



October 3, 2022

Submitted via the Federal eRulemaking Portal

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services, Office of Civil Rights
Attention: Section 1557 NPRM, RIN 0945-AA17
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW Washington, DC 20201

Re: RIN 0945-AA17: Nondiscrimination in Health Programs and Activities

Dear Secretary Becerra:

We are writing on behalf of the HIV Health Care Access Working Group (“HHCAWG”) of the Federal AIDS Policy Partnership – a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV-related health care and support services. We appreciate the opportunity to provide comments to the Department of Health and Human Services (“HHS” or “the Department”) on “Nondiscrimination in Health Programs and Activities” (“Proposed Rule”), the proposed changes to current regulations (“2020 Final Rule”) implementing Section 1557 of the Patient Protection and Affordable Care Act (“ACA”).

We support the Proposed Rule, as it restores many of the broad protections that were inappropriately rolled back with the 2020 Final Rule. Section 1557 protects individuals from discrimination on the basis of race, color, national origin, sex, age, and disability, and it is of the utmost importance that regulation reflects the broad reach of the provision. The Proposed Rule should be finalized, with changes that would strengthen and clarify the rule as noted below. Once finalized, the rule should be robustly enforced so people living with HIV and other chronic illnesses and disabilities, lesbian, gay, bisexual, transgender, queer, intersex, and asexual (“LGBTQIA+”) people, people who need reproductive health care (including abortion), women of color, and people whose primary language is not English will face fewer barriers when accessing health care.

- I. *We strongly support the Proposed Rule’s definition of a “covered entity” and “health program or activity” and the broad application of Section 1557’s nondiscrimination protections to all operations of a covered entity.*

HHCAWG supports the Department’s definition of “health program or activity” in proposed Section 92.4. Notably, the proposed definition explicitly includes health research, health education, and health insurance coverage, and includes *all* operations of an entity engaged in the provision or administration of health programs or activities.

The 2020 Final Rule had narrowed the scope of application by eliminating the definition of “covered entity” and limiting “health program or activity” to mean “operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance.”¹ Entities “principally or otherwise engaged in the business of providing health insurance” were excluded from this definition.² For operations of entities not considered “principally engaged in the business of providing healthcare,” Section 1557 applied “only to the extent any such operation receives Federal financial assistance.”³ This severely undermined the reach of the law. This interpretation severely undermined the reach of the law, for example by permitting health insurers to employ discriminatory plan designs and adopt categorical exclusions for critical health care that many transgender and gender non-conforming people need.⁴ This lack of protection created uncertainty for transgender and gender non-conforming people over whether they could obtain medically necessary care and imposed anxiety, fear, and emotional distress on such patients.⁵

Further, ensuring a broad application of Section 1557 is necessary to achieve the goals of the National HIV/AIDS Strategy. The White House’s objectives and strategies to “Reduce HIV-related stigma and discrimination,” “Strengthen enforcement of civil rights laws,” “Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities,” and “Adopt policies that reduce cost, payment, coverage, and/or access barriers to improve the delivery and receipt of services for people with or who experience risk for HIV” cannot be realized without applying Section 1557’s protections to the full range of health programs and activities.⁶ For example, discrimination on the basis of disability and other protected bases (including intersectional discrimination⁷) is a direct threat to the ability of people living with HIV to access the treatment, services, and supports they need to live and thrive. The patchwork applicability of the 2020 Final Rule allowed for unequal protections depending on what type of health care coverage a person had, and we support the Proposed Rule’s efforts to eliminate that.

¹ Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37244 (June 19, 2020).

² *Id.* at 37244–45.

³ *Id.* at 37244.

⁴ Complaint at 1, *Fain v. Crouch*, 2020 WL 6688918 (S.D.W.Va.) (No. 3:20-cv-00740).

⁵ See Complaint at 51–52, *Asapansa-Johnson Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. Aug. 17, 2020) (No. 20-cv-2834), <https://perma.cc/XHZ6-CZ3F>.

⁶ The White House, *National HIV/AIDS Strategy for the United States 2022–2025* at 47–55 (2021) (Objective 3.1; Strategy 3.1.1; Objective 3.4; and Strategy 3.4.2, respectively), <https://perma.cc/8YKQ-XSBU>.

⁷ To include more explicit references to intersectional discrimination in the regulatory text, we urge the Department to add “or any combination thereof” after “on the basis of race, color, national origin, sex, age, or disability” in Sec. 92.101(a)(1). Similar changes should be made in 92.207(a), (b)(1), and (b)(2).

