IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF HIV MEDICINE; *et al.*, *Plaintiffs*, v. HEALTH RESOURCES AND SERVICES ADMINISTRATION; *et al.*, *Defendants*.	Case No. 1:26-cv-12638-WGY

PLAINTIFFS' PRETRIAL BRIEF – PHASE I (APA CLAIMS)

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INTRODUCTION

Effectively addressing the HIV/AIDS epidemic requires tailoring healthcare services to the needs of people living with HIV, including transgender people. Yet, as part of the administration's campaign to repudiate the existence of transgender people and "eliminate transgender insanity," Dkt. 67-21; *see also* Dkt. 67-22, Defendants have adopted a policy prohibiting healthcare providers participating in the Ryan White HIV/AIDS Program ("the Ryan White Program") from acknowledging, affirming, documenting, or respecting their transgender patients' identities, including through medical care for gender dysphoria. They have promulgated this policy through agency guidance, documents, and Ryan White Notices of Funding Opportunity (the "**Challenged Conditions**" or "**Conditions**," *see* Compl. at ¶¶ 164–187 and Background § C, *infra*).

These Conditions are not just harmful; they are illegal. They violate the Administrative Procedure Act ("APA")[1] because they are arbitrary and capricious, exceed statutory authority, and are contrary to law or constitutional right. And they will immediately and gravely harm Plaintiffs and their transgender patients, as well as damage the Ryan White Program's remarkable success.

Plaintiffs urge this Court to set aside and vacate the Conditions, as well as permanently enjoin Defendants from adopting any similar policy in the future. Such relief is necessary to protect the lives, health, and wellbeing of the transgender people living with HIV who rely on the Ryan White Program for their healthcare, as well as our Nation's HIV care infrastructure.

BACKGROUND

This case challenges Defendants' implementation of Executive Order 14168 (Dkt. 19-5, "**Gender Order**") through Ryan White funding conditions, including through the FY 2026 HRSA

[1] Pursuant to the parties' Joint Stipulation and Proposed Pre-Trial Schedule, this pretrial brief and the upcoming bench trial are "limited to the claims under the Administrative Procedures Act, i.e., Claims I – IV." Dkt. 51. As such, this brief does not address Plaintiffs' non-APA claims, i.e., Claims V-VII, for which "they may be entitled to discovery." *Orr v. Trump*, No. 1:25-CV-10313 (D. Mass. July 1, 2026) (ECF 190).

General Terms and Conditions (Dkt. 1-1, "**Updated FY2026 General Terms**"), HHS Revision to Departmental Notice of Funding Opportunity Content and Clearance Guidance FY 2026 (HRSA 0003–0025), HHS's *Defining Sex* guidance (Dkt. 59-8), HHS Grants Policy Statement (Dkt. 59-9), and Ryan White Program Notices of Funding Opportunity ("**NOFOs**").[2] The Gender Order and the Conditions prohibit Ryan White funding recipients from promoting "gender ideology," such as by providing their transgender patients living with HIV with affirming, culturally competent healthcare (*i.e.*, care that acknowledges and respects a transgender patient's identity) and the medical care that enables many of them to live as who they are (*i.e.*, treatment for gender dysphoria, also known as "gender-affirming medical care").

Provider Plaintiffs and Associational Plaintiffs' members (*see* Dkt. 1 ("Compl.") ¶¶ 22–41) are healthcare providers who offer comprehensive HIV care and primary care, including gender-affirming medical care, to their transgender patients living with HIV through the Ryan White Program.[3] The Conditions harm not only these healthcare providers, but also their transgender patients living with HIV who rely on the Ryan White Program for their healthcare needs.[4]

A. HIV/AIDS Disproportionately Affects Transgender People.

Transgender people—particularly transgender women—bear a disproportionate burden of the country's HIV epidemic. Dkt. 67-11 at 7. Notwithstanding progress to end the epidemic, the risk of acquiring HIV among transgender individuals is thirteen times that of the cisgender population. Zuniga Decl. ¶¶ 19, 20; Dkt. 67-14 at 39–40. According to the Centers for Disease Control and Prevention ("CDC"), transgender people make up 2% of new HIV diagnoses in recent

[2] Dkt. 1-2 (**Part B Suppl. NOFO**); Dkt. 1-3 (**Part C NOFO**); Dkt. 1-4 (**Part F NOFO**); Dkt. 47-2 (**Part D NOFO**); *see also* Dkt. 19-4 (**ADAP NOFO**) (also at HRSA 0034–0072).
[3] *See* Dkt. 14 (Brody Decl.) ¶ 20; Dkt. 15 (Fox Decl.) ¶¶ 31–34; Dkt. 16 (Doe Decl.) ¶¶ 22–27; Dkt. 17 (Collins-Ogle Decl.) ¶¶ 20–23; Dkt. 18 (Roe Decl.) ¶ 20; Dkt. 11 (Packett Decl.) ¶ 23; Dkt. 12 (Weddle Decl.) ¶ 10; Dkt. 13 (Zuniga Decl.) ¶ 13.
[4] Brody Decl. ¶¶ 5, 17; Fox Decl. ¶¶ 42–45; Collins-Ogle Decl. ¶¶ 5, 15–16; Roe Decl. ¶ 7; Doe Decl. ¶¶ 8, 14; Packett Decl. ¶¶ 5–6; Weddle Decl. ¶¶ 5–6, 17–18; Zuniga Decl. ¶¶ 5–6.

year-to-year data despite comprising only about 1% of the U.S. population aged 13 and older. *Id.* As such, approximately 14% of transgender women in the United States live with HIV, with prevalence rates reaching 44% among Black transgender women and 26% among Hispanic/Latina transgender women. Dkt. 19-1 at 2. This disproportionate impact is driven by structural barriers like stigma, discrimination, poverty, homelessness, and lack of access to culturally competent and affirming healthcare, all of which significantly impair access to HIV prevention and treatment services. Zuniga Decl. ¶¶ 24–25; *see also* Dkt. 13-4 at 1–2.

B. Providing Affirming Medical Care to Transgender People Through the Ryan White Program Furthers the Program's Purpose as Set by Congress.

Congress created the Ryan White Program as a comprehensive, integrated system of HIV care. The Program offers a safety net for people living with HIV who lack or experience gaps in coverage by providing funding for outpatient HIV care, treatment, and support services.[5] Congress has directed the Program address the unmet care and treatment needs of people living with HIV by focusing funding on primary healthcare and support services to enhance access to and retention in care and adherence to daily treatment. Weddle Decl. ¶ 17. The Ryan White Program serves over half of those diagnosed with HIV in the U.S., many of whom would not have access to necessary healthcare services and treatment without it. *Id.* ¶ 15. Because HIV is a complex, chronic condition that disproportionately affects medically and socially vulnerable populations, Congress structured the Program to address the full spectrum of health and support services needed to prevent new HIV infections, improve health outcomes for people living with HIV, and reduce health disparities. Packett Decl. ¶ 25. The Ryan White statute repeatedly references coordinated systems of care, continuity of care, retention in care, and outpatient primary healthcare for people living with HIV.[6]

[5] Weddle Decl. ¶ 16; Packett Decl. ¶ 25; Collins-Ogle Decl. ¶ 5.
[6] *See* 42 U.S.C. §§ 300ff–11, 300ff–12(b)(4), 300ff–21, 300ff–23(a), (c), 300ff–51, 300ff–71.

The Health Resources and Services Administration ("HRSA"), a component of the U.S. Department of Health and Human Services ("HHS"), administers the Ryan White Program. However, Congress directed that local planning councils and state consortia be the ones to set funding priorities based on the localized needs and priorities of the communities affected by HIV.[7] Planning councils, bodies, and consortia across the country have long recognized transgender people as a population disproportionately affected by HIV and prioritized strategies that fund affirming, culturally competent care and gender-affirming medical care to improve engagement in HIV care and health outcomes. *See* Compl. ¶¶ 116–125.

Providing affirming, culturally competent HIV care and gender-affirming medical care furthers the Ryan White Program's central goals of retention in care, treatment adherence, and long-term viral suppression.[8] Since at least 2004, HRSA has promoted respect for transgender patients' identities and gender-affirming medical care as necessary to reduce the negative effects that stigma can have on HIV care. *See*, *e.g.*, Dkt. 67-10 at 5; Dkt. 67-27 at 6. And until 2025, HHS guidelines explained that "it is important for HIV care providers to be knowledgeable about the specific HIV care needs of [transgender] individuals," that "HIV care services should be provided within a gender-affirmative care model to reduce potential barriers to ART [antiretroviral therapy] adherence and to maximize the likelihood of achieving sustained viral suppression," and that "[i]ntegrating hormone therapy with HIV services is the recommended practice."[9] Ryan White-funded providers have long treated their transgender patients with respect and included gender-affirming medical care in integrated HIV care models, which improves adherence and retention.[10]

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[7] *See* 42 U.S.C. §§ 300ff–12(b)(1), (b)(4)(B)(ii), (d); 300ff–23(a), (c); 300ff–27(b)(7)(B); *see also* HRSA 0002.
[8] Brody Decl. ¶¶ 5, 17; Fox Decl. ¶¶ 5, 16–18; Collins-Ogle Decl. ¶ 5; Roe Decl. ¶ 7.
[9] Dkt. 12-6 at I-100, I-102–I-103; *see also* Weddle Decl. ¶¶ 28-32.
[10] Brody Decl. ¶¶ 5, 12–17; Fox Decl. ¶¶ 5, 11, 16–18; Collins-Ogle Decl. ¶¶ 5, 10, 14–15; Weddle Decl. ¶¶ 10, 12, 17; Zuniga Decl. ¶¶ 13–14.

C. The Challenged Conditions Prevent Healthcare Providers from Acknowledging their Transgender Patients and Providing Gender-Affirming Medical Care.

The Gender Order commands federal agencies to reject the reality that transgender people exist and to implement policies based solely on sex assigned at birth, including by denying gender-affirming medical care to transgender people. *See* Gender Order §§ 2(f), 3(e), 3(g).

HHS and HRSA have implemented the Gender Order through the Challenged Conditions. For example, the Updated FY2026 General Terms require Ryan White funding recipients to "apply[] sex-based definitions grounded in biological reality" and incorporate HRSA's "strategic priorities," Dkt. 1-1, which specify that "[i]t is a HRSA priority to recognize that a person's sex as either male or female is unchangeable and determined by objective biology, and to ensure its programs accurately reflect science, including the biological reality of sex." Dkt. 19-3 ("**HRSA Priorities**"). The NOFOs incorporate the Updated FY2026 General Terms by prohibiting the use of funds for "sex-trait modification procedures" or "to fund, promote, encourage, subsidize, or facilitate … denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic." Dkts. 1-2, 1-3, 1-4, 47-2, 19-4.

