March 31, 2023

DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, VA 22152

Submitted via regulations.gov

RE: Public Comment in Response to Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407)

To Whom It May Concern,

On behalf of the undersigned 62 organizations committed to researching and advancing the well-being of lesbian, gay, bisexual, transgender, queer, intersex, and other sexual and gender minority (LGBTQI+) people, we write in response to the above-captioned notice of proposed rulemaking issued by the Drug Enforcement Administration (DEA) under its authority per the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) to facilitate patients' continued access to substances scheduled under the Controlled Substances Act (CSA) through the use of telemedicine (the "Proposed Rule").[1]

As advocates for and researchers on LGBTQI+ individuals, we believe that all people deserve to receive quality treatment from competent, affirming medical providers regardless of their geographic proximity to those providers. Unfortunately for many LGBTQI+ people—especially transgender or gender nonconforming people, people living with HIV, LGBTQI+ people of color, and LGBTQI+ individuals living in rural areas—access to health care is severely hampered by a shortage of knowledgeable providers and specialists in their local area. For too many LGBTQI+ people, it is a common occurrence to travel several hours each way to see an affirming provider with expertise on their specific needs. In many cases, they must wrangle with increasingly hostile state legislation targeting the LGBTQI+ community.

We are strongly in favor of administrative action by the DEA to provide continued flexibility to providers so that they may reach their patients through telemedicine, and write to affirm the need for additional regulatory activity by the DEA to ensure that all individuals are given the same meaningful opportunity to continue—and in some cases, initiate—their care as we reach the end of the nationwide COVID-19 public health emergency declared by the Secretary of Health and Human Services (the "Secretary") on January 31, 2020 (the "Public Health Emergency"). We believe, however, that the Proposed Rule could go further to provide additional flexibility to health care providers and patients.

In particular, we are concerned that 1) the initial six-month transition period for existing prescriptions should be expanded to also include new prescriptions issued during that period, as there is no justification for the distinction, it creates unnecessary administrative burdens for providers and pharmacists, and enforcement will be difficult (if not impossible); 2) the 30-day

[1] Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12,875 (Mar. 01, 2023) (to be codified at 21 C.F.R. §§ 1300, 1304, 1306).

initial prescription period for Schedule III–V controlled substances is unrealistically short for patients and providers; and 3) the rules should clarify that related in-person appointments, e.g., for blood tests or other lab work, qualify for purposes of prescribing controlled substances through telemedicine visits. We are especially concerned about how the Proposed Rule will impact the ability of many transgender people to access testosterone, a Schedule III controlled substance. Because of this, we also request the DEA work with other federal agencies to consider additional ways transition-related care may be provided over telemedicine, including, for instance, the rescheduling of testosterone.

Background on LGBTQI+ People Relevant to the Proposed Rule

LGBTQI+ people are a growing population in the United States, living in every state and county and reflecting the breadth of diversity and lived experiences of the communities in which they live. For example, LGBTQI+ people are a demographically diverse population, with the Williams Institute using Gallup Daily Tracking survey data from 2012–2017 to estimate that 58% of LGBT adults identify as female, and that 21% of LGBT adults identify as Latino/a or Hispanic, 12% as Black, and 5% as more than one race.[2] Likewise, the Williams Institute recently reported on evidence that individuals belonging to certain communities of color appear more likely than their White counterparts to identify as transgender.[3]

Using data collected through the U.S. Census Bureau's Household Pulse Survey, the Human Rights Campaign Foundation recently estimated that at least 20 million adults in the U.S. identify as LGBTQ+.[4] Researchers have also found evidence that younger people are more likely to identify as LGBTQ+.[5] Intersex people with innate variations in their physical sex characteristics are estimated to make up as many as 1.7% of the global population.[6] And, as below we focus our discussion on care impacted by the Proposed Rule that is particularly relevant to transgender and gender nonconforming people, here we note that the Williams Institute has previously estimated that over 1.6 million adults (ages 18 and older) and youth (ages 13 to 17) in the U.S. identify as transgender.[7]

Research has long documented persistent negative health outcomes—and therefore needs for ongoing medical care—among LGBTQ+ populations, including disparities in their physical and

---

[2] *LGBT Demographic Data Interactive*, WILLIAMS INST. (Jan. 2019), https://williamsinstitute.law.ucla.edu/visualization/lgbt-stats/?topic=LGBT#demographic.