However, we are concerned about the limited application of Section 1557 to Third Party Administrators (TPAs). While we support the Proposed Rule’s clarification that TPAs would be responsible for discrimination relating to the administration of a plan or for discriminatory plan designs if the TPA was responsible for the development of group health plan policies ultimately adopted by the plan sponsor, we believe TPAs should be responsible for *identifying* plan designs that are discriminatory and contrary to law, and *informing* their client and others of the violation and options to correct. Given longstanding relationships between TPAs and their clients, it can be difficult to determine the origin of discriminatory plan designs, leaving parties with little opportunity or incentive to acknowledge when a plan is discriminatory. TPAs that agree to administer plans for entities that violate the civil rights of their members play a role themselves in enabling and furthering discrimination of protected individuals and ultimately capitalize on weak enforcement of nondiscrimination protections. We urge the Department to clarify and strengthen expectations for TPAs and the responsibility they have not to discriminate against people in violation of Section 1557. We also urge the Department, when processing a complaint against a TPA for discriminatory plan design, to consider the actions the TPA took (or did not take) to address the violation with the plan sponsor.

We also urge HHS to extend Section 1557 to HHS’ non-health programs and activities. The Department operates agencies and offices that support the social and economic well-being of children, families, and older adults, emergency and disaster preparation, public health, health and policy research, regulation of food and medical devices, disease control, and many aspects of administrative and legislative coordination. While some of these bodies are not directly involved in the delivery or financing of health care, their activities set the framework and priorities for federally-funded and –conducted health care efforts. People living with HIV have long faced discrimination in health-adjacent spaces, and it is critical that civil rights protections are applied across the Department’s activities and that implicit bias, racism, ableism, ageism, and discrimination on the basis of sex are addressed at early stages of health-related planning. A separate rulemaking that extends nondiscrimination protections to “non-health” HHS programs and activities that plan, coordinate new initiatives, set inter-agency priorities, and grant funding will lead to much needed consideration throughout the Department on how to involve protected groups under Section 1557 and achieve greater equity in all of HHS’ work.

II. We strongly support the Proposed Rule’s approach to prohibiting discrimination in health insurance and other health-related coverage.

People living with HIV and other chronic conditions have long faced discrimination in health insurance and health-related coverage. For example, people seeking short-term, limited-duration insurance face pre-existing condition coverage exclusions for HIV care, keeping necessary medications out of reach and undermining efforts to support viral suppression. As another example, some private insurance plans sold on the Marketplace place most or all of the combination drugs used in frontline HIV treatment on the most expensive tiers, making treatment altogether unaffordable. Furthermore, some health insurance plans place drugs used to treat HIV, hepatitis C, and other conditions into specialty pharmacy programs that add unnecessary and

burdensome administrative barriers to obtaining these prescription drugs and require mail delivery, which can delay treatment and threaten privacy.⁸

We support the Department’s approach to prohibiting discrimination in health insurance and other health-related coverage in Sec. 92.207 and, given the breadth of situations where people living with HIV have unfairly faced barriers in health insurance and health-related coverage, we highlight examples that the Department should consider and address in the finalization of the Proposed Rule:

- *Adverse tiering and high cost-sharing for medications:* People living with HIV and other chronic conditions often face high cost sharing requirements for selected medications and services that ultimately shift costs and can dissuade them from enrolling in certain plans. Evidence strongly indicates that health insurers operating on the federally-facilitated and state health insurance exchanges are discriminating against individuals with HIV by placing most or all HIV medications – including medications considered the standard of care for people with HIV⁹ – on a formulary tier with high cost sharing.¹⁰ This practice, known as adverse tiering, has resulted in people living with HIV needing to pay \$3,000 more in out-of-pocket drug costs each year than they would in non-adverse tiering plans.¹¹ As reported by people with HIV and their medical providers, some individuals are forced to forgo treatment due to excessively high cost sharing. Health insurers are also using adverse tiering to discriminate against individuals with a range of other chronic conditions,¹² who pay more than twice as much (105%, on average) in cost sharing in an exchange plan than they would in the average employer-sponsored plan.¹³
- *Coverage exclusions:* Many insurance providers impose categorical exclusions of gender-affirming care. That is, insurers will deny transgender and gender non-conforming members the coverage of treatment and services, such as hormone treatments and certain surgeries, which insurers will provide for cis-gender members. Insurers have also denied what they consider gender-specific care to transgender members, such as mammograms, pap smears, or prostate exams.¹⁴ Such exclusions force transgender and gender non-

⁸ Brief for Center for Health Law and Policy Innovation et al. as Amicus Curiae supporting Respondents, *CVS Pharmacy v. Doe* (No. 20-1374), cert. dismissed 142 S. Ct. 480 (2021), <https://perma.cc/KEJ3-CMBZ>.

