March 31, 2023

Submitted via www.regulations.gov[1]

Drug Enforcement Administration (DEA)
ATTN: DEA-2023-0029
Dept. of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: DOCKET ID DEA-407, RIN 1117-AB40, 88-FR-12875, Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

I am writing on behalf of Equitas Health, which is headquartered in Columbus, Ohio, to express comments and concerns with the rule proposed by the Drug Enforcement Agency (DEA) in regard to 1) telehealth regulations and 2) prescriptions for controlled substances like testosterone. As such, Equitas Health is pleased to submit these comments in response to the Drug Enforcement Agency's (DEA's or Agency's) proposed rule – Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation.

Equitas Health is a federally designated community health center and one of the largest LGBTQ+ and HIV/AIDS serving healthcare organizations in the country. Each year, we serve tens of thousands of patients in Ohio, Texas, Kentucky, and West Virginia, and since 1984, we have been working to advance "care for all." Our mission is to be the gateway to good health for those at risk of or affected by HIV; for the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ+) community; and for those seeking a welcoming healthcare home. In doing so, we offer primary and specialized medical care, pharmacy services, dentistry, mental health and recovery services, HIV/STI prevention and treatment services, Ryan White HIV case management, overall care navigation, and a number of community health initiatives.[2] Regarding this public comment, our agency, our patients, and our broader community are concerned about this proposed rule.[3] As such, we urge the DEA to ensure that this final

[1] Document prepared by Rhea Debussy, Ph.D. (she/her), Director of External Affairs with assistance from Rick Barclay (he/him), Community Relations Manager – Harm Reduction, and Oliver Licking (they/them), Legal Clinic Coordinator. Document reviewed by Sam Brinker (he/him), General Counsel; Adrianna Udinwe (she/her), Associate General Counsel; and Sarah Green (they/she), Administrative Assistant – Advancement.
[2] https://equitashealth.com/about-us/
[3] https://www.instagram.com/p/CqA-H66uCau/

rule does not 1) limit access to care for patients needing telehealth options and/or 2) restrict access to gender affirming care and/or intersex-related care.

Recommendation 1: We strongly recommend the DEA to recognize the importance of telehealth in accessing care, especially when patients cannot physically travel to their medical provider.

In its current form, this proposed rule would require an in-person appointment for a patient, before the medical provider could write a prescription for a controlled substance (with only limited exceptions). We understand that the DEA is interested in ensuring that patients form a relationship with their medical provider, before taking a prescription that has a risk of dependency. However, telehealth options have become more widely available, since the start of the COVID-19 pandemic, and as such, these telehealth options have increased access to care. In fact, telehealth options are particularly important for patients who may not be able to physically travel to a health center or doctor's office, and such patient demographics include but are not limited to the following: patients living in rural areas, lower-income patients, and patients with disabilities/chronic illnesses.

By not recognizing this reality and the impacts that this would have on access to gender affirming care for trans masculine people, the DEA risks replicating failed policies of the past. In reflecting upon this, Rick Barclay (he/him), who is the Community Relations Manager – Harm Reduction for Equitas Health, notes that:

> "The proposed changes to testosterone access follow a path of failed and knee-jerk policies where limiting access to substances is seen as an effective solution, but instead, this may result in the same pain, hardship, isolation, and death seen for decades with previous DEA policies. Most notably, such policies have been implemented by the DEA during the War on Drugs, which is a war that the DEA themselves have been tasked with executing. Effectiveness in both safety and efficacy with substances of any sort – including testosterone when used as a form of gender affirming care – is increased when people are provided access to appropriate and unbiased education, in addition to knowledgeable professionals/medical providers who are committed to providing evidence-based care and resources regardless of their own personal beliefs and opinions."[4]

As such, we strongly recommend the DEA to recognize the importance of telehealth in accessing care, especially 1) when patients cannot physically travel to their medical provider and 2) when patients need access to gender affirming care and/or intersex-related care.

Recommendations 2 and 3: We strongly recommend the DEA to ensure greater access to gender affirming care and intersex-related care by removing testosterone from its current Schedule III classification. Subsequently, we also strongly recommend the DEA *either* a) to grant testosterone a

[4] Quotation provided on March 20, 2023.