[3] JODY L. HERMAN ET AL., WILLIAMS INST., HOW MANY ADULTS AND YOUTH IDENTIFY AS TRANSGENDER IN THE UNITED STATES? at 6 (2022), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Pop-Update-Jun-2022.pdf;

[4] HUMAN RIGHTS CAMPAIGN FOUND., WE ARE HERE: UNDERSTANDING THE SIZE OF THE LGBTQ+ COMMUNITY (2021), https://hrc-prod-requests.s3-us-west-2.amazonaws.com/We-Are-Here-120821.pdf.

[5] *See, e.g.*, SHOSHANA K. GOLDBERG ET AL., HUMAN RIGHTS CAMPAIGN & BOWLING GREEN STATE UNIV., EQUALITY ELECTORATE: THE PROJECTED GROWTH OF THE LGBTQ+ VOTING BLOC IN COMING YEARS (2022), https://hrc-prod-requests.s3-us-west-2.amazonaws.com/LGBTQ-VEP-Oct-2022.pdf.

[6] Melanie Blackless et al., *How Sexually Dimorphic Are We? Review And Synthesis*, 12 AM. J. HUMAN BIOLOGY 151 (2000).

[7] HERMAN ET AL., *supra* note 3, at 4; KERITH J. CONRON, WILLIAMS INST., LGBT YOUTH POPULATION IN THE UNITED STATES (2020), https://williamsinstitute.law.ucla.edu/wp-content/uploads/LGBT-Youth-US-Pop-Sep-2020.pdf.

mental health when compared to their non-LGBTQ+ counterparts.[8] Available research on intersex people indicates that like LGBTQ+ communities more broadly, they too face a host of negative health outcomes: many of which appear to be driven by inequality.[9] A wealth of studies highlight that LGBTQ+ people of color often fare worse than their White and non-LGBTQ counterparts on several aspects of their health and related measures of well-being.[10] Other studies similarly show that even among LGBTQI+ communities, the burden of observed negative health outcomes is not evenly distributed, with often outsized consequences for groups like bisexual people and women.[11] Transgender people in particular often report poorer health when compared to their cisgender counterparts,[12] and even when compared to cisgender LGB people.[13]

These and other observed health outcomes have been linked to a number of factors, including exposure to minority stress due to experiences with stigma and discrimination.[14] While Americans from all walks of life are vulnerable to and can experience discrimination, LGBTQI+ people uniquely experience harassment and discrimination based on their sexual orientation, gender identity, and variations in sex characteristics, and do so across a broad range of contexts

---

[8] *See, e.g.*, Kellan E. Baker, *Findings From the Behavioral Risk Factor Surveillance System on Health-Related Quality of Life Among US Transgender Adults, 2014-2017*, 179 JAMA INTERNAL MEDICINE 1141 (2019), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2730765; Gilbert Gonzales & Carrie Henning-Smith, *Health Disparities by Sexual Orientation: Results and Implications from the Behavioral Risk Factor Surveillance System*, 42 J. COMMUNITY HEALTH 1163 (2017), https://pubmed.ncbi.nlm.nih.gov/28466199/.

[9] *See, e.g.*, Jane Ussher et al., *LGBTQI Cancer Patients' Quality of Life and Distress: A Comparison by Gender, Sexuality, Age, Cancer Type and Geographical Remoteness*, 12 FRONTIERS IN ONCOLOGY 873642 (2022), https://pubmed.ncbi.nlm.nih.gov/36203463/; Amy Rosenwohl-Mack et al., A National Study on the Physical and Mental Health of Intersex Adults in the U.S., 15 PLOS ONE e0240088 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7546494/; Henrik Falhammar, Health Status in 1040 Adults with Disorders of Sex Development (DSD): A European Multicenter Study, 7 ENDOCRINE CONNECTIONS 466 (2018), https://pubmed.ncbi.nlm.nih.gov/29490934/.