⁹ For more information about federally-approved clinical practice guidelines, including for antiretroviral therapy, and prevention and treatment of opportunistic infections, see Clinical Guidelines, HIV.gov, <https://clinicalinfo.hiv.gov/en/guidelines> (accessed Oct. 3, 2022).

¹⁰ See, e.g., AIDS Institute and National Health Law Program, Administrative Complaint, “Re: Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida,” submitted to HHS, Office of Civil Rights (May 29, 2014) (noting Florida insurers that placed all HIV medications for all plans within an actuarial class on nonpreferred tier with 40-50% coinsurance rates); CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living With HIV In Seven States, CHLPI BLOG (2016), <https://perma.cc/ZP5K-MRBR>.

¹¹ Douglas B. Jacobs & Benjamin D. Sommers, Using Drugs to Discriminate – Adverse Selection in the Insurance Marketplace, 372:5 NEW ENGLAND J. OF MED. 399, 401 (2015).

¹² See Avalere, *Coverage Without Access: An Analysis of Exchange Plan Benefits for Certain Medicines* (June 2014) (showing that 52% of marketplace plans required very high cost sharing on all covered drugs for high-cost chronic illnesses, including cancer, diabetes, mental illness, and rheumatoid arthritis).

¹³ Kenneth E. Thorpe, Lindsay Allen, & Peter Joski, *Out-of-Pocket Prescription Costs Under a Typical Silver Plan Are Twice as High as They Are in the Average Employer Plan*, 34 Health Affairs 1695, 1701, Exh. 3 (2015).

¹⁴ S. E. James, et al., *The Report of the 2015 U.S. Transgender Survey* 95 (National Center for Transgender Equality, 2016), <https://perma.cc/6SVS-UEQ8>.

conforming members to pay out of pocket for life saving treatments for which other members receive coverage. Many individuals are then forced to forgo care due to the extremely high out-of-pocket costs for such treatments or experience significant delays as they proceed through insurance appeals processes.

- *Utilization management policies:* People living with HIV and other chronic conditions often face utilization management policies that unfairly deny or restrict access to care. For instance, some insurers and other covered entities may impose categorical prior authorization requirements on most or all drugs required to treat a particular chronic condition.¹⁵ This can result in delayed or lapsed treatment that deviates from best practices articulated in federal treatment guidelines.
- *Specialty drug programs:* People living with HIV and other chronic conditions often find the drugs necessary for the management of their health categorically covered only through specialty drug programs (while other drugs remain accessible through the plan’s standard formulary).¹⁶ These programs may require people living with HIV to obtain their HIV drugs through mail-order pharmacy programs or limited brick-and-mortar locations instead of a typical in-network pharmacy. This can lead to privacy concerns, delayed access and timeliness of treatment, and compromised integrity of medications, which can be particularly harmful for people living with HIV who need reliable and safe access to medications.
- *Copay accumulators and similar policies:* Some covered entities have copay accumulators or similar policies that undermine the financial assistance that people living with HIV and other chronic conditions obtain from manufacturer copay assistance programs to afford high-cost specialty medications.¹⁷ In these situations, insurers will accept the financial assistance as part of the member’s cost-sharing responsibility due for the HIV drug, but refuse to apply the amount towards the member’s annual deductible or out-of-pocket limit. Thus, when they are no longer able to use the copay assistance program, people living with HIV can find themselves many months into the plan year with no progress made towards their deductible. Members living with HIV then face the full cost of an HIV drug each month until they meet their deductible and coverage kicks in. In other evolutions of this type of policy, specialty drugs are deemed to be “excluded” from a plan’s formulary and instead covered under a special program that requires members to apply for copay assistance programs or face exorbitant cost-sharing responsibilities.¹⁸ These policies typically target specialty medications, which in some instances has been defined to include “HIV medications.”¹⁹

¹⁵ See, e.g., Quartz 2022 Standard Choice Drug Formulary, <https://perma.cc/V6TM-9WWY>.

¹⁶ See, e.g., Brief for Center for Health Law and Policy Innovation et al. as Amicus Curiae supporting Respondents, CVS Pharmacy v. Doe (No. 20-1374), cert. dismissed 142 S. Ct. 480 (2021), <https://perma.cc/KEJ3-CMBZ>.

¹⁷ See The AIDS Institute, *Double-dipping: Insurance Companies Profit at Patients’ Expense* (March 2021), <https://perma.cc/RL2E-5Q6E>; HIV and Hepatitis Policy Institute v. HHS, 1:22-cv-02604 (D.D.C. 2022), <https://perma.cc/864C-JZZH>.