The Challenged Conditions apply across Ryan White funding streams, including Parts A, B, C, D, and F. Compliance with the Conditions would require providers to either (1) refrain from acknowledging, affirming, documenting, and respecting the identities of transgender people and from providing medically indicated healthcare to transgender patients living with HIV or (2) risk losing critical Ryan White funding necessary to operate their HIV programs and to care for their patients living with HIV, including transgender people.[11]

[11] Brody Decl. ¶¶ 5, 17; Fox Decl. ¶¶ 5, 16–18; Collins-Ogle Decl. ¶¶ 5, 15–16; Roe Decl. ¶ 7; Doe Decl. ¶¶ 8, 14, 19; Packett Decl. ¶¶ 5–6; Weddle Decl. ¶¶ 5–6, 17–18; Zuniga Decl. ¶¶ 5–6; Compl. ¶¶ 188–202; Dkt. 19-12 at 35-37.

D. The Conditions Are Part of a Broad Campaign Against Transgender People.

The Challenged Conditions do not arise in a vacuum. They are part of a broad government-wide effort to erase any recognition of transgender people and restrict access to medical care they need. *See* Compl. ¶¶ 130–163; Dkts. 59-12 to 59-16, 67-17 to 67-26. As a court noted, the Administration's actions seek "to identify, to demonize, and ultimately to eradicate an entire population of transgender people." Teleconference Decision, *Coe v. Blanche*, No. 26-CV-04641 (S.D.N.Y. July 6, 2026) (ECF 77), *appeal pending*, No. 26-1886 (2d Cir.).

The Administration has trumpeted its animosity towards transgender people. *E.g.*, Dkts. 59-11, 67-28–67-31. The Gender Order decries the notion that a person might have a gender identity different from their birth-assigned sex as a "false claim." Gender Order § 2. Executive orders and proclamations cast transgender people and transgender-inclusive policies as a "sinister threat," Dkt. 67-23, to "the validity of the entire American system," Gender Order § 1, antithetical to "an honorable, truthful, and disciplined lifestyle," lacking "humility and selflessness," Dkt. 67-17 at § 1, and a source of "endangerment, humiliation, and silencing of women and girls," Dkt. 67-20 at § 1. The Administration has thus denounced "transgenderism," prohibited funding for research related to transgender people, and directed agencies to terminate all programs and grants that "promote or reflect gender ideology." Dkt. 67-24, 67-25, 67-26.

HRSA and HHS have proclaimed that recognition of transgender people's identities is "delusional," Dkt. 67-28, "destructive," Dkt. 67-29, and "extremely inaccurate," Dkts. 59-12 to 59-16; that it "does not reflect biological reality," *id.*; and that it constitutes a "radical ideological agenda[]" that amounts to "social or medical experimentation," Dkt. 59-10.

Notwithstanding the Administration's actions and rhetoric dripping with animus, the fact remains that transgender people are part of the fabric of America. Put simply, "[g]ender identity is real." *Dekker v. Weida*, 679 F.Supp.3d 1271, 1278 (N.D. Fla. 2023), *appeal pending*, No. 23-12155

(11th Cir.). Indeed, "gender diversity is present throughout the lifespan and has been present throughout history."[12] As such, "diversity in gender identity and expression is part of the human experience and transgender and gender nonbinary identities and expressions are healthy."[13] Volumes of case law, some discussed *infra*, acknowledge transgender people's existence and experience. *See*, *e.g.*, *Bostock v. Clayton Cnty.*, 590 U.S. 644 (2020). So do several laws enacted by Congress.[14] And, as demonstrated herein, so have Defendants, across administrations.[15] In this regard, it is the Administration's animus-laden denial of transgender people's existence that is devoid of common sense and unmoored from science and lived reality. The Administration may not deny transgender people "what is due: their right to exist, to live more and die less." *Arroyo Gonzalez v. Rossello Nevares*, 305 F.Supp.3d 327, 334 (D.P.R. 2018).

E. The Challenged Conditions Will Harm Plaintiffs and Their Patients.

The Conditions threaten immediate and concrete harm to Provider Plaintiffs, Associational Plaintiffs' members, and their transgender patients living with HIV. Ryan White-funded programs are structured around integrated models of care that depend on providers being able to offer culturally competent, affirming, comprehensive, and continuous treatment to patients living with HIV.[16] Acknowledging and respecting transgender patients' identities and providing them with gender-affirming medical care when indicated is "critical to maintaining patient trust, adherence to antiretroviral therapy, retention in care, and sustained viral suppression."[17] And "if transgender

[12] Am. Psych. Ass'n, *APA Policy Statement on Affirming Evidence-Based Inclusive Care for Transgender, Gender Diverse, and Nonbinary Individuals, Addressing Misinformation, and the Role of Psychological Practice and Science* (Feb. 2024), https://tinyurl.com/4dvvkauk.
[13] Am. Psych. Ass'n*, APA Resolution on Gender Identity Change Efforts* 2 (Feb. 2021), https://tinyurl.com/4y5a5b2x.
[14] *See*, *e.g.*, 18 U.S.C. § 249 (penalizing crimes motivated by a person's "gender identity"); 34 U.S.C. § 12291(b)(13)(A) (prohibiting discrimination by programs funded under the Violence Against Women Act based on "gender identity"); 42 U.S.C. § 283p (requiring NIH to prioritize research relating to "gender minorities").
[15] *See*, *e.g.*, Dkts. 12-6, 12-10, 13-4, 19-1, 67-10, 67-11, 67-12, 67-13, 67-14, 67-27.
[16] Brody Decl. ¶¶ 13–17; Fox Decl. ¶¶ 5, 10–11; Collins-Ogle Decl. ¶¶ 14–16; Doe Decl. ¶¶ 13, 22.
[17] Collins-Ogle Decl. ¶ 5; *see also* Brody Decl. ¶ 5; Fox Decl. ¶¶ 16–18; Collins-Ogle Decl. ¶¶ 15–16.

people feel supported and affirmed in their identity by health care providers, they are more likely to access HIV testing, engage with pre-exposure prophylaxis, adhere to ART, and achieve viral suppression." Zuniga Decl. ¶ 35. The Challenged Conditions threaten this.

Transgender patients living with HIV already face substantial barriers to healthcare engagement, including stigma, discrimination, unstable housing, mental health conditions, and distrust of medical systems.[18] If Ryan White-funded clinics and providers are prohibited from providing affirming HIV and primary care, patients will be less "open and honest with their healthcare providers about symptoms, behaviors, and healthcare needs," which will lead to "misdiagnosis, missed diagnosis, not being offered preventative health services like screenings, and other adverse health outcomes." Fox Decl. ¶ 40. Causing "transgender patients to lose trust in their healthcare providers and [] clinic[s] in general," in turn, "lead[s] to a lack of engagement in healthcare and avoidance of dealing with acute or chronic illness."[19] This can result in "missed medications," "treatment interruptions," "loss of viral suppression," "significant deterioration in mental health, including increased depression and suicidality," and drug-resistance to previously effective medications, which limits treatment options.[20] Transgender patients who disengage from care may develop preventable complications relating to their HIV and other conditions, "which are significantly more difficult to treat once they have progressed." Brody Decl. ¶ 37.

These harms are especially acute in medically underserved communities like rural and non-Medicaid expansion jurisdictions where Ryan White-funded HIV clinics often are the only viable source of HIV care and gender-affirming medical care for transgender patients living with HIV, as well as for homeless patients who "often have lasting consequences because re-engagement is

[18] Brody Decl. ¶¶ 5, 11, 17; Packett Decl. ¶ 32; Zuniga Decl. ¶ 38.
[19] Brody Decl. ¶ 17; *see also* Fox Decl. ¶ 40; Doe Decl. ¶ 44; Packett Decl. ¶ 31; Brody Decl. ¶ 26; Roe Decl. ¶ 36.
[20] Packett Decl. ¶¶ 32, 42; Zuniga Decl. ¶ 38; Weddle Decl. ¶ 53; Doe Decl. ¶¶ 43–45; Roe Decl. ¶¶ 35–37.

extremely challenging."[21] The Conditions also harm Plaintiffs by disrupting integrated HIV care programs and hampering their ability to deliver evidence-based HIV treatment consistent with medical standards.[22] The Conditions cause Plaintiffs and their patients to suffer irreparable harm, including disruption of treatment relationships, loss of medically necessary care, reduced retention in HIV treatment, worsening health outcomes, and increased risk of HIV transmission.[23]

ARGUMENT

Under the APA, the Court must "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C), or "contrary to constitutional right, power, privilege, or immunity," *id.* § 706(2)(B). The Court must subject the Administrative Record (A.R.) to "'a thorough, probing, in-depth review' and a 'searching and careful inquiry.'" *Am. Fed'n of Gov't Emps. v. U.S. Fed. Lab. Rels. Auth.*, No. 26-CV-11747, 2026 WL 1870987, at *4 (D. Mass. June 29, 2026) (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415–16 (1971)). Plaintiffs are entitled to judgment on the merits because the Conditions violate these standards.

I. The Court Has Jurisdiction Over Plaintiffs' APA Claims.

A. Plaintiffs Have Standing.

Standing requires a plaintiff to "present an injury that is concrete, particularized, and actual or imminent; fairly traceable to the defendant's challenged behavior; and likely to be redressed by a favorable ruling." *Dep't of Com. v. New York*, 588 U.S. 752, 766 (2019) (citation modified).

Provider Plaintiffs have standing. "[I]f a plaintiff is 'an object of the action (or forgone

[21] Collins-Ogle Decl. ¶¶ 11–12; Roe Decl. ¶¶ 7, 9, 11; Brody Decl. ¶ 53.
[22] Packett Decl. ¶¶ 5–6, 11–13; Weddle Decl. ¶¶ 5–6, 11–13; Zuniga Decl. ¶¶ 5–6, 11–14, 31.
[23] *See* Brody Decl. ¶¶ 5, 17; Fox Decl. ¶ 20; Collins-Ogle Decl. ¶¶ 15–16; Roe Decl. ¶ 7.

action) at issue,' then 'there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.'" *Diamond Alternative Energy, LLC v. Env't Prot. Agency*, 606 U.S. 100, 112 (2025) (cleaned up). Further, "los[ing] access to money" is "a classic pocketbook injury sufficient to give … standing." *Nat'l Ass'n of Diversity Officers in Higher Educ. v. Trump*, 167 F.4th 86, 98 (4th Cir. 2026) ("*NADOHE*"); *see also Dep't of Com.*, 588 U.S. at 767–68. Here, Provider Plaintiffs will lose access to Ryan White funding unless they comply with the Conditions. To maintain their ability to receive Ryan White funding, Plaintiffs "face the forced choice" of either having to "change" the way they treat transgender patients living with HIV—including by refusing to acknowledge their identities or provide gender-affirming care—or "give up federal funds." *NADOHE*, 167 F.4th at 98 (quotation omitted); *see also Freedom Network v. Trump*, 830 F.Supp.3d 681, 696, 699 (N.D. Ill. 2026) (standing to challenge NOFOs).[24]

Associational Plaintiffs also satisfy the requirements for associational standing because: "(a) [their] members would otherwise have standing to sue in their own right; (b) the interests [they] seek[] to protect are germane to the organization[s'] purpose[s]; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). *See* Dkt. 10 at 11–12.