[10] *See, e.g.*, LAUREN J.A. BOUTON ET AL., WILLIAMS INST., LGBT ADULTS AGED 50 AND OLDER IN THE US DURING THE COVID-19 PANDEMIC (2023), https://williamsinstitute.law.ucla.edu/publications/older-lgbt-adults-us/; BIANCA D.M. WILSON ET AL., WILLIAMS INST., RACIAL DIFFERENCES AMONG LGBT ADULTS IN THE U.S.: LGBT WELL-BEING AT THE INTERSECTION OF RACE (2022), https://williamsinstitute.law.ucla.edu/wp-content/uploads/LGBT-Race-Comparison-Jan-2022.pdf.

[11] HUMAN RIGHTS CAMPAIGN FOUND., HEALTH DISPARITIES AMONG BISEXUAL PEOPLE (2015), https://assets2.hrc.org/files/assets/resources/HRC-BiHealthBrief.pdf?_ga=2.133429966.1119069861.1674767241-1055970791.1669664582; BIANCA D.M. WILSON ET AL., WILLIAMS INST., HEALTH AND SOCIOECONOMIC WELL-BEING OF LBQ WOMEN IN THE US (2021), https://williamsinstitute.law.ucla.edu/wp-content/uploads/LBQ-Women-Mar-2021.pdf.

[12] *See, e.g.*, JODY L. HERMAN & KATHRYN K. O'NEILL, WILLIAMS INST., WELL-BEING AMONG TRANSGENDER PEOPLE DURING THE COVID-19 PANDEMIC (2022), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Pulse-Toplines-Nov-2022.pdf.

[13] *See generally* ILAN H. MEYER ET AL., WILLIAMS INST., LGBTQ PEOPLE IN THE US: SELECT FINDINGS FROM THE GENERATIONS AND TRANSPOP STUDIES (2021), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Generations-TransPop-Toplines-Jun-2021.pdf (results of a nationally-representative sample of LGBTQ people).

[14] *See* INSTITUTE OF MEDICINE, THE HEALTH OF LESBIAN, GAY, BISEXUAL, AND TRANSGENDER PEOPLE: BUILDING A FOUNDATION FOR BETTER UNDERSTANDING 20–21 (2011), https://www.ncbi.nlm.nih.gov/books/NBK64806; *see also See, e.g.*, Logan S. Casey et al., *Discrimination in the United States: Experiences of Lesbian, Gay, Bisexual, Transgender, and Queer Americans*, 54 HEALTH SERVS. RESEARCH 1454 (2019), https://pubmed.ncbi.nlm.nih.gov/31659745/.

covering every aspect of public life.[15] Numerous surveys, studies, and reports have documented the increased risk of discrimination faced by LGBTQI+ individuals and their families within the health care system specifically.[16]

Certain LGBTQI+ subpopulations report distinct needs for health care that in turn can inherently leave them at a heightened risk of experiencing discrimination by medical providers. For example, transgender populations are disproportionately affected by gender dysphoria,[17] while gay and bisexual men of color and transgender women who have sex with men are disproportionately affected by HIV.[18] These conditions can require ongoing, lifelong care, increasing both the likelihood and impacts of encountering discrimination for those LGBTQI+ people.

