March 31, 2023

VIA ELECTRONIC TRANSMISSION

Administrator Anne Milgram
Drug Enforcement Administration
Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: Docket No. DEA-407
Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

Dear Administrator Milgram,

The National Health Law Program (NHeLP) is a public interest law firm that fights for equitable access to quality health care for people with low incomes and underserved populations and for health equity for all. For over fifty years, we have litigated to enforce health care and civil rights laws, advocated for better federal and state health laws and policies, and trained, supported, and partnered with health and civil rights advocates across the country. We believe that all people should have access to the health care they need, regardless of geography, race, ethnicity, language, income, disability, sex, gender identity, sexual orientation, immigration status, or other factors. Ensuring access to controlled medication prescribing via telemedicine is key to achieving that vision. Accordingly, we submit these comments to the Drug Enforcement Administration (DEA) in opposition to its proposed regulation titled "Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation" (hereinafter "Proposed Rule").[1]

The COVID-19 pandemic has underscored telemedicine's importance and illustrated its overall success in expanding access to critical health services when people are unable to receive them in person.[2] Long before the COVID-19 public health emergency (PHE), telemedicine's use was on the rise.[3] Pandemic-era telemedicine flexibilities have enabled the U.S. to finally make progress in easing longstanding structural barriers to care via telemedicine. A growing body of evidence shows that when people use telemedicine services, access to care improves.[4] Moreover, access to telemedicine may provide an equal or better standard of care compared to traditional in-person practices.[5] Expansions in access to care via telemedicine have proven especially critical for people with low incomes and underserved populations, such as transgender, gender-diverse, and intersex (TGI) people and people with disabilities, who previously lacked the means to access the medications they needed to achieve their highest attainable standards of health.

We appreciate that the DEA is considering how to incorporate lessons from COVID-19 PHE telemedicine flexibilities into permanent policy. However, we are deeply concerned that if finalized, the Proposed Rule will dismantle the historic gains in access to care enabled through telemedicine during the PHE, catalyze widespread suffering, and worsen health inequities nationwide. We are particularly concerned about how this will harm Black, Indigenous, and other people of color (BIPOC); people with disabilities, lesbian, gay, bisexual, transgender, queer, and intersex (LGBTQI+) people, women, immigrants and their families, rural communities, and people with low incomes. We urge the DEA to withdraw the Proposed Rule and instead pursue more expansive parameters for telemedicine prescribing that will protect and build upon recent gains in access to care and health equity.

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[1] Drug Enforcement Agency, *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*, 88 Fed. Reg. 12875, 12888 (Mar. 1, 2023), https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had (hereinafter "Proposed Rule").

[2] Fabiola Carrión, Nat'l Health Law Prog., *Medicaid Principles on Telehealth*, May 11, 2020, https://healthlaw.org/resource/medicaid-principles-on-telehealth/.

[3] *Id*.

[4] *Id*.

[5] *E.g.*, George M. Hanna, et al., *Development and Patient Satisfaction of a New Telemedicine Service for Pain Management at Massachusetts General Hospital to the Island of Martha's Vineyard*, 17(9) PAIN MEDICINE (Apr. 27, 2016), https://academic.oup.com/painmedicine/article/17/9/1658/2399351 (finding that telemedicine pain care can provide a better standard of care than in-person options).

I. Requiring an in-person medical evaluation is unnecessary and would create an immense and sometimes insurmountable barrier to vital health care

We strongly oppose the DEA's proposal to require an in-person medical evaluation or satisfy one of two alternative schemes before certain controlled substances can be prescribed.[6] We disagree with the DEA's contention that an in-person medical evaluation is required by the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Act).[7] The Act generally requires that a prescribing practitioner conduct at least one in-person medical evaluation with the patient before delivering, distributing, or dispensing controlled medications via the internet with a valid prescription.[8] Yet it also clearly states that this requirement does not apply to the delivery, distribution, or dispensing of controlled medications by practitioners engaged in the practice of telemedicine.[9] We urge the DEA to instead install safeguards such as patient assessments and prescriber training that will strike the right balance between protecting public safety and ensuring telemedicine access to care for those who already face ample unjust barriers.