"The second and third standing requirements—causation and redressability—are often flip sides of the same coin." *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 380–81 (2024) (citation modified). "If a defendant's action causes an injury, enjoining the action . . . will typically redress that injury." *Id.* Here, the Conditions are the cause of Plaintiffs' injuries, as "[g]overnment regulations that require or forbid some action by the plaintiff almost invariably

[24] Brody Decl. ¶¶ 5, 17; Fox Decl. ¶¶ 5, 16–18; Collins-Ogle Decl. ¶¶ 5, 15–16; Roe Decl. ¶ 7; Doe Decl. ¶¶ 8, 14, 19; Packett Decl. ¶¶ 5–6; Weddle Decl. ¶¶ 5–6, 17–18; Zuniga Decl. ¶¶ 5–6; Dkt. 19-12.

satisfy both the injury in fact and causation requirements." *Id.* at 382. And "[a]n injunction would absolve plaintiffs from having to make their 'lose-lose-lose choice.'" *NADOHE*, 167 F.4th at 99; *see also Woonasquatucket River Watershed Council v. U.S. Dep't of Agric.*, No. 25-1428, 2026 WL 2279789, at *5 (1st Cir. Aug. 7, 2026).

Finally, Provider Plaintiffs and Associational Plaintiffs' members have standing to assert the rights of their transgender patients living with HIV who would be deprived of access to culturally competent HIV care and gender-affirming medical care. Courts have routinely recognized the ability of medical providers to bring claims on behalf of third parties—their patients. *See*, *e.g.*, *Singleton v. Wulff*, 428 U.S. 106, 112–13 (1976). To assert a third party's rights, (1) "[t]he litigant must have suffered an 'injury in fact'"; (2) "the litigant must have a close relationship to the third party"; and (3) "there must exist some hindrance to the third party's ability to protect his or her own interests." *Powers v. Ohio*, 499 U.S. 400, 410–11 (1991) (citation omitted). As to the latter two requirements, the bar is relatively low. *See Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004); *New Jersey v. Trump*, 131 F.4th 27, 38 (1st Cir. 2025). Plaintiffs meet the requirements of third-party standing. They undisputedly have suffered an "injury in fact." *See* Background § E, *supra*. And they have the necessary close relationship with their transgender patients, who "likely face barriers to being able to protect their own interests under these circumstances." *San Francisco A.I.D.S. Found. v. Trump*, 786 F.Supp.3d 1184, 1213 (N.D. Cal. 2025) ("*SFAF*"), *appeal pending*, No. 25-4988 (9th Cir.); *see also Am. Ass'n of Physicians for Hum. Rts., Inc. v. Nat'l Institutes of Health*, 795 F.Supp.3d 678, 693–94 (D. Md. 2025) ("*GLMA*"); *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F.Supp.3d 1, 35, 36 (D.D.C. 2020); *City & Cnty. of S.F. v. Azar*, 411 F.Supp.3d 1001, 1011 (N.D. Cal. 2019).[25]

[25] Associational Plaintiffs also have derivative standing to assert claims on behalf of the transgender patients of their provider members. *See Council of Ins. Agents & Brokers v. Juarbe-Jimenez*, 443 F.3d 103, 109 (1st Cir. 2006); *Pa.*

B. This Court Has Subject-Matter Jurisdiction.

Plaintiffs have comprehensively briefed why this Court has jurisdiction over Plaintiffs' APA claims, which do not challenge any termination of funds or seek any monetary relief, but rather challenge agency policies and seek equitable injunctive relief. *See* Dkt. 47 at 2–5.[26] Binding precedent in *Massachusetts v. Nat'l Institutes of Health*, 164 F.4th 1, 10–12 (1st Cir. 2026), and *Nat'l Institutes of Health v. Am. Pub. Health Ass'n*, 145 S.Ct. 2658 (2025), confirms this Court's subject-matter jurisdiction over Plaintiffs' APA claims. Plaintiffs challenge agency policy promulgated through various agency actions (*i.e.*, the "Challenged Conditions") that prohibits recipients of Ryan White funding from promoting so-called "gender ideology" by acknowledging transgender people's identities and providing gender-affirming medical care. *See* Background § C, *supra*; Compl. ¶¶ 164-187; *see also* Dkts. 1-1, 1-2, 1-3, 1-4, 19-3, 47-2. As in *Massachusetts*, Plaintiffs here "challenge only the agency-wide guidance … that affects future grants as much as it does current ones." 164 F.4th at 12. "That guidance is a precise analogue to the agency-wide guidance in *APHA*," where "a majority [of the Court] … agreed that the plaintiffs' challenge to that guidance belonged in the district court." *Id.*

II. The Challenged Conditions Are Arbitrary and Capricious.

Agency action is arbitrary and capricious when:

- it "relie[s] on factors which Congress has not intended it to consider, entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise," *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983);
- the agency has failed to "consider[] the factors relevant to" its decision "that will best

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Psychiatric Soc'y v. Green Spring Health Servs., Inc., 280 F.3d 278, 293 (3d Cir. 2002); *see also* Dkt. 10 at 13.

[26] Plaintiffs have also already briefed how their claims are ripe for review and the Challenged Conditions constitute final agency action. *See* Dkt. 10 at 13–14 (final agency action); Dkt. 47 at 6–8 (ripeness), 10–11 (final agency action). Pursuant to the parties' joint stipulation, Plaintiffs will be filing their response in opposition to Defendants' motion to dismiss (Dkt. 54), further addressing these issues, on September 15, 2026. *See* Dkt. 62 (modifying Dkt. 56).

serve the purposes" of the statute it is applying, *Am. Paper Inst., Inc. v. Am. Elec. Power Serv. Corp.*, 461 U.S. 402, 413 (1983); *see also River Street Donuts, LLC v. Napolitano*, 558 F.3d 111, 117 (1st Cir. 2009) (same);

- it deviates from past policy or practice, and the agency fails to provide a "more detailed justification than what would suffice for a new policy created on a blank slate," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); or
- the prior policy "has engendered serious reliance interests," *id.*, and the agency fails to "assess [those] reliance interests, determine whether they were significant, and weigh any such interest against competing policy concerns," *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020).

The Challenged Conditions are arbitrary, capricious, and not the product of any reasoned decision-making. To the contrary, the A.R. reveals the lack of consideration as to whether the Conditions were warranted; how or whether the Conditions aligned with or furthered the purpose and structure of the Ryan White Program; whether there was awareness of prior agency guidance and, if so, whether there was a reason supporting a change; or whether and how the Conditions would affect the interests of Ryan White funding recipients or transgender patients living with HIV. Instead, the A.R. reveals that Defendants adopted the Conditions and reflexively incorporated them into the Ryan White Program to further the Administration's animus-laden campaign against transgender people. OMB "require[d] common language in NOFOs," and HRSA staff was directed to add the language "as is" and send NOFOs to "political OGC." HRSA 0073, 0076–77. Indeed, the Director of the Division of State HIV/AIDS Programs, part of HRSA's HIV/AIDS Bureau ("HAB"), noted that the "language was not added by HAB," although HAB is the component with expertise responsible for administering the Program. HRSA 0031.

While HHS's own grantmaking instructions require that programs be designed consistently with their authorizing statutes, with attention to affected communities and "available data, evidence, and evaluation results from past programs," HRSA 0011–14, the A.R. here is devoid of such consideration with regard to the Conditions. Because "[m]ere compliance with an executive

order," *Rhode Island Coal. Against Domestic Violence v. Kennedy*, No. 25-CV-00342, 2026 WL 2364298, at *4 (D.R.I. Aug. 14, 2026) ("*RICADV*"), or the Administration's "push to eliminate transgender insanity," Dkt. 67-21, "does not satisfy the APA's demand for a showing of reasoned decision making," *RICADV*, 2026 WL 2364298, at *4, the Conditions must be set aside and vacated.

A. The Conditions Conflict With the Ryan White Program's Purpose and Structure.

Congress built the Ryan White Program around four core public health pillars: (1) comprehensive medical and support services; (2) special attention to underserved and disproportionately affected populations; (3) access to and retention in care to promote adherence and viral suppression; and (4) state and local priority setting responsive to each jurisdiction's needs vis-à-vis the epidemic.[27] The A.R. recognizes this structure. For example, the A.R. as to the ADAP NOFO describes the Ryan White Program's five parts as "a comprehensive system of medical care, support, and medications for low-income people with HIV" and calls the HIV care continuum "a key strategy" for achieving treatment and viral suppression. HRSA 0037–38. Yet the A.R. never analyzes how the Conditions advance, or even affect, those statutory and programmatic objectives. It is arbitrary and capricious "to prioritize non-statutory objectives to the exclusion of the statutory purpose." *See Gresham v. Azar*, 950 F.3d 93, 104 (D.C. Cir. 2020), *vacated as moot and remanded sub nom. Arkansas v. Gresham*, 142 S.Ct. 1665 (2022).

1) Defendants failed to consider Ryan White's comprehensive care mandate.

Congress did not create the Ryan White Program as a narrow reimbursement program limited solely to antiretroviral medication. It created coordinated systems of outpatient medical care and support services designed to address the barriers that prevent low-income people living

[27] *See, e.g.,* 42 U.S.C. §§ 300ff, 300ff–12(b)(1), (b)(4)(A)–(D), 300ff–14(a)(1), (c)–(d), 300ff–22(b)–(c), 300ff–23(b)–(c), 300ff–27(b)(3), (5), 300ff–51(c)–(d), 300ff–52(a)(2), 300ff–71(b).

with HIV from obtaining and remaining in effective treatment. The statute funds core medical services and care for co-occurring conditions alongside mental health services, substance use treatment, medical case management, transportation, outreach, treatment adherence services, and more.[28] The A.R. itself documents this, describing Ryan White as a "comprehensive system of medical care, support, and medications." HRSA 0038.

Applying this comprehensive-care model to transgender people living with HIV, HRSA has recognized that "gender-affirming care is an important strategy to effectively address the health and medical needs of transgender people with HIV" and that "RWHAP funds may be used to support gender affirming care across various HRSA RWHAP core medical and support service categories." Dkt. 12-10 at 1. HRSA identified social recognition, including use of correct names and pronouns, and gender-related care, like hormone therapy, as forms of gender affirmation that—along with mental-health services, case management, and other services—can meet transgender patients' needs, reduce disparities, and improve HIV outcomes. *Id.* at 1–2.