Research indicates that experiencing discrimination while in pursuit of health care is an acute fear for transgender people in particular: in a 2015 survey of more than 27,000 transgender adults (the "USTS"), 33% of respondents who had seen a provider in the past year reported one or more negative experiences due to their transgender or gender non-conforming status.[19] In turn, 23% of respondents reported that they avoided seeking necessary health care when sick or injured in the past year because of fear of being mistreated as a transgender person.[20]

Experiencing discrimination and/or outright being denied access to medical care can have a direct impact on anyone's ability to respond to the health needs for which they were seeking attention. For LGBTQI+ people, this can easily cascade, further entrenching negative health outcomes already prevalent among their communities. For example, while LGBTQ+ people have the same general risk factors as their non-LGBTQ+ counterparts with respect to suicide, research shows they report additional risk factors tied to experiences as LGBTQ+ people,[21] such as transgender people experiencing unique and additional distress when denied access to medically necessary gender-affirming care.[22] Historically, transgender people have faced significant

---

[15] *See generally* NPR, ROBERT WOOD JOHNSON FOUND. & HARVARD T.H. CHAN SCH. OF PUB. HEALTH, DISCRIMINATION IN AMERICA: EXPERIENCES AND VIEWS OF LGBTQ AMERICANS (2017), https://legacy.npr.org/documents/2017/nov/npr-discrimination-lgbtq-final.pdf (experiences in variety of contexts).

[16] *"You Don't Want Second Best" Anti-LGBT Discrimination in US Health Care*, HUMAN RIGHTS WATCH (July 23, 2018), https://www.hrw.org/report/2018/07/23/you-dont-want-second-best/anti-lgbt-discrimination-us-health-care; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AM. PROGRESS (Jan. 18, 2018), https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/; LAMBDA LEGAL, WHEN HEALTH CARE ISN'T CARING: LAMBDA LEGAL'S SURVEY OF DISCRIMINATION AGAINST LGBT PEOPLE AND PEOPLE WITH HIV (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.

[17] Kate Cooper et al., *The Phenomenology of Gender Dysphoria In Adults: A Systematic Review and Meta-Synthesis*, 80 CLINICAL PSYCHOLOGY REV. 101875 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7441311/.

[18] CENTERS FOR DISEASE CONTROL & PREVENTION, HIV SURVEILLANCE REPORT: DIAGNOSES OF HIV INFECTION IN THE UNITED STATES AND DEPENDENT AREAS, 2020 (2022), https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-33/index.html.

[19] SANDY E. JAMES ET AL., NAT'L CTR. FOR TRANSGENDER EQUALITY, THE REPORT OF THE 2015 U.S. TRANSGENDER SURVEY 5 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.

[20] *Id.*

[21] *See, e.g.*, Amy E. Green et al., *Cumulative Minority Stress and Suicide Risk Among LGBTQ Youth*, 69 AM. J. COMMUNITY PSYCHOLOGY 157 (2021), https://onlinelibrary.wiley.com/doi/10.1002/ajcp.12553.

[22] JODY L. HERMAN & KATHRYN K. O'NEILL, WILLIAMS INST., SUICIDE RISK AND PREVENTION FOR TRANSGENDER PEOPLE: SUMMARY OF RESEARCH FINDINGS 2 (2021), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Suicide-Summary-Sep-2021.pdf.

barriers to being able to access gender-affirming care, including acutely the issue of being able to travel to a culturally competent, affirming provider. Indeed, looking at data from the 2015 USTS,

> Respondents reported having to travel further for transition-related care than routine care. While 63% indicated that they received routine care from providers within 10 miles of their home, less than half (45%) reported that they received transition-related health care within 10 miles of their home. Respondents were three times more likely to have to travel more than 50 miles for transgender-related care than for routine care [].[23]

Various federal agencies have long recognized the need for culturally competent, affirming providers for LGBTQI+ people, with many offering training, curricula, and resources to providers to help increase the likelihood that LGBTQI+ people will have equitable access to medical care.[24] Likewise, resources like the Human Rights Campaign Foundation's annual Healthcare Equality Index have been developed to provide information on and encourage facilities to adopt equitable, knowledgeable, sensitive, and welcoming health care practices free from stigma and discrimination for LGBTQI+ people.[25]

Telemedicine has been a major boon for LGBTQI+ people and in particular transgender people seeking to access these affirming providers, by removing the long-standing limitation that they be able to physically travel to avail themselves of those services. While telemedicine does not outright eliminate the barriers to care faced by many LGBTQI+ people, it can make attempting to access that care a much safer and therefore accessible process. And indeed, analysis of data from the Census Bureau's Household Pulse Survey indicates that transgender people have taken advantage of the current flexible landscape for telemedicine, with "the groups with higher odds of utilizing video-enabled telemedicine services [being] respondents who self-identified as transgender or those with Medicare health insurance coverage."[26]

