm unless set aside. It is well established that challenges to agency action as arbitrary and capricious are fit for review. The agency's action "necessarily stands or falls on [the] administrative record" and the agency's statutory authority. *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1282 (D.C. Cir. 2005). To accept defendants' argument would mean any decision to eliminate regulatory protections would be insulated from judicial review, which is not the law. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1910 (2020); *Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34 (1983).

Defendants' assertion that plaintiffs' challenge to the elimination of the definition of "on

the basis of sex" is not ripe for review because HHS denies promulgating the policy plaintiffs purport it has promulgated, likewise, is unavailing. (ECF No. 57-1 at 22 (quoting *Aulenback, Inc. v. FHA*, 103 F.3d 156, 167 (D.C. Cir. 1997).) Defendants cannot hide behind the Revised Rule's purported "silence" on the meaning of prohibited sex discrimination in an effort to evade review. Defendants' position that Section 1557 permits discrimination on the basis of sex stereotyping and gender identity is set forth clearly and repeatedly in the preamble. *See, e.g.*, 85 Fed. Reg. 37,175, 37,180, 37,183, 37,191, 37,194, 37,198. In addition, in promulgating the Revised Rule, HHS expressly stated it was doing so to "better comply with the mandates of Congress," further "substantive compliance," reduce confusion, and "clarif[y] the scope of Section 1557." *Id.* at 37,161. HHS further asserted it was reverting "to longstanding statutory interpretations that conform to the plain meaning of the underlying civil rights statutes and the United States Government's official position concerning those statutes." *Id.* Defendants cannot now claim that all the Revised Rule did was eliminate protections and allow the statute to fill in the gaps.

Nor can defendants claim that "further administrative action is needed to clarify the agency's position" by vaguely pointing to any applicable Supreme Court case law and maintaining there is no reason to think the agency would not properly recognize a claim of sex stereotyping. (ECF No. 57-1 at 12-13.) As this Court already noted, despite the plain import of the Supreme Court's decision in *Bostock*, "[t]he agency . . . clung to its position that 'Title IX does not encompass discrimination on the basis of sexual orientation or gender identity,' 85 Fed. Reg. at 37,168, and it repeatedly invoked that conclusion as justification for its elimination of the 2016 Rule's provision to the contrary. *Id*. at 37,161-62." *Whitman-Walker*, 2020 WL 5232076, at *25.

This case thus is nothing like *Aulenback*, where plaintiffs challenged a training manual, but the agency had "not had an opportunity to explain, in an authoritative way, the purpose of the Manual and how it is used." *Aulenback*, 103 F.3d at 167. Here, the preamble clearly explains defendants' interpretation of Section 1557, and there is an administrative record on which to assess whether HHS complied with the APA and whether the Revised Rule is lawful.

Defendants also suggest this case may be advisory because adjudication of future cases

may establish that the Revised Rule "covers the very type of discrimination plaintiffs fear it does not cover." (ECF No. 57-1 at 24.) In addition, defendants ask plaintiffs to wait for "actual discrimination" to occur. (*Id.* at 21.) Defendants misconstrue the nature of the injury. Plaintiffs are not challenging "mere uncertainty" about the meaning of the Revised Rule. (ECF No. 57-1 at 21.) They are challenging defendants' actual excision of LGBTQ people from the Revised Rule's protections and the logical and predictable harms that have flowed and will continue to follow to plaintiffs, their members, and their patients. And the Court has agreed in granting preliminary relief, recognizing the concrete injuries and harm arising from the Revised Rule. *See Whitman-Walker*, 2020 WL 5232076, at *10-13, *38. Postponement of judicial review would result only in additional injury and hardship. This case is thus distinguishable from *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 732-33 (1998), and *Nat'l Park Hosp. Ass'n v. U.S. Dep't of Interior*, 538 U.S. 803, 808 (2003), neither of which involved agency action with immediate and concrete effects. Plaintiffs' challenges to the Revised Rule is ripe for review.

To the extent the Court has any questions about the ripeness of plaintiffs' claims, the Court should defer ruling until after the administrative record is produced so that plaintiffs can test HHS's denial that it has promulgated a regulation that permits discrimination on the basis of sex stereotyping and gender identity and associational discrimination and also HHS's position on whether a private right of action exists, the availability of compensatory damages, and the legal standards for enforcing Section 1557.

III. PLAINTIFFS STATE A CLAIM THAT THE REVISED RULE VIOLATES THE APA.

Defendants contend that whether HHS "'adhered to the standards of decisionmaking required by the APA' is a legal question that may be answered on a Rule 12(b)(6) motion." (ECF No. 57-1 at 14 (quoting *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993).) However, where, as here, plaintiffs challenge defendants' agency action as arbitrary and capricious, it is well established that the administrative record is necessary to resolve defendants' motion to dismiss.

Judicial review "under the 'arbitrary' or 'capricious' standard *requires* the court to examine the existing administrative record to assure that the agency had factual support for its decision." *Ctr. for Auto Safety v. Dole*, 828 F.2d 799, 811 (D.C. Cir. 1987), *aff'd on reh'g*, 846 F.2d 1532 (D.C. Cir. 1988) (emphasis added). The Court cannot properly assess the merits of each provision plaintiffs challenge as arbitrary and capricious without the administrative record because it must have before it "neither more nor less information than did the agency when it made its decision." *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984). What is more, when provisions challenged as contrary to law also are challenged as arbitrary and capricious, because the arguments overlap, the proper course is to consider the claims at summary judgment with the aid of the full administrative record. *See City of Columbus v. Trump*, 453 F. Supp. 3d 770, 799-800 (D. Md. 2020).

The sole case defendants cite in support of their position that the Court may decide on a motion to dismiss whether promulgation of the Revised Rule violated the APA is *Marshall County*. Notably, in *Marshall County*, which involved a challenge to HHS's refusal to grant an exception to its general Medicare reimbursement rules, plaintiffs did not argue HHS failed "arbitrarily" to "consider material in the record" or "unreasonably relied on other material in the record that was logically flawed." 988 F.2d at 1226. Rather, they claimed they were "entitled to discovery and to a trial to test the validity of" HHS's reasoning and conclusions. *Id.* at 1227.

Here, in contrast, plaintiffs have alleged that the Revised Rule is arbitrary and capricious because, among other things, it "run[s] counter to the evidence before the agency and disregard[s] material facts and evidence," "defendants fail[ed] to supply a reasoned explanation for their policy change from the 2016 Final Rule to the Revised Rule," "defendants have failed to consider important aspects of the problem, including the Revised Rule's interference with current law," and "defendants failed to account properly for the costs and benefits of the Revised Rule." (Compl. ¶ 228.) To evaluate plaintiffs' claims and determine whether HHS acted arbitrarily and capriciously in promulgating the Revised Rule, which erects a barrier to access to health care for millions of Americans, the Court necessarily will need to look to the administrative record. *See,*

e.g., Vargus v. McHugh, 87 F. Supp. 3d 298, 301 (D.D.C. 2015); *Dist. Hosp. Partners, L.P. v. Sebelius*, 794 F. Supp. 2d 162, 173 (D.D.C. 2011).

Because defendants have not yet produced the administrative record, plaintiffs are not able to respond fully to defendants' motion to dismiss on 12(b)(6) grounds. In accordance with the Court's instructions in its November 3, 2020 Order (ECF No. 65), plaintiffs respond to defendants' arguments and point out which require access to the administrative record. Plaintiffs respectfully request that the Court deny without prejudice those portions of defendants' motion to dismiss that require such access.

A. Plaintiffs State a Claim that HHS's Elimination of the Prohibition on Categorical Coverage Exclusions is Arbitrary and Capricious and Contrary to Law.

Defendants contend the Court should dismiss plaintiffs' claim that the elimination of the prohibition on categorical coverage exclusions is arbitrary and capricious (*see* Compl. ¶¶ 98-99, 228-29) because HHS purportedly confronted its prior policy under the 2016 Final Rule and delivered a sufficiently reasoned explanation for its new policy. (ECF No. 57-1 at 26-27.) The Revised Rule's authorization for health insurers to institute categorical exclusions, however, is arbitrary and capricious and contrary to law for multiple reasons.

First, plaintiffs are entitled to test defendants' assertion that "HHS 'consulted scientific studies, government reviews, and comments from a host of medical professionals regarding treatment for gender dysphoria'" and "reasonably determined that 'the medical community is divided on many issues related to gender identity.'" (*Id.* at 27 (quoting *Whitman-Walker*, 2020 WL 5232076, at *30).) Without access to the administrative record, plaintiffs and the Court cannot determine whether HHS "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (cleaned up).

Indeed, plaintiffs are skeptical about the reasonableness of HHS's conclusion that "the medical community is divided on many issues related to gender identity" and that evidence in the administrative record supports the decision to eliminate the ban on categorical exclusions. The

medical consensus is that gender-affirming care for gender dysphoria "is safe, effective, and medically necessary in appropriate circumstances." *Edmo v. Corizon, Inc.*, 935 F.3d 757, 770 (9th Cir. 2019), *cert. denied*, 19-1280, 2020 WL 6037411 (U.S. Oct. 13, 2020). As the court stated in *Flack v. Wisconsin Department of Health Services*, 395 F. Supp. 3d 1001, 1018 (W.D. Wis. 2019) ("*Flack II*"), "any attempt by defendants or their experts to contend that gender-confirming care – including surgery – is inappropriate, unsafe, and ineffective is unreasonable, in the face of the existing medical consensus." *See also Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 595-96 (4th Cir. 2020), *as amended* (Aug. 28, 2020); Nat'l Acad. of Sciences, Engineering, and Medicine, *Understanding the Well-Being of LGBTQI+ Populations* (2020), at 12-14, https://perma.cc/XH5G-MT3L ("[A]vailable evidence generally indicates that gender-affirming medical interventions, including surgeries, are associated with improvements in gender dysphoria, mental health, and quality of life for transgender people.").[2]

HHS failed to give weight to this consensus and instead simply asserted that the 2016 Final Rule's prohibition on categorical coverage exclusions "inappropriately interfered with the ethical and medical judgment of health professionals." 85 Fed. Reg. at 37,187. But that assertion is plainly incorrect. The 2016 Final Rule did not mandate coverage be provided or that medical professionals provide gender-affirming treatment. The 2016 Final Rule prohibited *categorical* exclusions that eliminate considered, patient-centric decision-making about whether a treatment is adequate and medically necessary for a particular patient. By definition, categorical exclusions of gender-affirming coverage are the ones that interfere with medical judgment as they deny access to care *even when health professionals deem a procedure to be medically necessary*. The Revised Rule purports to endorse and facilitate such inappropriate interference.

