March 31, 2023

Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

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

We greatly appreciate the opportunity to offer comments on the proposed regulation titled, "*Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*" (hereinafter, the "Proposed Telemedicine Rule").

The Massachusetts Transgender Health Coalition is a multidisciplinary group supporting access to gender-affirming care. We comprise many professional and community organizations throughout the state, including legal professionals, health care providers, and LGBTQI+ advocates and activists. As professionals and community members, we see first-hand the benefits of gender-affirming care for trans and gender diverse individuals, as well as the harm caused when people cannot access this care.

We write to oppose the increased regulation of telemedicine prescription of testosterone, a Schedule III controlled substance, in the Proposed Telemedicine Rule. We propose, instead, that the Department continue to permit testosterone prescriptions without the requirement of an in-person examination.

Today, in honor of Transgender Day of Visibility, the Biden Administration pledged to stand beside the transgender community and "celebrat[ed] their resilience in the face of hateful anti-transgender laws being advanced across the country."[1] Yet even as President Biden promises that trans Americans "have an unwavering champion in the President," the Department's Proposed Telemedicine Rule threatens to significantly curtail access to gender-affirming health care for trans men and nonbinary and gender diverse individuals. By re-imposing an in-person requirement to access testosterone, an extremely common and safe form of gender-affirming hormone therapy, the DEA's Proposed Telemedicine Rule needlessly disrupts an essential path to care for gender diverse individuals who may live far from gender-affirming care providers or face discrimination from their local medical practice.

[1] *Fact Sheet: White House Honors Transgender Day of Visibility*, March 31, 2023, https://www.whitehouse.gov/briefing-room/statements-releases/2023/03/31/fact-sheet-white-house-honors-transgender-day-of-visibility.

1. Telemedicine fills a particular and crucial need for the transgender and gender diverse community.

Testosterone is commonly prescribed as a medically necessary, gender-affirming therapy for transgender men and nonbinary or gender diverse individuals.[2] All forms of gender-affirming care, including testosterone and other hormone therapies, are "crucial to transgender and nonbinary individuals, as these resources and services activate and enhance the interactive process of receiving recognition for one's gender, sense of self, and sense of humanity."[3] When prescribed as gender-affirming hormone therapy, testosterone is correlated with improved mental health, including "reduced depression, increased confidence, decreased anxiety, and improved emotional stability."[4]

The declaration of the COVID-19 public health emergency, and the suspension of the usual requirements for telemedicine prescription of controlled substances under the Ryan Haight Act, led to a significant increase in the use of telemedicine provided to patients at home, including the provision of gender-affirming care and hormone therapies such as testosterone. Under the current regulations, appropriately licensed medical practitioners are able to prescribe testosterone to trans and gender diverse patients seeking gender-affirming care via telemedicine, without performing an in-person medical examination of the patient. This important policy development—now put at risk by the Department's Proposed Telemedicine Rule—helped preserve and expand access to life-saving gender-affirming care during the pandemic.

a. Transgender and gender diverse individuals have long struggled to access culturally competent gender-affirming care.

Transgender and gender diverse individuals struggle to access health care in person. As the Department of Health and Human Services recently observed in its Notice of Proposed Rulemaking for Section 1557 of the Affordable Care Act, the increased availability of telemedicine during the pandemic enabled many "transgender individuals . . . to access gender-affirming care without geographical constraints or fear of stigma and discrimination."[5]

Many trans and gender diverse patients must travel long distances to access gender-affirming care in person because of a dearth of competent providers where they live. "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."[6] And distance-related barriers are not limited to patients living in rural areas. In one clinic-specific

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[2] *See* World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (2022), https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.

[3] Brooke A. Jarrett, *Gender-Affirming Care, Mental Health, and Economic Stability in the Time of COVID-19: A Multi-National, Cross-Sectional Study of Transgender and Nonbinary People*, PLOS ONE, July 9, 2021, https://pubmed.ncbi.nlm.nih.gov/34242317.

[4] Samuel A. Davis, *Effects of Testosterone Treatment and Chest Reconstruction Surgery on Mental Health and Sexuality in Female-to-Male Transgender People*, 26 International Journal of Sexual Health 113, 123 (2014), https://doi.org/10.1080/19317611.2013.833152.

[5] 87 Fed. Reg. 47884 (Aug. 4, 2022).