Schedule V classification with telehealth exemptions both for gender affirming care and intersex-related care *or* b) to remove any Schedule classification from testosterone altogether.

As noted above, this proposed rule would require an in-person appointment for a patient, before the medical provider could write a prescription for a controlled substance (with only limited exceptions). As currently written, this proposed rule would impact prescriptions for substances in any of the DEA's Schedule classifications, including even the lowest tier of Schedule V.

In 1990, Congress added testosterone to a list of drugs under the Controlled Substances Act. Since then, testosterone has been under the DEA's Schedule III classification; this means that the DEA believes it can presumably be prescribed "with a moderate to low potential for physical and psychological dependence."[5] Given the advancement in technology that helps us to better understand the effects of testosterone, we strongly recommend that the DEA works to ensure greater access to gender affirming care and intersex-related care by removing the testosterone from its current Schedule III classification. And of course, it is important to note that elected officials in the U.S. Senate are currently making similar calls to action, given the importance of expanding access to testosterone for gender affirming care across the country.[6]

When considering 1) the importance of expanding access to gender affirming care for trans masculine people and 2) the negative impacts that creating additional barriers to care may cause, Oliver Licking (they/them), who is the Legal Clinic Coordinator for Equitas Health, notes that:

> "Access to gender affirming hormone replacement therapy (HRT) – in the form of testosterone for trans men and the trans masculine population – is both necessary and life-saving. Testosterone access is used responsibly and safely every day to affirm our gender, and it helps to make our world safer. Across the country, many trans masculine folks live in rural areas, which are geographically far away from health centers that will offer testosterone as HRT. Because of this, many people live hours long drives from places that offer testosterone as HRT. For so many people, access to testosterone is life-saving, and with the additional restrictions placed on access to care via this the telehealth option, many people across the country will be unable to access a health center that can offer them their life-saving medically necessary medicine. Furthermore, trans masculine folks with disabilities, who may be living anywhere in the country, will have less access to their life-saving testosterone HRT, because of the additional restrictions of this currently proposed rule. We know that telehealth has been accessed by people with disabilities at a higher rate than the general population, and this further demonstrates the importance of telehealth options in removing barriers to care."[7]

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[5] https://www.dea.gov/drug-information/drug-scheduling

[6] https://www.markey.senate.gov/download/letter-on-expanding-access-to-gender-affirming-hormone-therapy

[7] Quotation provided on March 20, 2023; see also https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9098125/#:~:text=Our%20findings%20revealed%2039.8%25%20of,telehealth%20use%20based%20on%20sociodemographics and

In addition to strongly recommending that the DEA works to ensure greater access to gender affirming care and intersex-related care by removing testosterone from its current Schedule III classification, we also strongly recommend the DEA *either* a) to grant testosterone a Schedule V classification with telehealth exemptions both for gender affirming care and intersex-related care *or* b) to remove any Schedule classification from testosterone altogether.

In that first option, the DEA would still be able to acknowledge that they believe testosterone has a low risk of abuse, but it would ensure that this newly proposed rule does not negatively impact access to care via telehealth options for trans masculine and/or intersex people. The second option would alternatively remove that classification for testosterone and, thus, the additional restrictions that the DEA places on substances in general, which would also ensure greater access to care for trans masculine and/or intersex people via telehealth appointments.

Concluding Remarks: To conclude, we strongly recommend that the DEA do the following:

1) To recognize the importance of telehealth in accessing care, especially when patients cannot physically travel to their medical provider;

2) To ensure greater access to gender affirming care and intersex-related care by removing testosterone from its current Schedule III classification; and

3) *Either* a) to grant testosterone a Schedule V classification with telehealth exemptions both for gender affirming care and intersex-related care *or* b) to remove any Schedule classification from testosterone altogether.

Equitas Health would like to thank you for this opportunity to present comments and concerns on the proposed rule. Should you have any questions about our comments, please feel free to contact Dr. Rhea Debussy (she/her), Director of External Affairs at Equitas Health.

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https://www.cdc.gov/nchs/products/databriefs/db445.htm#:~:text=Summary-,In%202021%2C%2037.0%25%20of%20adults%20used%20telemedicine%20in%20the%20past,level%2C%20region%2C%20and%20urbanicity