While we share the DEA's concerns about high-profile reports of inappropriate prescribing of certain medications, we believe that an in-person medical evaluation is an inappropriate diversion measure that will only serve to raise barriers to essential health care and worsen health inequities. Moreover, we recognize that some practitioners may prefer to conduct at least one in-person medical evaluation, yet this is not medically necessary. Requiring one will erect a high and at times insurmountable barrier to essential health care. If finalized as drafted, the Proposed Rule may counterproductively encourage more people who will no longer be able to access proper health care via telemedicine to seek dangerous alternatives beyond the health care system.

We are deeply concerned that the Proposed Rule's narrow alternatives would not help patients most underserved by our health care system. Many people–particularly in rural communities–do not have access to another DEA-registered practitioner in the relevant practice area nearby.[10] As of 2017, more than sixty percent of U.S. counties and eighty percent of all rural counties do not have a single psychiatrist.[11] Moreover, the DEA's

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[6] Proposed Rule §§ 1300.04(o)(1), 1306.31(d).
[7] 88 Fed. Reg. 12877 (claiming that the statutory exemption for telemedicine applies only after an in-person medical evaluation has occurred).
[8] 21 U.S.C. § 829(e)(1).
[9] 21 U.S.C. § 829(e)(3).
[10] Proposed Rule § 1306.31(d)(2)(i) (discussing how a prescribing provider, DEA-registered practitioner on site with the patient, and the patient could participate in a real-time audio-video conference for a medical evaluation).
[11] New American Economy, *The Silent Shortage: How Immigration Can Help Address the Large and Growing Psychiatrist Shortage in the United States* 2 (Oct. 2017), https://www.newamericaneconomy.org/wp-content/uploads/2017/10/NAE_PsychiatristShortage_V6-1.pdf.

proposed referral scheme will not help individuals who have never had an in-person medical evaluation with their prescribing provider.[12] Maintaining expanded access to prescribers via telemedicine is critical to ensuring that people can continue to access their medications.

Telemedicine prescribing is particularly critical for people with low incomes and underserved populations for whom even one in-person medical evaluation is not feasible or local quality care options are unavailable or unaffordable. There are many reasons why communities across the country lack quality care options, such as provider shortages, inadequate health system funding, lack of linguistic and cultural competency, or systemic and often intersecting forms of discrimination in health care, such as racism, sexism (including on the basis of sexual orientation, gender identity, sex characteristics, and pregnancy or related conditions), ableism, and xenophobia. The DEA's proposed requirement will disproportionately raise existing barriers for people who need prescriptions such as testosterone therapy for gender-affirming care or androgen deficiency, or stimulants or opioids to manage chronic conditions such as post-COVID fatigue and brain fog, attention-deficit/hyperactivity disorder (ADHD), chronic pain, or narcolepsy.

The DEA's proposed in-person medical evaluation requirement will subject patients to time and financial burdens as well as legal risks that many cannot afford. It will be especially difficult for people with low incomes—who often lack adequate transportation or paid sick leave—to satisfy this requirement. People in rural communities without local behavioral health, pain management, or gender-affirming care providers, or those who cannot find a local option free from discrimination may need to take unpaid time off from work, travel hundreds of miles, and even pay higher copays that they would for a telemedicine appointment.[13] For some people with disabilities such as chronic pain, long COVID, and narcolepsy, traveling to and from in-person appointments can be incredibly physically, mentally, and emotionally challenging.

Requiring an in-person medical evaluation will especially harm BIPOC, LGBTQI+ people, people with disabilities, women, and immigrants, who are subjected to persistent structural and interpersonal violence and consequently, tend to have lower incomes and are among the most medically underserved populations in the U.S. For example, due to systemic sexism and racism in our health care system, women and Black people with chronic pain are less likely to be believed by their doctors, and their pain is often undertreated.[14] Black and Latine

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[12] *Id*. (discussing how a referring provider who previously had an in-person medical evaluation with the patient could issue a written qualifying telemedicine referral to a new prescribing practitioner).