In addition, none of the three sources HHS cited in the Revised Rule refute that gender-

[2] As a "Consensus Study Report," this National Academies of Sciences, Engineering, and Medicine report documents "the evidence-based consensus on the study's statement of task," "has been subjected to a rigorous and independent peer-review process," and "represents the position of the National Academies on the statement of task."

affirming care generally is accepted in the medical community to treat gender dysphoria. *See* 85 Fed. Reg. at 37,187 & nn.157, 159-60 (citing CMS, *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* ("2016 CMS Memo") (CAG-00446N) (Aug. 30, 2016), https://perma.cc/9S73-4WQB; Dep't of Defense, *Report and Recommendations on Military Service by Transgender Persons* (Feb. 22, 2018), https://perma.cc/7369-K2VC; Thomas D. Steensma, *et al*., *Factors Associated with Desistance and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study*, 52(6) J. of the Am. Acad. of Child & Adolescent Psychiatry 582-90 (2013)). To the contrary, although the 2016 CMS Memo declined to institute a coverage *mandate* for gender-affirming care, it encouraged case-by-case determinations following CMS's 2014 determination that its "National Coverage Determination (NCD) denying Medicare coverage of all transsexual surgery as a treatment for transsexualism is not valid under the 'reasonableness standard' the Board applies." HHS, Dep't Appeals Bd., *Decision - NCD 140.3, Transsexual Surgery*, Docket No. A-13-87, Decision No. 2576 (May 30, 2014) ("2014 NCD Decision"), https://perma.cc/W6T9-WYEB. CMS's 2014 NCD Decision makes clear there is "a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for transsexualism." *Id.* at 20; *see also Boyden v. Conlin*, 341 F. Supp. 3d 979, 1003 n.17 (W.D. Wis. 2018).

Second, HHS failed to explain how categorical exclusions that allow insurance companies to deny gender-affirming care to transgender people on a blanket basis can be justified. All HHS offered is that the "large number of comments received from healthcare providers who perform such treatments and procedures suggests that there is no shortage of providers willing to do so." *Id.* Such an explanation plainly is insufficient to meet the APA's standards for reasoned decision-making. The issue is whether health insurers can deny gender-affirming treatment on a categorical basis, not whether there are health care providers willing to perform such procedures. Further, HHS's assertion is based only on HHS's characterization of the comments. Plaintiffs and the Court need access to the administrative record to ascertain and evaluate HHS's reasoning, particularly given that these defendants have previously made "demonstrably false" representations of the

administrative record to justify their rulemaking. *New York v. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 541 (S.D.N.Y. 2019).

Third, in eliminating the prohibition on categorical exclusions, HHS also disregarded the case law holding that categorical exclusions violate Section 1557's statutory prohibition of discrimination on the basis of sex, which extends to discrimination on the basis of transgender status. As the Supreme Court held in *Bostock*, "discrimination based on . . . transgender status necessarily entails discrimination based on sex; the first cannot happen without the second." *Bostock*, 140 S. Ct. at 1747. For this reason, courts have found categorical exclusions like those defendants intend to permit to be unlawful discrimination under Section 1557. *See, e.g.*, *Kadel v. Folwell*, 446 F. Supp. 3d 1, 14-17 (M.D.N.C. 2020); *Flack II*, 395 F. Supp. 3d at 1014-15; *Boyden*, 341 F. Supp. 3d at 997, 1002-03; *Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 953 (D. Minn. 2018); *Flack v. Wis. Dep't of Health Servs.*, 395 F. Supp. 3d 931, 951 (W.D. Wis. 2018) ("*Flack I*"); *cf. Fletcher v. Alaska*, 443 F. Supp. 3d 1024, 1030 (D. Alaska 2020). Section 1557 thus prohibits categorical exclusions, and HHS's decision to eliminate the ban when such exclusions are *per se* unlawful under Section 1557 was arbitrary and capricious and contrary to law.

Finally, HHS failed to consider the harm caused by eliminating the prohibition on categorical coverage exclusions for gender-affirming care and the reliance of transgender patients, insurance companies, and organizations like plaintiffs on the protections in the 2016 Final Rule. Because HHS was "not writing on a blank slate," it was "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Dep't of Homeland Sec.*, 140 S. Ct. at 1915. HHS's decision to allow covered insurance providers to impose categorical exclusions was arbitrary and capricious.

B. Plaintiffs State a Claim that HHS's Elimination of Notice Requirements and Language Access Protections is Arbitrary and Capricious and Contrary to Law.

Defendants urge dismissal of plaintiffs' challenge to the Revised Rule's elimination of the notice and tagline requirements and language access protections (Compl. ¶¶ 131-37, 218-19, 236, 248, 256), claiming HHS's decision to eliminate these protections was lawful and reasonable

because it "displayed awareness that it changed positions and showed good reasons for the new policy." (ECF No. 57-1 at 27.) According to defendants, it determined that the requirements were difficult to implement, the costs imposed were larger than originally anticipated, and they yielded only minimal benefits. (*Id.* at 27-28 (citing 84 Fed. Reg. at 27,857, 85 Fed. Reg. at 37,163, 37,224, 37,233, 37,211 & n. 28).)

But HHS cited very little to support its claim that the notice and tagline requirements and meaningful language access protections in the 2016 Final Rule (formerly §§ 92.7, 92.8, 92.201) were difficult and costly to implement and yielded only minimal benefits. *See, e.g.*, 84 Fed. Reg. at 27,858 (citing data collected from only three covered entities); 84 Fed. Reg. at 27,882 & n.230 (citing "anecdotal[]" reports that "utilization of translation services did not appreciably rise after the Rule's imposition of notice and taglines requirements"); 85 Fed. Reg. at 37,233 n.370 (anecdotal report consists of single comment from one insurance company); 85 Fed. Reg. at 37, 235 (citing only Bureau of Labor Statistics data in support of cost savings from changes to language access plans). And HHS cited no support for its assertion that the nondiscrimination notices were "unnecessary" and "led to an unjustifiable burden and understandable confusion." 85 Fed. Reg. at 37,204.

Without access to the administrative record, neither plaintiffs nor the Court can sufficiently assess HHS's reasoning or whether the evidence before the agency supported its decision to eliminate these provisions. Nor can they assess HHS's assertions that it did not have "data enabling it to fulfill the request of commenters who urged the Department to calculate the value of such benefits lost as the result of this final rule." 85 Fed. Reg. at 37,233. Indeed, the record suggests there is ample evidence of the benefits lost as a result of the Revised Rule, as well as the barriers to health care the elimination of these protections erects. In promulgating the 2016 Rule, HHS found that:

> safe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other purposes. This

> exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.

81 Fed. Reg. at 31,431 (footnote omitted). To address this issue, HHS promulgated robust notice, tagline, and language access requirements. *Id.* at 31,398. HHS relied on studies documenting the barriers to care for people with LEP and the benefits to patients and health care providers of having robust language assistance services, including relevant studies HHS had published. *Id.* at 31,413 n.173, 31,416 n.192, 31,459. Without the administrative record, neither plaintiffs nor the Court can determine what the evidence showed concerning the continuing need for these requirements. This is precisely the sort of "asymmetry in information" that deprives plaintiffs and the Court of the ability to fully explore HHS's reasoning. *Vargus*, 87 F. Supp. 3d at 302 (cleaned up).

HHS disregarded its prior factual findings demonstrating the need for robust language assistance requirements to ensure meaningful access to health care for LEP individuals. HHS also appears to have dismissed the numerous comments warning that the Revised Rule would likely "result in a number of LEP individuals [being] unable to access healthcare, and will contribute to discrimination and to healthcare disparities for LEP individuals." 85 Fed. Reg. at 37,210. HHS's failure to consider these harms and provide factual support for its contention that they are "unnecessary" and "confusing" renders its elimination of these requirements arbitrary and capricious. Where, as here, an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy," "a more detailed justification than what would suffice for a new policy created on a blank slate" is required. *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). The elimination of these requirements also violates Section 1554 of ACA by creating unreasonable barriers to accessing health care and impeding timely access, as the 2016 Final Rule recognized.

C. Plaintiffs State a Claim that the Revised Rule Imposes Unreasonable Barriers to Health Care in Violation of Section 1554 of the ACA.

Section 1554 of the ACA explicitly prohibits the Secretary of HHS from promulgating any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care" or "impedes timely access to health care services." 42 U.S.C. § 18114. HHS

contends this provision "is meant to prevent direct government interference with health care," relying on the Ninth Circuit's *en banc* opinion in *California v. Azar* from earlier this year. (ECF No. 57-1 at 28 (quoting *California v. Azar*, 950 F.3d 1067, 1094 (9th Cir. 2020) (en banc).)

