IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., et al.,

Plaintiffs,

v.

Case No. 1:20-cv-01630 (JEB)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION OR, IN THE ALTERNATIVE, A STAY PENDING JUDICIAL REVIEW PURSUANT TO 5 U.S.C. § 705

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Plaintiffs respectfully submit this memorandum of points and authorities in support of their motion for a preliminary injunction enjoining implementation of the rule promulgated by the U.S. Department of Health and Human Services ("HHS") entitled, Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020) (to be codified at 42 C.F.R. pts. 438, 440, & 460 and 45 C.F.R. pts. 86, 92, 147, 155, & 156) (the "Revised Rule"), or, in the alternative, staying the Revised Rule pending judicial review pursuant to 5 U.S.C. § 705.

Plaintiffs are two private health care facilities that provide services to LGBTQ people (Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health and Los Angeles LGBT Center); two LGBTQ-service organizations that provide a wide range of services to the LGBTQ community (the TransLatin@ Coalition and Bradbury-Sullivan LGBT Community Center); two national associations of health professionals (American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality and AGLP: The Association of LGBTQ+ Psychiatrists); and three individual physicians and one behavioral health provider who work for the private health care provider plaintiffs (Dr. Sarah Henn, Dr. Randy Pumphrey, Dr. Robert Bolan, and Dr. Ward Carpenter) (collectively, "plaintiffs").

INTRODUCTION

The Patient Protection and Affordable Care Act ("ACA") has a clear statutory command: HHS "shall *not* promulgate any regulation that," among other things, "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 (emphasis added). But that is precisely what HHS has done. In willful disregard of this command and in defiance of the Supreme Court's decision in *Bostock v. Clayton County, Georgia*, 590 U.S. ____, 2020 WL 3146686 (June 15, 2020), HHS has published a regulation that invites discrimination against LGBTQ people, people with limited English proficiency ("LEP"), and others; burdens affirming health care providers; endangers public health; and harms the health and well-being of LGBTQ people, individuals with LEP, and countless others. And HHS has done so in the midst of a global pandemic.

As of the time of this filing, more than 130,000 Americans have died as a result of what may be the worst public health crisis in America in over a century. An nearly 3 million Americans have tested positive for COVID-19. An effective response to this pandemic turns on the unprecedented testing of patients and tracing the contacts of any person who tests positive. For this to occur, people need to trust their health care providers. The Revised Rule will create the opposite effect. It will cause people to delay health care because of fear of discrimination and undermine our nation's ability to respond to the COVID-19 pandemic.

The Revised Rule is a paradigmatic example of arbitrary and capricious agency action. It purports to implement Section 1557 of the ACA, which specifically and explicitly prohibits discrimination in the provision of health care services on the basis of a person's sex, race, color, national origin, age, and disability. But instead of effectuating the statute's purpose, the Revised Rule undermines it. HHS also failed entirely to consider the harms to LGBTQ people and people with LEP, among others, that will result from the Revised Rule, including denial of access to health care and information. This failure permeated the entire rulemaking process, rendering the entire rule arbitrary and capricious. The Revised Rule also conflicts with existing laws that prohibit discrimination in health care and protect access to care and information. Put simply, the Revised Rule is infected in its entirety by a failure to consider the harms to the health and well-being of LGBTQ people and those with LEP, as well as to public health. Each of its provisions erects a barrier to access to health care for millions of Americans.

Plaintiffs, their members, and their patients will suffer immediate and irreparable harm if the Revised Rule is allowed to go into effect on August 18, 2020, only 60 days after publication. The Court should enjoin the Revised Rule or stay its effective date.

¹ Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Cases in the U.S.*, https://perma.cc/A8VV-MFB6 (last visited July 9, 2020).

² *Id*.

³ See A National Plan to Enable Comprehensive COVID-19 Case Finding and Contact Tracing in the US (Apr. 10, 2020), at 3 ("COVID-19 Plan"), https://perma.cc/GY86-WXNL.

FACTUAL BACKGROUND

A. Discrimination Against LGBTQ People Prior to the Affordable Care Act

HHS has documented that before the ACA was enacted in 2010, Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), transgender people experienced many forms of discrimination in accessing health care services, insurance coverage, and facilities. HHS reported that for "transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them." *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 31,460 (May 18, 2016) (formerly 45 C.F.R. pt. 92) (the "2016 Final Rule"). For example, "[i]n a 2010 report, 26.7% of transgender respondents reported that they were refused needed health care. A 2011 survey revealed that 25% of transgender individuals reported being subject to harassment in medical settings." *Id*.

Some entities providing insurance or health care discriminated against transgender patients by refusing to cover medically necessary treatments for gender dysphoria—a serious medical condition codified in the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and International Classification of Diseases (ICD-11)—based on the misguided assumption that such treatments were cosmetic and experimental. *Id.* at 31,429. Those discriminatory exclusions prevented transgender people from obtaining medically necessary treatment for gender dysphoria in accordance with accepted standards of care. *Id.* at 31,460.

Today, medical consensus recognizes that such exclusions have no basis in medical science.⁴ As HHS recognized in 2016, the overwhelming consensus among medical experts and every major medical organization is that treatments for gender dysphoria, including surgical procedures, are effective, safe, and medically necessary when clinically indicated to alleviate gender dysphoria. *See* 81 Fed. Reg. at 31,429.

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⁴ See Decision No. 2576, National Coverage Determination 140.3: Transsexual Surgery at 18 (Docket No. A-13-87) (U.S. Dep't of Health & Human Servs. Appeals Bd. App. Div. 2014), https://perma.cc/3BGA-F9DH; see also Ettner ¶¶ 48–51.

B. Sections 1554 and 1557 of the ACA

In enacting the ACA, Congress recognized the importance of providing patients with prompt and nondiscriminatory access to medical care and information about all treatment options. These principles are codified in Sections 1554 and 1557 of the ACA.

Section 1554 prohibits HHS from promulgating regulations that conflict with the primary purpose of the Act—increasing access to timely, effective, and ethical health care. Specifically, it forbids the Secretary of HHS from promulgating any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impedes timely access to healthcare services," or "interferes with communications regarding a full range of treatment options between the patient and the provider," among other things. 42 U.S.C. § 18114.

Section 1557 prohibits discrimination based on sex, which includes discrimination based on gender identity, transgender status, sexual orientation, and failure to conform to sex stereotypes. It also prohibits discrimination on the basis of race, color, national origin, age, and disability. Section 1557 provides, in relevant part:

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

42 U.S.C. § 18116(a).

Because Section 1557 applies to "any health program or activity," it covers nearly every health care provider in the country. Section 1557 authorizes HHS to "promulgate regulations to implement this section," limited, of course, by the restrictions in Section 1554. *Id.* § 18116(c).

C. The 2016 Final Rule

On May 18, 2016, HHS published the 2016 Final Rule implementing Section 1557, which specifically defined the statute's prohibition on discrimination "on the basis of . . . sex," to include

"discrimination on the basis of . . . sex stereotyping, and gender identity." 81 Fed. Reg. at 31,467 (formerly 45 C.F.R. § 92.4). The 2016 Final Rule defined "gender identity" as "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth." *Id.* at 31,467. The 2016 Final Rule defined "sex stereotypes" as stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. *Id.* at 31,468. The 2016 Final Rule explained that its express references to gender identity and sex stereotyping were necessary to mitigate ongoing discrimination against transgender patients:

[D]espite the ACA improving access to health services and health insurance, many . . . transgender individuals continue to experience discrimination in the health care context, which can lead to denials of adequate health care and increases in existing health disparities in underserved communities. This continued discrimination demonstrates the need for further clarification regarding the prohibition of discrimination on the basis of sex.

Id. at 31,460 (emphasis added).

HHS intentionally included gender identity and sex stereotyping within the definition of "on the basis of sex" to expand and protect the improvements in coverage and access to health services transgender people had continued to experience since Section 1557's enactment. *Id.*; *see also id.* at 31,455. HHS also supported the increased protections from an economic perspective as insurers would compensate health care providers for an expanded menu of services, resulting in significant savings to the federal government. *Id.* at 31,461. Finally, HHS took into account the intangible benefits of providing "equal access to health care for all." *Id.*

The 2016 Final Rule specifically required covered entities to treat individuals consistent with their gender identity and prohibited covered entities from having or implementing "a categorical coverage exclusion or limitation for all health care services related to gender transition" because such an exclusion is "discriminatory on its face." *Id.* at 31,456; 31,471 (formerly 45 C.F.R. § 92.206); 31,472 (formerly 45 C.F.R. § 92.207(b)(4)).

The 2016 Final Rule applied to "every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity." *Id.* at 31,466 (formerly 45 C.F.R. § 92.2(a)). HHS estimated that the rule would "likely cover almost all licensed physicians because they accept Federal financial assistance." *Id.* at 31,445.

The 2016 Final Rule also included provisions to ensure that the approximately 25 million Americans with LEP have access to the health care they need.⁵ It required health care providers and other covered entities to post nondiscrimination notices, include "taglines"—short statements that inform individuals of their right to language assistance and how to seek such assistance—in the top 15 languages spoken throughout the state, and adopt grievance procedures. *Id.* at 31,469 (formerly 45 C.F.R. §§ 92.7, 92.8). The 2016 Final Rule also included standards for language assistance services for persons with LEP. *Id.* at 31,470-71 (formerly 45 C.F.R. § 92.201).

Consistent with the plain language of Section 1557, the 2016 Final Rule adopted a unitary legal standard for addressing discrimination in health care and enforcing Section 1557. *Id.* at 31,472 (formerly 45 C.F.R. § 92.301). HHS explained that all enforcement mechanisms available under the statutes listed in Section 1557 are available for purposes of Section 1557 enforcement, regardless of an individual's protected characteristic or characteristics. *Id.* at 31,439-40. The preamble reinforced this plain meaning understanding of Section 1557's unitary standard. *See id.* at 31,439-40.

The 2016 Final Rule also ensured its application would not unduly impinge on religious freedoms and liberties. HHS did not include Title IX's blanket religious exemption because Section 1557 "contains no religious exemption," and HHS determined religious exemptions in the

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⁵ U.S. Census Bureau, *Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1601 (2018), https://perma.cc/Z452-RSWR; U.S. Census Bureau, *Characteristics of People by Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1603, https://perma.cc/R59J-HG4K.

educational context of Title IX were not directly transferable to the health care context. *Id.* at 31,380. Instead, HHS determined a "more nuanced approach in the health care context" was warranted because "a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results." *Id.* The 2016 Final Rule thus provided: "Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required." *Id.* at 31,466 (formerly 45 C.F.R. § 92.2(b)(2)).

The 2016 Final Rule has resulted in a decrease in discriminatory policies and practices. It also helped persuade Medicaid administrators, insurance companies, and employee health plan sponsors to eliminate outdated exclusions that discriminated on the basis of sex and to cover procedures supported by evidence of medical necessity.⁶ For example, a recent study of 37 states in the federal marketplace showed that in 2020, 97% of plans did not contain blanket exclusions of transition-related care.⁷

D. The Proposed Revisions to the 2016 Final Rule

As part of the Trump Administration's concerted and aggressive effort to undermine protections for LGBTQ people,⁸ on June 14, 2019, HHS issued a Notice of Proposed Rulemaking, proposing to "make substantial revisions" to the 2016 Final Rule. *See* Notice of Proposed Rulemaking, Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846, 27,848 (June 14, 2019) ("Proposed Rule"). Those revisions included: repealing the definition of "on the basis of sex" and the specific prohibition on discrimination on the basis of

⁶ See Sharita Gruberg and Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (Mar. 7, 2018), https://perma.cc/CTP2-UMEJ.