The Proposed Rule Provides Needed Continued Flexibility, But Should Create Parity Across Patient Types

We are grateful for the Proposed Rule, and for the DEA and Biden Administration's recognition of how transformative policy changes connected to the Public Health Emergency allowing expanded access to providers via telemedicine have been for ensuring people from all communities, but particularly LGBTQI+ people, can access quality medical care regardless of geography. Indeed, the Proposed Rule will likely help facilitate continued treatment for individuals who prior to the Public Health Emergency were often left without access to any meaningful sources of care whatsoever.

---

[23] JAMES ET AL., *supra* note 19, at 99.
[24] *See generally* LGBTQI+ Resources, HHS.gov (Mar. 29, 2022), https://www.hhs.gov/programs/topic-sites/lgbtqi/resources/index.html.
[25] HUMAN RIGHTS CAMPAIGN FOUND., HEALTHCARE EQUALITY INDEX 2022 (2022) https://reports.hrc.org/hei-2022.
[26] MADJID KARIMI ET AL., NATIONAL SURVEY TRENDS IN TELEMEDICINE USE IN 2021: DISPARITIES IN UTILIZATION AND AUDIO VS. VIDEO SERVICES at 9 (2022), https://aspe.hhs.gov/sites/default/files/documents/4e1853c0b4885112b2994680a58af9ed/telemedicine-hps-ib.pdf.

Unfortunately, the Proposed Rule does not go far enough to ensure that existing patients will be able to continue to access their care in the manner they may have grown accustomed to over the past three years, nor to ensure that new patients or patients who change medical providers are able to access care in a comparable manner. As such, we encourage the DEA to exercise the full weight of its regulatory authority to better "ensure a sufficient supply of controlled substances for medical, scientific, and other legitimate purposes . . . ."[27]

Under the Ryan Haight Act, the Administrator of the DEA is authorized to promulgate rules, in concert with the Secretary, that "would allow practitioners to treat patients via telemedicine without having had an in-person evaluation in certain circumstances . . . ."[28] Notably, such rulemakings are permitted specifically when "conducted under . . . circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety."[29] The Proposed Rule was issued under and consistent with this authority.

The Proposed Rule provides that patients may, through a telemedicine provider, receive a prescription for a "schedule III, IV, or V non-narcotic controlled substance" (including testosterone), as well as other controlled substances as outlined, but with the limitation that "prescriptions do not authorize the dispensing of more than a total quantity of a 30 day supply of the controlled substance."[30] Once a patient has received such a 30-day supply, they are required to undergo an in-person medical evaluation, with the DEA allowing that evaluation to have been one that took place in the past provided that the practitioner was either an employee of the Department of Veterans Affairs or one "who has a telemedicine relationship established during the COVID-19 public health emergency with the patient," as defined within the Proposed Rule.[31]

Individuals in established care with providers via telemedicine will be subject to the same 30-day supply limitation as those patients initiating their care after the Public Health Emergency ends, but with one key distinction. Specifically, the DEA has called for regulations "to facilitate a six-month transition of doctor-patient relationships from the use of telemedicine prescribing flexibilities established during the [Public Health Emergency] to the use of the prescribing authority set forth" for those patients with established care within the Proposed Rule.[32]

Given the purpose of rules promulgated under the Ryan Haight Act's grant of authority referenced above, we would urge the DEA to work to create parity between all types of patients and extend that six-month transition period to all individuals seeking care regardless of their relationship with their prescribing provider. The DEA's proposal for a transition period suggests there is no clinical, diversion, public health, or other safety-based need requiring that covered individuals abide by the 30-day supply requirement immediately following the end of the Public Health Emergency. If there is no such need for individuals in established care, we believe that the same is the case for those who might only now be initiating their care.