Defendants' reliance on *California* is misplaced. They omit that the court's analysis was grounded almost entirely in a *pre-ACA* decision – *Rust v. Sullivan*, 500 U.S. 173 (1991) – that addressed the fraught interaction between government funding and abortion. In *California*, several states and private plaintiffs challenged a 2019 rule prohibiting Title X projects from providing referrals to abortion providers as a method of family planning or telling patients which primary care providers provide abortions on, among other grounds, that it ran afoul of Section 1554. *See California*, 950 F.3d at 1081-82. *Rust* held a previous iteration of the rule constitutional, ruling that it did not impermissibly restrict speech in violation of the First Amendment or interfere with the Fifth Amendment right to terminate a pregnancy and make informed medical decisions. *Rust*, 500 U.S. at 192-203. The Ninth Circuit determined that reasoning controlling because, in its view, the ACA "did not seek to alter the relationship between federally funded grant programs and abortion in a fundamental way" and "did not address the implementation of Congress's choice not to subsidize certain activities." *California*, 950 F.3d at 1094-95. With respect to Section 1554, the court stated: "The ACA itself makes clear that § 1554 is meant to prevent direct government interference with health care, not to affect Title X funding decisions." *Id.* at 1094. Based on *Rust*'s pre-ACA analysis of the constitutionality of similar restrictions, the court concluded the 2019 rule "places no substantive barrier on individuals' ability to obtain appropriate medical care or on doctors' ability to communicate with clients or engage in activity when not acting within a Title X project, and therefore the Final Rule does not implicate § 1554." *Id.* at 1095.

When the Court ruled on plaintiffs' motion for preliminary relief, *California* was the sole Court of Appeals decision construing Section 1554. But one day after the Court's ruling, the Fourth Circuit, also sitting *en banc*, rejected the Ninth Circuit's analysis, holding the same 2019 rule violated Section 1554 of the ACA. *See Mayor & City Council of Baltimore v. Azar*, 973 F.3d 258 (4th Cir. 2020) (en banc). The court determined the rule "requires health care providers to

hide the ball from their patients by giving them a list of providers without telling them which ones actually perform abortions" and that "*this attempt to hoodwink patients creates 'unreasonable barriers' to 'appropriate medical care,' and 'impedes timely access' to health care services*." *Id.* at 288 (emphasis added). The Fourth Circuit declined to find *Rust* controlling because Section 1554 "was enacted after that decision" and "since *Rust*, Congress has explicitly recognized in the ACA *the importance of removing barriers to full disclosure in a health care setting*." *Id.* at 289 (emphasis added).

Baltimore thus rejected the Ninth Circuit's cramped reading of Section 1554 as barring only those rules that impose additional "regulatory burdens on doctors and patients," *California*, 950 F.3d at 1094, in favor of a flexible analysis that recognizes governmental actions can create unreasonable barriers to access. The Revised Rule imposes exactly such barriers. HHS promulgated the Revised Rule knowing that a substantial percentage of transgender individuals are discriminated against and denied care by medical providers based on their transgender status. *See* 81 Fed. Reg. at 31,460 (2016 Rule). Yet, the Revised Rule revokes protections and allows such discrimination to continue, thereby creating barriers to adequate care. As the Court recognized in granting preliminary relief, the Revised Rule's "elimination of the explicit prohibition on discrimination based on sex stereotyping and gender identity has caused – and will continue to cause – patients to fear discrimination at the hands of third parties." *Whitman-Walker*, 2020 WL 5232076, at *12. The same is true of the Revised Rule's adoption of broad and improper religious exemptions that burden LGBTQ people's access to health care by allowing health care institutions and providers to deny care to LGBTQ people based on religious, conscience, or moral grounds. (*Id.* at *15; *see also* Compl. ¶¶ 126-30.) The Revised Rule also discourages LGBTQ people from seeking care in the first instance and disclosing fully information. (Compl. ¶¶ 187-96.) And it eliminates notice and language access protections creating barriers for LGBTQ people with LEP to obtain health care information. (Compl. ¶¶ 136, 220.) Without a doubt, the Revised Rule violates Section 1554 by creating "unreasonable barriers to the ability of individuals to obtain appropriate medical care" and impeding "timely access to health care services."

D. Plaintiffs State a Claim that the Revised Rule's Narrowing of the Scope of 1557 is Arbitrary and Capricious and Contrary to Law.

i. The Revised Rule's narrowing of the scope of covered programs is arbitrary and capricious and contrary to law.

Section 1557 applies to "any program or activity that is administered by an Executive Agency *or* an entity established under this title." 42 U.S.C. § 18116(a) (emphasis added). The Revised Rule, however, arbitrarily and capriciously and impermissibly limits Section 1557 to "any program or activity administered by the Department under Title I of the ACA." 85 Fed. Reg. at 37,244 (C.F.R. § 92.3 (a)(3)). (*See* Compl. ¶¶ 138-141, 233, 247.) This interpretation is inconsistent with the plain language of the statute and makes little sense. It reads the word "or" out of the statute and reads "under this title" into the phrase "any program or activity that is administered by an Executive Agency."

HHS defends this construction, noting the 2016 Final Rule did not cover every program or activity administered by any executive agency. (ECF No. 57-1 at 30.) But the scope of the 2016 Rule made sense: it applied to "every *health* program or activity *administered by the Department*." 81 Fed. Reg. at 31,466 (formerly § 92.2(a)) (emphasis added). HHS claims its construction is preferable—or, at least, reasonable—because it relies on "the limitation already in the text—that is, Title I programs and activities." (ECF No. 57-1 at 30.) But HHS's construction unreasonably ignores the first half of the phrase "*any entity established* under this title": the phrase is clearly meant to identify the entities that would be created under Title I of the ACA, such as federal and state health insurance marketplaces and community health insurance councils. *See* 42 U.S.C. §§ 18031(b), 18051, 18061; *see also* 81 Fed. Reg. at 31,446. It was not meant to limit the overall scope of the statute to only those programs administered by HHS "under Title I." In "statutory construction, the rule of last antecedent provides that a limiting clause or phrase should ordinarily be read as modifying only the noun or phrase that it immediately follows." *Sierra Club v. Wheeler*, 956 F.3d 612, 617 (D.C. Cir. 2020) (cleaned up); *see also Grecian Magnesite Mining, Indus. & Shipping Co., SA v. Comm'r of IRS*, 926 F.3d 819, 824 (D.C. Cir. 2019). HHS's narrow interpretation is contrary to the statute and unreasonably excludes health programs that fall outside

of Title I, including Medicare Part B, any non-Title I programs and activities of the Centers for Disease Control and Prevention or the Indian Health Service, any self-funded group health plans, the Federal Employees Health Benefits Program, and others. *See* 81 Fed. Reg. at 31,445-46. Limiting the reach of Section 1557 in this way is inconsistent with the ACA's goal of increasing access to health care and health insurance. *See, e.g.*, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538-39 (2012); Amicus Br. of U.S. House of Representatives (ECF No. 36) at 1-2, 8-12.

Further, HHS failed to take into account the confusion that its interpretation creates and the harms that flow from narrowing the scope of covered entities under Section 1557, rendering the provision arbitrary and capricious. *See Stewart v. Azar*, 366 F. Supp. 3d 125, 135 (D.D.C. 2019). For example, commenters noted that "excluding non-Title I HHS-administered programs and activities," contrary to HHS's Section 504 regulation, which applies to "all programs or activities" conducted by HHS, would "result in confusion and cause illogical results, whereby recipients would be covered by Section 1557 but the agencies administering the program would not be covered." 85 Fed. Reg. at 37,171. Other commenters expressed concerns that "the narrowed application would reduce the number of covered entities and would lead to more discrimination, lack of care, and adverse health outcomes, which they argued is contrary to the stated Congressional intent and purpose of the ACA to expand access to and end discrimination in health insurance." *Id.* at 37,169. HHS simply brushed off these concerns asserting: "The Department must follow the text of the ACA. To the extent that Congressional intent and purpose are relevant, they are best determined by looking to the plain meaning of the statutory text." *Id.*

HHS also did not consider the reliance interests of LGBTQ people, like Dr. Fabian, who receive insurance health through an entity that no longer is a covered entity under the Revised Rule. Those individuals no longer have the legal protections provided under the 2016 Final Rule. Where, as here, an agency changes its policy, it is required to take into account the "serious reliance interests" present. *Regents of the Univ. of Cal.*, 140 S. Ct. at 1913.

Without the administrative record, plaintiffs do not know what evidence was presented to HHS concerning the harms or costs from narrowing the scope of covered entities under Section

1557, again presenting an "asymmetry in information" that deprives plaintiffs and the Court of the ability to fully explore HHS's reasoning. *Vargus*, 87 F. Supp. 3d at 302 (cleaned up). What plaintiffs do know is that there is an absence of any consideration in the preamble. HHS's failure to consider the harms and reliance interests at stake alone warrants that HHS's motion be denied.

ii. The Revised Rule's elimination of most health insurance providers is arbitrary and capricious and contrary to law.

Defendants also arbitrarily and capriciously and impermissibly constricted Section 1557 by interpreting "health program or activity" to exclude most health insurance providers. (Compl. ¶ 142; *see also* 85 Fed. Reg. at 37,244-45.) Defendants attempt to defend HHS's policy change from the 2016 Final Rule, which applied to most health insurance providers, by claiming that because of the "statute's silence as to the precise reach of the term 'health program or activity,' HHS reasonably defined" the term by looking to the Civil Rights Restoration Act ("CRRA"). (ECF No. 57-1 at 31.) Defendants point to the CCRA's definition of "program or activity" as "all of the operations" of an entity that "is principally engaged in the business of providing healthcare." (*Id.* at 30-31 (quoting 85 Fed. Reg. at 37,172).) The 2020 Revised Rule thus purports to define the phrase "any health program or activity, any part of which is receiving Federal financial assistance," 42 U.S.C. § 18116(a), as limited to "all operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance." 85 Fed. Reg. at 37,244 (§ 92.3(b)). The Rule further asserts that "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare." *Id.* at 37,244-45 (§ 92.3(c)).