Not only is the A.R. devoid of any recognition of HRSA's prior position, but the Conditions undermine the integrated delivery model. The Updated FY2026 General Terms require recipients to apply "sex-based definitions grounded in biological reality," which effectively erases transgender people, while the "Required Language for Discretionary NOFOs and NoAs" and the challenged NOFO language prohibit funded activities that recognize sex as mutable and restrict certain gender-affirming medical care.[29] Consistent with the Gender Order, HRSA has stated that websites that even mention transgender people "promot[e] gender ideology," "do[] not reflect biological reality," and are "extremely inaccurate and disconnected from the immutable biological

[28] *See*, *e.g.*, 42 U.S.C. §§ 300ff–11, 300ff–12(b)(4), 300ff–14(c)–(d), 300ff–21, 300ff–22(b)–(c), 300ff–23(a), (c), 300ff–51(c)–(d), 300ff–71(b).
[29] *See* Dkts. 1-1, 1-2, 1-3, 1-4, 19-3, 47-2; *see also* HRSA 0013–0014.

reality," noting "the Administration … rejects it." Dkts. 59-12, 59-13, 59-14, 59-15, 59-16.

Yet the A.R. never addresses whether the Conditions will fracture comprehensive care, force providers to separate services that HRSA previously encouraged them to integrate, or make the Ryan White Program less effective as the safety-net system Congress designed. The record ignored by Defendants, as evidenced by their own prior guidance and Plaintiffs' testimony, shows that it is best practice for HIV care and gender-affirming care to be integrated rather than delivered in isolated silos.[30] Defendants have reversed their position arbitrarily and capriciously.

2) Defendants ignored Congress's focus on underserved and disproportionately affected populations, as well as the impact of culturally competent care on retention in care and viral suppression.

Congress has repeatedly directed the Ryan White Program toward the populations affected by HIV facing the greatest barriers to HIV care. For example, Part A planning councils must identify "disparities in access and services among affected subpopulations and historically underserved communities," Part A councils and Part B consortia must address the populations the epidemic disproportionately affects in their localities, and Part C recipients must "serve underserved populations."[31] Transgender people are one such disproportionately impacted population.[32] For example, the National HIV/AIDS Strategy identifies transgender women as a priority population for reducing HIV disparities. Dkt. 67-14 at 25–26. HRSA itself has emphasized the "tremendous disparities" for transgender people with HIV, reiterating that they are a priority population. Dkt. 67-12 at 19; Dkt. 12-10; Dkt. 67-13 at 3–4.

The A.R. contains no evidence that these disparities were considered, let alone accounted for. It contains no assessment of how the Conditions will affect transgender patients living with

[30] *See* Dkt. 12-6 at I-100, I-102–I-103; Brody Decl. ¶¶ 11–24; Collins-Ogle Decl. ¶¶ 14–24; Roe Decl. ¶¶ 20–24.
[31] 42 U.S.C. §§ 300ff–52(a)(2); 300ff–12(b)(1), (b)(4)(B)(ii); 300ff–23(b)(1)(A), (c)(1)(A)(ii), (B), (F).
[32] Zuniga Decl. ¶¶ 20–24; Weddle Decl. ¶¶ 22–23; Brody Decl. ¶ 11; Roe Decl. ¶¶ 25–28; *see also* Dkt. 13-4.

HIV who rely on the Ryan White Program, no analysis of whether the Conditions will increase barriers to care, and no explanation for imposing barriers to care for a population that HRSA and CDC had specifically identified as experiencing HIV-related disparities. Such silence is especially difficult to reconcile with HHS's instruction that grant programs account for populations "affected by health disparities." HRSA 0011. The evidence shows that stigma, discrimination, and prior negative healthcare experiences already make transgender people with HIV less likely to access care,[33] and that Ryan White-funded clinics and providers serve as an entry point for HIV care for many transgender patients in large part precisely because they allow transgender patients to have their broader health needs addressed in an affirming setting.[34]

Defendants' decision is particularly problematic in light of their failure to consider Congress's directive to structure the Ryan White Program around access, retention, adherence, and successful treatment. The Program's enabling statute requires planning bodies to identify individuals who have HIV but are not receiving HIV-related services, directs outreach to people who are difficult to reach, and, for ADAP, requires States to "facilitate access to treatments" and "encourage, support, and enhance adherence to and compliance with treatment regimens."[35] This reflects a foundational public health principle for the Program: effective treatment depends on keeping people engaged in care long enough to achieve and maintain viral suppression.[36]

The government has previously connected transgender inclusive care to those same outcomes. HRSA has explained patient-centered, trauma-informed, inclusive environments and gender-affirming care reduce barriers to ART adherence, "maximize the likelihood of achieving

[33] Dkt. 19-1 at 21 (explaining that discrimination and denial of services cause transgender people to avoid or delay care); Brody Decl. ¶¶ 18–19; Roe Decl. ¶¶ 25–26; *see also* Dkt. 67-12 at 19 (describing HAB initiatives designed to reduce medical mistrust and barriers to treatment adherence).
[34] Zuniga Decl. ¶¶ 20–25, 34–38; Brody Decl. ¶¶ 5, 13–17; Collins-Ogle Decl. ¶¶ 5–16; Roe Decl. ¶ 7.
[35] 42 U.S.C. §§ 300ff–12(b)(4)(B)(i), (D)(i), 300ff–26(c)(3)–(6), 300ff–27(b)(3)(A), (5)(B).
[36] *See*, *e.g.*, 42 U.S.C. §§ 300ff–12(b)(4)(B)(i)–(ii), 300ff–81, 300ff–26(c)(4), (6); H.R. Rep. No. 109-695, at 2, 15 (2006) (reauthorization aimed to enhance care access and retention).

viral suppression," and play a key role in entry and engagement in HIV care. Dkt. 12-10 at 2; Dkt. 67-11 at 6–9. HHS's HIV Guidelines have likewise explained that adherence to gender-affirming hormone therapy correlates with ART adherence, and that integrating HIV and gender-related care is associated with higher rates of viral suppression. Dkt. 12-6 at I-102–03.

The CDC has similarly independently identified the other side of that causal chain. For example, its treatment guidelines warn that discrimination, lack of provider knowledge, and denial of services cause transgender people to avoid or delay care, resulting in missed HIV and STI prevention opportunities, such that the CDC recommends welcoming clinical environments and patient-selected terminology and pronouns. Dkt. 19-1 at 21. Yet the A.R. contains no analysis of the role that affirming HIV care and gender-affirming medical care play in patient trust, treatment engagement, ART adherence, viral suppression, or transmission, let alone how the Conditions affect these aspects of care. Plaintiffs have explained that the ability of providers to acknowledge and affirm transgender patients, as well as to offer gender-affirming medical care, are essential to the trust and engagement necessary to retain patients in HIV care.[37]

3) Defendants failed to account for Congress's local decision-making structure.

In creating the Ryan White Program, Congress recognized that the HIV epidemic looks different in Boston than in rural Tennessee and deliberately assigned important Program-related decisions to state and local planning bodies. For example, Part A requires planning councils to assess local HIV demographics, unmet needs, and disparities and set funding priorities based on community needs and the priorities of people with HIV. 42 U.S.C. § 300ff–12(b)(4)(A)–(C). Part B likewise requires States and consortia to allocate resources based on local demographics, disparities, areas of greatest need, and the needs of underserved populations, including those with

[37] Fox Decl. ¶¶ 39–40; Roe Decl. ¶¶ 25, 31–36; Doe Decl. ¶ 44; Brody Decl. ¶ 17.

"special" or "unique service requirements." *Id.* §§ 300ff–23(b)–(c), 300ff–27(b)(5).

Defendants themselves have operationalized this statutory design. HRSA guidance requires jurisdictions to assess epidemiology, resources, service gaps, and *community needs* and to develop jurisdiction-specific plans through stakeholder engagement. Dkt. 67-13 at 3–4. And Ryan White Program materials likewise tell recipients that they must base service priorities and resource allocations on the size, demographics, and *needs of people with or affected by HIV*.[38]

The plans produced through this Congressionally mandated process reflect both the importance of local decision-making and the widespread recognition that transgender people experience distinct HIV-related disparities. Plans from Massachusetts, New York State, Boston, Los Angeles, Dallas, San Diego, San Francisco, Florida, and New York City identify transgender people as a priority population and call for tailored and culturally competent services responsive to the needs of transgender people living with HIV, including gender-affirming medical care. *See*, *e.g.*, Dkts. 16-1, 16-2, 67-1 to 67-9. These plans reflect the epidemiological evidence, community participation, and locally responsive priority-setting Congress required.

Yet Defendants never considered the localized planning structure of the Ryan White Program, nor the views of such local planning entities, in enacting the Conditions. The A.R. contains no analysis of the priorities established by Part A councils, the statewide and consortium planning required under Part B, or existing plans produced through that process. It does not address whether jurisdictions could continue implementing locally selected strategies for reaching transgender people, whether those strategies would have to be abandoned, or what effect overriding them would have on access, retention, or viral suppression. Instead, the record shows that HRSA staff were instructed to insert "common language" "as is." HRSA 0073, 0076.

[38] Weddle Decl. ¶ 38; *see also* Dkt. Nos. 12-11, 12-12.

The decision-making leading to the Conditions was the inverse of the structure Congress established. Defendants imposed uniform national restrictions without considering the Congressionally mandated planning process, the priorities it produced, or the consequences of displacing locally tailored strategies for addressing HIV-related disparities.[39]

B. Defendants' Policy Change Ignored the Evidence and Reliance Interests and Was Not Reasonably Explained.

Defendants also failed to consider the longstanding policies and practices pertaining to the provision of HIV care to transgender people through the Ryan White Program. While Defendants can reconsider their policies, they were required to acknowledge the change and explain why a different course was warranted, including by confronting the factual premises underlying the earlier policy. *See Fox Television*, 556 U.S. at 515–16. Likewise, in adopting and implementing the Conditions, Defendants were required to identify and weigh any serious reliance interests. *See Dep't of Homeland Sec.*, 591 U.S. at 30–33. The A.R. shows that Defendants did not do either.

1) Defendants departed from prior policy without a reasonable explanation.

Until now, HRSA and HHS had long recognized and supported consideration of the specific needs of transgender people living with HIV. And HRSA had stated that gender-affirming medical care is an important strategy for addressing their health needs, Dkt. 12-10 at 1, which it emphasized was "not a new policy or approach." Dkt. 67-12 at 20; *see also* Dkt. 67-11 at 7. This policy was consistent with over two decades of federal HIV guidance. *See*, *e.g.*, Dkt. 12-6 at I-100–15 (2024 HHS HIV guidelines); Dkt. 67-10 at 5 (2014 HRSA HIV care guide); Dkt. 67-14 at 31–32 (2021 National HIV/AIDS Strategy); Dkt. 67-27 at 6 (2004 HRSA HIV care guide).

The Conditions mark a radical departure from those longstanding positions. They prohibit Ryan White funding recipients from recognizing that transgender people exist, respecting their

[39] *See* Brody Decl. ¶¶ 11–20; Packett Decl. ¶ 27.

patients' identities, and providing affirming HIV care and gender-affirming medical care. Yet, Defendants never acknowledged that they were "changing position," much less explained the new course. *See Fox Television*, 556 U.S. at 515–16.