---

[27] 88 Fed. Reg. at 12,877.
[28] 88 Fed. Reg. at 12,876.
[29] 21 U.S.C. § 804(54)(G).
[30] Proposed 21 C.F.R. § 1306.31(c).
[31] Proposed 21 C.F.R. § 1306.31(c)(ii).
[32] 88 Fed. Reg. at 12,879.

Individuals may choose to initiate care with new providers following the Public Health Emergency for a variety of reasons, including having recently changed jobs and/or insurance providers; receiving information on providers that are more affirming and culturally competent than what they may have had access to in the past; having developed (or at least, developed awareness of) a medical need requiring the prescribing of a controlled substance following that point in time; and as discussed further below, being forced to find new providers after losing access to those in their communities due to increasing state-level restrictions on their care. These patients should not be penalized when compared to existing patients in established care given that we expect patients in both groups to ultimately receive care consistent with best practice regardless of that timing. As seen with patients being prescribed testosterone, such care often involves blood work and seeing of additional health care providers for testing that can provide sufficient checks deterring "the diversion of controlled substances for illicit purposes."[33]

Additionally, as patients in every corner of the country begin to transition back from being able to easily access a wide variety of providers via telemedicine, we anticipate a severe in-person appointment backlog, especially among specialist providers and providers in rural areas. The past three years have demonstrated the relative ease with which patients can schedule and attend appointments via telemedicine, and in contrast, the amount of time and effort it can require to both schedule and ultimately get to see a provider in person. Patients have responded to this flexibility by embracing telemedicine for everything from routine care to specialized care, which will only drive challenges in accessing appointments as telemedicine-expanding flexibilities continue to expire. And, of course, we expect these challenges will be faced by all patients regardless of whether they have established a relationship with their chosen provider before, during, or after the Public Health Emergency. However, the Proposed Rule would only acknowledge this reality for patients in established care, despite the fact that individuals without established care relationships encounter significantly greater difficulties in scheduling appointments than those with such relationships.

Individuals without established provider relationships at the time the Public Health Emergency ends will likely still have at least some awareness of the current telemedicine landscape that they will need time to transition away from. While the Proposed Rule and the DEA's authority under the Ryan Haight Act are limited to specific telemedicine encounters where certain controlled substances are being prescribed, we anticipate that a more expansive rule would nonetheless provide much needed relief to providers and patients alike, so they may continue to work in tandem toward ensuring individuals can access care.

The Proposed Rule's 30-Day Initial Prescription Period Is Unrealistically Short and Does Not Reflect the Realities of Patients or Providers

Regardless of whether the DEA believes that individuals not already in established care must be subject to different requirements to fulfill the diversion goals of the Ryan Haight Act, we strongly recommend the DEA revise the Proposed Rule to permit for an initial prescription of Schedule III–V controlled substances lasting longer than 30 days. For patients facing increased difficulties in seeing providers in-person, a 30-day supply of medication will almost always be insufficient, particularly for those who need to seek care outside of their local community (e.g.,

[33] 88 Fed. Reg. at 12,877.

those in rural areas or individuals needing to travel out of state). Travel logistics, combined with work/school schedules and limited appointment availability, can in many circumstances make it nearly impossible to schedule an in-person appointment before the initial 30-day prescription runs out.

Instead, we recommend all patients prescribed a Schedule III–V controlled substance be able to obtain at least a 90-day initial supply, which would allow much greater flexibility for patients and providers to ensure quality of care without risk of the patient being cut off too soon from critical medication. Indeed, we would encourage the DEA to consider whether a period of six months (or, in the alternative, 180 days) would be appropriate for initial prescriptions, given the fact that six months was not deemed too long for the Public Health Emergency transition period.