HHS's re-interpretation of the scope of Section 1557 has several flaws. First, HHS's reading of the CRRA is incorrect. The CRRA was enacted to amend four civil rights statutes to make clear that if any part of a program or activity receives federal financial assistance, the entire program must comply with the applicable civil rights laws, not simply those aspects of covered entities directly receiving funding. *See* Pub. L. No. 100-259, 102 Stat. 28 (Mar. 22, 1998); *Doe v. Salvation Army in U.S.*, 685 F.3d 564, 571-72 (6th Cir. 2012).

Second, HHS attempted to justify its re-interpretation of Section 1557 by claiming providing "health insurance" is different than providing "healthcare." 85 Fed. Reg. at 37,172-73. But Section 1557 plainly covers "health programs and activities," not just direct health care. And health insurance clearly is a health program or activity. It is what enables the vast majority of Americans to access health care. Such an understanding also is consistent with other definitions of "health program" and "health care" in the ACA, which refers to "health programs" and "health care entities" as including insurers and insurance plans in other provisions. *See*, *e.g.*, 42 U.S.C. § 18051 (Section 1331) (permitting states flexibility to provide a "basic health program" by offering "1 or more standard health plans providing at least the essential health benefits described in section 1302(b) to eligible individuals"); 42 U.S.C. § 18113 (Section 1553) (defining "health care entity" to include "*a health maintenance organization*, *a health insurance plan*, or any other kind of health care facility, organization, or *plan*") (emphasis added). Further, contrary to defendants' assertion, the CRRA offers no support for distinguishing between providing "healthcare" and providing "health insurance." The CRRA does not define "health care" or suggest that "being principally engaged in the business of providing healthcare" excludes health insurance companies. Although HHS claimed that the CRRA applied "to all health programs or activities receiving Federal financial assistance, but not to all providers of health insurance," 85 Fed. Reg. at 37,171, HHS provided no support for this assertion because there is none.

Third, HHS's new interpretation violates Section 1554 of the ACA and also undermines the ACA's purpose, which was designed to expand access to health insurance and create new nondiscrimination protections in health insurance. *See, e.g.*, *Nat'l Fed'n of Indep. Bus.*, 567 U.S. at 519; Amicus Br. of U.S. House of Representatives (ECF No. 36 at 1-2, 8-12.) The Revised Rule's narrow definition of "health program or activity" frees health insurance providers from the ACA's non-discrimination provisions, creating unreasonable barriers to individuals seeking medical care.

Finally, HHS "entirely failed to consider an important aspect of the problem" – the harm caused by this new interpretation. *Stewart*, 366 F. Supp. 3d at 135 (quoting *State Farm*, 463 U.S.

at 43). For example, commenters expressed concern that the exclusion of "many of the plans, products, and operations of most health insurance issuers, such as self-funded group health plans, the Federal Employees Health Benefits (FEHB) Program, third-party administrator services, or short-term limited duration insurance plans," allowing health insurers to conduct their activities "in a discriminatory manner." 85 Fed. Reg. at 37,173. Commenters were "particularly concerned about excluding short-term limited duration insurance plans because these plans have been known to engage in discriminatory practices based on disability, age, and sex." *Id.* HHS arbitrarily and capriciously ignored these concerns, responding only that HHS "will robustly enforce the nondiscrimination requirements for [qualified health plans] under Title I of the ACA, for Exchange plans established by the ACA, and for any other insurance plans that Section 1557 covers." *Id.*

Given HHS's unreasonable interpretation of "health program or activity" and its failure to consider the harms from its re-interpretation of Section 1557, HHS's motion should be denied at this early stage in the proceedings—particularly given that the administrative record has not been produced. *See State Farm*, 463 U.S. at 43. Plaintiffs are entitled to examine the record to review the adequacy of HHS's decision-making process and explanation for its change in policy.

E. Plaintiffs State a Claim that HHS's Elimination of Enforcement Mechanisms is Arbitrary and Capricious and Contrary to Law.

Plaintiffs allege HHS's repeal of the enforcement mechanisms in the 2016 Final Rule – the unitary standard, compensatory damages, and private right of action – was arbitrary and capricious because HHS failed to offer a reasoned justification for eliminating these provisions. It also was contrary to the statutory language and purpose of Section 1557. (Compl. ¶¶ 102-118, 230-31, 245.) Although HHS is correct that the agency "cannot change what the statute does," (ECF No. 57-1 at 35), its decision to remove language that clarified how the statute would and could be enforced was arbitrary and capricious and contrary to law.

The Revised Rule conflicts with the statutory language and purpose of Section 1557 by failing to make the enforcement mechanisms provided by Title VI, Title IX, the Age Discrimination Act, and the Rehabilitation Act available in any case of discrimination against a

person based on any characteristic protected by these statutes. Section 1557's context, structure, and text make evident that Congress did not intend to import multiple, piecemeal legal standards and burdens of proof derived from different statutory contexts into the doctrinal patchwork HHS proposes. Rather, "looking at Section 1557 and the Affordable Care Act as a whole, it appears that Congress intended to create a new, health specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status." *Rumble v. Fairview Health Servs.*, No. 14 Civ. 2037, 2015 WL 1197415, at *11 (D. Minn. Mar. 16, 2015) (footnote omitted). In particular, Congress's use of the disjunctive "or" indicates that the enforcement mechanisms applicable under any of the incorporated statutes are available to every claim of discrimination under Section 1557, regardless of the particular type of discrimination. *See In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996) (cleaned up); 73 Am. Jur. 2d Statutes § 147.

Defendants assert, erroneously, that their contrary interpretation is entitled to *Chevron* deference. They are incorrect for two reasons. First, where, as here, the reasonableness of HHS's decision-making process is at issue, arbitrary and capricious review applies, not *Chevron* deference. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126-27 (2016). Second, the D.C. Circuit has held repeatedly that "*Chevron* step 2 deference is reserved for those instances when an agency recognizes that the Congress's intent is not plain from the statute's face." *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (collecting cases). Here, defendants defend HHS's elimination of the enforcement provisions by asserting that it is what the statute requires. *See* 85 Fed. Reg. at 37,202.

In addition, defendants provided no sound reason to remove references to the availability of compensatory damages and private causes of action from the Revised Rule. With respect to the elimination of a reference to a private right of action, HHS asserted only that it elected not to take a position "in its regulations on the issue of whether Section 1557 provides a private right of action." 85 Fed. Reg. at 37,202-03. HHS claims this position "cannot plausibly violate the APA" because "it is not contrary to law because nothing in Section 1557 compels HHS to promulgate a regulation taking a position on the issue." (ECF No. 57-1 at 34-35.) But again, HHS ignores that

it did not adopt the Revised Rule in a vacuum or devoid of context. The 2016 Final Rule expressly recognized a private right of action to "challenge a violation of Section 1557 or this part." 81 Fed. Reg. at 31,472 (formerly codified 45 C.F.R. § 92.302(d)). And as commenters pointed out, the existence of such a right is clear from the statutory language of Section 1557, which explicitly references and incorporates the "enforcement mechanisms" of four civil rights laws, all of which have a private right of action. What is more, commenters observed that every court that had ruled on the question had held that the statutory language of Section 1557 confers a private right of action. *See* 85 Fed. Reg. at 37,203 & n.252. HHS's blatant disregard of the law and its change in policy without a reasoned explanation was arbitrary and capricious and also contrary to law.

The same is true of HHS's elimination of § 92.301(b) in the 2016 Final Rule, which recognized "[c]ompensatory damages for violations of Section 1557 are available in appropriate administrative and judicial actions brought under this rule." 81 Fed. Reg. at 31,472 (formerly 45 C.F.R. § 301(b)). HHS claims it was entitled to change its position so long as it "delivered a sufficiently reasoned explanation for its new position." (ECF No. 57-1 at 34.) But that is precisely what HHS failed to do. HHS did not explain why it was departing from HHS's prior statement in the preamble to the 2016 Final Rule that its interpretation of Section 1557 as authorizing compensatory damages was consistent with HHS's "interpretations of Title VI, Section 504, and Title IX," as providing for compensatory damages. *See* 81 Fed. Reg. at 31,440. The only justification HHS offered is that "the Department has concluded that its enforcement of Section 1557 should conform to the Department of Justice's Title VI Manual," which states that "under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on a Federal agency's disparate impact regulations." 85 Fed. Reg. at 37,202. HHS said nothing about controlling U.S. Supreme Court decisions holding that damages are available under these civil rights statutes. *See, e.g.*, *Alexander v. Sandovar*, 532 U.S. 275, 279-80 (2001) (damages available under Title VI for claims of intentional discrimination); *Franklin v. Gwinnett Cnty. Pub. Schs.*, 503 U.S. 60, 76 (1992) (damages remedy available under Title IX); *Consol. Rail Corp. v. Darrone*, 465 U.S. 624, 630-31 (1984) (backpay available under Section 504).

HHS's statements cannot change the statute, but elimination of these provisions deprives LGBTQ people and people with LEP of important information about their rights and available remedies and are likely to mislead persons into not asserting their rights. They also are inconsistent with HHS's obligation to provide the public with accurate statements of their legal rights.

F. Plaintiffs State a Claim that the Elimination of Regulatory Protections Against Discrimination on the Basis of Association is Arbitrary and Capricious and Contrary to Law.