[13] Health insurance plans increasingly provide free virtual primary care visits for enrollees. *See, e.g.*, Cigna, *Zero in on $0 Virtual Care* (last visited March 27, 2023), https://www.cigna.com/static/www-cigna-com/docs/individuals-families/2023/medical/marketing/944177-ifp-virtual-care-broker-customer-flyer-all.pdf.

[14] *See* Kelly Hoffman et al., *Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs About Biological Differences Between Blacks and Whites*, 113(16) PROC. NAT'L ACAD. SCI. U.S.A. 4296 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4843483/; National Pain Report, *Women in Pain Survey* (2014), https://www.surveymonkey.com/results/SM-P5J5P29L/ (finding that ninety-one percent of surveyed U.S. women with chronic pain believe the health care system discriminates against women, and forty-five percent had been told that their pain was in their

people and women are less likely to be diagnosed with or receive proper treatment for ADHD.[15] These populations need better access to care, not the additional barriers contemplated by this Proposed Rule.

Consider also the potential harm to TGI people. Due to systemic homophobia and transphobia in the U.S., at the time of this writing, a mere six states have not yet introduced a bill attempting to restrict the rights of LGBTQI+ people.[16] There are approximately 116 bills in state legislatures today targeting access to health care for TGI people.[17] Within a few months, almost half of the country has banned gender-affirming care for TGI minors. Prior to 2023, that number was only three states. Amid these attacks, pathways for access to care for TGI individuals such as telemedicine must be protected, not restricted. Requiring an in-person visit to continue or initiate treatments will likely delay or end these populations' access to vital care.

TGI individuals are already forced to jump through multiple hoops before they can obtain a testosterone prescription for gender-affirming hormone therapy (GAHT). This process not only requires authorization from a both behavioral health provider and a prescribing practitioner such as an endocrinologist or primary care provider (both of whom should be experienced with treating TGI patients), but also the financial means and insurance coverage to afford a prescription. Given the limited resources to identify TGI-competent providers and the influx of gender-affirming care bans and criminalization, finding a provider is a huge barrier to obtaining testosterone treatment, and has been since before the start of the PHE.[18] Telemedicine has advanced a more equitable and accessible means for TGI individuals to obtain GAHT, particularly for those in more rural areas or states that are under-resourced in

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heads); National Pain Report, *Women in Pain Report Significant Gender Bias* (Jun. 1, 2022), https://nationalpainreport.com/women-in-pain-report-significant-gender-bias-8824696.html; Madeline T. Morcelle, Nat'l Health Law Prog., How the Proposed Section 1557 Rule Addresses Discrimination Based on Sex Stereotypes (Sep. 27, 2022), https://healthlaw.org/how-the-proposed-section-1557-rule-addresses-discrimination-based-on-sex-stereotypes-2/; Laura Kiesel, Harvard Health Blog, Women and Pain: Disparities in Experience and Treatment (Oct. 9, 2017), https://www.health.harvard.edu/blog/women-and-pain-disparities-in-experience-and-treatment-2017100912562.

[15] *See* Patricia Quinn & Manisha Madhoo, *A Review of Attention-Deficit/Hyperactivity Disorder in Women and Girls: Uncovering This Hidden Diagnosis*, 16(3) PRIM. CARE COMPANION CNS DISORD (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195638/; Devon Frye, *The Children Left Behind,* ADDITUDE, March 31, 2022, https://www.additudemag.com/race-and-adhd-how-people-of-color-get-left-behind/.

[16] Solcyre Burga, *What to Know About the Gender-Affirming-Care Bans Spreading Across the Country*, TIME MAGAZINE (March 23, 2023), https://time.com/6265755/gender-affirm-care-bans-u-s/.

[17] American Civil Liberties Union, 2023 Legislative Session (last visited March 24, 2023), https://www.aclu.org/legislative-attacks-on-lgbtq-rights?state=&impact=health.

[18] Ashley Kerzinger et al., Kaiser Family Found., *KFF/The Washington Post Trans Survey* (March 24, 2023), https://www.kff.org/report-section/kff-the-washington-post-trans-survey-trans-in-america/.

or hostile to TGI-related health care. TGI people who live in states with no practitioners who provide culturally competent care to TGI patients will not be able to satisfy the proposed in-person medical evaluation requirement. They will lose access to essential care.