The Proposed Rule Should Clarify that In-Person Appointments with Related Medical Providers, e.g., for Blood Work or Other Laboratory Tests, Qualify for Continued Telemedicine Prescribing of Schedule III–V Controlled Substances

We also recommend that the DEA revise the Proposed Rule to ease burdens on providers and patients through its proposed requirements for a "qualifying telemedicine referral."[34] Under that provision, the Proposed Rule would allow individuals to receive prescriptions for covered controlled substances beyond a 30-day supply and without being seen by their prescribing provider in person, but only so long as they have seen a referring practitioner who conducted "at least one medical evaluation in the physical presence of the patient . . . ."[35]

Patients prescribed controlled substances will often have to visit a laboratory or similar type of provider for blood work and/or other testing intended to monitor the impacts of taking their prescription or to ensure that medication is being taken as prescribed (rather than being diverted). In many cases, medical providers rely significantly (if not exclusively) on the results of these tests to determine whether a prescription should be refilled, at what dosage, and for what period of time. Where patients have visited a medical provider for blood tests or other laboratory work, the likelihood of diversion is significantly reduced, and will in few circumstances be reduced further by a subsequent in-person visit with the prescribing provider.

As such, the DEA should therefore clarify that visits such as these can satisfy the in-person requirement and therefore increase the Proposed Rule's ability to facilitate continued access to care. To the extent that such visits would not fulfill the in-person requirement given how the DEA has currently proposed same, we would instead recommend the issuing of a modified proposal that would allow these visits to serve as that required physical medical evaluation.

The Proposed Rule Will Improve Access to Health Care for LGBTQI+ People

This rulemaking, and especially an amended rulemaking as we suggest here, will undoubtedly benefit LGBTQI+ people in their efforts to access medical care free from discrimination and harassment. It is our opinion that this will be of particular benefit to transgender people and others currently especially vulnerable to possible provider discrimination both because of their needs for ongoing care as explained above and the current policy environment. The DEA should

[34] Proposed 21 C.F.R. § 1300.04(k).
[35] *Id.*

therefore move to expeditiously implement regulations allowing continued access to providers via telemedicine before the end of the Public Health Emergency, and to ensure that such regulations can truly meet the needs of the most vulnerable patients facing barriers to their ability to access care.

For transgender, gender nonconforming, and other individuals being prescribed testosterone as part of their gender-affirming care, the Proposed Rule will be lifesaving. In the past few years, there has been a deluge of legislative efforts across the states to restrict access to gender-affirming care, primarily targeting transgender youth but in some cases being proposed to the detriment of a broader range of transgender patients.[36] Likewise, some state health departments and other agencies have sought to restrict equitable access to gender-affirming care services for transgender people, including through state funding.[37] As these restrictions only continue to increase, we expect more and more transgender people will be forced to seek care beyond the confines of their local communities. While the Proposed Rule as written will certainly facilitate some continued access to this care over state lines, amending that proposal to, for example, give all patients a six-month transition period and not simply for those in established care, will do more in ensuring providers are able to meet shifting patient needs as these anti-transgender bills and other policies continue to be enacted.

The DEA Should Engage in Further Activity to Protect Access to Gender-Affirming Care

Alongside a modified Proposed Rule, we would urge the DEA to consider engaging in additional, necessary regulatory activity to ensure access to medical care through telemedicine can continue to be feasible for people across the country. For example, the DEA should explore use of its regulatory authority to ensure that cross-state prescribing can continue to occur without interruption after the Public Health Emergency. Likewise, it should seek to create a mechanism through which providers can register with the DEA to provide services, including the prescribing of certain controlled substances like testosterone, through telemedicine. Finally, the DEA, together with the Departments of Justice and Health and Human Services, should consider working to reschedule testosterone under the CSA if appropriate.

Such changes would beneficially impact all patients and not simply transgender people being prescribed testosterone, though the benefits will undoubtedly be noticeably high for those individuals living in states with increasing restrictions on access to gender-affirming care. As a Schedule III substance under the CSA, testosterone is currently subject to certain restrictions, including limitations on refills and on which and how many providers may register with the DEA to be allowed to prescribe such substances in the first place. Historically, these limitations have meant that transgender people relying on testosterone as part of their gender-affirming care were forced to find and regularly interact with providers at risk of discriminating against them, alongside being tracked as part of some states' prescription drug monitoring programs. However, under the current telemedicine framework and despite many of these limitations remaining, those

---

[36] *See generally* Human Rights Campaign Found., *Map: Attacks on Gender Affirming Care by State*, HUMAN RIGHTS CAMPAIGN, https://www.hrc.org/resources/attacks-on-gender-affirming-care-by-state-map (last visited Mar. 27, 2023).