Defendants urge dismissal of plaintiffs' claim that the elimination of protections against discrimination on the basis of association is arbitrary and capricious and contrary to law (*see* Compl. ¶¶ 85(g), 91(g), 235, 244), because HHS claims it provided "a good reason for [its] policy change." (ECF No. 57-1 at 35 (quoting *District of Columbia*, 444 F. Supp. 3d at 20.) According to defendants, HHS "explained that the 2020 Rule 'neither abrogates nor withdraws any protections available under the incorporated civil rights statutes or their implementing regulations.'" (*Id.* (quoting 85 Fed. Reg. at 37,199).) Defendants also rely on HHS's assertion in the preamble that it "simply declines to use the Section 1557 regulation to identify protections beyond those specifically identified in the text of the relevant statutes and regulations." 85 Fed. Reg. at 37,199. But as the Court recognized in ruling on defendants' elimination of the definition "on the basis of sex," defendants' insistence that the Revised Rule merely hews to the statutory text misconstrues plaintiffs' argument: "HHS did not adopt the 2020 Rule in a vacuum devoid of context or history." *Whitman-Walker*, 2020 WL 5232076, at *26. Where, as here, an agency changes its position and opts to repeal a prior regulatory provision, the agency must provide "a reasoned analysis for the change" and "a satisfactory explanation for its action." *State Farm*, 463 U.S. at 42-43; *see also Encino Motorcars*, 136 S. Ct. at 2126-27.

The only justification HHS asserted for the change in policy is that it purportedly would "decrease confusion" because protections against discrimination on the basis of association already exist. 85 Fed. Reg. at 37,199. But HHS did not point to any evidence of any confusion. Without access to the administrative record, plaintiffs cannot determine whether the record, in fact, contains any evidence of confusion that supports HHS's justification.

To the contrary, commenters opposed the repeal of the prohibition against associational discrimination because they believed it would *cause* confusion for covered entities and individuals who would be unsure of their rights, especially in light of other federal nondiscrimination laws HHS enforces. In the 2016 Final Rule, HHS explained that "a prohibition on associational discrimination is consistent with longstanding interpretations of existing anti-discrimination laws" and the approach in the ADA, which includes a specific prohibition on discrimination based on association with an individual with a disability. 81 Fed. Reg. at 31,439 & nn.278-79 (citing *McGinest v. GTE Serv. Corp.*, 360 F.3d 1103, 1118 (9th Cir. 2004), *cert. denied*, 552 U.S. 1180 (2008); *Tetro v. Elliot Popham Pontiac, Oldsmobile, Buick & GMC Trucks Inc.*, 173 F.3d 988, 993-96 (6th Cir. 1999); *Parr v. Woodmen of the World Life Ins.*, 791 F.2d 888, 892 (11th Cir. 1986); 42 U.S.C. § 12182(b)(1)(E); 28 C.F.R. § 35.130(g)). Courts also have recognized that sexual orientation discrimination often is explained as associational sex discrimination. *See Zarda*, 883 F.3d at 124; *Hively v. Ivy Tech. Community College of Ind.*, 853 F.3d 339, 347-49 (7th Cir. 2017) (en banc). Repealing the prohibition thus causes inconsistency among different regulations to which covered entities are subject. Commenters also noted the repeal would make it more difficult for individuals to enforce their rights, was inconsistent with existing case law, and would leave certain protected populations more exposed to discrimination. *See* 85 Fed. Reg. at 37,199. HHS ignored these comments, again asserting it was simply declining to "identify protections beyond those specifically identified in the text of the relevant statutes and regulations." *Id.*

Until the administrative record is produced, there is no telling what other evidence concerning the importance of this protection HHS might have ignored. *See Vargus*, 87 F. Supp. 3d at 302. HHS's unsupported assertion that the 2020 Rule would "decrease confusion," however, is insufficient to justify a change in policy where HHS was not writing on blank slate. *See Fox*, 556 U.S. at 515. The repeal also contravenes existing case law and underlying statutes and thus is contrary to law. Defendants' motion to dismiss should be denied.

G. Plaintiffs State a Claim that the Elimination of Protections in Unrelated Regulations is Arbitrary and Capricious and Contrary to Law.

The Court should reject defendants' motion to dismiss plaintiffs' challenge to the Revised Rule's elimination of protections against gender identity and sexual orientation discrimination in a series of unrelated regulations, including regulations related to Medicaid State Plans, Programs of All-Inclusive Care for the Elderly (PACE), and ACA state health insurance exchanges and plans. (*See* Compl. ¶¶ 148-58.) The sole basis defendants offer for dismissal is that HHS explained it "deem[ed] it appropriate to pursue a more uniform practice concerning nondiscrimination categories across programs and activities to which Section 1557 applies, and to do so consistent with the government's position concerning discrimination on the basis of sex." (ECF 57-1 at 26 (quoting 85 Fed. Reg. at 37,219).) Defendants claim that explanation shows HHS was aware it was changing position and had "good reasons" for the new policy. (*Id.* (quoting *Whitman-Walker*, 2020 WL 5232076, at *3).)

Defendants are incorrect. The Court already has determined that HHS failed to offer a "good reason" or "reasoned analysis" sufficient to justify its decision to adhere to the government's failed litigation position in *Bostock* without considering whether *Bostock* changed the legal landscape. *See Whitman-Walker*, 2020 WL 5232076, at *23-27. That conclusion applies in equal force to HHS's removal of protections against gender identity and sexual orientation discrimination in *other* regulations. *See* 85 Fed. Reg. at 37,218-21, 37,243-44. HHS's *consistent* adherence to the same arbitrary and capricious position is neither "good reason" nor "reasoned analysis" and fails to support these changes.

These changes also are contrary to law. In *Bostock*, the Supreme Court held that discrimination on the basis of transgender status or sexual orientation is discrimination on the basis of sex. *Bostock*, 140 S. Ct. at 1747. *Bostock* forecloses the defendants' attempt to deny LGBTQ people and patients in the health care setting protections against discrimination based on gender identity and sexual orientation in unrelated regulations promulgated under different statutes. The elimination of protections against discrimination on the basis gender identity and sexual

orientation in regulations related to health care programs and activities also violates Section 1554 by imposing unreasonable barriers and impeding timely access to health care services.

IV. PLAINTIFFS HAVE STATED CLAIMS FOR CONSTITUTIONAL VIOLATIONS.

A. Plaintiffs State an Equal Protection Claim.

The Revised Rule discriminates on the basis of sex, transgender status, and sexual orientation by inviting health care discrimination against LGBTQ people and carving them out of regulatory nondiscrimination protections under Section 1557. Such discrimination is subject to heightened scrutiny. *See United States v. Virginia*, 518 U.S. 515, 531 (1996) (sex discrimination subject to heightened scrutiny); *SmithKline Beecham Corp. v. Abbott Labs.*, 740 F.3d 471 (9th Cir. 2014) (same for sexual orientation discrimination); *Windsor v. United States*, 699 F.3d 169, 185 (2d Cir. 2012) (same), *aff'd on other grounds*, 570 U.S. 744 (2013); *Grimm*, 972 F.3d at 611; *Karnoski v. Trump*, 926 F.3d 1180, 1201 (9th Cir. 2019) (transgender status); *Ray v. McCloud*, No. 2:18-cv-00272, slip op. (S.D. Ohio Dec. 16, 2020) (same); *F.V. v. Barron*, 286 F. Supp. 3d 1131, 1145 (D. Idaho 2018) (same); *Evancho v. Pine-Richland Sch. Dist.*, 237 F. Supp. 3d 267, 288 (W.D. Pa. 2017) (same). Yet, the Revised Rule is not even rationally related to any of HHS's asserted goals—"to better comply with the mandates of Congress," reduce confusion, further substantive compliance, and revert to "longstanding statutory interpretations." *See* 85 Fed. Reg. at 37,161. Inviting discrimination against LGBTQ people in health care advances none of these goals, particularly given *Bostock*'s confirmation that discrimination on the basis of gender identity or sex stereotyping are forms of prohibited sex discrimination.

Plaintiffs also allege unconstitutional discriminatory animus as the exclusion of LGBTQ people from the nondiscrimination protections under Section 1557 is "just the latest step" in the Trump administration's and HHS's "multi-step erasure of LGBTQ people from health care-related nondiscrimination protections." (Compl. ¶ 167.) Plaintiffs allege, in particular, that defendant Severino has a history of anti-LGBTQ sentiments, advocacy, and comments. (*Id.* ¶¶ 168-173.)

Nevertheless, defendants seek dismissal of this claim, arguing plaintiffs have not alleged any government action. (ECF No. 57-1 at 36.) This argument pretends HHS has not taken a clear

position that Section 1557 permits discrimination on the basis of gender identity and sex stereotyping. *See, e.g.*, 85 Fed. Reg. 37,175, 37,180, 37,183, 37,191, 37,194, 37,198. These unambiguous statements represent HHS's interpretation of the statutory text, which combined with the elimination of the definition of "on the basis of sex" constitute government action purporting to permit discrimination on the basis of gender identity and sex stereotyping under Section 1557. *See Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999).

Defendants also contend plaintiffs have not shown any discriminatory animus behind the Revised Rule's exclusion of LGBTQ people from Section 1557. In particular, defendants characterize plaintiffs' allegations regarding defendant Severino as "mere legal and policy disagreements." (ECF No. 57-1 at 37.) However, his comments reflect a broad and explicit bias against LGBTQ people. (*See, e.g.*, Compl. ¶ 169 (citing Severino, *DOJ's Lawsuit Against North Carolina Is Abuse of Power*, The Daily Signal (May 9, 2016)); *see also* Compl. ¶¶ 167, 171-77.)