The proposed in-person medical evaluation requirement will also force some immigrants and their family members to make an unconscionable choice between risking family separation and forgoing access to vital treatments for disabilities or gender-affirming care. U.S. Customs and Border Protection checkpoints in border communities make it nearly impossible to safely reach health care facilities.[19] Enforcement checkpoints restrict movement for both documented and undocumented immigrants and family members, such as citizen children in mixed-status families. In practical terms, the DEA's proposed requirement of at least one in-person medical evaluation will create an insurmountable barrier to health care for many. It will cut off access to health-promoting and potentially lifesaving GAHT, medications that make severe chronic pain bearable, testosterone therapy to support the sexual health of women and others with androgen deficiency, and stimulants that address persistent cognitive disabilities among immigrants and their family members with long COVID, ADHD, narcolepsy, and other conditions.[20]

Finally, despite the federal government's decision to wind down the PHE, COVID-19 is still with us. Many people who would be subjected to the proposed in-person medical evaluation requirement are immunocompromised or at high risk of severe illness from COVID. For example, chronic pain weakens immune system function. ADHD is associated with increased COVID severity.[21] Structural oppression places TGI people at an increased risk of both COVID exposure and complications.[22] Forcing TGI people and people with disabilities who are immunocompromised or at high risk of complications to choose between potential COVID exposure and forgoing vital medications is ableist and dangerous.

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[19] *See* John Burnett, *Fearing Checkpoints, Undocumented Immigrants Cut off From Medical Care*, NPR (Nov. 3, 2017), https://www.npr.org/2017/11/03/561883665/fearing-checkpoints-undocumented-immigrants-cut-off-from-medical-care; Elena Mejia Lutz, *At Border Patrol Checkpoints, An Impossible Choice Between Health Care and Deportation*, TEXAS OBSERVER (Feb. 13, 2018), https://www.texasobserver.org/border-patrol-checkpoints-impossible-choice-health-care-deportation/.

[20] Without access to stimulants, many will be subjected to greater chronic fatigue, brain fog, and executive dysfunction, jeopardizing their health and wellbeing and also increasing their risk of dangerous accidents and injuries. *See, e.g.*, Zheng Chang, *Serious Transport Accidents in Adults With ADHD, and The Effect of Medication: A Population-Based Study*, JAMA PSYCH. 319 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3949159/.

[21] Eugene Merzon, *The Association Between ADHD and the Severity of COVID-19 Infection*, 26(4) J. ATTEN. DISORD. 491 (2022), https://pubmed.ncbi.nlm.nih.gov/33797281/ (finding that ADHD was associated with increased COVID-19 symptom severity and referral to hospitalization).

[22] Peter D. Goldie & Isha Catterjee, *Examining the Elevated Risk of COVID-19 in Transgender Communities with an Intersectional Lens*, 1(10) SN SOC. SCI. 249 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8492083/.

II. Limiting telemedicine prescribing of controlled medications to FDA-approved indications deviates from established standards of care will block access to essential care

We strongly oppose the Proposed Rule's effort to limit telemedicine prescribing of controlled medications to indications approved by the Food and Drug Administration (FDA). We urge the DEA to preserve the use of telemedicine prescribing for both on and off-label uses. We believe that the DEA's proposed restriction not only deviates from established standards of care and uses for off-label prescriptions but would compound barriers to necessary and lifesaving treatments.

While we understand the importance of ensuring medications are appropriately prescribed, off-label use is commonplace in medical practice to treat numerous conditions. Prescribing practitioners often exhaust FDA-approved care options and find that off-label prescriptions are the only means of successful treatment of their patients' conditions. Common off-label prescriptions include antidepressants, antipsychotics, immune globulin, chemotherapy, pediatric medications, stimulants for persistent fatigue and brain fog from long COVID, GAHT, and testosterone therapy for sexual dysfunction in women.[23] Limiting telemedicine to FDA-approved indications will harshly cut off critical care for and seriously harm people who simply cannot afford to go without their medication(s), particularly for people with disabilities, BIPOC, LGBTQI+ individuals, women, immigrants, and residents of rural communities.