¹⁸ See, e.g., City of Albuquerque 2020 SaveonSP Specialty Drug List, <https://perma.cc/WUH9-NCNC>.

¹⁹ See, e.g., City of Smyrna Georgia: 2022 Benefits Overview, <https://perma.cc/Y2LG-SXYQ> (“Specialty Drugs are not covered by the plan”) (“Examples of Commonly Prescribed Specialty & International Tier Drugs: . . . HIV medications”).

- *Lack of transparency:* People living with HIV and other chronic conditions have often faced cost sharing policies that have lacked transparency or are inaccurate.²⁰ These practices, such as not clearly reporting copay accumulator policies or not providing adequate information about cost sharing and coverage of HIV-related drugs can discourage people living with HIV from enrolling into certain plans or subject them to unexpected costs related to their treatment.
- *Short-term, limited-duration insurance:* People living with HIV and other chronic conditions often face coverage exclusions for pre-existing conditions in short-term, limited-duration insurance.²¹ These exclusions can be particularly harmful for people living with HIV, as steady access to lab testing, doctors' visits, and antiretroviral therapy are core components of modern HIV treatment. Moreover, a 2018 study found that a person living with HIV could also be denied short-term, limited duration insurance altogether after confirming they were diagnosed with HIV.²² Concerns are not limited to pre-existing conditions though. Even when some services are covered (for example, urgent or emergency room care or inpatient and outpatient treatment for mental illness), short-term, limited duration insurance often excludes coverage if the injury results from drug or alcohol use or is a self-inflicted injury.²³
- *Provider exclusions:* Inadequate physician network size and composition serve to discourage people living with HIV and other chronic and complex conditions from accessing insurance by excluding providers who are able to deliver quality care for these populations. A plan network that systematically excludes qualified HIV providers, including Ryan White providers, should be considered a discriminatory plan design practice that forecloses meaningful access to care and is prohibited by Section 1557.

We also appreciate the Department's request for comment regarding value-based assessment and purchasing methodologies for drug treatments. We support a movement that places a fair, appropriate, and sustainable value on drug treatments according to how much they benefit patients. However, certain value assessment methods begin with the premise that the benefits or life extension that a treatment brings to the lives of people living with disabilities is worth less than benefits or life extension for people without disabilities.

²⁰ The AIDS Institute, *Double-dipping: Insurance Companies Profit at Patients' Expense* (March 2021), <https://perma.cc/RL2E-5Q6E>.

²¹ See, e.g., Everest, *FlexTerm Health Insurance* (Accessed Sept. 28, 2022), <https://perma.cc/8WF5-3JDQ> ("This coverage contains a Pre-Existing Condition Exclusion. Pre-Existing Condition means a condition for which a Covered Person received medical treatment, diagnosis, care or advice, including diagnostic tests or medications, during the months prior to the Covered Person's effective date of coverage.")

²² Lindsey Dawson & Jennifer Kates, *Short-term Limited Duration Plans and HIV* (June 21, 2018), <https://perma.cc/48T2-3PE4> ("In all 38 applications, when the HIV/AIDS question was answered affirmatively, the applicant was rejected from coverage. In some cases, this was explicit in the question wording; in others, the rejection was only provided afterward.")

²³ FamiliesUSA et al., *Short-term plans do not cover life-saving mental health and substance use treatment* (Aug. 2018), <https://perma.cc/B3D6-F8F4>. See, e.g., Pivot Health, *Latitude* (Accessed Sept. 28, 2022), <https://perma.cc/VY8W-PY52> ("The Policy does not provide any benefits for the following: . . . suicide,") ("In addition to the exclusions in the policy, this rider does not provide any benefits for a Critical Illness that is: . . . Caused by abuse or addiction to alcohol, drugs, or chemicals").

One prime example of such a biased value assessment method is the “Quality Adjusted Life Year” (QALY). The QALY focuses on evaluating how a drug or therapy extends or improves the quality of a person’s life as a way to determine the economic worth of any given treatment. Health insurers and those that contract with insurers and health plans (such as pharmacy benefit managers) use QALY evaluations to decide if they should include a drug among a plan’s covered benefits, and to determine the conditions that must be met for an insured beneficiary to access a drug. Unfortunately, the QALY bases its assessment of quality-of-life improvements and life values on subjective general public assessments on quality of life, and these assessments are deeply influenced by implicit bias and stereotypes about living with disabilities, and which fail to account for the lived experience of people with disabilities. Unsurprisingly, QALY’s assign lower values to improvements that a treatment can bring to the length and quality of life of people with disabilities, making it more likely that drugs which help people living with disabilities maintain their quality of life and independence will “not make the cut” for being included in an insurer’s formulary, or that access to the drug will involve layers of utilization management.²⁴