In short, plaintiffs' allegations that the Revised Rule's elimination of protections for LGBTQ individuals reflects nothing but a "desire to harm a politically unpopular group," *U.S. Dep't of Agric. v. Moreno*, 413 U.S. 528, 534 (1973), are sufficient to state an equal protection claim. Just as a "State cannot so deem a class of persons a stranger to its laws," neither can federal defendants deem LGBTQ people strangers to regulatory protections and administrative enforcement mechanisms. *Romer v. Evans*, 517 U.S. 620, 635 (1996). In any event, dismissal would be premature. Defendants concede their alleged animus needs to be tested based on the administrative record. In opposing preliminary relief, defendants expressly acknowledged "plaintiffs' claims arise under the APA, so 'the focal point for judicial review should be administrative record.'" (ECF No. 42 at 47 (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973)); s*ee also* ECF No. 43 at 27 n.6 (allegations of animus are part of the administrative record).)

B. Plaintiffs State a Substantive Due Process Claim.

Defendants' challenges to plaintiffs' due process claim likewise fail. First, plaintiffs' complaint is sufficiently specific regarding the nature of the deprivation of due process. The complaint alleges that the Revised Rule "encourage[es] health care providers and insurers to deny

or otherwise interfere with individuals' access to gender-affirming medical care . . . and by interfering with the ability of transgender and gender non-conforming individuals to live and express themselves in accordance with their gender identities." (Compl. ¶ 278.) This claim is largely premised on the elimination of the 2016 Rule's definition of "on the basis of sex," *Whitman-Walker*, 2020 WL 5232076, at *37, although it also targets HHS's decision to permit healthcare providers and insurers to adopt "categorical coverage exclusion[s] or limitation[s] for all health care services related to gender transition." (Compl. ¶¶ 98, 278.)

Second, the Court should reject defendants' cramped framing of the issue as to whether there is a "substantive due process right to the specific medical care described in the Complaint." (ECF No. 57-1 at 38.) The Due Process Clause protects individuals' rights to make certain decisions central to privacy, bodily autonomy, bodily integrity, self-definition, intimacy, and personhood without unjustified governmental intrusion. *See Obergefell v. Hodges*, 576 U.S. 644, 651-52 (2015); *Lawrence v. Texas*, 539 U.S. 558, 562 (2003). Those decisions include the right to live openly and express oneself consistent with one's sexual orientation or gender identity. *See Arroyo Gonzalez v. Rossello Nevares*, 305 F. Supp. 3d 327, 333 (D.P.R. 2018). Rules that invite healthcare providers and insurers to discriminate against and deny care to LGBTQ people unduly impinge these core rights without any justification.

Third, defendants misplace their reliance on *DeShaney v. Winnebago Cnty. Dep't of Soc. Servs.*, 489 U.S. 189, 195 (1989). *DeShaney* held there is no general right of due process to have the state intervene to protect an individual from a known or foreseeable risk of harm at the hands of a non-state actor (in that case, a father with a history of child abuse). *Id.* at 194-97. Here, the Revised Rule creates the risk of harm by removing measures HHS had purposefully included in a regulation promulgated just four years earlier to address well-documented patterns of discrimination against LGBTQ people in the provision of health care. Having elected to remove these protections despite the well-documented evidence of their necessity, HHS cannot avoid plaintiffs' due process claim by insisting that it has no duty to "aid" victims of the discriminatory practices it has encouraged and fostered. *See Reitman v. Mulkey*, 387 U.S. 369, 370-71, 380-81

(1967) (amendment to California's constitution violated citizens' substantive due process right where it repealed a law that prohibited private racial discrimination and replaced it with a law that was "intended to authorize, and does authorize, racial discrimination in the housing market").

C. Plaintiffs State a Free Speech Claim.

The First Amendment protects individuals from conduct that is "likely deter a person of ordinary firmness from continuing to engage in protected activity." *Hartley v. Wilfert*, 918 F. Supp. 2d 45, 53 (D.D.C. 2013) (quotation omitted). By removing the "explicit prohibition on discrimination based on sex stereotyping and gender identity," *Whitman-Walker*, 2020 WL 5232076 at *12, and encouraging medical providers to assert religious objections to treating LGBTQ patients, the Revised Rule impermissibly chills LGBTQ patients who seek medical care from being open about their gender identity, transgender status, or sexual orientation, and from expressing themselves in a manner consistent with their gender identity or sexual orientation. *Cf. Arroyo Gonzalez v. Rossello Nevares*, 305 F. Supp. 3d 327, 333 (D.P.R. 2018) (policy prohibiting transgender people from correcting the gender marker on their birth certificates resulted in forced disclosure of transgender status that impermissibly chilled speech).

Defendants characterize this claim as alleging only "subjective chill" and argue that such fears are not judicially cognizable. But the concrete harms alleged in the complaint are nothing like the harms alleged in the cases cited in defendants' motion. In two of the cases – *Laird* and *Amnesty International* – the Supreme Court held that litigants lacked standing to pursue challenges to government surveillance programs premised on the theory that the mere existence of such programs chills their speech because their fears of future unlawful action were insufficiently concrete. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410-20 (2013); *Laird v. Tatum*, 408 U.S. 1, 9-16 (1972). *American Library Association v. Barr* is also inapposite: the D.C. Circuit held that litigants must demonstrate a "credible threat" of prosecution in order to pursue a pre-enforcement challenge to a child pornography statute, and found that "subjective" claims that the statute chills speech are not enough to confer standing. 956 F.2d 1178, 1194 (D.C. Cir. 1992).

Here, in contrast, plaintiffs have already presented "'substantial evidence' . . . that the 2020

Rule's elimination of the explicit prohibition on discrimination based on sex stereotyping and gender identity has caused – and will continue to cause – patients to fear discrimination at the hands of third parties." *Whitman-Walker*, 2020 WL 5232076, at *12 (citation omitted). As the Court observed in enjoining aspects of the Revised Rule, there is "no denying that transgender individuals face discrimination, harassment, and violence because of their gender identity." *Id.* at *22 (quoting *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034, 1051 (7th Cir. 2017)).

Defendants are not saved by a single, explicit reference to the First Amendment in the Revised Rule. The provision they cite is not part of the regulations implementing Section 1557 – it is part of an amendment to an unrelated regulation pertaining to educational programs. *See* 85 Fed. Reg. at 37,243 (45 C.F.R. § 86.18(c)). Defendant's motion to dismiss plaintiffs' Free Speech Claim should be denied.

D. Plaintiffs State an Establishment Clause Claim.

The Establishment Clause prohibits the government from providing religious accommodations or exemptions to the detriment of third parties without regard to their interests. *See Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005); *Est. of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709-10 (1985). Such religious exemptions impermissibly prefer the religion of those who are benefited over the beliefs and interests of those who are not. *See, e.g.*, *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 15 (1989) (plurality opinion); *McCreary Cnty., Ky. v. ACLU of Ky.*, 545 U.S. 844, 860 (2005); *Santa Fe Indep. Sch. Dist. v. Doe*, 530 U.S. 290, 302 (2000).

Plaintiffs allege the Revised Rule violates these principles by imposing costs, burdens, and harms on plaintiffs, their members, and patients to facilitate the religious beliefs of objecting providers, without exception. (*See* Compl. ¶¶ 295-300.) By incorporating Title IX's blanket religious exemption, as well as the "definitions, exemptions, affirmative rights, or protections" from unrelated statutes, 85 Fed. Reg. at 37,245, defendants purport to allow health care institutions and providers to deny care or treatment to LGBTQ people based on religious, conscience, or moral grounds. And defendants shift these undeniably substantial burdens onto Plaintiffs, their members, and their patients without an exception "for special circumstances," *Caldor*, 472 U.S. at 709 – such

as if an LGBTQ patient seeks care in a rural area with only one hospital for miles (*see* 85 Fed. Reg. at 37,218 (religious exemptions would make it harder to find healthcare in low provider areas), or if "a high percentage" of a health care provider's work force denies care. *Caldor*, 472 U.S. at 709. Defendants also ignore that the burdens are especially acute in the healthcare context.

In moving to dismiss, defendants advance a plainly faulty argument that "the 2020 Rule merely makes clear that existing statutory protections for religious objectors apply to the 2020 Rule, so plaintiffs must show that those existing statutory provisions violate the Establishment Clause." (ECF No. 57-1 at 40.) Defendants also contend plaintiffs do not "distinguish the exemptions here from the many that have been upheld against Establishment Clause challenges." *Id*. Both arguments, however, ignore that the central problem with the religious exemption – its "unyielding weighting in favor of [objectors] over all other interests" – is exactly what the Establishment Clause forbids. *Caldor*, 472 U.S. at 709.

In any event, dismissal of plaintiffs' Establishment Clause claim would be premature without access to the administrative record. Evidence from the administrative record likely will reveal and detail the burdens on access to health care for LGBTQ people that will result from Revised Rule's sweeping religious exemptions and the harms to plaintiffs, their members, and patients, thereby demonstrating the blind favoring of religion at others' expense in violation of the Establishment Clause.

CONCLUSION

For the foregoing reasons, plaintiffs respectfully request that the Court deny defendants' motion to dismiss.

Dated: December 18, 2020

Respectfully submitted,

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** *Application for admission to U.S. District Court for the District of Columbia forthcoming.*

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

[PROPOSED] ORDER

Upon consideration of defendants' motion to dismiss, plaintiffs' opposition to the motion and the declarations and exhibits in support, any reply, and any oral argument, defendants' motion to dismiss is **DENIED**.