The A.R. does not address HRSA's 2021 program letter, its acknowledgment that the policy was longstanding, decades of HRSA and HHS HIV-care guidance, or the National HIV/AIDS Strategy's focus on transgender people with HIV. Nor does it identify new clinical evidence that would undermine those prior judgments or assess the new policy's impacts on engagement, adherence, retention, viral suppression, or transmission. The record thus reflects "an arbitrary and capricious departure from prior practice … without explanation." *Nat'l Parks Conservation Ass'n v. U.S. Dep't of Interior*, No. 26-CV-10877, 2026 WL 1706963, at *15 (D. Mass. June 12, 2026).

2) Defendants ignored evidence and important aspects of the issue.

As noted, HRSA and HHS have long recognized that transgender people face disproportionate HIV burdens and barriers to care; that discrimination and non-affirming care can deter engagement; and that affirming, patient-centered care can reduce those barriers, promote adherence and viral suppression, and thereby improve health and prevent transmission.[40] Plaintiffs' testimony reinforces the importance of these concerns.[41] So does guidance from national medical organizations[42] and peer-reviewed medical literature.[43]

The A.R. does not engage with any of these aspects of the issue. It identifies no clinical literature concerning transgender people with HIV, contains no evaluation of the approach under the Ryan White Program for decades, and no assessment of the impact of the Conditions on patient

[40] *See*, *e.g.*, Dkts. 12-6, 12-10, 13-4, 19-1.
[41] *See* Collins-Ogle Decl. ¶¶ 27, 30–33, 41–48; Fox Decl. ¶¶ 39–40; Brody Decl. ¶¶ 23–26, 32–36; Roe Decl. ¶¶ 25, 31–36.
[42] *See* Dkts. 11-1, 12-1, 13-3; *see also* Dkt. 19-8 (LaValley et al., collecting organizations' statements).
[43] *See* Dkt. 11-2 (AAHIVM clinical research update); Dkt. 11-3 (Reisner et al.); Dkt. 12-4 (Ciszek et al.); Dkt. 12-5 (Stutterheim et al.); Dkt. 12-8 (Cirrincione et al.); Dkt. 12-9 (Braun et al.); Dkt. 13-5 (de la Paz and Barbee).

trust, engagement with HIV care, ART adherence, viral suppression, or transmission. Nor does the A.R. contain any evidence that Defendants considered how the Conditions would affect the *Ending the HIV Epidemic in the U.S.* national initiative or the National HIV/AIDS Strategy, which recognize that "[f]ocusing efforts" on identified priority populations, including "transgender women," is essential to "ending the HIV epidemic by 2030." Dkt. 67-14 at 26. This is so notwithstanding HRSA promising to prioritize "gold-standard science," "high-impact, data-supported interventions," and measurable results, HRSA 0001–02, and HHS instructing agencies to consider existing data, evidence, and evaluation results, HRSA 0011–12. Defendants did neither.

In short, the A.R. contains no evidence that Defendants considered these clinical and public health consequences or their effect on efforts to end the HIV epidemic. *See Massachusetts v. Nat'l Institutes of Health*, 770 F.Supp.3d 277, 309 (D. Mass. 2025), *aff'd*, 164 F.4th 1.

3) Defendants failed to assess and address serious reliance interests.

For more than two decades, Defendants have encouraged Ryan White providers to serve transgender people through respectful, responsive care. *See* Section II.B.2, *supra*. Ryan White funding recipients have acted in reliance on this guidance. They trained staff, developed referral and treatment relationships, integrated HIV and gender-affirming medical care, and built care models in which primary care, behavioral health, support services, and gender-affirming care are delivered together.[44] This reliance includes not only staffing and training investments but also treatment relationships and patient trust, on which continuity of HIV care depends. *Id.*

HRSA nevertheless made the Updated FY2026 General Terms immediately applicable to "all active awards." HRSA 0027. The A.R. does not account for the reliance interests of Ryan White-funded providers. Absent are: assessment of programs already structured under prior policy,

[44] *See* Brody Decl. ¶¶ 11–20, 28–30; Collins-Ogle Decl. ¶¶ 17, 21–24; Roe Decl. ¶¶ 20–22, 42–43; Doe Decl. ¶¶ 22–23, 31–41; Packett Decl. ¶¶ 35, 37–38; Weddle Decl. ¶¶ 48–50.

inventory of affected integrated services, analysis of sunk staffing or training investments, consideration of local plans developed under HRSA and CDC guidance (*see* Section II.A.3, *supra*), assessment of treatment relationships, and transition or narrower-alternative analysis.

Transgender people living with HIV who rely on the Ryan White Program also have substantial reliance interests in receiving affirming HIV care and, for those who need it, gender-affirming medical care.[45] The Conditions threaten to eliminate access to such care and will likely drive many patients from HIV care altogether, particularly where effective treatment requires coordination between HIV medications and hormone therapy.[46]

Defendants needed 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.*, 591 U.S. at 33. The A.R. does not identify, much less address, these reliance interests. This failure to "consider[] the reliance interests that naturally inure" from the Program is arbitrary and capricious. *Am. Pub. Health Ass'n v. Nat'l Institutes of Health*, 791 F.Supp.3d 119, 183 (D. Mass. 2025).

* * * *

These defects converge on the central problem: the A.R. never supplies the factual bridge between what Defendants knew about the Ryan White Program, HIV care, and transgender care, on the one hand, and the restrictions they adopted, on the other hand. The resulting absence of any "rational connection between the facts found and the choice made" renders the Conditions arbitrary and capricious. *See State Farm*, 463 U.S. at 43.

III. The Challenged Conditions Are Not in Accordance with Law.

An agency must follow "statutory commands" and act only as "'authoritatively prescribed

45 Zuniga Decl. ¶ 35; Collins-Ogle Decl. ¶ 5.
46 Compl. ¶ 191; Doe Decl. ¶ 44; Fox Decl. ¶ 39; Roe Decl. ¶ 25; see also Brody Decl. ¶ 17.

by Congress.'" *City of Providence v. Barr*, 954 F.3d 23, 31 (1st Cir. 2020) (quoting *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013)). It may not "decline to follow a statutory mandate … simply because of policy objectives." *In re Aiken Cnty.*, 725 F.3d 255, 259 (D.C. Cir. 2013). When an agency action "conflicts with an agency's own statute" or "another federal law," *NextWave Pers. Commc'ns, Inc. v. FCC*, 254 F.3d 130, 149 (D.C. Cir. 2001), *aff'd*, 537 U.S. 293 (2003), the APA requires a reviewing court to "hold unlawful and set aside" the agency action as "not in accordance with law," 5 U.S.C. § 706(2)(A). *See Rhode Island v. Trump*, 810 F.Supp.3d 283, 308 (D.R.I. 2025).

Courts "may not defer to an agency interpretation of the law." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 413 (2024). They must instead "exercise [] independent judgment in deciding whether an agency has acted within its statutory authority[.]" *Id.* at 412.

A. The Challenged Conditions Are Contrary to the Ryan White Enabling Statute.

The Conditions violate the plain text of the Ryan White statute. *See* Dkt. 10 at 22–23. That statute mandates that funding be provided to establish a system of comprehensive care that "improve[s] the quality, availability[,] and organization of health care services for individuals and families with HIV/AIDS."[47] Those systems of comprehensive care must provide, among other things, "core medical services" for persons living with HIV, to improve access to and retention of HIV-related care, increase viral suppression, and improve overall health outcomes.[48] The term "core medical services" encompasses "outpatient and ambulatory health services,"[49] including treatments for "co-occurring conditions" of individuals living with HIV.[50]

Because the term *outpatient services* is not defined in the Ryan White statute, it "carries its plain and ordinary meaning," *City of Providence*, 954 F.3d at 31. The plain and ordinary meaning

[47] 42 U.S.C. §§ 300ff-21 (Part B), 300ff-11 (Part A), 300ff-29a (Part B Supp.), 300ff-51 (Part C), 300ff-71 (Part D).
[48] *See* 42 U.S.C. § 300ff-14(c)–(d); *id.* § 300ff-22(a); *id.* § 300ff-29a; *id.* § 300ff-51(b); *id.* § 300ff-71.
[49] 42 U.S.C. §§ 300ff-14(b)(1); *id.* § 300ff-22(b)(1); *id.* § 300ff-51(c).
[50] *Id.* § 300ff-14(c); *id.* § 300ff-22(b), *id.* § 300ff-51(c).

of *outpatient services* is "medical procedures, surgeries, therapies, classes, or tests that are done in a qualified medical center without the need for an overnight stay."[51] This definition tracks with the term's definition in other parts of the U.S. Code and Code of Federal Regulations.[52]

The term *co-occurring conditions* is expressly defined in the Ryan White statute. It means "one or more adverse health conditions in an individual with HIV/AIDS, without regard to whether the individual has AIDS and without regard to whether the conditions arise from HIV." 42 U.S.C. § 300ff-88(2). Thus, the condition need *not* stem directly from HIV to qualify as "co-occurring"; it need only exist simultaneously with HIV/AIDS.[53] Accordingly, *core medical services* includes *all* services performed without an overnight stay that treat the adverse health conditions of an individual with HIV/AIDS—even conditions that do not arise directly from HIV.

Transgender people may experience gender dysphoria—a "serious medical condition" characterized by "significant distress" resulting from "the incongruence between [one's] gender identity and their birth-assigned sex." Fox Decl. ¶ 23; *see Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 594 (4th Cir. 2020), *as amended* (Aug. 28, 2020). "Left untreated, gender dysphoria can result in debilitating anxiety, severe depression, self-harm, and even suicidality." Fox Decl. ¶ 25. Gender-affirming medical care reduces, and often even eliminates, those adverse health conditions by helping a "transgender person live in accordance with their gender identity." Fox Decl. ¶ 25. It

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[51] *Outpatient Services*, Health Library, New York-Presbyterian Hospital (May 1, 2025), https://tinyurl.com/z3vhrdxy; *cf. Outpatient in Stedman's Medical Dictionary* 1396 (28th ed. 2005) (defining *outpatient* as "a patient treated in a hospital dispensary or clinic instead of in an overnight room or ward").

[52] *See* 38 U.S.C. § 1803 ("The term 'outpatient care' means care and treatment of a disability, and preventive health services, furnished to an individual other than hospital care or nursing home care."); 42 C.F.R. § 440.20(a)(1) ("Outpatient hospital services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that [a]re furnished to *outpatients*." (emphasis added)); 42 C.F.R. § 440.2(a)(2) ("*Outpatient* means a patient of an organized medical facility . . . who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission" (emphasis added)).

[53] In that respect, the term *co-occurring conditions* mirrors the common definition of *comorbidity*. *See Comorbidity in Stedman's Medical Dictionary* 417 (28th ed. 2005) ("A concomitant but unrelated pathologic or disease process; usually used in epidemiology to indicate the coexistence of two or more disease processes."); *Comorbid*, *Merriam-Webster.com Dictionary*, Merriam-Webster, https://tinyurl.com/33c2ajee (accessed Sept. 6, 2026) (defining *comorbid* as a condition "existing simultaneously with and usually independently of another medical condition").

may include "hormone therapy," Fox Decl. ¶ 24, as well as "providing referrals to appropriate specialists, coordinating care with outside providers, [and] supporting medication management where available through other coverage," Roe Decl. ¶ 22. Indeed, "[g]ender affirmation is often described across several dimensions," including, *inter alia*, "social support and acceptance," "use of pronouns, names, or clothing that align with … gender identity," and "medical (e.g., use of hormones or surgery)." Dkt. 12-10 at 1; Dkt. 12-6 at I-100–I-101. Gender-affirming treatments are often provided to patients on an outpatient basis. *See* Roe Decl. ¶ 22; Zuniga Decl. ¶ 36.