[6] *See, e.g.*, 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, 165 (2022),

study, the authors noted that "gender-expansive" patients at an urban community health center had to travel farther for health care compared with the center's cisgender clients.[7]

For some patients, travel for gender-affirming care isn't just burdensome, it's impossible: one study focusing on health care access for trans and gender diverse youth noted that trans youth who "live in rural areas or who are economically disadvantaged" may not be able to access gender-affirming care *at all*, "due to travel costs."[8] Patients may struggle to make it to in-person appointments for other reasons as well. In the words of one gender-affirming care provider: "Before the pandemic, many of my current telemedicine patients missed multiple clinic appointments due to limited transportation and other logistical barriers. Others hadn't left their houses in months due to limited mobility, or had repeatedly deferred care due to anxiety around entering a clinical space."[9]

For transgender patients who lack the resources to travel long distances, and do not have access to a culturally competent gender-affirming care provider in their area, requiring attendance at even one in-person local health care appointment may significantly increase their risk of "exposure . . . to discrimination and victimization."[10] This can take many forms, including "restrictions on bathroom use or misgendering by providers or staff,"[11] and mistreatment of patients "in entering the practice, sitting in the waiting room, or moving about the hospital."[12] Indeed, trans and gender diverse people are often denied care outright. According to a recent report by the Center for American Progress, over 32 percent of transgender or nonbinary respondents, including 46 percent of transgender or nonbinary respondents of color, reported that they had been denied care by a health care provider at least once in the past year–either because the provider refused to perform a specific health service (such as reproductive or sexual health services, gender-affirming health care, or assistance forming a family), or because the provider had refused to see the patient outright (due to religious beliefs or due to the patient's actual or perceived gender identity).[13] Negative experiences in a health care setting can have "long-lasting effects and deter trans people from seeking further support, making them more vulnerable to mental and physical problems."[14] Particularly in conservative regions, "many trans people avoid

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https://doi.org/10.1089/trgh.2020.0161.

[7] Rebecca McGarity-Palmer and Anne Saw, *Transgender Clients' Travel Distance to Preferred Health Care: A Clinic-Specific Study*, 7 Transgender Health 282 (2022), https://pubmed.ncbi.nlm.nih.gov/36643061/.

[8] Danielle E. Apple et. al, *Acceptability of Telehealth for Gender-Affirming Care in Transgender and Gender Diverse Youth and Their Caregivers*, 7 Transgender Health 159, 163 (2022), https://www.liebertpub.com/doi/epub/10.1089/trgh.2020.0166.

[9] Ben Kaplan, *Access, Equity, and Neutral Space: Telehealth Beyond the Pandemic*, 19 Annals of Family Medicine 75, 76 (2021), https://www.annfammed.org/content/19/1/75.long.

[10] Nadia Dowshen et al., *Telehealth for Gender-Affirming Care: Challenges and Opportunities*, 7 Transgender Health 111, 111 (2022), https://www.liebertpub.com/doi/pdf/10.1089/trgh.2021.0206.

[11] *Id.*

[12] Ole-Petter R. Hamnvik et al., *Telemedicine and Inequities in Health Care Access: The Example of Transgender Health*, 7 Transgender Health 113, 114 (2022), https://www.liebertpub.com/doi/epub/10.1089/trgh.2020.0122.

[13] Center for American Progress, *Advancing Health Care Nondiscrimination Protections for LGBTQI+ Communities* (Sept. 8, 2022), https://www.americanprogress.org/article/advancing-health-care-nondiscrimination-protections-for-lgbtqi-communities/.

[14] Jannis Renner et al., *Barriers to Accessing Health Care in Rural Regions by Transgender, Non-Binary, and Gender Diverse People: A Case-Based Scoping Review*, Frontiers in Endocrinology, Nov. 2021 at 1, 7, https://pubmed.ncbi.nlm.nih.gov/34867775/; see also Grasso, *Gender-Affirming Care Without Walls*, *supra* note 25 at 135 ("Factors including financial constraints, transportation difficulties, public accommodations

health care services entirely."[15] A recent analysis of data from 2015 showed that 22.8% of trans participants "reported avoiding health care due to anticipated stigma," with trans men "among the most likely to report avoiding care."[16]