The Court finds that plaintiffs have standing to challenge the Revised Rule's narrowing of covered entities under Section 1557 of the ACA, the elimination of protections against discrimination on the basis of association and sex discrimination in unrelated regulations, and the elimination of enforcement mechanisms. Plaintiffs' challenges to the Revised Rule are ripe for review. Plaintiffs also have stated claims that: (1) the Revised Rule's elimination of the prohibition on categorical coverage exclusions is arbitrary and capricious and contrary to law; (2) the elimination of notice requirements and language access protections is arbitrary and capricious and contrary to law; (3) the Revised Rule imposes unreasonable barriers to health care in violation of Section 1554 of the ACA; (4) the narrowing of the scope of Section 1557 is arbitrary and capricious and contrary to law; (5) the elimination of enforcement mechanisms is arbitrary and capricious and contrary to law; (6) the elimination of regulatory protections against discrimination on the basis of association is arbitrary and capricious and contrary to law; and (7) the elimination

of protections in unrelated regulations arbitrary and capricious and contrary to law. Plaintiffs also have stated claims for violations of the Equal Protection Clause, the Due Process Clause, the Free Speech Clause, and the Establishment Clause of the United States Constitution.

DATE: _____, 2020

_____
James E. Boasberg
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*, *Plaintiffs,* v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 1:20-cv-1630

DECLARATION OF AMY NELSON, DIRECTOR OF LEGAL SERVICES, WHITMAN-WALKER HEALTH

I, Amy Nelson, declare as follows:

1. I am the Director of Legal Services at Whitman-Walker Clinic, Inc., d/b/a Whitman-Walker Health ("Whitman-Walker"). I received my J.D. degree with honors from the George Washington University Law School in 2001. I have worked at Whitman-Walker since 2008. Between 2008 and 2014, I was the Supervising Attorney for Whitman-Walker's Legal Services Department; and since 2015, I have served as the Director of Legal Services. Before joining Whitman-Walker's staff, I was first an Associate at McDermott, Will & Emery LLP in Washington, DC. I am a member of the Bars of the District of Columbia, Maryland and New York. My resume is attached as Exhibit A.

2. Whitman-Walker's in-house Legal Services Program provides no-cost advice and representation to patients of our health center, and to others in the greater Washington, DC metropolitan area who identify as lesbian, gay, bisexual, transgender or queer ("LGBTQ"), and to persons living with HIV regardless of sexual orientation or gender identity, on a wide range of health-related legal issues. These issues include access to affordable and affirming healthcare,

including health insurance coverage, and discriminatory denials of healthcare based on sexual orientation, gender identity or HIV status. Legal Services staff and volunteer attorneys have represented clients in cases raising issues of discrimination in federal and state courts; before the Equal Employment Opportunity Commission, the Office for Civil Rights in the U.S. Department of Health and Human Services ("HHS OCR"), and the Department of Labor's Office of Federal Contract Compliance; and the District of Columbia Office on Human Rights and Commission on Human Rights; and civil rights agencies of the State of Maryland, Montgomery and Prince George's Counties in Maryland, and Arlington and Fairfax County and the City of Alexandria in Virginia. We also provide legal representation on issues related to workplace rights, immigration relief, access to public benefits, name and gender changes and identity document updates for transgender persons, elder law issues, estate planning, and more.

3. I have advised many clients who encountered discrimination in healthcare settings, insurance, employment, housing, and educational settings, as to their rights and options for redress. In the twelve months from December 2, 2019 to November 30, 2020, the Legal Services staff represented 42 clients in 43 cases of healthcare discrimination, and all but one of those clients were transgender, and at least 20 of these 42 clients identified as a racial minority, as living with HIV, and/or as a non-U.S. citizen.

5. In my experience, and in the experience of my colleagues at Whitman-Walker Legal Services, most individuals with meritorious healthcare discrimination cases benefit greatly from the availability of administrative agency relief. This route provides benefits to claimants that are not available from the courts. The administrative process often prioritizes access to justice for all claimants by being low cost, prompt, and user friendly. Many of our clients file a free, immediate, on-line complaint with an enforcement agency like HHS OCR before contacting our

office to move forward. In this process, claimants are readily able to identify the multiple bases related to the alleged discrimination and identify witnesses and relevant evidence. The administrative process usually leads next to a careful examination of the alleged discrimination by the respondent. Litigation in federal or state trial courts, even when clients have substantial evidence and solid legal arguments to support their claims, is a daunting prospect for our clients. The time and energy required to work with counsel, in our cases, always pro bono counsel, is significant, exhausting, and lengthy. Our clients are living at or near the federal poverty level, have marginalized and stigmatized identities, and/or suffer significant health challenges. Such litigation is almost always prolonged and quite stressful for plaintiffs and their families and caregivers.

6. Complaints filed with agencies such as HHS OCR are an important alternative to litigation in federal or state court – particularly when agency regulations have established a complaint process which is clear, expansive, and provides substantial relief from unlawful discrimination. Such complaints can be pursued at lower cost and with considerably less stress on our clients. In many situations, the administrative complaint process can be a valuable vehicle for obtaining a resolution that is satisfactory to Whitman-Walker's client and also acceptable to the respondent. Moreover, most of Whitman-Walker's clients who seek redress from discrimination are interested not only in relief for themselves, but in changes in the respondents' policies and behavior that will make it less likely that others will experience discrimination. Since agency mandates encompass the public interest as well as the interest of individual complainants, the broad relief many of our clients seek is often more readily obtainable in an administrative proceeding.

7. Whitman-Walker staff and volunteer attorneys, over the years, have used the availability of complaint proceedings before HHS OCR – under Section 1557 and under Section

504 of the Rehabilitation Act, which addresses disability (including HIV) discrimination by federal financial assistance recipients – to pursue relief for clients who have suffered discriminatory denials of healthcare, or discriminatory health insurance policies or practices, based on gender identity or HIV status. Attorneys also have employed the complaint process to obtain significant reforms in insurance practices, particularly related to the coverage of gender-affirming care for transgender persons. The final rule issued by HHS in 2020 restricts the administrative compliant process in ways that narrow its likelihood to address our clients' discrimination and harassment, requiring our staff to undertake additional educational efforts to provide our clients and WWH staff with information about the scope of protections, ways to seek relief, and remedies available to combat the discrimination they face.

8. Whitman-Walker Legal Services depends on persons who have experienced discrimination, or others on their behalf, to contact our offices to report their experiences and seek legal advice or assistance. These individuals learn of their rights, and potential avenues of redress, through various sources of information, including notices by HHS OCR, and information provided to persons who contact those offices. In many situations, our attorneys are contacted by a potential client after that person has already filed an administrative complaint. The 2020 final HHS rule makes it less likely that individuals who have encountered discrimination will understand their rights under Section 1557; and in fact, has already chilled clients' perceptions of their right to be free from healthcare discrimination based on gender identity. We know that some clients are not reaching out to our lawyers in a timely fashion based on this misunderstanding; and we have been asked repeatedly to clarify the applicability of Section 1557 to transgender and gender expansive people for clients and for WWH staff.

9. The limitations enumerated in the final rule may also make it less likely that an

individual who has experienced discrimination that is actionable under Section 1557 will submit or pursue a timely administrative complaint. The confusion created by the final rule has resulted in increased inquiries from WWH medical and behavioral health providers who treat patients with questions about their legal right to access safe and affirming medical care. The legal team has already worked to increase our educational outreach to clients and to staff to clarify the protections that remain available under Section 1557, including the path forward for those clients who experience discrimination because of multiple aspects of their identities. Specifically, the removal of a unitary standard for all healthcare discrimination claims will make these claims even more difficult to pursue and require still more time and resources from our legal team and from our clients, who do not have time and resources to spare. If our clients are unable to access and obtain relief from the administrative process at HHS OCR because of the final rule's disaggregated approach to intersectional discrimination and failure to recognize the availability of a private right of action and compensatory damages, they will more likely abandon their claims than go to court. Thus the Rule has reduced the likelihood that our clients will seek or receive any relief under Section 1557.

I declare under penalty of perjury under the laws of the United States of America that the forgoing is true and correct.

Dated this 18th day of December, 2020.

/s/ Amy Nelson
Amy Nelson, JD

EXHIBIT A

AMY E. NELSON

201 Q St NE #3137 ● Washington DC 20002 ● 703-585-6082 ● anelson@whitman-walker.org

EMPLOYMENT HISTORY

Whitman-Walker Health (WWH)
Director of Legal Services 2015 – Present
Supervising Attorney 2008 – 2014

- Manage all aspects of nation's oldest medical-legal partnership serving 3,000 clients annually from three sites in DC; legal services are provided free of charge and prioritize low-income and vulnerable populations to address health-harming legal needs in pursuit of improved health outcomes.
- Oversee and manage casework related to living with HIV, sexual orientation and gender identity (SOGI) protections, HIPAA, medical privacy, disability law, the Affordable Care Act, Medicare, Medicaid, Ryan White HIV/AIDS Program, Social Security programs, workplace rights, private health insurance, name and gender changes, estate planning, medical debt, and immigration relief.
- Evaluate and promote programmatic coordination with other health center programs, including research, population health, and medical departments.
- Oversee pro bono volunteer recruitment and training; community engagement, including outreach and programmatic partnerships; and staff recruitment and professional development.
- Administer 9 annual grants from local and national entities, including federal grants.
- Manage and promote 2 annual fundraising events raising in excess of $400k.
- Developed and co-taught 40-hour curriculum to certify DC's first in-person assisters under the Affordable Care Act on behalf of DC's Health Benefit Exchange Authority.
- Launched the region's first name and gender change clinic in 2012 which to date has served more than 1,600 clients and trained in excess of 300 volunteers.
- Frequent speaker on transgender legal and health matters, including SOGI data collection.

Georgetown University Law Center
Adjunct Faculty, Public Interest Lawyering: Access to Health Care Fall 2016, Fall 2017

- Co-taught semester long practicum for law students at Georgetown University Law Center addressing issues related to Social Security disability programs, Medicare, and transgender health; supervised weekly student work at Whitman-Walker Health.