Because gender-affirming medical care treats a co-occurring condition of HIV (gender dysphoria) and can be delivered without an overnight stay in a facility, it qualifies as a *core medical service* for purposes of the Ryan White statute. Plaintiffs have thus structured their integrated care models to provide not only "HIV specialty care, sexual healthcare, counseling, mental-health support, medication monitoring, and assistance addressing social determinants of health such as transportation barriers, food insecurity, and housing instability," Roe Decl. ¶ 21—but also, when appropriate, "gender-affirming medical care for the transgender people living with HIV who need it."[54] By forcing Plaintiffs to exclude gender-affirming medical care from those models, the Conditions "directly undermine" Plaintiffs' efforts to provide holistic care and core medical services to patients living with HIV, as the Ryan White statute mandates. Packett Decl. ¶ 46.[55]

B. The Challenged Conditions Contradict Section 1554 of the Affordable Care Act.

The Challenged Conditions also violate the plain text of the Affordable Care Act ("ACA").[56] Section 1554 of the ACA prohibits HHS, or any component thereof, from promulgating any rule that "creates any unreasonable barriers to the ability of individuals to obtain

[54] Weddle Decl. ¶ 48; *see also* Roe Decl. ¶ 7; Brody Decl. ¶ 5; Fox Decl. ¶¶ 27–30.
[55] *See also* Doe Decl. ¶¶ 58–59; Weddle Decl. ¶¶ 46, 48, 50; Zuniga Decl. ¶ 40 ("The restriction would also undermine our members' ability to treat their patients by erasing data on transgender people living with or at risk of HIV.").
[56] For the reasons set forth in Section V, *infra*, the Conditions violate Section 1557 of the ACA.

appropriate medical care," "impedes timely access to health care services," "interferes with communications regarding a full range of treatment options between the patient and the provider," "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," "violates … the ethical standards of health care professionals," or "limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114. The Challenged Conditions flout these statutory commands.

First, the Conditions create unreasonable barriers to the ability of transgender patients living with HIV to obtain appropriate HIV care as well as gender-affirming medical care for their gender dysphoria and impede timely access to such care. The Ryan White Program seeks to curb the HIV/AIDS epidemic by providing funding to entities—such as Plaintiffs—to satisfy the "unmet care and treatment needs of persons living with HIV/AIDS." H. Rep. 109-695, at 1 (2006). Yet, the Conditions bar Plaintiffs from respecting their transgender patients' identities while providing HIV-related care and from providing gender-affirming medical care altogether. In doing so, the Conditions "make[] it harder" for transgender patients living with HIV to access such forms of care, thereby imposing an "unreasonable barrier" to medical care. *See Planned Parenthood of Maryland, Inc. v. Azar*, No. 20-CV-00361, 2020 WL 3893241, at *9 (D. Md. July 10, 2020).

Further, the Conditions impede the provision of care that transgender patients living with HIV need. HHS has acknowledged that "HIV care services should be provided within a gender-affirmative care model to reduce potential barriers to ART [antiretroviral therapy] adherence and to maximize the likelihood of achieving sustained viral suppression." Weddle Decl. ¶ 30. Yet, the Conditions prohibit HIV care providers from offering integrated health services that incorporate gender-affirming care. That prohibition promises to "disrupt the whole HIV care system." Fox Decl. ¶ 43. By prohibiting providers from acknowledging and affirming their transgender patients'

identities, patients may lose trust in their providers, "miss appointments," avoid the traditional healthcare system, or may "disengage from care altogether."[57] That disengagement will reduce antiretroviral therapy adherence and lower levels of viral suppression across all communities.[58] Because the Ryan White Program is often the only means by which transgender patients may obtain gender-affirming medical care, the Conditions will effectively cut off access to such care for many transgender individuals.[59] The Conditions thus "amount to direct government interference with health care by requiring providers or patients to perform or abstain from certain conduct." *Whitman-Walker Clinic*, 485 F.Supp.3d at 53.

Second, the Conditions interfere with communications between HIV care providers and their transgender patients regarding the full range of treatment options and information they need to make informed and clinically appropriate healthcare decisions. Acknowledging a transgender patient's identity and gender incongruence would, in Defendants' view, "promote gender ideology," Gender Order §§ 3(e), 3(g), and "promote [or] encourage … denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic." Dkts. 1-2, 1-3, 1-4, 47-2. HIV care providers, therefore, will be prohibited from discussing concerns about drug interactions between HIV treatment and gender-affirming hormone therapy, patient priorities regarding care, treatment options regarding gender dysphoria, and other issues related to a patient's needs and circumstances.[60] The Conditions "require[] health care providers to hide the ball from their patients" and thus "quite clearly 'interfere[] with communications' about medical options between a patient and her provider." *Mayor of Baltimore v. Azar*, 973 F.3d 258, 288 (4th Cir. 2020).

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[57] Brody Decl. ¶¶ 26–27, 33–35; Collins-Ogle Decl. ¶ 33; *see also* Fox Decl. ¶ 41; *cf.* Doe Decl. ¶¶ 34–40.
[58] *See* Packett Decl. ¶ 42; Zuniga Decl. ¶ 38; Brody Decl. ¶ 55; Fox Decl. ¶ 43; Roe Decl. ¶¶ 32–34; Collins-Ogle Decl. ¶ 39.
[59] *See* Zuniga Decl. ¶ 39; Collins-Ogle Decl. ¶¶ 40–42; Roe Decl. ¶¶ 38–40; Doe Decl. ¶ 59.
[60] *See* Dkt. 12-6 at I-102–03; Zuniga Decl. ¶¶ 38, 41; Brody Decl. ¶ 42; Fox Decl. ¶¶ 27, 29; Doe Decl. ¶ 56.

Finally, the Conditions will require Plaintiffs to "act against their ethical obligations as medical providers" by "forc[ing]" them to withhold medical care they consider necessary and essential for the care of their patients, Packett Decl. ¶ 36, and to discriminate against their patients in violation of state and federal non-discrimination laws, *see* Weddle Decl. ¶ 47.[61]

IV. The Challenged Conditions Violate the APA Because They Are in Excess of Statutory Authority and Violate the Separation of Powers.

Courts must "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706(2)(C), or "contrary to constitutional right, power, privilege, or immunity." *Id.* § 706(2)(B). An agency "'literally has no power to act'—including under its regulations—unless and until Congress authorizes it to do so by statute." *Fed. Elec. Comm'n v. Cruz*, 596 U.S. 289, 301 (2022) (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)). To determine whether an agency has exceeded its authority, "the court looks to the scope of the agency's statutory authority and discretion and determines whether the agency's statutory authority encompasses the action taken." *Nat'l Educ. Ass'n v. U.S. Dep't of Educ.*, 779 F.Supp.3d 149, 197 (D.N.H. 2025) (citation modified). "Phrased simply, the question is 'whether the agency has gone beyond what Congress has permitted it to do.'" *Id.* (quoting *City of Arlington*, 569 U.S. at 298).

For two independent reasons, the Conditions are "in excess of statutory … authority" and "contrary to constitutional right," 5 U.S.C. § 706(2)(B), (C), and should be set aside. *First*, the Conditions violate the Appropriations Clause because they impose extra-statutory conditions on funds appropriated by Congress. *Second*, Defendants effectively seek to amend the Ryan White statute by imposing grant conditions that were not mandated by Congress.

[61] *See also* Brody Decl. ¶¶ 39–41; Fox Decl. ¶ 45; Collins-Ogle Decl. ¶¶ 47–51.

A. Defendants cannot impose extra-statutory conditions on Ryan White funding.

"The Appropriations Clause … gives Congress exclusive power over federal spending." *Nat'l Council of Nonprofits v. Off. of Mgmt. & Budget*, 763 F.Supp.3d 36, 55 (D.D.C. 2025) (citation modified); *see also Biden v. Nebraska*, 600 U.S. 477, 505 (2023). Only Congress can "impose appropriate conditions on the use of federal property or privileges," including on federal grants. *Massachusetts v. United States*, 435 U.S. 444, 461 (1978). When Congress intends to place conditions on federal funds, "it has proved capable of saying so explicitly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17-18 (1981); *see*, *e.g.*, 42 U.S.C. § 300ff-1 (proscribing use of Ryan White funds to provide "individuals with hypodermic needles or syringes" for illegal drug use); Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 526, 138 Stat. 460 (grant conditions regarding provision of sterile needles); 42 U.S.C. § 202 (grant condition regarding salary caps). The Executive Branch "does not have the power to place conditions on federal funds" that run counter to the will of Congress. *Cnty. of Santa Clara v. Trump*, 250 F.Supp.3d 497, 531-32 (N.D. Cal. 2017) (attempt to put new conditions on federal funds is "improper attempt to wield Congress's exclusive spending power" and violates "the Constitution's separation of powers principles").

The Challenged Conditions "run[] headlong into the Ryan White Program's statutory mandate" to provide comprehensive care and services for patients living with HIV. *SFAF*, 786 F.Supp.3d at 1230. Congress did not condition the issuance of Ryan White grants on whether the recipient promotes "gender ideology," denies the "sex binary" in humans, expresses the belief that sex is a "chosen or mutable characteristic," or provides gender-affirming medical care. To the contrary: Congress explicitly directed the Executive Branch to refrain from taking actions that burden access to and communications regarding appropriate healthcare, or that discriminate based on sex. *See* 42 U.S.C. § 18114(1)-(5); *id.* § 18116; *see also* Sections IV.B and VI, *infra*. And it

expressly structured the Ryan White Program so that entities and individuals like Plaintiffs would be able to provide care to all individuals living with HIV, especially historically underserved communities "experiencing rapid increases" in HIV case counts, like the transgender population. S. Rep. No. 106-294, at 12 (2000); *see also* H.R. Rep. No. 109-695, at 2 (2006) (Ryan White statute embodies broad mandate to "address the unmet care and treatment needs of persons living with HIV/AIDS by funding primary health care and support services that enhance access to and retention in care"). Moreover, the Conditions "contravene the antidiscrimination requirements within the ACA." *SFAF*, 786 F.Supp.3d at 1231. In so doing, the Conditions unconstitutionally intrude upon the Congressional prerogative to control the public fisc. *See California v. Trump*, 786 F.Supp.3d 359, 388–89 (D. Mass. 2025); *New York v. Trump*, 764 F.Supp.3d 46, 51 (D.R.I. 2025) (subsequent history omitted); *City of Chicago v. Noem*, No. 25-CV-12765, 2025 WL 3251222, at *7 (N.D. Ill. Nov. 21, 2025).