Notably, studies indicate that trans men—whose access to testosterone may be cut off by the ending of the Public Health Emergency and the Department's proposed rule—may experience uniquely high rates of medical discrimination and health care avoidance. One study "demonstrat[ed] that trans men were 3 times as likely to report anticipated health care discrimination and were more likely to have experienced discrimination when compared with their trans counterparts,"[17] while another study reached a similar conclusion that "transgender men, those living in poverty, and visually non-conforming individuals had increased odds of avoiding health care due to fear of mistreatment."[18] Another study showed that, in a gender-expansive sample, trans men (along with trans women and nonbinary people assigned female at birth) were "most likely to report attending one behavioral health appointment"—yet trans men attended disproportionately few behavioral health appointments overall, "suggesting that even when trans men have access to care, they may face additional challenges that make attending appointments undesirable."[19] A survey of over a thousand LGBTQ+ individuals living in rural areas of the United States showed that trans people who were assigned female at birth are likely to "accept health risks [by foregoing care] if they lack access to specific and trans-informed clinics."[20] And another analysis found that rural trans men are almost nine times less likely to have a primary care doctor than their urban peers.[21]

b. During the pandemic, telemedicine greatly expanded access to gender-affirming care, including gender-affirming hormone therapy, for transgender and gender diverse patients.

Telemedicine greatly expanded the options available to trans and gender diverse patients during the pandemic, allowing people to access gender-affirming care treatments, including testosterone

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discrimination, and more prevalent depression or anxiety often create an increased burden for patients, preventing them from attending appointments and following through on treatment recommendations that would help them achieve their health goals.").

[15] Renner, *Barriers to Accessing Health Care in Rural Regions*, *supra* note 14.

[16] *Id.*

[17] 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, Nov.-Dec. 2021, at 1, 2, https://pubmed.ncbi.nlm.nih.gov/34861796; *see also* Natalie M. Alizaga, *Experiences of Health Care Discrimination Among Transgender and Gender Nonconforming People of Color: A Latent Class Analysis*, 9 Psychology of Sexual Orientation and Gender Diversity 141, 147 (2022), https://doi.org/10.1037/sgd0000479.

[18] Luisa Kcomt et al., *Healthcare Avoidance Due to Anticipated Discrimination Among Transgender People: A Call to Create Trans-Affirmative Environments*, SSM - Population Health, May 28, 2020, 1-8, 7.

[19] D'Angelo, *Health and Access to Gender-Affirming Care During COVID-19*, *supra* note 17 (citing Amelia M. Stanton et al., *Differences in Mental Health Symptom Severity and Care Engagement Among Transgender and Gender Diverse Individuals: Findings from a Large Community Health Center*, PLOS ONE, January 25, 2021, 1-15, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0245872).

[20] Renner, *Barriers to Accessing Health Care in Rural Regions*, *supra* note 14 at 7.

[21] Kristie L. Seelman, *Do Transgender Men Have Equal Access to Health Care and Engagement in Preventive Health Behaviors Compared to Cisgender Adults?*, 57 Social Work in Health Care 502, 517, https://www.tandfonline.com/doi/full/10.1080/00981389.2018.1462292?scroll=top&needAccess=true&role=tab.

prescriptions, that would otherwise have remained out of reach. In the words of one health care practitioner, telemedicine "serves as a bridge between our healthcare system and some of its most marginalized patients, many of whom struggled to access care long before the COVID-19 pandemic began."[22]

These benefits have taken many forms. Many logistical and travel-related barriers have gone away thanks to telemedicine: one trans patient living in the Midwest noted that with telemedicine, he no longer has to make a "three hour round trip drive" to access the doctor who prescribes his hormones.[23] Telemedicine has also improved trans patients' ability to access higher quality care, giving patients an unprecedented freedom of choice in their providers: according to one patient, he can now get "much better healthcare" because more providers are available to him via remote appointments.[24] "[B]eing able to access an organization specialized in gender-affirming care . . . regardless of where a [transgender or gender diverse] person lives in the United States" can enable trans and gender diverse patients "who are deterred by distance and fear to engage in care" when they otherwise would not.[25]

Some providers and patients have even noted that a telemedicine appointment can improve the dynamic between trans and gender diverse patient and their providers, because it empowers the patient. "Telehealth offers TGD patients more control over their visit experience, providing a mechanism to separate oneself from negative clinical experiences."[26] One practitioner noted, "I pause more during my telehealth visits, leaving space for patients to ask questions and share thoughts. I use the teach-back method to confirm their understanding, and check in more frequently regarding their comfort and concerns. Sometimes, it feels as if seeing my patients over video helps to level the inherent power dynamic between us."[27]

These opportunities offered by telemedicine have allowed more transgender and gender diverse individuals to receive care than ever before. In the six-month period between March through August 2020, Boston's Fenway Health served "close to as many unique [transgender and gender diverse] patients . . . as it did via in-person services during calendar year 2019"—including patients from twenty-four different states.[28] And Plume, an award-winning and entirely telemedicine-based provider of testosterone and other gender-affirming hormone therapies, supported 16,000 patients as of October 2022.[29]

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[22] Kaplan, *Telehealth Beyond the Pandemic*, *supra* note 9, 76.