McDermott, Will & Emery LLP
Associate, Trial Department April 2007 – September 2008

- Practice included criminal representation, complex civil litigation, and antitrust matters before federal and state courts, arbitrators, the U.S. Department of Justice and the Securities and Exchange Commission; entire White Collar practice group moved to McDermott from Chadbourne & Parke.
- Pro bono matters included volunteering with the Washington Legal Clinic for the Homeless to represent individuals appealing denials of Social Security benefits, individuals complaining of housing violations, and individuals working to secure DC public benefits; prepared petition to Board of Corrections for Naval Records to change client's discharge status from "other than honorable" to "honorable" in case referred by Servicemembers Legal Defense Network; and advised complaining witness in a DC hate crime/assault case; coordinated with U.S. Attorney's Office.

Chadbourne & Parke LLP
Associate, White Collar Litigation — September 2004 – April 2007
Associate, Project Finance — September 2001 – September 2004

- Litigation practice focused on special investigations, criminal matters, and complex civil litigation before federal and state courts, DOJ, SEC, and the Federal Election Commission. Sample experience included presenting clients' interests to government attorneys and federal agents; fielding press inquiries and working with public relations firms to develop strategies for cases of national interest; and working with outside IT consultants to manage data transfer and production.
- Pro bono matters included drafting appellate brief and related pleadings on behalf of Florida death row inmate before the U.S. Court of Appeals for the Eleventh Circuit; victory resulted in remand to district court for evidentiary hearing; through Washington Legal Clinic for the Homeless, represented individuals in public benefits, housing, and employment discrimination matters; and establishing and advising 501(c)(3) corporation advocating public health disaster relief and veterinary assistance following 2004 tsunami.
- Project Finance practice included representation of project developers, commercial lenders, and multilateral agencies in connection with international and domestic financings, restructurings, acquisitions, and political risk insurance placement and litigation.

Neighborhood Legal Services Program
Legal Intern — Summer 1999

- Conducted initial client interviews, met with DC Housing Authority and Department of Consumer and Regulatory Affairs representatives, and assisted with Social Security claims and consumer debt issues.

Coastal Corporation
Analyst, Coastal Power Company — June 1995 – August 1997

- Participated in all aspects of project development in Latin America including energy sector research, responding to government requests for proposals, and negotiating project agreements; managed ongoing business needs of newly acquired power project in Dominican Republic and newly constructed power project in El Salvador; resident in Dominican Republic office for three months to implement operating procedures at project site.

EDUCATION

George Washington University Law School — Washington, DC
J.D. with honors — May 2001
Member, *The George Washington International Law Review*
Dean's Fellow (instructor for first year law student writing and research program)
President, Lambda Law (LGBT law students' association)

Texas A&M University — College Station, Texas
B.S., Economics — May 1995
Recipient, Lechner Honors Fellowship

PUBLICATIONS

Transgender Surgery—Not the Benchmark for Gender Marker Determination
JAMA Surgery, Dec. 2017; Vol. 152, No. 12; Co-authored with Justin D. Arnold, MMSc and Erin M. Loubier, JD; https://jamanetwork.com/journals/jamasurgery/article-abstract/2653995

Trends in Insurance Coverage for Gender-Affirming Surgeries
JAMA Surgery, published online July 18, 2018; Co-authored with Justin D. Arnold, MMSc and Erin M. Loubier, JD; http://jamanetwork.com/journals/jamasurgery/article-abstract/2688233

VOLUNTEER ACTIVITIES / HONORS

DC Mayor's Advisory Committee on Street Harassment December 2018 – Present
LGBTQ/Immigration Representative

DC Bar Board of Governors July 2018 – Present
Treasurer

We the People January 2018 – Present
Founding Member "May Is All About Trans"

GW Lambda Law Alumni Association March 2017 – Present
Board Member

Rainbow Response Coalition, Steering Committee April 2014 – August 2015
2014 Mayor's Office of Victim Services Grant

Recipient of Capital TransPride's Engendered Spirit Award May 2014

Recipient of DC Mayor's Office of LGBTQ Affairs 2014 Shero of the Movement Award March 2014

N Street Village October 2011 – December 2013
Member, HIV/AIDS Programmatic Planning Committee

Obama For America – Virginia Fall 2008; Fall 2012
Outside Poll Observer / Voter Advocate in Stephens City and Norfolk, VA

Lawyers' Committee for Civil Rights Under Law Fall 2004; Fall 2012
Election Protection Voter Hotline Volunteer

Miriam's House July 2006 – October 2011
Board of Directors, served as President, Vice President, and Secretary

Washington Legal Clinic for the Homeless December 2003 – September 2008
Volunteer Attorney, intake sessions located at Miriam's Kitchen

BAR ADMISSIONS

Admitted to practice in District of Columbia, Maryland, and New York (inactive)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DECLARACIÓN DE KELLAN VALENTIN PEDROZA

Yo, Kellan Valentín Pedroza, por la presente, declaro y expongo lo siguiente:

1. Yo soy un residente de San Juan, Puerto Rico y oriundo de Puerto Rico. Soy una persona transgénero no binario y tengo 31 años de edad.

2. Estoy presentando esta declaración en apoyo de los demandantes en este caso en contra de la regulación revisada bajo la Sección 1557 del "Affordable Care Act" ("ACA"), publicada por el Departamento de Salud y Servicios Humanos de los Estados Unidos el 19 de junio de 2020 (la "Regla Revisada"). La Regla Revisada elimina las protecciones reglamentarias explícitas para las personas LGBT en el cuidado de salud que se incluyeron en la regla final de 2016, que se promulgó en virtud de la sección 1557 en mayo de 2016.

3. Yo he colaborado con Arianna's Center, una organización afiliada de la Coalición TransLatin@. Adicionalmente, yo soy un miembro individual de la Coalición TransLatin@.

4. Yo recibo mi cobertura de salud por el Plan de Salud del Gobierno de Puerto Rico ("Vital"), que es como se conoce al Programa de Medicaid en Puerto Rico.

5. Como persona transgénero viviendo con disforia de género, necesito accesso a tratamientos de salud para el propósito de afirmación de género.

6. Parte del tratamiento de afirmación de género que deseo y necesito es círugia de afirmación de género.

7. Sin embargo, no puedo obtener dicha cirugía porque mi seguro médico excluye categóricamente la cobertura de tratamiento de afirmación de género, particularmente la cirugía.

8. El Plan de Salud del Gobierno de Puerto Rico ("Vital") específicamente excluye: "Procedures for sex changes, including hospitalizations and complications." Dicha exclusión está delineada en https://www.sssvital.com/en/non-covered-services/.

9. Como residente y oriundo de Puerto Rico, español es mi primer idioma.

10. Es importante para mí el poder conocer mis derechos y recursos disponibles a mi persona mediante notificaciones en mi idioma, español. Temo que no conoceré mis derechos y los recursos disponibles a mí si mis proveedores de salud o asegurador de salud no tienen que notificarme de dichos derechos y recursos en español.

[Firma en la página siguiente].

Declaro bajo pena de perjurio bajo las leyes de los Estados Unidos que lo anterior es verdadero y correcto.

Firmado en día 18 de diciembre del año 2020.

DocuSigned by:
61DDC2A6DE9E45C...

_____
Kellan Valentín Pedroza

Multilingual CONNECTIONS

Certificate of Accuracy

I certify that **Statement of Kellan Valentin Pedroza** was translated into **English** by translators and editors working for Multilingual Connections who are competent and qualified to perform translation into these languages. These documents have not been translated for a family member, friend, or business associate. I believe, to the best of my knowledge and abilities, that the attached materials are accurate and complete translations of the original **Spanish** version.

The original document consists of **3** page(s). The translated document consists of **3** page(s).

Theodore Jackson
Multilingual Connections, LLC

State of Illinois
County of Cook

Signed and attested before me on December 16th, 2020 by Theodore Jackson.

Notary Public

[stamp]

RACHEL SCHASTOK
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
March 13, 2024

ata American Translators Association CORPORATE MEMBER

Multilingual Connections, LLC #255450
PM: Hasan - 1568

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

STATEMENT OF KELLAN VALENTIN PEDROZA

I, Kellan Valentín Pedroza, hereby state and declare the following:

1. I am a resident of San Juan, Puerto Rico and a native of Puerto Rico. I am a non-binary transgender person, and I am 31 years old.

2. I am presenting this statement in support of the plaintiffs in this case against the revised regulation under Section 1557 of the "Affordable Care Act" ("ACA"), published by the United States Department of Health and Human Services on June 19, 2020 (the "Revised Rule"). The Revised Rule removes the explicit regulatory protections for LGBT people in health care that were included in the 2016 final rule, which was enacted under section 1557 in May 2016.

3. I have collaborated with Arianna's Center, an affiliate organization of the TransLatin@ Coalition. Additionally, I am an individual member of the TransLatin@ Coalition.

4. I receive my health coverage through the Puerto Rico Government Health Plan ("Vital"), which is how Puerto Rico's Medicaid Program is known.

5. As a transgender person living with gender dysphoria, I need access to health treatments for the purpose of gender affirmation.

6. Part of the gender affirmation treatment that I want and need is gender affirmation surgery.

7. However, I cannot get such surgery because my health insurance categorically excludes coverage for gender affirming treatment, particularly surgery.

8. The Puerto Rico Government Health Plan ("Vital") specifically excludes: "Procedures for sex changes, including hospitalizations and complications." Such exclusion is outlined at https://www.sssvital.com/en/non-covered-services/.

9. As a resident and native of Puerto Rico, Spanish is my first language.

10. It is important for me to be able to know my rights and resources available to me through notifications in my language, Spanish. I fear that I will not be aware of my rights and the resources available to me if my healthcare providers or health insurer are not obliged to notify me of those rights and resources in Spanish.

[Signature in the next page].

I declare, under penalty of perjury, and under the laws of the United States, that the above information is true and correct.

Signed on December __ of the year 2020.

_____
Kellan Valentín Pedroza