B. Defendants cannot amend the Ryan White statute through executive grant conditions.

The Conditions also contravene Articles I and II of the Constitution. They usurp the legislative prerogative, in violation of separation of powers principles, by effectively amending the Ryan White statute to add their own grant conditions. Article I requires that every bill pass both the House of Representatives and the Senate before it is presented to the President. U.S. Const. art. I, § 7, cl. 2. That non-negotiable procedure was designed to "erect enduring checks on each Branch and to protect the people from the improvident exercise of power by mandating certain prescribed steps." *INS v. Chadha*, 462 U.S. 919, 957 (1983). And Article II requires the Executive Branch to "take Care that the Laws be faithfully executed[.]" U.S. Const. art. II, § 3. The Executive Branch has an "affirmative[]" duty to execute duly enacted law, *PFLAG, Inc. v. Trump*, 769 F.Supp.3d 405, 432 (D. Md. 2025), *appeal pending*, No. 25-1279 (4th Cir.), irrespective of "policy reasons" it may have for disagreeing with Congressional allocations. *See In re Aiken Cnty.*, 725 F.3d at 260-

61 n.1 (Kavanaugh, J.) (commission's "policy disagreement with Congress's decision about nuclear waste storage [was] not a lawful ground for the Commission to decline to continue the congressionally mandated licensing process"). Should the Executive Branch "believe[] that appropriations are inconsistent with the President's priorities—it must ask Congress, not act unilaterally." *New York*, 764 F.Supp.3d at 51.

Even if the President had legitimate, non-animus-based reasons for disagreeing with Congress, he cannot simply modify a statutory mandate by skirting the legislative process. Neither Article I nor Article II authorizes Defendants to effectively amend the Ryan White statute through the Conditions. Rather than following the "single, finely wrought and exhaustively considered procedure" for adding substantive grant conditions, *Chadha*, 462 U.S. at 951, Defendants attempt to "impose by brute force [such] conditions" through the grant conditions, *City of Providence*, 954 F.3d at 30, 34. Such brute force approach defies Articles I and II.

V. The Challenged Conditions Discriminate Based on Transgender Status and Sex.

The Conditions impermissibly discriminate based on transgender status and sex, violating the ACA and the Fifth Amendment, and are therefore "not in accordance with law" and "contrary to constitutional right." 5 U.S.C. §§ 706(2)(A) & (B). The Challenged Conditions seek to prohibit transgender people from accessing federally funded healthcare if it is provided in a way that respects or affirms their identities. However, the federal government cannot engage in discrimination, either directly or by forcing grantees to engage in discrimination that is directly prohibited by federal law or the Constitution. *See Norwood v. Harrison*, 413 U.S. 455, 465 (1973).

Section 1557 of the ACA: Section 1557 provides that an individual shall not, on a ground prohibited by Title IX, "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." 42 U.S.C. § 18116(a). To succeed, a plaintiff must show that (1) the

defendant is a covered health program or activity, and (2) the plaintiff was excluded from participation in, denied the benefits of, or subjected to discrimination, (3) on the basis of sex. *Id.*

Plaintiffs easily meet this standard. *First*, Defendants HHS and HRSA are covered entities that fall within the scope of Section 1557. *See* 45 C.F.R. § 92.4; *GLMA*, 795 F.Supp.3d at 695. *Second*, Plaintiffs and their patients will be excluded from participation in, denied the benefits of, and subjected to discrimination under the Ryan White Program. As a condition of receiving Ryan White funding, the Conditions require that grantees stop respecting their transgender patients' identities and stop providing gender-affirming medical care because it promotes "gender ideology." However, providing integrated care is the norm and developing a relationship of trust is crucial both to engaging and maintaining patients in HIV care and to treating their conditions effectively. Fox Decl. ¶¶ 5, 17–19, 40; Brody Decl. ¶¶ 23–24, 35. The Conditions present Plaintiffs with the Hobson's Choice of discriminating against their transgender patients by excluding them from care or losing all of their Ryan White funding.

Third, the Conditions explicitly turn on sex. *See* Background § C, *supra*. They expressly require funding recipients to "[a]pply[] *sex-based* definitions grounded in biological reality," require recipients to "recognize that a person's *sex* as either male or female is unchangeable," and "ensure its programs accurately reflect … the biological reality of *sex*." Dkt. 1-1 at 5; Dkt. 19-3 at 4 (emphasis added). And the Gender Order they seek to effectuate expressly defines sex to "not include the concept of gender identity," Gender Order § 2(a); defines the terms "male," "female," "man," and "woman" in ways that exclude transgender men and women, *id.* §§ (b)-(e); and asserts that transgender identities are "false" and "[do] not provide a meaningful basis for identification and cannot be recognized as a replacement for sex," *id.* §§ 2(f)-(g).

Furthermore, discrimination based on transgender status is discrimination based on sex. In

Bostock v. Clayton County, the Supreme Court held that "it is impossible to discriminate against a person for being … transgender without discriminating against that individual based on sex." 590 U.S. at 660. The Supreme Court recently reaffirmed this proposition. *See West Virginia v. B.P.J.*, 146 S.Ct. 2356, 2383 (2026) (Gorsuch, J., concurring) ("discriminating against a person for being … transgender necessarily entails discriminating against that person at least in part *because of* … sex" (emphasis added)). The First Circuit generally interprets Title IX's protections consistently with Title VII. *See*, *e.g.*, *Ing v. Tufts Univ.*, 81 F.4th 77, 82 (1st Cir. 2023). Numerous courts of appeal, and district courts in this Circuit, have applied *Bostock* to Title IX claims. *See*, *e.g.*, *Grimm*, 972 F.3d at 616-17; *Doe v. Snyder*, 28 F.4th 103, 114 (9th Cir. 2022); *Tirrell v. Edelblut*, 748 F.Supp.3d 19, 42-43 (D.N.H. 2024), *voluntarily dismissed*, ECF 142, Jul. 8, 2026.

Courts have enjoined policies with language virtually identical to the Conditions or involving the Gender Order that the Conditions implement because they facially discriminated based on transgender status and sex. *See*, *e.g.*, *GLMA*, 795 F.Supp.3d at 695; *SFAF*, 786 F.Supp.3d at 1231; *PFLAG*, 769 F.Supp.3d at 444. In finding that the prohibition on using grant money to "promote gender ideology" and the statement that "[i]t is the policy of the United States to recognize two sexes, male and female" and that "[t]hese sexes are not changeable" discriminated based on sex, one court stated: "The Court cannot fathom discrimination more direct than the plain pronouncement of a policy resting on the premise that the group to which the policy is directed does not exist." *PFLAG*, 769 F.Supp.3d at 443–44. The same is true here.

Fifth Amendment: For similar reasons, the Conditions are contrary to constitutional right because they discriminate based on sex and transgender status and because they are motivated by animus towards an unpopular minority in violation of the Fifth Amendment. Classifications based on sex or gender are subject to intermediate scrutiny and must be "'substantially related' to

achieving an 'important' governmental objective." *B.P.J.*, 146 S.Ct. at 2374. The burden of justification "is demanding and it rests entirely on the State." *United States v. Virginia*, 518 U.S. 515, 533 (1996). The government's justification for the policy "must be genuine, not hypothesized or invented *post hoc* in response to litigation." *Id.* at 533.

In addition, classifications based on transgender status are classifications based on sex and so warrant intermediate scrutiny. *See*, *e.g.*, *Roe v. Critchfield*, 137 F.4th 912, 923 (9th Cir. 2025); *Grimm*, 972 F.3d at 608-09; *Tirrell*, 748 F.Supp.3d at 33–36; *Doe v. Austin*, 755 F.Supp.3d 51, 68-69 (D. Me. 2024); *Bos. All. of Gay, Lesbian, Bisexual & Transgender Youth v. U.S. Dep't of Health & Hum. Servs.*, 557 F.Supp.3d 224, 244 (D. Mass. 2021) (citing *Bostock*, 590 U.S. at 669). Further, discrimination based on the failure of transgender people to conform to sex stereotypes is sex discrimination and subject to heightened scrutiny. *See*, *e.g.*, *Tirrell*, 748 F.Supp.3d at 37–38; *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 285–86, 296–97 (W.D. Pa. 2017).[62]

Here too the Conditions turn on sex and transgender status, but there is no important governmental interest that justifies excluding Plaintiffs and their patients from the Ryan White Program. Far from it, the wholesale exclusion of healthcare that supports transgender people conflicts with Congress's directive to support minority populations under the Ryan White Statute and with HRSA's past practice of funding these services. *See SFAF*, 786 F.Supp.3d at 1230; *cf. GLMA*, 795 F.Supp.3d at 697–98. Rather than simply limiting a specific medical treatment, the Conditions broadly prohibit providers from providing affirming, respectful healthcare to transgender people. Their broad scope shows that they seek to regulate transgender persons, not

[62] Classifications based on transgender status independently warrant heightened scrutiny. *See*, *e.g.*, *Grimm*, 972 F.3d at 608; *Karnoski v. Trump*, 926 F.3d 1180, 1200-01 (9th Cir. 2019); *Talbott v. United States*, 775 F.Supp.3d 283, 319–22 (D.D.C. 2025), *aff'd in part, vacated in part, remanded,* 176 F.4th 720 (D.C. Cir. 2026); *F.V. v. Barron*, 286 F.Supp.3d 1131, 1144–45 (D. Idaho 2018) (subsequent history omitted); *Evancho*, 237 F.Supp.3d at 288; *Adkins v. City of New York*, 143 F.Supp.3d 134, 140 (S.D.N.Y. 2015).

just medical procedures. *See Talbott*, 176 F.4th at 751 (Rogers, J., concurring in part and dissenting in part).

The Conditions also warrant heightened scrutiny because they are "motivated by an invidious discriminatory purpose." *United States v. Skrmetti*, 605 U.S. 495, 516 (2025). And our Constitution forbids policies based on such "negative attitudes" and "irrational prejudice." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 448, 450 (1985). The Conditions are part of the Administration's sustained campaign against transgender people. *See* Background § D, *supra.* Their "stated purpose is to deny the existence of transgender persons entirely," and punish organizations that provide them necessary care. *SFAF*, 786 F.Supp.3d at 1216; *see also id.* ("[T]he Gender Order necessarily singles out transgender people and excludes them from being able to benefit from federal funds."); *Endocrine Soc'y v. FTC*, 832 F.Supp.3d 1, 5 (D.D.C. 2026).

Even if the Conditions were not subject to heightened scrutiny, under First Circuit precedent, the Court must apply a more searching review than ordinary rational basis scrutiny for policies targeting groups that have "long been the subject of discrimination." *Massachusetts v. U.S. Dep't of Health & Hum. Servs.*, 682 F.3d 1, 11 (1st Cir. 2012). "[T]ransgender people have been the subject of a long history of discrimination that continues to this day." *F.V.*, 286 F.Supp.3d at 1145. In fact, disclosure of a person's transgender status may expose them "to a substantial risk of stigma, discrimination, intimidation, violence, and danger." *Arroyo*, 305 F.Supp.3d at 333.