⁷ Out2Enroll, *Summary of Findings: 2020 Marketplace Plan Compliance with Section 1557*, https://perma.cc/WU25-C9BN.

⁸ See, e.g., Erica L. Green, Katie Benner & Robert Pear, 'Transgender' Could Be Defined Out of Existence Under Trump Administration, N.Y. Times (Oct. 21, 2018), https://perma.cc/YQR6-YN2F; Notification of Nonenforcement of Health and Human Services Grants Regulation, 84 Fed. Reg. 63,809 (Nov. 19, 2019).

gender identity and sex stereotyping; eliminating the notice and critical language access requirements; narrowing the scope of entities covered under Section 1557; eliminating the unitary legal standard and mechanisms for enforcing violations of Section 1557; incorporating sweeping religious exemptions; eliminating gender identity and sexual orientation protections in unrelated regulations; and eliminating protections related to discrimination on the basis of association. *Id.* at 27,848-49.

HHS received nearly 200,000 comments during the public comment period. 85 Fed. Reg. at 37,164. Those comments identified and expressed concerns about many of HHS's proposed revisions, emphasizing that the proposed changes, individually or combined, will cause immediate and irreparable harm to LGBTQ people. For example, they noted that repealing the definition of "on the basis of sex" and the specific prohibition on discrimination on the basis of gender identity and sex stereotyping will invite covered health care providers and insurers to discriminate against transgender people and cause confusion about patients' rights. *Id.* at 37,164-65. Commenters also observed that eliminating notice requirements and critical language access provisions will result in decreased access to health care for patients with LEP. *Id.* at 37,204. In addition, narrowing the scope of entities covered under Section 1557 will cause drastic reductions in protections and insurance coverage for LGBTQ people. *Id.* at 37,170-74.

E. The Revised Rule

Despite the significant concerns raised during the comment period, HHS published the Revised Rule on June 19, 2020, with only "minor and primarily technical corrections." *Id.* at 37,161. HHS claimed it was promulgating the Revised Rule to "better comply with the mandates of Congress," further "substantive compliance," reduce confusion, and "clarify 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.*

In publishing the Revised Rule, HHS did not take into account that, just four days earlier, on June 15, 2020, the Supreme Court held that discrimination based on transgender status or sexual

orientation "necessarily entails discrimination based on sex." *Bostock*, 2020 WL 3146686, at *11.9 Rather, HHS proceeded with its elimination of the definition of "on the basis of sex" and the 2016 Final Rule's specific prohibitions on discrimination on the basis of gender identity and sex stereotyping, despite having acknowledged that "a holding by the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the basis of sex' under Title IX." 85 Fed. Reg. at 37,168.

Relying essentially on one district court opinion—*Franciscan Alliance, Inc.* v. *Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016)—which the preamble cites more than 40 times, HHS claimed "the ordinary public meaning of the term 'sex' in Title IX is unambiguous" and refers to a "biological binary meaning of sex." 85 Fed. Reg. at 37,178-80. HHS also declared that discrimination on the basis of sex under Title IX does not encompass discrimination based on gender identity or sex stereotyping. *Id.* at 37,183-86. According to HHS, it means "discrimination on the basis of the fact that an individual is biologically male or female." *Id.* at 37,178.

HHS also adhered to its other proposed revisions, repealing the notice and access to language provisions; excluding from Section 1557's scope certain health programs and activities and health insurance plans; incorporating sweeping religious exemptions; repealing the unitary legal standard; and repealing gender identity and sexual orientation protections in unrelated regulations and provisions relating to nondiscrimination based on association. *Id.* at 37,161-62.

F. Harms to Plaintiffs, Their Members, Their Patients, and Health Care Providers and Patients Nationwide

The Revised Rule's elimination of the specific prohibitions on discrimination on the basis of gender identity and sex stereotyping means plaintiffs' members and LGBTQ patients will face a greater risk of discrimination in health care. Patients may even be outright denied care on the

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⁹ Although the 2016 Final Rule framed discrimination against transgender people in terms of "gender identity" and *Bostock* framed it in terms of "transgender status," the result is the same: discrimination against transgender people is sex discrimination. *See*, *e.g.*, *Bostock*, 2020 WL 3146686, at *19 n.6 (Alito, J., dissenting) ("[T]here is no apparent difference between discrimination because of transgender status and discrimination because of gender identity.").

basis of their gender identity, transgender status, or sexual orientation. Many LGBTQ patients (including patients of Whitman-Walker Health and the LA LGBT Center) report being discriminated against on the basis of their sexual orientation, gender identity, or transgender status when seeking health care. Shafi ¶¶ 9, 17; Henn ¶ 9; Pumphrey ¶ 10; Cummings ¶ 22; Bolan ¶¶ 8-9, 12, 23; Carpenter ¶¶ 4, 8, 22; *see also* Vargas ¶¶ 10, 20-22; Harker ¶¶ 8-9; Shanker ¶¶ 17, 19. The problem is particularly acute for transgender patients who seek treatment for gender dysphoria or gender-affirming care, although transgender patients are discriminated against and misgendered even when they seek basic care. Shafi ¶ 17(c)-(e); Henn ¶ 9(a), (c), (g)-(j), (n), (o); Pumphrey ¶ 10(a); Cummings ¶¶ 22(a)-(c), 22(g), 22(h); Bolan ¶¶ 8-9, 12, 23; Carpenter ¶¶ 8, 22; *see also* Vargas ¶ 20(a)-(b); Harker ¶ 9; Shanker ¶¶ 8, 17, 19; Salcedo ¶¶ 11, 14, 20, 22, 31; Lint ¶¶ 16, 24, 28-31, 42-43.

In addition, patients will face and fear increased discrimination, which for many patients will cause them to delay or avoid obtaining needed medical care. Shafi ¶¶ 21, 22; Henn ¶¶ 7, 11, 19; Pumphrey ¶¶ 7, 12, 13; Cummings ¶¶ 5, 8, 16-19, 22(k), 22(m); Bolan ¶¶ 11-12, 15, 19-20; Carpenter ¶¶ 8(c), 9, 11, 16, 18-19; see also Salcedo ¶¶ 24, 25, 31, 33; Lint ¶ 48; Vargas ¶ 20(c); Harker ¶ 8; Shanker ¶¶ 22-23; Fabian ¶ 20. And if they do seek care, they will be discouraged from fully disclosing personal information that health care providers need for proper diagnosis and treatment. Cummings ¶¶ 22(g), (l)-(m), 24, 29; Carpenter ¶¶ 9, 11, 12 14; see also Harker ¶ 19; Shanker ¶¶ 22-23. Patients' delays or failures to obtain treatment will increase the direct cost of treating physical medical conditions and create risks to patient safety that can lead to poor patient outcomes. The Revised Rule thus will increase costs to patients, insurers, providers, and the overall health care system. Shafi ¶¶ 19-23; Cummings ¶¶ 14, 18, 20, 26, 33; see also Shanker ¶ 25; Salcedo ¶ 36.

The Revised Rule's elimination of the explicit prohibitions on categorical coverage exclusions for gender-affirming care, combined with its narrow interpretation of what constitutes a covered entity, will result in a reduction in coverage and access to medically necessary health care for transgender and gender nonconforming patients. Shanker ¶ 28; Shafi ¶¶ 24-29; Cummings

¶ 30; Salcedo ¶ 39; Lint ¶¶ 48, 57-58. As a result, the private health care provider plaintiffs will face increased costs because many private and public plans will refuse to cover medically necessary procedures based on the Revised Rule's elimination of protections against gender identity discrimination. Shafi ¶ 35; see also Salcedo ¶ 44. Plaintiffs, in turn, will be forced to 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. Likewise, patients may forgo necessary care due to the high cost of these procedures.

The Revised Rule also will immediately scale back the notice and language access requirements from the 2016 Final Rule. The elimination of these notices will harm LGBTQ patients with LEP, in particular, because it will be more difficult for them to be aware of their rights, which language services and aids are available, how to access such services, and how to handle discrimination and complaints. Salcedo ¶¶ 40-41; Lint ¶ 53; Shafi ¶ 32; Cummings ¶¶13, 33. The health care system was already difficult to navigate for individuals with LEP, and the Revised Rule exacerbates these difficulties, undermining access to health care, health insurance, and legal redress. Salcedo ¶ 41; Lint ¶ 55; Shafi ¶ 32; Cummings ¶¶ 13, 27.

LEGAL STANDARD

A preliminary injunction is a stopgap measure to "preserve the relative positions of the parties" pending judicial review on the merits. *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). The Administrative Procedure Act ("APA") separately authorizes the Court to "postpone the effective date of an agency action" pending judicial review to "preserve status" and "prevent irreparable injury." 5 U.S.C. § 705. Section 705 "plainly and simply authorizes courts to stay agency rules pending judicial review." *District of Columbia v. U.S. Dep't of Agric.*, No. 20 Civ. 119, 2020 WL 1236657, at *34 (D.D.C. Mar. 13, 2020) (cleaned up).

A party seeking a preliminary injunction must "make a 'clear showing that four factors, taken together, warrant relief: likely success on the merits, likely irreparable harm in the absence of preliminary relief, a balance of the equities in its favor, and accord with the public interest."

Pursuing Am.'s Greatness v. FEC, 831 F.3d 500, 505 (D.C. Cir. 2016) (quoting Winter v. Natural Resources Def. Council, 555 U.S. 7, 20 (2008)).

Although plaintiffs seeking a preliminary injunction "have the burden of demonstrating likelihood of success on the merits, they are not required to prove their case in full at the preliminary injunction stage, but only such portions that enable them to obtain the injunctive relief that they seek." *Jacinto-Castanon de Nolasco v. U.S. Imm. & Customs Enforcement*, 319 F. Supp. 3d 491, 499 (D.D.C. 2018). Similarly, where "multiple causes of action are alleged, plaintiff need only show likelihood of success on one claim to justify injunctive relief." *Kirwa v. U.S. Dep't of Defense*, 285 F. Supp. 3d 21, 35 (D.D.C. 2017) (cleaned up). Courts in this district routinely grant motions for preliminary injunctions upon a finding that plaintiffs are likely to prevail on at least one claim entitling them to injunctive relief. *See, e.g., Jubilant DraxImage Inc. v. U.S. Int'l Trade Comm'n*, 396 F. Supp. 3d 113, 123 (D.D.C. 2019); *FBME Bank Ltd. v. Lew*, 125 F. Supp. 3d 109, 118 (D.D.C. 2015).

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.

A. The Revised Rule Violates the APA.

1. The Revised Rule is Arbitrary and Capricious.

The APA requires courts to "hold unlawful and set aside agency actions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency rule is arbitrary and capricious if the agency has "entirely failed to consider an important aspect of the problem," or "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency "is required to 'examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Stewart v. Azar*, 366 F. Supp. 3d 125, 135 (D.D.C. 2019) (Boasberg, J.) (quoting *State Farm*, 463 U.S. at 43). Where an agency departs from a prior policy, it must "display awareness that it is changing position," show that "there are good reasons" for the

reversal, and demonstrate that its new policy is "permissible under the statute." F.C.C. v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009). The agency must also "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account." Dep't of Homeland Sec. v. Regents of the Univ. of California, 140 S. Ct. 1891, 1913 (2020) (quoting Encino Motorcars LLC v. Navarro, 136 S. Ct. 2117, 2126 (2016)). It is "arbitrary and capricious to ignore such matters." Id.