We recommend that the examples of specific discriminatory actions under Sec. 92.207 of the Proposed Rule include a reference to how a covered entity’s use of QALYs and other value-based assessment methods can discriminate by assigning, or having the impact of assigning, lower values to drug treatments/therapies that increase length or quality-of-life for people with disabilities, people of color, LGBTQ+ individuals, or older adults, for the purpose of making coverage or benefit design decisions. The federal government is already restricted in its use of QALYs in Medicare.²⁵ By logical extension, Medicare Advantage plans, Part D plans, and PBMs that receive Medicare dollars or any kind of federal financial assistance and that make drug coverage decisions should also be required to avoid QALYs that use discriminatory inputs.

III. We strongly support the Department’s interpretation of sex-based nondiscrimination protections.

We applaud HHS for articulating a clear and expansive explanation of discrimination on the basis of sex. Supreme Court case law, including *Price Waterhouse v. Hopkins* and *Bostock v. Clayton County*, makes clear that federal sex discrimination law includes sex stereotypes and sexual orientation and gender identity, including transgender status. It is essential that this rule track those decisions to provide assurance to participants, beneficiaries, and enrollees—and notice to covered entities—that these bases are unequivocally included. We also support the explicit inclusion of discrimination based on sex characteristics, including intersex traits, as such discrimination is inherently sex-based.

Access to health programs and activities that do not discriminate on the basis of sex is especially important for people living with or at risk of HIV. A report of findings from the first National HIV Behavioral Surveillance Trans data collection cycle (2019-2020, focused on 7 U.S. cities) showed

²⁴ Disability Rights Education and Defense Fund, *Pharmaceutical Analyses Based on the QALY Violate Disability Nondiscrimination Law*, September 21, 2021, <https://perma.cc/DC77-BDQH>.

²⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6301(c), 124 Stat. 119, 740 (2010).

that 42% of transgender women surveyed were living with HIV.²⁶ Transgender people living with HIV often face challenges accessing gender-affirming care (including surgery, hormone replacement therapy, and mental health care) and obtaining care from a competent and welcoming provider.²⁷ Furthermore, many transgender and gender non-conforming people avoid or delay care after experiencing sex-based discrimination from a health care provider.²⁸ Federal HIV guidelines urge people to initiate antiretroviral therapy “as soon as possible after HIV diagnosis” as when people living with HIV have regular access to HIV care, they may be able to maintain an undetectable viral load and experience improved health outcomes and a reduced risk of HIV transmission.²⁹ Ensuring that transgender and gender non-conforming people have safe and protected access to health programs and activities must remain a top priority for the Department in both the regulatory text and in enforcement activities.

We also support explicit protections against discrimination on the basis of pregnancy and related conditions, including termination of pregnancy. Abortion is essential health care and is critical to ensuring that people living with HIV have full bodily autonomy.³⁰ Due to a culture that stigmatizes abortion and a coordinated effort by policymakers to restrict access to abortion care and coverage, many people were not able to access abortion care prior to *Dobbs v. Jackson Women’s Health*. In the fallout of the *Dobbs* decision, individuals, especially people of color, people with low incomes, immigrants, young people, people with disabilities, and LGBTQIA+ people, are facing numerous logistical and legal barriers to accessing care with an increased threat of arrest and prosecution as states seek to criminalize abortion care. The consequences of the *Dobbs* decision will fall especially heavy on those who experience intersectional discrimination, such as transgender men who navigate compounded stigma when seeking abortion care.

In line with this support, we ask the Department to amend Sec. 92.101(a)(2) to explicitly include “transgender status” and “termination of pregnancy.”³¹ While the terms “gender identity” and “transgender status” are often used interchangeably, those seeking to permit discrimination against transgender people have sometimes justified discrimination by pressing distinctions between the two concepts. It is therefore preferable to enumerate both in the regulatory text. Additionally, given the increasing restrictions on termination of pregnancy, we believe the Department should make clear in the final rule that “pregnancy or related conditions” includes the termination of pregnancy.

²⁶ Centers for Disease Control and Prevention. HIV Infection, Risk, Prevention, and Testing Behaviors Among Transgender Women—National HIV Behavioral Surveillance, 7 U.S. Cities, 2019–2020 5 (April 2021), <https://perma.cc/U8LP-6WZ6>.

