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Submitted via regulations.gov

U.S. Drug Enforcement Administration
DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Proposed Rule on Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, Docket No. DEA-407, 88 FR 12875, RIN: 1117-AB40, Document Number 2023-04248

Dear U.S. Drug Enforcement Administration Representative:

The Center for Constitutional Rights is a national, not-for-profit legal, educational, and advocacy organization dedicated to protecting and advancing rights guaranteed by the United States Constitution, federal statutes, and local and international law. Since our founding in 1966, we have litigated landmark civil rights and human rights cases before the Supreme Court and other tribunals concerning government overreach and policies that discriminate against marginalized communities, including members of the lesbian, gay, bisexual, queer, transgender, two spirit, non-binary and intersex (LGBTQI+) community. The Center for Constitutional Rights has fought to expand access to gender-affirming healthcare in carceral settings as well as the free-world, including in *Diamond v. Ward*, No. 5:20-cv-00453-MTT (M.D. Ga. 2020), a legal challenge that led to a landmark Statement of Interest by the U.S. Department of Justice which affirmed that denying gender-affirming care to transgender people behind bars constitutes cruel and unusual punishment violative of the Eighth Amendment to the U.S. Constitution.¹

We write to express our strong concern about the Proposed Rule by the U.S. Drug Enforcement Administration (DEA) entitled “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation.” As a legal and advocacy organization dedicated to promoting and protecting the rights of marginalized communities, we are deeply concerned that this Proposed Rule will have a devastating impact on transgender people, specifically those who rely on testosterone hormone replacement therapy (HRT) for gender-affirming care, due to its classification as a Schedule III controlled substance.

¹ Statement of Interest of the United States, *Diamond v. Ward*, No. 5:20-cv-00453-MTT (M.D. Ga. Apr. 22, 2021), ECF No. 65, available at https://ccrjustice.org/sites/default/files/attach/2021/04/65_4-22-21_DOJ-SOI_w.pdf.

While the intent of the Ryan Haight Act (RHA)² to prevent prescription poisoning and overdose is laudable, the DEA's Proposed Rule sweeps much too broadly and would restrict safe, affirming, best practice medical care for transgender and gender non-conforming communities.

Specifically, the Proposed Rule's requirement that an in-person medical evaluation be completed before a practitioner can prescribe HRT via telemedicine will be catastrophic to the transgender community, as it will exacerbate the significant barriers that transgender individuals already face when accessing healthcare due to persistent discrimination and stigma. Gender-affirming HRT includes estrogen, which is not considered a controlled substance, and testosterone, a Schedule III drug. The RHA was intended to prevent lethal substances from being administered through unauthorized medical providers. Although the inclusion of testosterone may have been an oversight of the Administration, by including testosterone in this Proposed Rule, the Rule is subject to review under 5 U.S.C. § 706 and likely to fail the *Chevron* agency deference test³ by contradicting the Congressional intent of the RHA.

This Proposed Rule comes at a time when record numbers of states are banning and criminalizing gender-affirming healthcare for transgender and gender non-conforming people. These efforts involve concerted and aggressive legislative attacks on gender-affirming healthcare, including restricting access to HRT. States are advancing these bills with alarming speed, despite every major medical association and leading health authorities expressing resounding support for gender-affirming healthcare for transgender communities.⁴ Amid this landscape, Proposed Rule 88 Fed. Reg. 12875 (Mar. 1, 2023) would create significant barriers to access of HRT, particularly in areas where it is becoming increasingly dangerous for transgender people to access healthcare. For transgender youth alone, according to the Williams Institute at UCLA School of Law, 144,500 transgender youth have lost or are at risk of losing access to gender-affirming healthcare due to state bans and policies.⁵

Transgender people currently face systemic discrimination in employment and education that limits their financial resources and leads to higher rates of poverty and financial insecurity.⁶ Transgender students are also more likely to experience harassment and discrimination in school, which can lead to lower academic achievement and decreased access to higher education, and serves to limit their economic opportunities and financial resources.⁷

² Pub. L. No. 110-425, 122 Stat. 4820 (2008).

³ See *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-44 (1984).

⁴ See *FACT SHEET: Evidence Based Healthcare for Transgender People and Youth*, GLAAD (Oct. 26, 2022), <https://www.glaad.org/blog/fact-sheet-evidence-based-healthcare-transgender-people-and-youth> (featuring supportive statements from the American Medical Association, American Academy of Pediatrics, American Psychiatric Association, Endocrine Society, and American Academy of Child and Adolescent Psychiatry).

⁵ Elana Redfield et al., *Prohibiting Gender-Affirming Medical Care for Youth*, UCLA SCH. OF LAW WILLIAMS INST. (Mar. 24, 2023), <https://williamsinstitute.law.ucla.edu/publications/bans-trans-youth-health-care/>.