The Revised Rule fails on all accounts. HHS failed to supply a reasoned explanation for its policy change from the 2016 Final Rule, it adopted a regulation not supported by and contrary to the evidence in the administrative record, and it failed to address important issues raised during the notice-and-comment process – in particular, the substantial harms LGBTQ people will suffer as a result of the Revised Rule.

a. HHS Failed to Supply a Reasoned Explanation for its Policy Change from the 2016 Final Rule to the Revised Rule.

The Revised Rule represents a significant change in policy from the 2016 Final Rule, eliminating many of the 2016 Final Rule's protections from discrimination in health care for LGBTQ people. The record before HHS does not support its proffered justifications for the Revised Rule – "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. The Revised Rule conflicts with Section 1557's prohibitions on discrimination in health care and the *Bostock* decision. It conflicts with Section 1554's prohibition on rules that create unreasonable barriers and impede access to health care services. The Revised Rule creates confusion; it does not reduce it. And there is no evidence that the Revised Rule furthers substantive compliance. The problems with the Revised Rule are particularly apparent with respect to the elimination of the definition of "on the basis of sex," the elimination of the prohibition on categorical insurance coverage exclusions, the elimination of notice and language access requirements, and the narrowing of entities covered under Section 1557.

(1) Bostock Forecloses HHS's Elimination of the Definition of "On the Basis of Sex."

On June 15, 2020, in *Bostock*, the Supreme Court categorically held that discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex." *Bostock*, 2020 WL 3146686, at *11. The Court declared: "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual on the basis of sex." *Id.* at *7. Nevertheless, undeterred from its goal to foster discrimination against LGBTQ people, four days later on June 19, 2020, HHS published the Revised Rule repealing the 2016 Final Rule's definition of discrimination "on the basis of sex" and its specific prohibitions on discrimination on the basis of gender identity and sexual orientation. It did so even though the Revised Rule acknowledged that "a holding by the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the basis of sex' under Title IX." 85 Fed. Reg. at 37,168.

Moreover, HHS not only eliminated the definition of discrimination "on the basis of sex," but also declared affirmatively that discrimination on the basis of sex *does not* include discrimination on the basis of gender identity or sexual orientation. *See, e.g., id.* at 37,183 ("The Department disagrees with commenters who contend that Section 1557 or Title IX encompass gender identity discrimination within their prohibition on sex discrimination."); *id.* at 37,180 ("Unlike other bases of discrimination, the categories of gender identity and sexual orientation . . . are not set forth" in the statutes incorporated into Section 1557). HHS staked its position entirely on: (1) the *Franciscan Alliance* decision where HHS refused to defend the 2016 Final Rule's provisions or to appeal the district court's ruling; and (2) the government's litigation position in *Bostock* "that discrimination 'on the basis of sex' in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity." *Id.* at 37,168.

Bostock conclusively rejects HHS's position that Section 1557 does not encompass discrimination against LGBTQ people and forecloses its repeal of the definition of discrimination "on the basis of sex." Bostock also forecloses HHS's elimination of gender identity and sexual orientation protections in unrelated regulations. See 85 Fed. Reg. at 37,219.

In light of the Supreme Court's ruling in *Bostock*, HHS could have postponed publication of the Revised Rule, as commenters urged, *see* 85 Fed. Reg. at 37,168, or rescinded it altogether. *See, e.g., Williams Natural Gas Co. v. FERC*, 872 F.2d 438, 450 (D.C. Cir. 1989); *State Farm*, 463 U.S. at 42. It did neither.

Even apart from *Bostock*, HHS acted arbitrarily and capriciously in eliminating the definition of discrimination "on the basis of sex." HHS claimed in so doing it was reverting to "longstanding statutory interpretations" of the civil rights statutes underlying Section 1557 that conform with the government's "official position concerning those statutes." 85 Fed. Reg. at 37,161. But in 2012, OCR specifically stated, "Section 1557's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity," and took the position that Section 1557 prohibited discrimination on the basis of sexual orientation. ¹⁰ In addition, in 2015, OCR entered into a voluntary agreement with The Brooklyn Hospital Center resolving allegations of gender identity discrimination under Section 1557. *See* 85 Fed. Reg. at 37,191. Consistent with OCR's position, the 2016 Final Rule defined discrimination "on the basis of sex" to include discrimination against LGBTQ people. *See* 81 Fed. Reg. at 31,467 (formerly 45 C.F.R. § 92.4).

HHS also ignored the considered views of other agencies and dozens of federal district and appellate courts, which held that discrimination on the basis of transgender status is a form of sex discrimination. *See* Letter from Sasha Buchert, Senior Attorney, Lambda Legal, et al., to the Hon. Alex M. Azar, II, Sec'y, U.S. Dep't Health & Hum. Servs. (Aug. 13, 2019), at 9-11, https://perma.cc/FV38-3ZLC (documenting cases).

HHS did not provide a reasonable explanation for its change in position. Rather, HHS simply "disavow[ed] the views" in the 2012 letter and the voluntary resolution agreement, stating it had "concluded that the 2012 OCR letter reflected an incorrect understanding of Title IX, as

¹⁰ Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), https://perma.cc/RB8V-ACZU.

incorporated into Section 1557." 85 Fed. Reg. at 37,191. HHS provided no further explanation, as required under *Fox Television Stations* when there is a policy reversal. *See* 556 U.S. at 515. The Revised Rule is arbitrary and capricious and should be set aside.

(2) HHS's Elimination of the Prohibition on Categorical Coverage Exclusions is Unreasonable and Not Supported by the Evidence.

HHS attempts to justify its elimination of the 2016 Final Rule's prohibition on categorical coverage exclusions related to gender-affirming care by claiming the prohibition "inappropriately interfered with the ethical and medical judgment of health professionals." 85 Fed. Reg. at 37,187. HHS stated it "does not believe that the nondiscrimination requirements in Title IX, incorporated by reference into Section 1557, foreclose medical study or debate on these issues." *Id.*

HHS's reasoning is illogical. Nothing in the 2016 Final Rule foreclosed medical study or debate on gender-affirming care. It simply prohibited insurance companies from *categorically* excluding or limiting coverage for *all* health services related to gender-affirming care. *See* 81 Fed. Reg. at 31,429. As such, the 2016 Final Rule enabled doctors, rather than insurance companies, to use their medical expertise to make individualized treatment decisions. If the Revised Rule goes into effect, many doctors who deem gender-affirming care to be medically necessary will be forced to either forgo compensation from insurers or deny patients care. Thus, it is the Revised Rule, not the 2016 Final Rule, that "inappropriately interfere[s] with the ethical and medical judgment of health professionals." 85 Fed. Reg. at 37,187.

HHS's decision to allow insurers to once again categorically exclude or limit coverage for gender-affirming care is based on a supposed "lack of scientific and medical consensus" regarding "the value of various 'gender-affirming' treatments for gender dysphoria." *Id.* This statement runs counter to the national medical consensus, and the evidence on which HHS relies does not support its conclusions.

First, virtually every major medical and mental health organization in the United States, including the American Medical Association, the Endocrine Society, the American Psychological Association, and the American Psychiatric Association, among others, has endorsed the protocols

for gender-affirming treatment set forth in the *Standards of Care for the Health of Transsexual, Transgender and Gender-nonconforming People*, published by the World Professional Association for Transgender Health (WPATH). Ettner ¶ 31.

Second, HHS cites an August 30, 2016 decision in which the Centers for Medicare and Medicaid Services ("CMS") "declined to issue a National Coverage Determination (NCD) on sexreassignment surgery for Medicare beneficiaries with gender dysphoria." 85 Fed. Reg. at 37,187 & n.157 (citing CMS, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (Aug. 30, 2016), https://perma.cc/9S73-4WQB). But declining to issue a NCD only means coverage determinations are made on a case-by-case basis, not that such treatment is or may be categorically excluded. CMS specifically explained that in declining to issue a national policy, the result "is not national non-coverage" under the Medicare program. Rather, coverage determinations would continue to be made on a case-by-case basis. CMS, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (Aug. 30, 2016), at 2, https://perma.cc/9S73-4WQB (emphasis added). In addition, contrary to HHS's suggestion, CMS confirmed the value of gender-affirming treatments for gender dysphoria, specifically encouraging "robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes." Id.

Third, HHS cites a 2018 Department of Defense report regarding whether to allow transgender people to serve in the military. 85 Fed. Reg. at 37,187 n.159 (citing Department of Defense, *Report and Recommendations on Military Service by Transgender Persons* (Feb. 22, 2018), https://perma.cc/7369-K2VC ("DOD Report")). HHS quotes the report's finding that there is "considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments . . . remedy the multifaceted mental health problems associated with gender dysphoria." *Id.* at 37,187 (quoting DOD Report at 5). Relying on this report is patently unreasonable. DOD commissioned the report at the request of

President Trump, who was seeking to reverse the Obama Administration policy allowing transgender people to serve openly in the military. *See* DOD Report, Cover Letter at 1. And the report's recommendations were expressly "based on each Panel member's independent *military judgment*." DOD Report at 4 (emphasis added). The report was not based on medical or scientific evidence or judgment.

Finally, HHS refers to other research that "has found that children who socially transition in childhood faced dramatically increased likelihood of persistence of gender dysphoria into adolescence and adulthood." 85 Fed. Reg. at 37,187 & n.160. HHS mischaracterizes the research. What the study concluded is that the intensity of early gender dysphoria appears to be an important predictor of persistence of gender dysphoria into adolescence and adulthood. HHS's implication that "coming out" about one's gender identity in childhood somehow makes things worse later in life is both incorrect and misleading.

In addition, HHS fails to consider the reliance of transgender patients, insurance companies, and organizations like plaintiffs on the protections in the 2016 Final Rule. Indeed, some of the plaintiffs have relied on the 2016 Final Rule's prohibition on categorical coverage exclusions related to gender-affirming care to advocate for their transgender patients and clients. Shafi ¶ 25-26; Shanker ¶¶ 8-9, 11; see also Gruberg & Bewkes, supra. 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 exclude categorically or limit gender-affirming care is contrary to the evidence in the administrative record and unreasonable.

¹¹ 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, 582 (2013).

(3) HHS Provided No Reasoned Explanation for the Elimination of the Notice and Language Access Requirements.

HHS's only proffered justification for repealing the notice and language access requirements in the 2016 Final Rule was that they were "unnecessary" because the statutes underlying Section 1557 contained notice provisions, and compressing them "into a single standard under the 2016 Rule has led to an unjustifiable burden and understandable confusion." 85 Fed. Reg. at 37,204. But HHS did not explain how individuals will know about their rights under Section 1557 without these notices, when not all the underlying statutes apply to every health care provider. And it pointed to no evidence of "understandable confusion" attributable to them.