²⁷ Cecilia Chung et al., *Wellness for Our Communities: Cross-site report of key findings from a 2018 needs assessment of transgender and gender nonconforming people living with HIV across three communities: Detroit, Michigan; New Orleans, Louisiana; and South Florida* (Miami and Fort Lauderdale areas) (2019) <https://perma.cc/XPK6-M4HX>.

²⁸ See, e.g., Jo Yurcaba, Nearly half of trans people have been mistreated by medical providers, report finds (Aug. 18, 2021), <https://perma.cc/9XXD-WS6S>.

²⁹ HHS, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV E-2, <https://perma.cc/KY55-YLYR>. See Brief for Center for Health Law and Policy Innovation et al. as Amicus Curiae supporting Respondents at 4-8, *CVS Pharmacy v. Doe* (No. 20-1374), cert. dismissed 142 S. Ct. 480 (2021), <https://perma.cc/KEJ3-CMBZ>.

³⁰ See, e.g., Positive Women’s Network, *Bodily Autonomy: A Framework to Guide Our Future*, <https://perma.cc/8ZQL-A9CM>.

³¹ We suggest the provision be amended to: “Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions, including termination of pregnancy; sexual orientation; transgender status; and gender identity.”

Similar changes should be made throughout the proposed rule, including in Sec. 92.206(b)(1), (b)(2), and (b)(4), and 92.207(b)(3).

IV. *We strongly support the adoption of an explicit provision prohibiting discrimination through the use of clinical algorithms and urge the Department to strengthen the provision with clarifications regarding covered entity responsibilities and enforcement.*

We support proposed Sec. 92.210, which would make explicit that covered entities are prohibited from discriminating through the use of clinical algorithms on the basis of race, color, national origin, sex, age, or disability under Section 1557. Many clinical algorithms dictate that Black patients, in particular, must be more ill than white patients before they can receive treatment for a range of life-threatening conditions, including for kidney disease, heart failure, and pregnancy-related complications. Similarly, Crisis Standards of Care, which are also driven by clinical algorithms, have often reflected a bias against people living with disabilities and older adults. Given the deep legacy of racism and other forms of discrimination in health systems and health policy, we urge the Department to finalize this provision with clarity around expectations for covered entities (1) to inspect clinical algorithms prior to use, (2) to investigate clinical algorithms currently in use, (3) to inform patients when clinical algorithms makings adjustments for protected bases impact their treatment and care, and (4) to mitigate harm that has already occurred due to reliance on discriminatory algorithms.

We also urge the Department to make clear that covered entities are not permitted to employ algorithms that use demographic variables to add barriers to or deny access to gender-affirming care. Such algorithms would include coding used by insurers that rely on a person's recorded sex to automatically deny or otherwise stall claims for gender-affirming care (such as hormone therapy) or other care typically provided to individuals with a different sex marker (such as birth control).³² This would also include clinical guidelines or prior authorization criteria that exclude the coverage of certain procedures due to an individual's recorded sex, gender identity, or gender dysphoria.³³ While such discrimination would be prohibited in proposed Sec. 92.206 and 92.207, given the ubiquity of such discrimination, we believe it appropriate to clarify this in Sec. 92.210 as well.

V. *We support the Department's proposal to include a new provision specific to telehealth and urge the Department to enumerate clear standards for telehealth providers to ensure equitable and safe access to care.*

As the Department has observed, telehealth can be an important tool to improve access for patients who may be unable or prefer not to receive some services in person.³⁴ This need has been particularly highlighted during the COVID-19 pandemic, when use of telehealth expanded dramatically, making care more accessible for many patients including those seeking gender-

³² See, e.g., New York State Department of Financial Services, Insurance Circular Letter No. 13 (June 28, 2020) ("Issuers are prohibited from automatically denying claims for transgender individuals because the gender or sex with which the individual identifies does not match the gender or sex of someone to whom those services are typically provided.") https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2020_13.

³³ *Id.*

³⁴ Nondiscrimination in Health Programs and Activities, 87 Fed Reg 47824, 47884 (Aug. 4, 2022).

affirming care and other health services.³⁵ At the same time, inequitable access to telehealth, as well as a lack of parity between telehealth and in-person services, can contribute to health disparities, underscoring the need for strong antidiscrimination protections in this area.