⁶ Chinyere Ezie, *Dismantling the Discrimination-to-Incarceration Pipeline for Trans People of Color*, 19 UNIV. OF ST. THOMAS L.J. 277, 282-88 (2023) (discussing trend).

⁷ *Id.*

Transgender individuals also face high levels of employment discrimination, with one study finding that 80% of transgender individuals have experienced employment discrimination including hiring discrimination, harassment on the job, and denial of promotions.⁸ As a result, transgender individuals are more likely to experience unemployment or underemployment, leading to lower wages and fewer financial resources. Discrimination against transgender people in the area of employment can also lead to a lack of access to healthcare coverage, since employer-sponsored health insurance is the primary means by which many Americans are able to access healthcare and afford in-person clinical visits.⁹

The rates of unemployment, denial of health insurance, and denial of economic opportunities that transgender people experience are even more pronounced among transgender people of color, who are disproportionately likely to experience poverty and financial insecurity. According to the National Center for Transgender Equality, nearly one-third of transgender people live in poverty, with transgender people of color experiencing poverty at even higher rates.¹⁰ Black transgender individuals, for example, experience poverty at a rate of 38%, and Latinx transgender individuals experience poverty at a rate of 43%.¹¹

The Proposed Rule by the DEA will only serve to exacerbate these inequalities and further strain the financial resources of transgender individuals and their ability to access life-saving and medically-necessary gender-affirming healthcare. The Rule would also directly contradict President Biden's June 2022 Executive Order, Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals,¹² by creating substantial barriers for transmasculine people to access gender-affirming healthcare, particularly in states where gender-affirming healthcare has become criminalized.

In addition to the barriers faced by transgender individuals in accessing healthcare, there is a severe shortage of healthcare providers who are knowledgeable about the treatment of gender dysphoria and the healthcare needs of transgender people. As a result, many transgender individuals are forced to travel long distances to find providers who can offer adequate care. However, telemedicine providers such as Folx Health have emerged as a vital resource for transgender individuals seeking low-cost and culturally competent healthcare services. The Proposed Rule will further restrict access to these critical tele-healthcare providers and will effectively shutter services that provide essential, specialized, and life-saving care to transgender individuals across the country.

⁸ *Id.* at 286 (citing Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities*, CTR. FOR AM. PROGRESS (Aug. 18, 2021), <https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/>).

⁹ Regrettably, many insurance plans also exclude gender-affirming care from the scope of plan coverage, further rendering gender-affirming healthcare expensive and inaccessible to many, despite it being a medical necessity. *See id.* at 289-91 (collecting citations).

¹⁰ SANDY E. JAMES ET AL., THE REPORT OF THE 2015 U.S. TRANSGENDER SURVEY 144-45 (2016), available at <https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf> (reporting on findings of 2015 nationwide survey); *see also* Ezie, *supra* note 6 at 294 (noting that “[t]rans people of color experience unemployment at four times the rate of the general population, and at twice the rate of white trans people.”).

¹¹ 2015 U.S. TRANSGENDER SURVEY, *supra* note 10, at 144-45.

¹² Exec. Order No. 14,075, 87 Fed. Reg. 37,189 (June 21, 2022), available at <https://www.federalregister.gov/documents/2022/06/21/2022-13391/advancing-equality-for-lesbian-gay-bisexual-transgender-queer-and-intersex-individuals>.

Furthermore, given the ways that anti-trans discrimination and bias remain rampant among healthcare providers, the DEA’s proposed requirement will force many transgender individuals to travel long distances for an in-person medical evaluation or to go without medically-necessary and life-saving hormone replacement therapy *at all*, which will only serve to exacerbate the health disparities faced by transgender individuals and place them in jeopardy of suicidal ideation and attempts, and even death.

In conclusion, the DEA’s Proposed Rule on “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation” will have a devastating impact on transgender individuals if adopted—most grievously transgender people of color, who are already more likely to experience poverty and financial insecurity.

Accordingly, we urge the DEA to rescind this Proposed Rule as written, as well as testosterone’s ongoing classification as a Schedule III drug, which unnecessarily restricts its availability to transgender patients and others for whom it is a medical necessity.

We also call upon your agency to work to ensure that all individuals have access to the healthcare they need and deserve, regardless of their gender identity or economic status. This includes amending the language of 21 C.F.R. §§ 1306.01 *et seq.* and related rules to explicitly extend COVID-19 emergency authorization for telemedicine prescription of testosterone for gender-affirming care without a prior in-person doctor’s visit, so that transgender people can access life-saving treatment from trusted, culturally competent providers without interruption.

Thank you for your prompt attention to this important matter.

Respectfully submitted,

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