Indeed, it is the elimination of these notice and language access provisions that is likely to create confusion. Without the notice, tagline, and LEP requirements, individuals will not know about their health care rights under Section 1557, and patients with LEP in particular may fail to understand or assert their rights because of language barriers. Patients with LEP, in turn, may fail to receive adequate care because of difficulties in understanding their providers or other staff, undermining the purpose and intent of the nondiscrimination provisions of Section 1557.

This terse explanation, which says "almost nothing," is wholly inadequate to justify a policy reversal. *Encino Motorcars*, 136 S. Ct. at 2127; *see also New York* v. *Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 549 (S.D.N.Y. 2019).

(4) HHS's Narrowing of the Entities Covered Under Section 1557 is an Arbitrary Policy Reversal.

HHS's attempt to narrow the scope of entities covered under Section 1557 is also an arbitrary reversal in policy from the 2016 Final Rule. Although HHS acknowledged it was reversing course from the 2016 Final Rule, its explanation falls short of the required standard of a reasoned explanation for the change. See Fox Television Stations, 556 U.S. at 515.

HHS first attempts to limit Section 1557's nondiscrimination protections only to health programs or activities of HHS administered under Title I of the ACA, not to other health programs and activities that HHS administers. *See* 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(a)(2)). Such a limitation, however, is inconsistent with the plain language of Section 1557,

which states 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).

HHS's only explanation for its policy change was it no longer agreed with the 2016 Final Rule's decision to add "health" as a limiting modifier to "program or activity" because Congress had not included such a modifier in the statutory text. *See* 85 Fed. Reg. at 37,170. Instead, HHS decided, "Congress had already placed a limitation in the text of Section 1557 by applying the statute to any program or activity administered by an Executive Agency 'under this title' (meaning Title I of the ACA)." *Id.* But HHS's new interpretation reads the word "or" out of the statute.

The consequence of HHS's unreasonable interpretation is that numerous HHS health programs and activities, including health programs and activities of CMS, the Centers for Disease Control and Prevention, Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, are no longer covered under Section 1557. This result is illogical and inconsistent with Section 1557.

HHS's declaration that health insurers are not a "program or activity" under Section 1557 and not subject to Section 1557's nondiscrimination prohibitions because they are not "principally engaged in the business of providing healthcare," 85 Fed. Reg. at 37,244-45 (to be codified at 45 C.F.R. § 92.3(c)), is likewise unreasonable. To support its new interpretation, HHS contends that providing "health insurance" is different than providing "healthcare" and points to the definitions of "healthcare" and "health insurance" in unrelated statutes to support its distinction. *See id.* 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-related program or activity. It is what enables the vast majority of Americans to access health care.

HHS's reliance on unrelated statutes for its new interpretation is also unavailing. For example, HHS points to 42 U.S.C. § 300gg-91. *See id.* at 37,172. But 42 U.S.C. § 300gg-91, which defines terms for federal laws regulating health insurance, specifically defines "health insurance coverage" to include benefits consisting of medical care and acknowledges health insurance is one way of providing health care. HHS's appeal to language in the Civil Rights

Restoration Act ("CRRA") also misses the mark. See 85 Fed. Reg. at 37,171-73. The CRRA's general language amended four civil rights statutes in 1988 to make clear that if any part of a program or activity receives federal financial assistance, the entire program must comply with applicable civil rights laws. See Pub. L. No. 100-259, 102 Stat. 28 (Mar. 22, 1988). Congress enacted Section 1557 more than two decades later to prohibit discrimination in all "health programs and activities," any part of which is receiving federal financial assistance, based on the characteristics listed in Title IX and three other statutes. The CRRA did not address whether health insurance is a "health program or activity." Congress did not incorporate the definitions contained in the CRRA into Section 1557. And Section 1557 is more expansive than the statutes the CRRA amended. HHS's reliance on the CRRA to exclude health insurance providers from Section 1557 is unreasonable and contrary to Section 1557, which covers all health programs and activities.

(5) HHS Failed to Provide a Reasoned Explanation for Incorporating Sweeping Religious Exemptions.

The 2016 Final Rule declined to import Title IX's blanket religious exemption into Section 1557, explaining that it would be inappropriate in the health care setting because the Title IX exemption is framed for educational institutions, which are very different from health care settings, and those differences "warrant different approaches." 81 Fed. Reg. at 31,380. The Revised Rule reversed this policy by incorporating not only Title IX's blanket religious exemption, but also sweeping religious exemptions from a number of different statutes. *See* 85 Fed. Reg. at 37,245 (to be codified at 45 C.F.R. § 92.6(b)).

In so doing, HHS did not analyze why Title IX's blanket exemption, framed for educational institutions, suddenly was appropriate for the health care setting. *See id.* at 37,205-09. Nor did HHS address its prior factual finding that "a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results." 81 Fed. Reg. at 31,380. HHS also failed to address the concern that the Revised Rule decreases protections for patients while increasing exemptions for providers, even though at least one commenter pointed out that

between 2008 and January 2018, HHS received fewer than 50 complaints regarding violations of religious or conscience statutes while receiving 30,000 complaints of civil rights discrimination in 2017 alone. *See* 85 Fed. Reg. at 37,206.

HHS's primary justification for its policy reversal was its claim that avoiding burdens on conscience "will protect both providers' medical judgment and their consciences, thus helping to ensure that patients receive the high quality and conscientious care that they deserve." 85 Fed. Reg. at 37,206. But HHS provided no basis for its assertion that the religious conscience provisions will help "ensure that patients receive the high quality and conscientious care that they deserve." And it ignored HHS's prior factual finding that a blanket religious exemption could result in denial or delay of health care in favor of an unsupported, contradictory finding without acknowledging or explaining the inconsistency in positions. This unexplained inconsistency renders these provisions arbitrary and capricious. *See New York*, 414 F. Supp. 3d at 550-51.

HHS also ignored that the incorporation of these exemptions runs counter to medical ethics, standards of care, and other statutes, like the Emergency Medical Treatment and Labor Act ("EMTALA"). HHS failed to explain why the Revised Rule "does not conflict with EMTALA, which . . . does not contain an exception for conscience or other objections." *Id.* at 555.

b. HHS Failed to Consider Important Aspects of the Problem.

A rule is arbitrary and capricious, where, as here, the agency "entirely failed to consider an important aspect of the problem." *Stewart*, 366 F. Supp. 3d at 135 (quoting *State Farm*, 463 U.S. at 43). An agency "must respond to significant points raised during the public comment period." *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000). Defendants did not meet this standard.

HHS failed entirely to consider the harm the Revised Rule will cause to LGBTQ people, including those with LEP. Despite receiving nearly 200,000 comments, HHS published the Revised Rule with only "minor and primarily technical corrections." 85 Fed. Reg. at 37,161. It ignored the multitude of concerns that major medical organizations, patient advocacy organizations, and individuals raised that the Revised Rule would invite discrimination against

LGBTQ people and undercut access to health care. HHS's failure to consider these harms, which permeated the entire rulemaking process, renders the Revised Rule arbitrary and capricious.

(1) HHS's Dismissal of the Harm to LGBTQ People from the Revised Rule Does Not Withstand Scrutiny.

HHS brushed aside concerns that the Revised Rule would invite discrimination against LGBTQ people, and transgender individuals in particular, with the simple assertion: "The Department does not believe that this final rule will lead to significant burdens on entities due to changes to the gender identity language from the 2016 Rule, nor that the commenters have identified sufficient data to show that these negative consequences will occur or the extent to which they will occur." Id. at 37,225. Despite extensive evidence in the administrative record showing LGBTQ people already face particularly acute barriers to care and health disparities, HHS claimed it knew "of no data showing" that the Revised Rule would "disproportionately burden individuals on the basis of sexual orientation and/or gender identity." Id. at 37,182. HHS also specifically admitted it did not take into account the costs or harms to transgender patients, claiming it lacked "the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits after publication of this rule." Id. at 37,225. HHS further claimed it lacked data "to estimate what greater public health costs, cost-shifting, and expenses may result from entities changing their nondiscrimination policies and procedures after promulgation" of the Revised Rule. Id.

HHS is not entitled simply to disregard costs that are uncertain or difficult to quantify. As this Circuit has held, the "mere fact" that the effect of a rule "is *uncertain* is no justification for *disregarding* the effect entirely." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004).

HHS also contends the Revised Rule will not increase levels of discrimination because many states and localities already prohibit gender identity and sexual orientation discrimination, and the Revised Rule does not "prohibit[] entities from maintaining gender identity

nondiscrimination policies and procedures voluntarily." 85 Fed. Reg. at 37,225. But the effectiveness of a nondiscrimination statute and implementing regulation cannot be measured by reference to the entities that *voluntarily do not discriminate*. And, even if some states and localities offer the same level of protection as the 2016 Final Rule, *others do not*. HHS acknowledges receiving comments noting that many LGBTQ people live in states that do not prohibit insurers from discriminating based on LGBTQ status. *See id.* at 37,182. Furthermore, at least thirty (30) states do not have laws prohibiting health insurers from discriminating on the basis of gender identity. The Revised Rule will have a significant effect on access to health care for LGBTQ people across the country. Shafi ¶¶ 13-23, 27-29; Cummings ¶¶ 16, 18, 20, 22, 29, 30, 32-33; Shanker ¶¶ 9-18, 20-24; Vargas ¶¶ 20, 23; Harker ¶¶ 15-20; Salcedo ¶21, 26; Lint ¶¶ 37-48.

Finally, HHS reasons that if the Revised Rule does lead to increased discrimination, any such discrimination will result in a "net cost savings," including as a result of the fact that "some covered entities may no longer incur costs associated with processing grievances related to gender identity discrimination under Title IX, because such claims will not be cognizable under this final rule." 85 Fed. Reg. at 37,225. Such one-sided analysis is the height of arbitrary and capricious reasoning. Deeming discrimination a "net cost savings" not only fails to consider the significant costs of care not covered by insurance, but it also callously disregards the significant harm to those who suffer the effects of discrimination.

(2) HHS Failed Entirely to Consider How Elimination of Notice and Language Access Requirements Will Decrease Access to Health Care Information and Increase Costs.

HHS also failed to consider how repealing the notice, tagline, and language access requirements will decrease access to health care information and increase health care costs. HHS considered only the cost savings to covered entities from revoking those requirements.

For example, many commenters raised concerns that removal of these protections "may result in decreased access to, and utilization of, healthcare by people with disabilities, people with

¹² Movement Advancement Project, *Equality Maps – Healthcare Laws and Policies – Private Insurance* (last updated June 24, 2020), https://perma.cc/TJP4-KDNJ.

LEP, older adults, people who are LGBT, and other vulnerable populations." 85 Fed. Reg. at 37,204. HHS's only response was that the 2016 Final Rule's notice provisions were "unnecessary" because the statutes underlying Section 1557 contained notice provisions and it was "unaware of data suggesting that those regulations have been or are inadequate to their purpose of making individuals aware of their civil rights." *Id.* HHS fails entirely to explain how LGBTQ people and others will be notified of their *health care rights* under Section 1557, as opposed to rights under the underlying statutes which may not apply to every health care entity. HHS also does not explain how individuals with LEP will know about their rights to language assistance.

The Revised Rule also attempted to justify repealing these requirements on the ground that they might save money. *See* 85 Fed. Reg. at 37,224. But it failed to account for the increased costs that will flow from repealing these protections. If people with LEP are not able to access health care due to language barriers, they may not seek the care they need until their health problems worsen, or they may not seek care at all. When and if they do seek the care they need, people with LEP may not be able to communicate with English-speaking physicians and pharmacists. They also may not understand how to fill out paperwork for healthcare providers or applications for health insurers.