Beginning in the early days of the COVID-19 pandemic, the expansion of telehealth services did not just preserve access to health care, it also “serve[d] as a bridge between our health care system and some of its most marginalized patients, many of whom struggled to access care long before the COVID-19 pandemic began.”³⁶ For example, a number of recent studies have shown that transgender and gender non-conforming people have benefited greatly from expanded access to telehealth services as many have struggled to access in-person care due to transportation and logistical barriers, as well as anxiety and reluctance to enter clinical spaces due to past experiences of discrimination.³⁷ Similarly, telehealth is particularly helpful for people in certain areas of the country where appropriate care is limited. For example, telehealth can expand access to care for transgender and gender non-conforming people in underserved areas: “Baseline access to gender-affirming care services in the United States Heartland and South is . . . significantly limited, with many states and regions, including rural areas, having limited or no access to gender-affirming care providers at all.”³⁸ In particular, youth seeking access to gender affirming care may face insurmountable geographic barriers to care, because “few pediatric providers have the training and experience to support [gender diverse youth], and those who do frequently practice in clinics affiliated with large urban academic medical centers.”³⁹

While telehealth can lead to connections between traditionally underserved patients and culturally competent providers, it also has the potential to increase communication difficulties, leading to worse care. Concerns about effective patient-provider communication via telehealth may be magnified in the context of care that requires patients to self-advocate.⁴⁰ A lack of standardized reimbursement procedures for telehealth visits, sometimes referred to as “telehealth parity,” also poses problems,⁴¹ and can leave both clinicians and patients “with unpredictable price tags.”⁴² While CMS and several private insurers implemented temporary policy waivers to increase

³⁵ Sanuja Bose et al., *Medicare Beneficiaries in Disadvantaged Neighborhoods Increased Telemedicine Use During the COVID-19 Pandemic*, HealthAffairs (May 2022), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01706>. Telehealth has also been increasingly used to provide HIV-related care, with many people living with HIV likely to choose telehealth as an alternative to clinic visits due to increased privacy and when facing transportation barriers. Dima Dandachi et al., *Exploring the Attitude of Patients with HIV About Using Telehealth for HIV Care*, 34 AIDS Patient Care and STDs 166 (2020).

³⁶ Ben Kaplan, *Access, Equity, and Neutral Space: Telehealth Beyond the Pandemic*, Annals of Family Medicine (Jan. 2021), <https://perma.cc/2ANG-CFDB>.

³⁷ *Id.*

³⁸ Li Lock et al., *Transgender Care and the COVID-19 Pandemic: Exploring the Initiation and Continuation of Transgender Care In-Person and Through Telehealth*, 7 Transgender Health 165 (2022), <https://perma.cc/X4V3-4GU3>.

³⁹ *Id.*

⁴⁰ See, e.g., Alexa B. D’Angelo et al., *Health and Access to Gender-Affirming Care During COVID-19: Experiences of Transmasculine Individuals and Men Assigned Female Sex At Birth*, American Journal of Men’s Health (2021), <https://perma.cc/3JKB-XKJS>; Gina M. Sequeira, *Gender-Diverse Youth’s Experiences and Satisfaction with Telemedicine for Gender-Affirming Care during the COVID-19 Pandemic*, Transgender Health (April 11, 2022), <https://perma.cc/H32B-CFQR>.

⁴¹ Ben Kaplan, *Access, Equity, and Neutral Space: Telehealth Beyond the Pandemic*, Annals of Family Medicine (Jan. 2021), <https://www.annfammed.org/content/19/1/75.long>.

⁴² *Id.*

reimbursement for telehealth services during the pandemic, only “permanent adoption of telehealth parity across insurance providers will help to sustain these crucial services.”⁴³ We urge the Department to embrace telehealth parity by requiring insurers to provide comparable reimbursement for telephone, video, and in-person visits.

VI. *We urge the Department to vigorously review any requests for religious exemptions and to ensure that people living with or at risk of HIV have protected access to life-saving reproductive and sexual health care.*

The federal government has a compelling interest in preventing discrimination in health care. Section 1557 of the Affordable Care Act addresses long standing discrimination in health care that has created numerous barriers to quality care for people living with HIV, especially those who also identify as people of color and LGBTQIA+ people. Religious exemptions have often resulted in discrimination against those who seek sexual and reproductive health care and LGBTQIA+ competent care. Rural communities, people with low-incomes, and communities of color often rely on religiously-affiliated health care entities which make up a large part of the U.S. health care system and thus rely on these institutions to address the full spectrum of their health care needs.

Under the Religious Freedom Restoration Act, if a regulation places a substantial burden on religious exercise, the government must prove it has a compelling interest in doing so and is using the least restrictive means possible. In the context of discrimination in health care, the government has the strongest compelling interest to not only prevent discrimination but ensure taxpayer dollars are not used to further discrimination. Entities who participate in a federal health program and receive federal funding must be held to the highest nondiscrimination standard so people can access the sexual and reproductive health care they need and deserve, including pre-exposure prophylaxis, counseling for sexually transmitted infections, and contraceptive care.