[37] *See, e.g.*, Jo Yurcaba, *Florida Issues Texas-Like Guidance Seeking To Bar Transition Care For Minors*, NBC NEWS (Apr. 20, 2022), https://www.nbcnews.com/nbc-out/out-politics-and-policy/florida-issues-texas-guidance-seeking-bar-transition-care-minors-rcna25273.

individuals have reported an increased capacity to access their care, and in turn improved health outcomes, because of the flexibility they have been given to keep looking for a provider that can meet their needs. Of course, that flexibility is set to retract significantly with the end of the Public Health Emergency and despite the Proposed Rule, suggesting more must be done beyond that rulemaking to protect the health of transgender people.

The Attorney General maintains the authority to reschedule and outright remove substances from the schedules of the CSA and should work with the Secretary and the DEA to consider doing so for testosterone consistent with that authority[38] and standing executive orders on equity and access to comprehensive health care.[39] Rescheduling testosterone to, for example, Schedule V would eliminate limitations like pharmacies being unable to refill a prescription more than five times or after six months from when initially prescribed that will be left unchanged by the Proposed Rule—which would in turn decrease the rates at which people requiring this care must access potentially stigmatizing providers.

Thank you for the opportunity to submit comments in favor of this critical step toward ensuring transgender people, all LGBTQI+ people, and indeed, everyone across the country, can maintain the access to competent, affirming medical care that so many have come to rely on over the last three years and that many more will undoubtedly find themselves in need of in the future.

Sincerely,

Human Rights Campaign
National Center for Transgender Equality
Equality Federation
Howard Brown Health
International Association of Providers of AIDS Care
Movement Advancement Project
Equality California
Silver State Equality-Nevada
Lyon-Martin Community Health Services
GLMA: Health Professionals Advancing LGBTQ+ Equality
National LGBT Cancer Network
CA LGBTQ Health and Human Services Network
National Center for Lesbian Rights
PROMO Fund
Spectrum: The Other Clinic
HIV Alliance
Philly Trans March
Physicians for Reproductive Health
LGBT Life Center
Trans Youth Equality Foundation

[38] 21 U.S.C. § 811(a).
[39] Exec. Order. 14075, Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, 87 Fed. Reg. 37,189 (June 15, 2022); *see also* Exec. Order 14091, Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 88 Fed. Reg. 10,825 (Feb. 16, 2023).

NASW - Maine Chapter
Maine Transgender Network
Youth MOVE National
Fabulous Arts Foundation
Stand with Trans
Chattanooga Trans Liberation Collective
Gender Justice League
Impact Exchange
ForEver Caring Evonne
New Alternatives for LGBT Homeless Youth
The Transgender District
QueerMed
Campaign for Southern Equality
Plume
Ipas
CenterLink: The Community of LGBT Centers
Transhealth
A. Shayne Abelkop, PhD, PC
PFLAG Athens Area
Alyssa Rodriguez Center for Gender Justice
TRACTION
Massachusetts Transgender Political Coalition
Mazzoni Center
COLAGE
Callen-Lorde Community Health Center
OutNebraska
Hugh Lane Wellness Foundation
Lambda Legal
Whitman-Walker Institute
SAGE
Transgender Legal Defense & Education Fund
Transgender Law Center
American Humanist Association
All Families Healthcare
The Center for LGBTQ Health Equity, Chase Brexton Health Care
Legacy Community Health
The Myalgic Encephalomyelitis Action Network
We Are Family
interACT: Advocates for Intersex Youth
SIECUS: Sex Ed for Social Change
Center for American Progress
Omaha ForUs LGBTQ+ Center
Nebraska AIDS Project