Delays in seeking health care increase health care costs, inefficiency, and inadequacy in the provision of health care. Shafi ¶¶ 32-33; Henn ¶ 20; Pumphrey ¶ 7; Cummings ¶¶ 18, 33; Bolan ¶¶ 11, 13-16, 18, 20-21; Carpenter ¶¶ 8-9; Shanker ¶¶ 10, 14; Harker ¶ 19; Salcedo ¶ 44; Lint ¶ 55. These costs are passed on to taxpayers and patients through increased deductibles, copays, and premiums. Yet, the Revised Rule fails to account for any of these financial costs or the intangible costs to patients' well-being that flow from these increased barriers to health care.

2. The Revised Rule is Not in Accordance with Law.

The Revised Rule is "not in accordance with law," 5 U.S.C. § 706(2)(A), because it conflicts with Section 1554 of the ACA, Section 1557, and the *Bostock* decision.

a. Section 1554

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," "impedes timely access to health care services," or "interferes with communications regarding a full range of treatment options between the patient and the provider." 42 U.S.C. § 18114. But that is precisely what the Revised Rule does.

By inviting health care insurers and providers to discriminate against LGBTQ people seeking health care, the Revised Rule discourages LGTBQ people from seeking health care in the first instance and from fully disclosing personal information that health care providers need for proper diagnosis and treatment. Shafi ¶ 21; Henn ¶ 16; Pumphrey ¶ 12; Cummings ¶¶ 24, 28; Bolan ¶¶ 13-15, 17, 19; Carpenter ¶¶ 11, 15; Shanker ¶¶ 22-23; Vargas ¶¶ 21-22; Harker ¶¶ 8, 19; Salcedo ¶¶ 32-33; Lint ¶ 48. The repeal of the notice and language access provisions also creates unreasonable barriers to obtaining health care information. Shafi ¶ 32; Cummings ¶¶ 13, 27, 33; Salcedo ¶¶ 40-41; Lint ¶ 55; Vargas ¶ 23. The Revised Rule violates Section 1554.

b. Section 1557

The Revised Rule is not in accordance with Section 1557 in multiple ways. First, the Revised Rule conflicts with the statutory language of Section 1557 by limiting the entities covered under Section 1557 to health programs or activities of HHS that are administered under Title I of the ACA, not to other health programs and activities that HHS administers. *See* 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(a)(2)). This limitation contradicts the plain language of Section 1557, which states it applies to "any program or activity that is administered by an Executive Agency." 42 U.S.C. § 18116(a). Section 1557, by its terms, is not limited to health programs and activities administered under Title I of the ACA. The Revised Rule's exclusion of health insurance from the scope of Section 1557 also is not in accordance with Section 1557, which covers health programs and activities, not just direct health care. *See* 42 U.S.C. § 18116(a). Health insurance clearly is a health-related program or activity.

Second, 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 the case of discrimination against a person based on any characteristic protected by these statutes. Section 1557 provides: "The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of [Section 1557]." 42 U.S.C. § 18116(a) (emphasis added). 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 *10 (D. Minn. Mar. 16, 2015) (emphasis added).

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. "In its elementary sense, the word 'or,' as used in a statute, is a disjunctive particle indicating that the various members of the sentence are to be taken separately." 73 Am. Jur. 2d Statutes § 147. And "a statute written in the disjunctive is generally construed as setting out separate and distinct alternatives." *In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996) (cleaned up). The creation of a single legal standard for Section 1557 claims is also evident from Congress's desire to avoid absurd results. It is important to "recognize[] the absurd inconsistency that could result if the Court interpreted Section 1557 as Defendants [in this case] do." *Rumble*, 2015 WL 1197415, at *12. And "if different standards were applied based on the protected class status of the Section 1557 plaintiff, then courts would have no guidance about what standard to apply for a Section 1557 plaintiff bringing an intersectional discrimination claim." *Id.* Applying standard rules of construction, all enforcement mechanisms available under each of the statutes incorporated into Section 1557 are available to every claim of discrimination under Section 1557. The Revised Rule's elimination of a unitary

legal standard and enforcement mechanism is contrary to the text and structure of Section 1557.

Finally, the Revised Rule conflicts with the text of Section 1557 by importing sweeping exemptions based on religious or moral beliefs from the identified statutes in Section 1557 and other statutes. *See* 85 Fed. Reg. at 37,245 (to be codified at 45 C.F.R. § 92.6(b)). Section 1557 expressly incorporates the enforcement mechanisms from four civil rights statutes, but does not incorporate the religious exemptions from Title IX or any other statute. *See* 42 U.S.C. § 18116(a). Importing broad religious exemptions from other statutes conflicts with the plain language of Section 1557 and Congress's rejection of such exemptions. *See* 155 Cong. Rec. S13193-01 (2009).

c. Bostock

The Revised Rule also is not in accordance with law because it conflicts with the Supreme Court's ruling in *Bostock* that discrimination on the basis of a person's transgender status or sexual orientation is discrimination on the basis of sex. *See Bostock*, 2020 WL 3146686, at *7, 11. *Bostock* forecloses the Revised Rule's attempt to deny the full protection of Section 1557 to LGBTQ individuals and patients in health care settings, as well as its elimination of protections based on sexual orientation and gender identity in unrelated regulations promulgated under different statutes. *See* 85 Fed. Reg. at 37,218-22, 37,243.

B. Plaintiffs are Likely to Succeed on Their Equal Protection Claim.

By inviting health care discrimination against LGBTQ people and carving them out from regulatory nondiscrimination protections under Section 1557, the Revised Rule discriminates on the basis of sex, transgender status, and sexual orientation. Such discrimination is subject to heightened scrutiny. Yet, the Revised Rule fails any level of review because it is not rationally related to any legitimate governmental interest, let alone adequately tailored to further an exceedingly persuasive or compelling one.

Discrimination based on sexual orientation or transgender status is discrimination based on sex. See Bostock, 2020 WL 3146686, at *7, 11; Whitaker ex rel. Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., 858 F.3d 1034, 1048 (7th Cir. 2017); Latta v. Otter, 771 F.3d 456, 479-80 (9th Cir. 2014) (Berzon, J., concurring); Glenn v. Brumby, 663 F.3d 1312, 1316 (11th Cir.

2011). Sex discrimination is subject to heightened scrutiny. *See United States v. Virginia*, 518 U.S. 515, 531 (1996). Discrimination based on sexual orientation or transgender status is also subject to heightened scrutiny on its own. *See*, *e.g.*, *SmithKline Beecham Corp. v. Abbott Labs.*, 740 F.3d 471 (9th Cir. 2014) (sexual orientation); *Windsor v. United States*, 699 F.3d 169, 185 (2d Cir. 2012) (same), *aff'd on other grounds*, 570 U.S. 744 (2013); *Karnoski v. Trump*, 926 F.3d 1180, 1201 (9th Cir. 2019) (transgender status); *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).

To pass heightened scrutiny, the government bears the burden of demonstrating an "exceedingly persuasive justification" for the sex-based classification that "serves important governmental objectives" and that the discriminatory means employed are substantially related to the achievement of those objectives." *Virginia*, 518 U.S. at 531 (cleaned up).

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. The record does not support these justifications and inviting discrimination against LGBTQ people in health care does not advance any of these goals, particularly in light of *Bostock*'s confirmation that discrimination on the basis of gender identity or sexual orientation are forms of prohibited sex discrimination. To the contrary, the purpose and effect of the Revised Rule is to invite discrimination in health care against plaintiffs' members and their patients, and LGBTQ people nationwide, based on their gender identity, transgender status, sexual orientation, gender nonconformity, and exercise of their fundamental rights.

In addition, the exclusion of LGBTQ people from the nondiscrimination protections under Section 1557 is motivated by the Trump administration's and HHS officials' clear animus against LGBTQ people. Defendant Severino in particular has a history of anti-LGBTQ sentiments, advocacy, and comments. In 2016, before he became Director of OCR, defendant Severino decried the 2016 Final Rule because it ran counter to some people's "moral, and religious beliefs about

biology" and because, in his opinion, the 2016 Final Rule "create[d] special privileges, new protected classes, or new rights to particular procedures." The Revised Rule eliminates every one of the protections for LGBTQ people he decried. Defendant Severino also denounced the Department of Justice's enforcement of Title IX's sex discrimination protections under the Obama administration as applied to transgender people as "using government power to coerce everyone, including children, into pledging allegiance to a radical new gender ideology." ¹⁴

More broadly, the Revised Rule is just one of the latest in a long list of actions the current administration has taken to deprive LGBTQ people of the equal protection of the laws. Among these actions are: the removal of all mention of LGBTQ people from governmental websites;¹⁵ the withdrawal of guidance protecting transgender students from discrimination in schools;¹⁶ the institution of a ban prohibiting transgender people from serving openly, in a manner consistent with their gender identity, in the armed services;¹⁷ the revocation of Department of Justice guidance noting that discrimination based on transgender status is prohibited under Title VII (again, contrary to *Bostock*);¹⁸ the opposition to the reasoned position of the Equal Employment Opportunity Commission that Title VII prohibits discrimination based on sexual orientation or transgender status;¹⁹ the refusal to enforce regulations prohibiting discrimination based on sexual

¹³ Ryan Anderson & Roger Severino, *Proposed Obamacare Gender Identity Mandate Threatens Freedom of Conscience and the Independence of Physicians*, The Heritage Foundation (Jan. 8, 2016), https://perma.cc/5XKG-S79Z.

¹⁴ Roger Severino, *DOJ's Lawsuit Against North Carolina Is Abuse of Power*, The Daily Signal (May 9, 2016), https://perma.cc/3FFM-KFMB.

¹⁵ See Mary Emily O'Hara, *Trump Administration Removes LGBTQ Content From Federal Websites*, NBC News (Jan. 24, 2017), https://perma.cc/LU5P-V6ZG.

¹⁶ See Ariane de Vogue, et al., *Trump administration withdraws federal protections for transgender students*, CNN (Feb. 23, 2017), https://perma.cc/K6UD-DQAD.

¹⁷ See Abby Phillip, et al., *Trump announces that he will ban transgender people from serving in the military*, Wash. Post (July 26, 2017), https://perma.cc/E7J2-E7ZF.

¹⁸ See Charlie Savage, In Shift, Justice Dept. Says Law Doesn't Bar Transgender Discrimination, N.Y. Times (Oct. 5, 2017), https://perma.cc/WV2R-6MG4.

¹⁹ See Joseph Goldstein, Discrimination Based on Sex Is Debated in Case of Gay Sky Diver, N.Y. Times (Sept. 26, 2017), https://perma.cc/K83R-R33F.

orientation and gender identity;²⁰ and the invitation to health care providers to refuse to provide care to LGBTQ people based on their personal religious and moral beliefs.²¹

C. Plaintiffs are Likely to Succeed on Their Due Process Claim.

The Fifth Amendment's Due Process Clause protects individuals' substantive rights to be free to make certain decisions central to privacy, bodily autonomy, bodily integrity, self-definition, intimacy, and personhood without unjustified governmental intrusion. *See Obergefell v. Hodges*, 135 S. Ct. 2584, 2593 (2015) (due process protects a person's right to "define and express their identity"); *Lawrence v. Texas*, 539 U.S. 558, 562 (2003) ("Liberty presumes an autonomy of self that includes freedom of thought, belief, expression, and certain intimate conduct."). 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).