To adhere to Section 1557’s goals and ensure patient well-being is paramount, OCR’s review process for exemptions must address this compelling interest in each case-by-case analysis. Determinations must clearly explain how any exemption granted does not further discrimination and any exemption denied would have undermined the goals of Section 1557. Additionally, determinations of discrimination cannot be unduly delayed as people harmed by health care discrimination are often dealing with increased negative health outcomes or have been forced to forgo care entirely.

VII. *The Department should ensure proper enforcement of the Final Rule.*

We support strong enforcement of Section 1557 and welcome recognition that the law protects people who experience intersectional discrimination. This can include individuals living with HIV who also experience homophobia, transphobia, pregnancy discrimination, ageism, and discrimination on the basis of their English proficiency. We support clear, accessible procedures for filing, investigating, and remediating discrimination complaints and suggest OCR consider including a specific reference to intersectional discrimination in Sec. 92.301.

⁴³ *Id.*

While we support the Proposed Rule with changes that strengthen and clarify the protections provided under Section 1557, even a robust rule cannot stand on its own. The Office for Civil Rights (OCR) should update its complaint process to realize the Department's strategic goal of building trust, transparency, and accountability.⁴⁴ Under the current process through the Operations and Resources Division's Centralized Case Management Operations, it is nearly impossible to know the status of a complaint. This lack of any available information undermines confidence in the process among complainants and the public. OCR should consider the creation of a searchable database of complaints which would include information similar to Freedom of Information Act databases (as allowable under health information privacy law). Additionally, OCR should provide status updates that clearly indicate where in the process a complaint stands. OCR could use these status indicators to create new performance metrics that track the time complaints spend in each point along the review process, as well as identify outcomes. Such metrics could identify roadblocks to efficient Section 1557 complaint review and facilitate process improvement.

With newly proposed provisions, such as Sec. 92.210, it will be imperative for the federal government to dedicate robust financial and staff resources to identify conduct that is discriminatory. The United States health care system – in delivery, research, and financing, among other areas – has a troublesome history and relationship with vulnerable communities and the enforcement of such civil rights protections cannot fall primarily on patients filing complaints with OCR. For example, for clinical algorithms, people may not be aware of when or how algorithms may affect their course of care, and may not be privy to an algorithm's underlying design and development. Without this knowledge, they may be unable to file a complaint or unaware that they can or should. Furthermore, discriminatory algorithms are often used in time-sensitive situations and may not be adequately addressed by the Office of Civil Rights' current complaint process. Historically, complaints filed with the Office of Civil Rights can take months of investigation, with some complaints closed without decision after more than two years.⁴⁵ Many of the algorithms identified in the Proposed Rule have direct and immediate implications for people living with chronic and emergent health conditions, leaving a lengthy complaint process unsuited to addressing this type of discrimination. Thus, it will be imperative that the Department invest adequate resources to implement these regulations.

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Thank you for the opportunity to comment on the Proposed Rule. Our comments include citations to supporting research, in many cases including direct links for HHS' benefit in reviewing our comments. We direct the Department to each of the sources cited and we request that the full text of each source, along with the full text of our comments, be considered part of the administrative

⁴⁴ Assistant Secretary for Planning and Evaluation (ASPE), *Strategic Goal 5: Advance Strategic Management to Build Trust, Transparency, and Accountability*, HHS.gov (2021), <https://perma.cc/3WHX-S8NR>.

⁴⁵ For example, in 2016 CHLPI, along with partners in seven states, filed fourteen formal administrative complaints with HHS' Office of Civil Rights. See *CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living With HIV In Seven States*, CHLPI BLOG (2016), <https://perma.cc/ZP5K-MRBR>. Complainants received minimal information about the status of complaints until 2019, when at least nine were closed without conclusion because the insurer ceased offering QHPs on the Marketplace. Efforts to obtain information through the Freedom of Information Act relevant to community-led enforcement have been ineffective.

record. Please contact Maryanne Tomazic (mtomazic@law.harvard.edu) and Rachel Klein (rklein@tmail.org) with any questions.

Sincerely,

AHF
AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation Chicago
American Academy of HIV Medicine
APLA Health
Center for Health Law and Policy Innovation
Community Access National Network - CANN
Community Research Initiative, Inc. (CRI)
HealthHIV
HIV Dental Alliance
HIV Medicine Association
iHealth
International Association of Providers of AIDS Care
NASTAD
National Coalition of STD Directors
Positive Women's Network-USA
Prevention Access Campaign
San Francisco AIDS Foundation
The AIDS Institute
Vivent Health