For example, telemedicine has proven to be a highly effective tool for TGI individuals who need access to testosterone for their GAHT treatment. Currently, testosterone is prescribed off-label to treat Gender Dysphoria/Incongruence.[24] TGI individuals seeking any form of GAHT treatment must be assessed by a licensed behavioral health provider as well as a prescribing practitioner, such as an endocrinologist or primary care provider.[25] Gender-affirming care is already challenging to obtain due to the lack of specialized and culturally competent medical providers across the U.S., especially in more rural areas, and the harsh reality that many medical providers still discriminate against TGI patients.[26] State legislatures' current actions are undercutting the sparse proactive efforts to study and increase access to gender-affirming care such as GAHT. Unless TGI patients live in a metropolitan area that contains larger LGBTQI+ populations, they often struggle to access the gender-affirming treatment they need. Telemedicine is an invaluable tool for TGI patients who need

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[23] Heather Claverie, *On-Label Vs. Off-Label Drug Prescribing*, IG LIVING 28 (Dec. 2016), https://www.igliving.com/magazine/articles/IGL_2016-12_AR_On-Label-vs-Off-Label-Prescribing.pdf.
[24] Cecile A. Unger, *Hormone Therapy for Transgender Patients,* 5(6) TRANSL. ANDROL. UROL. 877 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5182227/; Louise Tomlins, *Prescribing for Transgender Patients,* 42(1) AUST. PRESCR. 10 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6370611/.
[25] E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, *Version 8*, 23(S1) INT'L J. OF TRANS. HEALTH S1 (Sept. 2022), https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.
[26] S. E. James et al., Nat'l Ctr. for Trans. Equality, *The Report of the 2015 U.S. Transgender Survey* (Dec. 2016), https://www.transequality.org/sites/default/files/docs/USTS-Full-Report-FINAL.PDF.

testosterone and do not live in metropolitan areas or live in areas that are rural or hostile to LGBTQI+ people. Since testosterone is prescribed off-label for TGI patients, barring practitioners from prescribing testosterone for this purpose via telemedicine would dry out already meager resources for TGI patients. These barriers are dangerous, as TGI people prescribed testosterone must consistently take it for the rest of their lives to maintain all of its effects, and some providers require that TGI individuals take testosterone for a period of time before obtaining certain gender-affirming care services.[27]

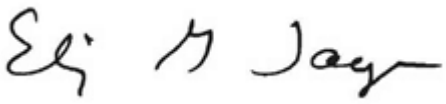
Conclusion

During the COVID-19 PHE, new flexibilities enabling practitioners to prescribe controlled medications via telemedicine have helped liberate many BIPOC, LGBTQI+ people, women, people with disabilities, immigrants, people in rural communities, and people with low incomes from longstanding and untenable constraints on access to care. Our country, and particularly our most underserved populations, simply cannot afford the human toll of restoring those pre-pandemic constraints. Accordingly, NHeLP urges the DEA to withdraw the Proposed Rule and halt efforts to require an in-person medical evaluation and restrict telemedicine prescribing to FDA-approved indications. We urge the DEA to instead pursue more expansive parameters for telemedicine prescribing that will protect and expand upon recent gains in access to care and health equity.

We have included numerous citations to supporting research, including direct links to the research. We direct the DEA to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act.

Thank you for your attention to our comments. If you have any questions, please reach out to Madeline T. Morcelle, Staff Attorney, at morcelle@healthlaw.org or Skyler Rosellini, Senior Attorney, at rosellini@healthlaw.org.

Sincerely,



Elizabeth G. Taylor
Executive Director

[27] Skyler Rosellini & Abigail Coursolle, Nat'l Health Law Prog., *Increasing Access to Testosterone to Improve the Lives of Transmasculine People* (Nov. 19, 2021), https://healthlaw.org/increasing-access-to-testosterone-to-improve-the-lives-of-transmasculine-people/.