By encouraging health care providers and insurers to interfere with and unduly burden patients' access to medically necessary health care, the Revised Rule violates the rights of plaintiffs, their members, and their patients to privacy, liberty, dignity, and autonomy guaranteed by the Fifth Amendment. There is no legitimate interest that supports such an infringement on patients' fundamental rights, let alone an interest that can survive the strict scrutiny required to justify infringement of these rights. The Revised Rule must be set aside. *See* 5 U.S.C. § 706(2)(B).

D. Plaintiffs are Likely to Succeed on Their Free Speech Claim.

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 each's gender identity or sexual orientation. *See Hartley v. Wilfert*, 918 F. Supp. 2d 45, 53 (D.D.C. 2013); *see also Henkle v. Gregory*, 150 F. Supp. 2d 1067, 1075-77 (D. Nev. 2001) (sexual orientation); *Doe ex rel. Doe v. Yunits*, No. 001060A, 2000

²⁰ Notification of Nonenforcement of Health and Human Services Grants Regulation, 84 Fed. Reg. 63,809 (Nov. 19, 2019).

²¹ Protecting Statutory Conscience Rights in Health Care, 84 Fed. Reg. 23,170 (May 21, 2019).

WL 33162199, at *3 (Mass. Super. Oct. 11, 2000) (gender identity), *aff'd sub nom.*, *Doe v. Brockton Sch. Comm.*, 2000 WL 33342399 (Mass. App. Ct. Nov. 30, 2000).

In discouraging LGBTQ individuals from engaging in this speech, the Revised Rule burdens speech based on its content and viewpoint because it attaches different consequences to the same speech depending on the identity of the speaker. *See Police Dep't of Chicago v. Mosley*, 408 U.S. 92, 96 (1972). For example, the Revised Rule facilitates discrimination when a transgender woman discloses her female identity, wears typically female attire, or checks the box marked "female" at her endocrinologist's office, in contrast to a cisgender²² woman who discloses her female identity, wears the same attire, or checks the same box. Courts long have held that government policies that penalize gay or transgender people for disclosing their gender identity or sexual orientation (where heterosexual or cisgender individuals would not be penalized for the same disclosures) are content- or viewpoint-based restrictions that must satisfy a searching level of scrutiny. *See, e.g., Log Cabin Republicans v. United States*, 716 F. Supp. 2d 884, 926 (C.D. Cal. 2010), *vacated as moot*, 658 F.3d 1162 (9th Cir. 2011); *Weaver v. Nebo Sch. Dist.*, 29 F. Supp. 2d 1279, 1286 (D. Utah 1998).

The government may not burden speech "because of disapproval of the ideas expressed." *R.A.V. v. City of St. Paul, Minn.*, 505 U.S. 377, 382 (1992) (citations omitted). Content-based regulation is subject to "the most exacting scrutiny," *Texas v. Johnson*, 491 U.S. 397, 412 (1989) (citation omitted), and "[v]iewpoint discrimination is . . . an egregious form of content discrimination." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 829 (1995). These restrictions are subject to "strict scrutiny" and will survive review only if they promote a "compelling interest" and employ the "least restrictive means to further the articulated interest." *Am. Library Ass'n v. Reno*, 33 F.3d 78, 84 (D.C. Cir. 1994). The Revised Rule fails to satisfy that rigorous standard. There is no compelling governmental interest in facilitating discrimination or

²² "Cisgender" refers to "a person whose gender identity corresponds with the sex the person had or was identified as having at birth." Cisgender, Merriam-Webster, https://perma.cc/T4GA-EQM9.

the denial of care to LGBTQ patients in the health care setting.

E. Plaintiffs are Likely to Succeed on Their Establishment Clause Claim.

The First Amendment's Establishment Clause prohibits the government from providing religious accommodations or exemptions that detrimentally affect third parties without regard to their interests. *See Cutter v. Wilkerson*, 544 U.S. 709, 720 (2005); *Estate 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. v. ACLU of Ky.*, 545 U.S. 844, 860 (2005); *Santa Fe Indep. Sch. Dist. v. Doe*, 530 U.S. 290, 302 (2000).

The Revised Rule violates these principles because it imposes costs, burdens, and harms on plaintiffs, their members, and patients to facilitate the religious beliefs of objecting providers, without exception. The Revised Rule incorporates Title IX's blanket religious exemption and the "definitions, exemptions, affirmative rights, or protections" from unrelated statutes. 85 Fed. Reg. at 37,245 (to be codified at 45 C.F.R. § 92.6(b)). These exemptions allow health care institutions and providers to deny care or treatment to LGBTQ people based on religious, conscience, or moral grounds, significantly burdening LGBTQ people's access to health care. These exemptions also impair plaintiffs' ability to refer patients to other providers because they may discriminate against, provide inadequate care to, or refuse to treat their LGBTQ patients, causing significant harm to such patients. Shafi ¶ 20, 39; Henn ¶¶ 14, 27; Pumphrey ¶ 16; Cummings ¶¶ 25-27; Bolan ¶¶ 8, 17, 22-23; Carpenter ¶¶ 8, 15; Harker ¶ 20; Vargas ¶¶ 16, 20, 25.

And HHS shifts these substantial burdens onto plaintiffs, their members, and their patients without exception. There is no exception under the Revised Rule "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, Shafi ¶ 4; Cummings ¶ 5; Shanker ¶¶16-17, 22, 28, or if "a high percentage" of a health care provider's work force denies care. *Caldor*, 472 U.S. at 709. Nor is there an exception when honoring the dictates of objectors would cause a health care provider substantial economic burdens. *See id.* at 709-10. This "unyielding weighting in favor of [objectors] over all other

interests" is exactly what the Establishment Clause forbids. *Id.* at 710.

II. THE REVISED RULE WILL IRREPARABLY HARM PLAINTIFFS, THEIR MEMBERS, AND THEIR PATIENTS.

The Revised Rule will cause significant irreparable harm to plaintiffs, their members, and their patients in a multitude of ways. First, the very issuance of the Revised Rule has caused and, unless enjoined, will continue to cause LGBTQ people to experience significant distress, mental anguish, and hopelessness. Second, the Revised Rule invites discrimination against LGBTQ patients by health care providers and insurers. It also reduces patients' ability to know their rights and diminishes their access to care. Third, by inviting discrimination against LGBTQ people, including those with LEP, the Revised Rule will substantially burden plaintiffs, frustrate their missions, impose additional costs, and inhibit many of the plaintiffs' programmatic activities. Finally, the Revised Rule will cause irreparable harm by eliminating employment protections for some of plaintiffs' members and by infringing on constitutional rights.

Although "[p]laintiffs need only show a *threat* of irreparable harm, not that irreparable harm already ha[s] occurred," for preliminary relief, here irreparable harm already has occurred and will continue unless the Revised Rule is enjoined. *New York v. U.S. Dep't of Homeland Sec.*, 408 F. Supp. 3d 334, 350 (S.D.N.Y. 2019) (cleaned up); see also League of Women Voters v. *Newby*, 838 F.3d 1, 8-9 (D.C. Cir. 2016).

A. The Revised Rule Will Irreparably Harm LGBTQ People by Causing Significant Distress, Mental Anguish, and Stigma.

The Revised Rule is an official governmental act that sends LGBTQ people, particularly transgender people, the message that: they are not worthy of protection; their identities need not be recognized; and their health care needs may be disregarded. Ettner ¶ 56; Carpenter ¶ 20; Cummings ¶ 18; Davis ¶¶ 8-9. This governmental message already has and will continue to result in significant distress, hopelessness, hypervigilance, depression, generalized anxiety disorder, and trauma for LGBTQ people, and, more specifically, for transgender people. Ettner ¶ 56; Carpenter ¶ 16; Cummings ¶¶ 9, 12, 14; Davis ¶ 6. Indeed, after the Revised Rule was announced, crisis hotlines dedicated to LGBTQ youth and transgender people, such as The Trevor Project and Trans

Lifeline, experienced an increase in the number of calls and saw a significant number of callers reaching out in distress specifically due to the Revised Rule. Davis ¶ 10; Vera ¶¶ 6-8.

The Revised Rule also imposes upon LGBTQ people a stigma that will further erode their health. Research documents that structural forms of stigma (namely, policies sanctioning discrimination) harm the health of transgender people, and that structural stigma is associated with all-cause mortality (i.e. deaths from any cause). Ettner ¶ 62. In other words, stigma—a chronic source of psychological stress—disrupts physiological pathways, increasing disease vulnerability, and leading to premature death. *Id*.

Stigmatization and loss of dignity alone are sufficient to constitute irreparable harm. *See, e.g., Whitaker*, 858 F.3d at 1044-46; *Caspar v. Snyder*, 77 F. Supp. 3d 616 (E.D. Mich. 2015); *Elzie v. Aspin*, 841 F. Supp. 439, 443 (D.D.C. 1993). Here, the Revised Rule causes not only stigma and loss of dignity, but also significantly and negatively affects the health and well-being of LGBTQ people.

B. The Revised Rule Invites Discrimination Against and Reduces Access to Care for LGBTQ People and Individuals with LEP, Irreparably Harming Plaintiffs' Members and Patients.

The Revised Rule sends a clear message to covered entities that they may discriminate against LGBTQ people with impunity. HHS acknowledged the 2016 Final Rule "likely induced many covered entities to conform their policies and operations to reflect gender identity as a protected category under Title IX." 85 Fed. Reg. at 37,225. And it also acknowledged that in connection with the 2016 Final Rule, it anticipated that 60% of the increase in its long-term caseload of discrimination claims would be attributable to claims based on gender identity or sex stereotyping. *Id.* at 37,235. In promulgating the Revised Rule, however, HHS stated that providers are free to revert to their former policies and notes that they will achieve cost savings because they "may no longer incur costs associated with processing grievances related to gender identity discrimination under Title IX, because such claims will not be cognizable under this final rule." *Id.* at 37,225; *see also id.* at 37,236. Through the Revised Rule, HHS is communicating that it believes Section 1557 does not prohibit discrimination against LGBTQ people and that such

discrimination is desirable. *See id.* at 37,184-91, 37,222. For example, HHS goes out of its way to tell medical providers that they are free to use incorrect pronouns when referring to transgender patients—that is, pronouns inconsistent with a patient's gender identity. *See id.* at 37,191.