Finally, the Conditions fail even rational basis review. "[A] bare … desire to harm a politically unpopular group cannot constitute a *legitimate* governmental interest." *Romer v. Evans*, 517 U.S. 620, 634–35 (1996) (cleaned up); *cf. Talbott*, 176 F.4th at 746 (Wilkins, J.) (harming transgender people not legitimate state interest). Yet, that is the case here. In any event, the A.R. is devoid of *any* rationale for the Conditions. And implementation of the Administration's priorities

"is not enough" under the APA. *RICADV*, 2026 WL 2364298, at *4; *see* Section IV, *supra*.

VI. The Challenged Conditions Violate the Right to Free Speech and Therefore the APA.

Ordinarily, "the government may not regulate speech based on its substantive content or the message it conveys." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 828 (1995). Although the government may attach certain conditions to eligibility for federal funding, *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213–15 (2013) ("*AID*"), there are limitations on the types of conditions that the government may attach to federal funds without violating the First Amendment. Funding conditions "can result in an unconstitutional burden on First Amendment rights" if the conditions "seek to leverage funding to regulate speech outside the contours of the program itself," *AID*, 570 U.S. at 214–15, or if the conditions seek to censor and suppress a recipient's disfavored ideas independent of any objective of the federally funded program, *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 587 (1998).

The Challenged Conditions are not simply a limitation on the government's choice to fund a specific activity. Rather, they express a disparaging and unscientific view of gender identity, repudiate the existence of transgender people, deem their identities to be false, order their exclusion from government recognition and protection, and seek to coerce others to do the same by threatening termination of federal funding and other penalties. This violates the First Amendment.

First, the Conditions create a funding condition that does not further the objectives of the Ryan White Program and thus place an unconstitutional burden on the free-speech rights of Plaintiffs. *See Thakur v. Trump*, 176 F.4th 1187, 1201 (9th Cir. 2026). Rather than imposing conditions on funding that are "relevant to the objectives of the program" itself, here the government is impermissibly seeking to control speech beyond the scope of the federally funded program by placing "a condition on the *recipient* of the subsidy rather than on a particular program or service." *AID*, 570 U.S. at 214, 218–19 (quoting *Rust v. Sullivan*, 500 U.S. 173, 197 (1991)).

The Ryan White Program, which pertains to HIV care, has "no programmatic message" that allows the government to regulate speech concerning *gender* as "deemed necessary" for the program's "legitimate objectives." *Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 548 (2001). The Conditions nevertheless seek to coerce and penalize Ryan White-funding recipients whose speech and services acknowledge the existence of transgender people and affirm their identities. For example, per the Conditions, providers "would not be able to refer to the clients they serve under th[e Ryan White Program] by any pronoun that would 'promote gender ideology,' even when addressing them by such pronouns is pure speech that has no relation to the public health objectives for which the federal grants they receive aim to fund." *SFAF*, 786 F.Supp.3d at 1219; *see also* Dkt. 19-12.

Second, "even in the provision of subsidies, the government may not 'ai[m] at the suppression of dangerous ideas.'" *Nat'l Endowment for the Arts*, 524 U.S. at 587 (quoting *Regan v. Taxation with Representation of Wash.*, 461 U.S. 540, 550 (1983)). Through the Conditions, the government unlawfully administers subsidy programs with a censorious purpose. *See Student Gov't Ass'n v. Bd. of Trs. of Univ. of Massachusetts*, 868 F.2d 473, 479 (1st Cir. 1989) (government conditions on subsidies or benefits based on viewpoint may violate free speech); *see also Ridley v. Mass. Bay Transp. Auth.*, 390 F.3d 65, 82, 95 (1st Cir. 2004) ("[V]iewpoint neutrality demands that the state not suppress speech where the real rationale for the restriction is disagreement with the underlying ideology or perspective that the speech expresses.").

The Challenged Conditions are designed and intended to silence, defund, and otherwise penalize Plaintiffs for acknowledging that transgender people exist and for providing them with healthcare services under the Ryan White Program in a manner that affirms who they are.

> The categorial and expansive nature of the Challenged Conditions telegraph that the Defendants will deny federal funding to a whole class of programs based on viewpoint alone. It cannot be mistaken that in this case federal funding is being employed as a carrot to impose a "disproportionate burden calculated to drive

certain ideas or viewpoints from the marketplace."

Rhode Island Coal. Against Domestic Violence v. Kennedy, 812 F.Supp.3d 180, 195 (D.R.I. 2025) ("*RICADV*") (quoting *Nat'l Endowment for the Arts*, 524 U.S. at 587).

VII. The Conditions Should Be Declared Unlawful and Vacated, and Defendants Enjoined.

Plaintiffs are entitled to a declaration that the Conditions violate the APA because they are arbitrary and capricious, not in accordance with law, in excess of statutory authority, and contrary to constitutional right or power. *See* 28 U.S.C. § 2201(a). Additionally, Plaintiffs are entitled to relief that "hold[s] unlawful and set[s] aside" the Challenged Conditions. 5 U.S.C. § 706(2). Under the APA, "[t]he normal remedy for a successful APA challenge is vacatur of the rule and its applicability to all who would have been subject to it." *Massachusetts*, 770 F.Supp.3d at 329.

Further, permanent injunctive relief enjoining Defendants from implementing, enforcing, effectuating, or giving effect to the Challenged Conditions or any materially similar policy against Provider Plaintiffs and Associational Plaintiffs' members is appropriate here, given "this administration's repeated flouting of court orders and the rule of law." *Oregon v. Kennedy*, 831 F.Supp.3d 1048, 1082 (D. Or. 2026). This is particularly true here, where Defendants adopted the Updated FY2026 General Terms even *after* a court had enjoined a prior version of the HRSA terms and conditions. *See RICADV*, 812 F.Supp.3d at 202. For APA claims, courts may issue injunctive relief if it has a "meaningful practical effect" independent of vacatur. *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010). Plaintiffs' requested prospective injunctive relief has such meaningful practical effect because it goes beyond the Challenged Conditions by including materially similar policies that Defendants might enact. *See Oregon*, 831 F.Supp.3d at 1081; *New York v. U.S. Dep't of Energy*, No. 25-CV-01458, 2025 WL 3140578, at *18 (D. Or. Nov. 10, 2025).

To obtain a permanent injunction, Plaintiffs must show: (1) they suffered or will suffer an irreparable injury; (2) remedies available at law are inadequate to compensate for that injury; (3)

considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) the public interest would not be disserved by a permanent injunction. *Glob. NAPs, Inc. v. Verizon New England, Inc.*, 706 F.3d 8, 13 (1st Cir. 2013) (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)). Plaintiffs satisfy each of these factors.

Here, Plaintiffs will suffer irreparable injury that cannot be compensated. *See* Background § E, *supra*. Acts that "diminish[] access to high-quality health care" cause irreparable harm. *PFLAG*, 769 F.Supp.3d at 449; *see also GLMA*, 795 F.Supp.3d at 699; *SFAF*, 786 F.Supp.3d at 1233. Indeed, "threats to patients' lives represent[] a dire risk of a quintessentially irreparable nature." *Massachusetts*, 770 F.Supp.3d at 320. Deprivations of constitutional rights also constitute irreparable injury. *See Sindicato Puertorriqueño de Trabajadores v. Fortuño*, 699 F.3d 1, 15 (1st Cir. 2012); *Talbott*, 176 F.4th at 747; *SFAF*, 786 F.Supp.3d at 1232–33.

There is also a "substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations," *New York v. McMahon*, 784 F.Supp.3d 311, 372 (D. Mass. 2025) (quotation omitted), and a "strong public interest in health and safety," *Massachusetts*, 770 F.Supp.3d at 326. The Conditions threaten to destroy a remarkable public health success story. The Conditions will adversely affect transgender patients' health and "will increase the viral load population wide and increase transmission rates" due to diminished HIV care adherence. Fox Decl. ¶ 43. Their impact in destabilizing the country's HIV service system "will necessarily cause long-term public health crises." Packett Decl. ¶ 42. They also are likely to place increased financial and workforce burdens on the healthcare system. In contrast, Defendants will suffer no harm: "[t]here is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters of the United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016).

CONCLUSION

The Court should enter judgment for Plaintiffs on their APA claims, *i.e.*, Claims I–IV.

Dated this 8th day of September 2026.

Respectfully submitted,

/s/ Omar Gonzalez-Pagan

Jeffrey S. Trachtman*
Jason M. Moff*
Stephen P. Ferguson*
Hannah Kanter*
Herbert Smith Freehills Kramer (US) LLP
1177 Avenue of the Americas
New York, New York 10036
Telephone: 212-715-9100
Jeffrey.Trachtman@hsfkramer.com
Jason.Moff@hsfkramer.com
Stephen.Ferguson@hsfkramer.com
Hannah.Kanter@hsfkramer.com

Ryan P. Trumbauer*
Herbert Smith Freehills Kramer (US) LLP
2000 K Street NW, 4th Floor
Washington, DC 20006
Telephone: 202-775-4500
Ryan.Trumbauer@hsfkramer.com

* Admitted *pro hac vice*.

Omar Gonzalez-Pagan (BBO No. 678517)
José I. Abrigo*
Jessica Polansky (BBO No. 663750)
Charlie Ferguson*
Lambda Legal Defense and Education Fund, Inc.
120 Wall Street, 19th Floor
New York, New York 10005
Telephone: 212-809-8585
Facsimile: 855-535-2236
ogonzalez-pagan@lambdalegal.org
jabrigo@lambdalegal.org
jpolansky@lambdalegal.org
cferguson@lambdalegal.org

Kenneth D. Upton, Jr.*
Lambda Legal Defense and Education Fund, Inc.
3656 North Halsted Street
Chicago, Illinois 60613
Telephone: 312-663-4413
Facsimile: 855-535-2236
kupton@lambdalegal.org

Pelecanos*
Lambda Legal Defense and Education Fund, Inc.
800 South Figueroa Street, Suite 1260†
Los Angeles, California 90017
Telephone: 213-382-7600
Facsimile: 855-535-2236
pelecanos@lambdalegal.org

† Mailing address only

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I certify that, on September 8, 2026, I filed the foregoing document electronically with the Clerk of the Court using the CM/ECF system, which will send notice of such filing to the registered participants as identified in the Notice of Electronic Filing (NEF), including the following counsel:

Peter R. ("P.R.") Goldstone
Trial Attorney, Federal Programs Branch, Civil Division
Department of Justice
1100 L Street NW, 11th Floor
Washington, DC 20530
Peter.R.Goldstone@usdoj.gov

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan (BBO No. 678517)
Lambda Legal Defense
and Education Fund, Inc.
120 Wall Street, 19th Floor
New York, New York 10005
Telephone: 212-809-8585
Facsimile: 855-535-2236
ogonzalez-pagan@lambdalegal.org