OCR has opened the door to discrimination against transgender individuals in particular by eliminating the provisions in the 2016 Final Rule prohibiting covered insurers from adopting "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition" and from denying, limiting, or restricting "specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual." 81 Fed. Reg. at 31,472 (formerly 45 C.F.R. § 92.207(b)(3)-(5)). Under the Revised Rule, HHS specifically noted that insurers now have the option "of providing such coverage or not." 85 Fed. Reg. at 37,181; *see also id.* at 37,187-88. This change creates an immediate threat to plaintiffs' members and patients who live in the thirty (30) states that do not have laws prohibiting health insurers from discriminating on the basis of gender identity. ²³

In the event entities elect to revert to their prior practices, plaintiffs' members, patients, and clients will encounter new obstacles to obtaining medical care and an increased risk that health care providers or insurers will discriminate against them on the basis of their LGBTQ status. It is no secret that LGBTQ people already face disproportionate rates of discrimination in health care. *See*, *e.g.*, Ettner ¶ 64; Salcedo ¶ 31, Exs. A & B; Lint ¶ 43, Ex. A; Harker ¶¶ 8-10; Shanker ¶ 19, Ex. A. Yet, the Revised Rule sends the clear and unmistakable message that such discrimination is tolerated and according to defendants, acceptable. *See*, *e.g.*, Salcedo ¶¶ 27, 32; Lint ¶ 40; Fabian ¶ 19; Shafi ¶¶ 13-14, 16, 20; Henn ¶¶ 8, 10; Pumphrey ¶ 11; Cummings ¶¶ 17, 32; Bolan ¶¶ 8, 10, 14, 23-24; Carpenter ¶¶ 7-8; Vargas ¶¶ 14, 19; Harker ¶ 18; Shanker ¶ 22; Ettner ¶ 56.

The likelihood of an increase in this discrimination that the Revised Rule invites is not speculative. It is firmly rooted in research and the experiences of plaintiffs' members and patients who already have been subjected to egregious discrimination in health care settings. For example,

²³ Movement Advancement Project, Equality Maps – Healthcare Laws and Policies – Private Insurance (last updated June 24, 2020), https://perma.cc/TJP4-KDNJ.

health care providers have told Bamby Salcedo, CEO of the TransLatin@ Coalition, that they "did not treat people like her." Salcedo ¶ 14. Arianna Lint, a member of the TransLatin@ Coalition, was misgendered and threatened by a health care provider with the specter of summoning police officers. Lint ¶ 31. Dr. Deborah Fabian, an experienced orthopedic surgeon and member of GLMA, has been denied job opportunities because of her transgender status, intentionally misgendered by colleagues, and told that she is "disgusting" and "God thinks you're disgusting." Fabian ¶ 16. Plaintiffs' declarations identify additional examples of LGBTQ patients, clients, and members who have experienced similar discriminatory conduct. Shafi ¶ 17; Henn ¶ 9; Pumphrey ¶ 10; Cummings ¶ 22; Carpenter ¶ 8; Bolan ¶ 8-9, 12, 23; Shanker ¶ 8, 17(c)-(d); Vargas ¶¶ 20-21. Research further documents the alarming pervasiveness of discrimination against transgender and gender nonconforming people in health care. *See*, *e.g.*, Ettner ¶ 64; Salcedo ¶ 31; Lint ¶ 43; Harker ¶ 9; Shanker ¶ 19. According to a 2018 study, eight percent of LGBTQ respondents were refused health care because of their sexual orientation, and twenty-nine percent of transgender respondents were denied care because of their gender identity.²⁴

These discriminatory experiences make it less likely that LGBTQ people will access the health care that they need because fear of discrimination. Shafi ¶ 22; Henn ¶¶ 11, 19; Pumphrey ¶ 7, 13-14; Cummings ¶¶ 8, 16-17; Carpenter ¶¶ 8-9, 22; Bolan ¶¶ 11-12; Shanker ¶ 19; Salcedo 31-33, 36; Lint ¶ 48. It is well documented that patients who fear discrimination tend to delay seeking care or avoid care altogether. Nearly one-quarter of transgender people report delaying or avoiding medical care when sick or injured, at least partially because they fear discrimination or disrespect by health care providers. Patients with LEP will also suffer diminished access to care as a result of the Revised Rule, which eliminates language access protections necessary for them to meaningfully access the care they need and to ensure proper treatment and diagnoses. Shafi ¶ 32; Henn ¶ 25; Pumphrey ¶ 7; Bolan ¶¶ 19-21; Salcedo ¶¶ 40-41; Lint ¶ 55.

²⁴ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People From Accessing Health Care*, Ctr. for Am. Progress (Jan. 18, 2018), https://perma.cc/ZG7E-7WK8.

²⁵ See Mirza & Rooney, supra.

By creating conditions under which LGBTQ patients, including those with LEP, are more likely to avoid or delay seeking care, the Revised Rule has caused and will continue to have dire consequences. Their health conditions will worsen and become more acute and difficult to treat. Shafi ¶ 21-22; Henn ¶ 20-21; Pumphrey ¶ 12; Cummings ¶ 16, 18, 22(m); Carpenter ¶ 11-15, 19; Bolan ¶ 19-21; Shanker ¶ 14-15; Salcedo ¶ 34; Lint ¶ 47-48, 51, 55. The delay or denial of health care, particularly in emergency situations, is likely to cause plaintiffs' patients wholly avoidable pain and injury. And it will have deadly consequences, as already occurred with a board member of the TransLatin@ Coalition, Lorena Borjas, who delayed going to a hospital for fear of discrimination and died as a result of COVID-19. Salcedo ¶ 25. These all are irreparable harms. See Harris v. Bd. of Supervisors, 366 F.3d 754, 765 (9th Cir. 2004).

The Revised Rule also reduces access to care by narrowing the entities covered under Section 1557. For example, the Indian Health Service will no longer be a covered entity. As such, patients like those at the Gallup Indian Medical Center in New Mexico will no longer have protections from discrimination in health care because state protections do not apply to federal facilities. Fabian ¶ 21. Additionally, the Revised Rule deems that health insurance is not a "health program or activity," which will directly affect the ability of plaintiffs' patients and members to access care. Shafi ¶ 28; Henn ¶ 22.

Numerous courts have recognized that loss of access to care causes irreparable harm that warrants immediate relief. *See, e.g., Planned Parenthood S. Atl. v. Baker*, 941 F.3d 687, 707 (4th Cir. 2019); *Planned Parenthood of Kans. & Mo. v. Andersen*, 882 F.3d 1205 (10th Cir. 2018); *Minney v. U.S. Office of Personnel Mgmt.*, 130 F. Supp. 3d 225, 235 (D.D.C. 2015); *Risteen v. Youth For Understanding*, Inc., 245 F. Supp. 2d 1, 16 (D.D.C. 2002).

C. The Revised Rule Will Irreparably Harm Plaintiffs by Impeding Their Programmatic Activities and Mission and Imposing Additional Costs.

An organization is irreparably "harmed if the actions taken by the defendant have perceptibly impaired the organization's programs." *League of Women Voters*, 838 F.3d at 8 (cleaned up). "[T]he organization's tasks must be impeded," *Ctr. for Responsible Sci. v. Gottlieb*,

346 F. Supp. 3d 29, 37 (D.D.C. 2018), aff'd sub nom. Ctr. for Responsible Sci. v. Hahn, No. 18-5364, 2020 WL 1919656 (D.C. Cir. Apr. 10, 2020), and the organization must "show that the defendant's actions directly conflict with the organization's mission," League of Women Voters, 838 F.3d at 8. "Obstacles that unquestionably make it more difficult for an organization to accomplish its primary mission provide injury for purposes of irreparable harm." Open Communities All. v. Carson, 286 F. Supp. 3d 148, 177 (D.D.C. 2017) (cleaned up). The Revised Rule impairs plaintiffs' programmatic activities in a multitude of ways.

Plaintiffs like Whitman-Walker Health and Los Angeles LGBT Center, which are committed to treating every patient without regard to their sex, sexual orientation, gender identity, or transgender status, will see an increased demand for their services. LGBTQ patients, including those with LEP, will turn to these providers because of their fear of discrimination from other providers that the Revised Rule invites and fosters. Shafi ¶ 34; Henn ¶ 29; Pumphrey ¶ 9; Cummings ¶¶ 9, 14, 20, 25-26, 28; Carpenter ¶¶ 16, 21; Bolan ¶¶ 18, 22-23. This increased demand will, in turn, require additional expenditures and the diversion of already limited resources. Shafi ¶ 36; Henn ¶ 29; Pumphrey ¶ 15; Cummings ¶ 8; Bolan ¶ 22. The Revised Rule also impedes plaintiffs' ability to provide crucial health care referrals because plaintiffs will have to (1) develop additional mechanisms to vet the health care providers to whom they refer patients, and (2) help their patients obtain timely and needed health care from affirming providers who are increasingly overburdened and have long waitlists. Shafi ¶ 38; Henn ¶¶ 14, 27; Pumphrey ¶ 16; Cummings ¶¶ 9, 25-26; Carpenter ¶¶ 21-22; Bolan ¶¶ 22-23; Vargas ¶¶ 11, 25; Harker ¶¶ 20-22.

Additionally, the Revised Rule directly impedes plaintiffs' ability to care for and treat LGBTQ patients, including those with LEP. It erodes trust between health care providers and their patients, even though such trust is necessary for appropriate treatment. Shafi ¶ 19; Henn ¶ 15-16; Pumphrey ¶ 13; Cummings ¶ 16; Carpenter ¶¶ 8-9, 11-19; Bolan ¶¶ 13, 16-18, 20. The Revised Rule also will cause patients to hide their LGBTQ status from providers, even though such information can be critical to their health care and the lack of disclosure can result in a patient's health issues left unaddressed, precipitating the development of more acute conditions. Shafi ¶ 21;

Henn ¶ 15-18; Pumphrey ¶ 12; Cummings ¶ 18, 22(m); Carpenter ¶¶ 14-15; Bolan ¶¶ 13-17; Vargas ¶ 22; Harker ¶ 19. This situation, in turn, will make it more difficult and costlier for the private health care provider plaintiffs to treat their LGBTQ patients, including those with LEP. Henn ¶ 18; Pumphrey ¶ 12; Carpenter ¶¶ 9, 18-19; Bolan ¶¶ 18-19, 22; see also Harker ¶¶ 20-21.

The Revised Rule also impedes the ability of plaintiffs to advocate on behalf of LGBTQ patients when they encounter discrimination. For example, plaintiffs have previously relied on the 2016 Final Rule's provisions and clear guidance to advocate for their patients and clients when they encounter discriminatory health care providers and insurance coverage exclusions. Shafi ¶¶ 25-26; Shanker ¶¶ 8-9, 11. Plaintiffs no longer will be able to rely on these provisions in advocating for patients when they encounter discrimination. Vargas ¶¶ 26-27; Harker ¶¶ 20-21.

To counteract the Revised Rule's harmful effects and the confusion it engenders, plaintiffs also will be required to spend and divert already limited resources to help LGBTQ patients navigate the discriminatory barriers to care that they will encounter and the Revised Rule fosters. Shafi ¶ 37; Cummings ¶¶ 25-26; Shanker ¶¶ 24-28; Vargas ¶¶ 16, 24-25, 27; Salcedo ¶ 42; Lint ¶ 66. LGBTQ-affirming providers already are overwhelmed in trying to combat the COVID-19 pandemic. Shafi ¶ 36; Henn ¶ 29; Pumphrey ¶ 15; Cummings ¶ 9; Bolan ¶¶ 15, 21; Carpenter ¶ 20; see also Fabian ¶ 24. To meet the increased demand for their health care services and reimagine the process of health care referrals, plaintiffs will be required to divert resources from their efforts to stem the COVID-19 pandemic. They also will have to divert resources from their other critical programmatic work, like the provision of emergency housing, ESL classes, and case management. Salcedo ¶¶ 44, 46-49; Lint ¶¶ 62, 64; Shanker ¶¶ 13, 18, 29. This Court has recognized that the expenditure of resources for these services is another form of irreparable harm. See District of Columbia, 2020 WL 1236657, at *28.

Plaintiffs will also have to engage in increased education efforts for their patients, members, and clients, as well as outside health care providers and insurance companies. Shafi ¶ 37; Vargas ¶ 24; Harker ¶¶ 21-22; Shanker ¶¶ 8-9, 11. Educational efforts will have to be reimagined to combat the confusion the Revised Rule has caused about whether Section 1557's

prohibition on sex discrimination encompasses discrimination based on sexual orientation, gender identity, transgender status, and sex stereotypes. *Id.* Such expenditure of resources for "additional education of and outreach" "beyond those normally expended" constitutes irreparable harm. *District of Columbia*, 2020 WL 1236657, at *28.

Additionally, the Revised Rule frustrates plaintiffs' ability to promote nondiscrimination in health care through the adoption and implementation of the hospital-accreditation nondiscrimination standards and guidelines. Vargas ¶ 16.

The Revised Rule will also negatively affect the finances of the private health care provider plaintiffs. For example, the elimination of the prohibition on categorical exclusions for genderaffirming care in insurance plans will result in private health care providers like Whitman-Walker Health picking up the tab. Shafi ¶ 35. It will also increase operational costs for LGBTQ-affirming health care providers. Shafi ¶ 34; Cummings ¶ 18.

All the organizational plaintiffs share a mission to improve the health and well-being of LGBTQ people, free from discrimination. Shafi ¶ 3; Cummings ¶ 3; Shanker ¶ 3; Harker ¶¶ 4-7; Vargas ¶¶ 4-5; Salcedo ¶ 5; see also Lint ¶ 6. The Revised Rule, which invites and fosters discrimination against LGBTQ people in health care, not only frustrates plaintiffs' ability to fulfill their missions, but it also impedes their programmatic activities in service of their missions.

D. The Revised Rule Invites Small Employers to Discriminate Against LGBTQ Employees, Including Members of GLMA and AGLP.

Title VII, which prohibits employers from discriminating against individuals because of transgender status or sexual orientation, applies only to entities with more than fifteen employees. *See* 42 U.S.C. §§ 2000e(b) & 2000e-2(a)(1); *Bostock*, 2020 WL 3146686, at *11. Under the Revised Rule, employers that do not meet Title VII's fifteen-employee threshold will be free to discriminate against LGBTQ employees with respect to the provision of health care and benefits. GLMA and AGLP are national organizations that represent the interests of hundreds of thousands of LGBTQ health professionals across the country and whose members include hundreds of health care professionals. Vargas ¶ 5; Harker ¶¶ 4-5, 17. At least some members of these organizations

who are employed by entities with fewer than fifteen employees will be irreparably harmed if the Revised Rule is allowed to go into effect. Vargas ¶¶ 16-21, 26; Harker ¶¶ 11-22. Courts have recognized that denying LGBTQ employees access to the full benefits of employment enjoyed by their heterosexual and/or cisgender counterparts constitutes irreparable harm. *See, e.g., Collins v. Brewer*, 727 F. Supp. 2d 797, 813 (D. Ariz. 2020); *Elzie*, 841 F. Supp. at 443.

E. Violations of Constitutional Rights Alone Amount to Irreparable Harm.

Because the Revised Rule unconstitutionally denies LGBTQ people equal protection under Section 1557 and infringes upon other constitutional rights, allowing the Revised Rule to go into effect will constitute irreparable harm *per se. See Mills v. District. of Columbia*, 571 F.3d 1304, 1312 (D.C. Cir. 2009); *see also Kimberly-Clark Corp. v. District of Columbia*, 286 F. Supp. 3d 128, 147 (D.D.C. 2017) (Boasberg, J.).

III. THE BALANCE OF EQUITIES FAVORS PLAINTIFFS, AND AN INJUNCTION OR STAY IS IN THE PUBLIC INTEREST.

The final two factors in determining whether to issue preliminary relief are whether the balance of equities tips in the moving party's favor and whether an injunction or stay is in the public interest. *See Winter*, 555 U.S. at 20. These factors "merge when the Government is the opposing party." *FBME Bank*, 125 F. Supp. 3d at 127 (cleaned up).

The Revised Rule unequivocally harms the public interest. Conversely, granting the requested preliminary relief serves the public interest in multiple ways. First, the irreparable harms that the Revised Rule will cause to plaintiffs also apply to a substantial number of nonparties. Thousands of LGBTQ individuals, organizations who support and serve those individuals, as well as health care providers across this country, will suffer increases in discrimination, detrimental health outcomes, impediments to health care, and increases in costs and burdens.

Second, the current COVID-19 pandemic also must be considered. Any barrier to the provision of health care services during this pandemic seriously endangers the public health, and the Revised Rule creates numerous barriers to care. Increasing testing capacity and contact tracing are key elements to combating the COVID-19 pandemic. *See* COVID-19 Plan, *supra*, at 3.

Rule will discourage LGBTQ people, including those with LEP, from seeking care, including getting tested and treated for COVID-19. Shafi ¶ 22; Henn ¶ 13; Pumphrey ¶ 14; Cummings ¶ 8; Carpenter ¶ 20; Bolan ¶¶ 16, 21; cf. Fabian ¶¶ 23, 25. Without testing and treatment, the virus will spread through the community at large, which, in turn, will jeopardize the public health, result in unnecessary and preventable deaths, and put additional strains on hospitals already overwhelmed with COVID-19 patients. Shafi ¶ 22; Carpenter ¶ 20. With the private health care provider plaintiffs already overwhelmed by the COVID-19 pandemic, the shifting of resources to respond to the Revised Rule's effects will make it even harder for them to help stem this pandemic. Shafi ¶ 36; Cummings ¶¶ 8-9; cf. Fabian ¶ 24.

This public health concern alone outweighs any interest defendants might claim in having the Revised Rule take effect on August 18, 2020. The health and safety of the public are paradigmatic considerations in the "public interest" factor of the preliminary injunction test. *See, e.g., California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018); *Roederer v. Treister*, 2 F. Supp. 3d 1153, 1163 (D. Or. 2014).

Third, enjoining the Revised Rule will prevent confusion that the Revised Rule creates, particularly in light of the *Bostock* decision. *Bostock*'s holding that discrimination on the basis of transgender status and sexual orientation is discrimination on the basis of sex directly conflicts with the Revised Rule's message that such discrimination is permissible and not a form of sex discrimination. And although *Bostock* controls, the general public cannot be expected to know how to resolve conflicting messages from different branches of government. LGBTQ patients will not know whether they are protected against discrimination when they go to the doctor, and health insurers and providers will be unsure of their legal obligations with regard to sex discrimination. Courts frequently consider the extent to which granting an injunction will remedy the public's confusion. *See, e.g., League of Women Voters*, 838 F.3d at 12-13.

Finally, the public interest is served by ensuring the government abides by the APA and plaintiffs' constitutional rights are not violated. There is "a substantial public interest in having

governmental agencies abide by the federal laws that govern their existence and operations." *Id.* (citation omitted).

On the other side of the scale, allowing the Revised Rule to take effect runs directly counter to the public interest. Executive action typically is taken in the public interest. See Schenck v. Pro-Choice Network of W.N.Y., 519 U.S. 357, 393 (1997) (Scalia, J., concurring in part and dissenting in part). Unfortunately, that is not the case here. The Revised Rule makes it more difficult to access and provide necessary health care during an unprecedented pandemic without any reasoned explanation.

There is no reason why the Revised Rule must take effect on August 18, 2020, as opposed to after a resolution on the merits of plaintiffs' claims. Because plaintiffs are likely to succeed on the merits, HHS's only harm "is that it will be required to keep in place the existing regulation . . . while judicial review of its new regulation runs its course." *District of Columbia*, 2020 WL 1236657, at *31. A preliminary injunction or stay of the effective date is warranted.

IV. THE COURT SHOULD ENTER A NATIONWIDE INJUNCTION AGAINST THE REVISED RULE IN ITS ENTIRETY.

Because the Revised Rule is so infected, there is no point in enjoining it on a piecemeal basis. Every provision erects a barrier to access to care for millions of Americans, particularly those who are LGBTQ or with LEP. The entirety of the Revised Rule runs counter to the statutory commands of Section 1554. Likewise, the Supreme Court's decision in *Bostock* has eviscerated completely the lynchpin of the Revised Rule – the rationale for eliminating the definition of discrimination "on the basis of sex" and its related provisions. HHS's refusal to reconsider the Revised Rule in light of *Bostock* is indicative of the lack of reasoned decision-making that permeates the entire Revised Rule. The Revised Rule's deficiencies "are numerous, fundamental, and far-reaching." *New York*, 414 F. Supp. 3d at 577. "[T]he rulemaking exercise here was sufficiently shot through with glaring legal defects as to not justify a search for survivors." *Id*.

In addition, a nationwide injunction enjoining the Revised Rule or, in the alternative, a stay of its effective date pursuant to 5 U.S.C. § 705 is the only appropriate remedy where, as here, an

agency action is likely unlawful and has nationwide applicability. *See Nat'l Mining Ass'n v. U.S. Army Corps*, 145 F.3d 1399, 1408-10 (D.C. Cir. 1998).

First, the Revised Rule violates the APA and the Constitution in the numerous ways. Because these are facial violations and the Revised Rule applies nationwide, it is not enough for a court to prevent the application of the facially invalid rule to a particular plaintiff. "Setting aside the rule just for the plaintiffs in this case would . . . be illogical given the fact that the APA violations found here would apply with equal force for any other plaintiff to whom the rule could apply." *City & Cnty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1025 (N.D. Cal. 2019). The scope of the injunction, therefore, must be nationwide to redress fully the violation. *See District of Columbia*, 2020 WL 1236657, at *34.

Second, plaintiffs, their members, and their patients are located throughout the United States, and plaintiffs provide health care services beyond the cities and states where they are based. Shafi ¶ 4; Cummings ¶¶ 4-5; Vargas ¶ 5; Harker ¶ 17; Salcedo ¶ 6; *see also*, *e.g.*, Lint ¶ 8; Fabian ¶¶ 17, 21. The irreparable harms that they will suffer will be felt nationwide.

This Circuit and others routinely grant nationwide injunctions in this context. *See, e.g.*, *Nat'l Mining Ass'n*, 145 F.3d at 1408-10; *Harmon* v. *Thornburgh*, 878 F.2d 484, 495 & n.21 (D.C. Cir.1989); *Planned Parenthood Fed'n of Am., Inc., v. Heckler*, 712 F.2d 650, 651 (D.C. Cir. 1983); *Doe* v. *Rumsfeld*, 341 F. Supp. 2d 1, 18-19 (D.D.C. 2004); *Doe* #1 v. *Trump*, 957 F.3d 1050, 1069-1070 (9th Cir. 2020); *Regents of the Univ. of Cal. v. DHS*, 908 F. 3d 476, 511-12 (9th Cir. 2018).

Not only is a nationwide injunction the appropriate remedy here, it is the only adequate remedy. Without nationwide relief at the preliminary stage, complete relief would not be available upon final adjudication because the Revised Rule's harms will have been realized. *See District of Columbia*, 2020 WL 1236657, at *34-35. Indeed, some harms already have occurred. The Court can prevent additional nationwide harms by preliminarily enjoining implementation of the Revised Rule or staying its effective date until judicial review has concluded.

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