[23] D'Angelo, *Health and Access to Gender-Affirming Care During COVID-19: Experiences of transmasculine individuals and men assigned female sex at birth*, *supra* note 17, at 5.

[24] *Id.*

[25] Chris Grasso et al., *Gender-Affirming Care Without Walls: Utilization of Telehealth Services by Transgender and Gender Diverse People at a Federally Qualified Health Center*, 7 Transgender Health 135, 141 (2022), https://www.liebertpub.com/doi/10.1089/trgh.2020.0155.

[26] *Id.*

[27] Kaplan, *Telehealth Beyond the Pandemic*, supra note 9 at 76.

[28] Grasso, *Gender-Affirming Care Without Walls*, *supra* note 25 at 135.

[29] *2022 Colorado Inno Awards Winner Plume Takes Gender-Affirming Care Nationwide*, ColoradoInno (Oct. 21, 2022), https://www.bizjournals.com/denver/inno/stories/awards/2022/10/21/2022-colorado-inno-awards-winner-plume.html; Deanna Cuadra, *How Plume Is Making Gender-Affirming Care Accessible Across the U.S.*, Employee Benefits News (Oct. 31, 2022), https://www.benefitnews.com/news/plume-is-making-gender-affirming-care-accessible-in-the-u-s.

This increase in care opportunities can be seen in the example of Tapestry Health, a Western Massachusetts health care provider. Since Tapestry began offering gender-affirming hormone care via telemedicine, staff noticed that patients who live in extremely rural areas, work nontraditional hours, or struggle to access in-person appointments more broadly, became better represented in the patient base. Telemedicine appointments for testosterone represent hundreds of patient experiences. Without telemedicine availability, many of these clients would need to drive over an hour for an in-person appointment.

In brief, telemedicine has enabled safe, high quality gender-affirming care for individuals who otherwise could only access that care with serious difficulty, or who otherwise could not access that care at all.

2. The Proposed Telemedicine Rule would significantly impede access to health care for the transgender and gender diverse community.

The Department's Proposed Telemedicine Rule puts at risk the many improvements in access to gender-affirming care made through the availability of telemedicine in the last few years. By preventing transgender and gender diverse individuals from having full access to testosterone via telemedicine, the proposed rule risks disrupting the ongoing care of, and preventing the start of care for, members of one of the country's most vulnerable communities. This disruption is not necessary for the safe prescription of testosterone for gender-affirming care, nor to prevent testosterone's diversion.

a. The proposed rule will impede and prevent care for transgender and gender diverse individuals.

The Department's Proposed Telemedicine Rule creates a scheme whereby, in general, patients must have an in-person appointment within 30 days of receiving an initial prescription for testosterone (and other Schedule III-V controlled substances) via a telemedicine appointment.[30] After this one in-person appointment, prescriptions via telemedicine appointments are permitted—but an initial in-person appointment is still required. The proposed rule also creates a 180-day delay in the implementation of this in-person requirement for individuals who received testosterone prescriptions through telemedicine during the public health emergency.[31] However, after this 180-day period has elapsed, individuals who were previously prescribed testosterone via telemedicine will also need to have an in-person appointment.

The Proposed Rule does include two exceptions that seem aimed to help patients who may live a long distance away from their prescriber: under Section 1306.31(d)(2), a prescribing practitioner may still prescribe remotely if the patient attends an in-person physical appointment with their local doctor, and if they participate in a three-way, "real-time, audio-video conference in which both the practitioners and the patient communicate simultaneously."[32] Likewise, Section 1306.31(d)(3) allows for "written qualifying telemedicine referrals" following an in-person medical appointment.[33] But both exceptions require the patient to have access to a local doctor they trust, and still ultimately require an in-person appointment.

[30] Proposed Telemedicine Rule, Executive Summary and § 1306.31(c)(2), (d).
[31] Proposed Telemedicine Rule, § 1300.04(o) and § 1306.31(c)(2), (d).
[32] Proposed Telemedicine Rule, § 1306.31(d)(2)(iv).
[33] Proposed Telemedicine Rule, § 1306.31(d)(3).

We appreciate the Department's efforts to preserve some availability of telemedicine for prescriptions of testosterone and other controlled substances. However, for the trans and gender diverse communities, the requirements laid out in the Proposed Telemedicine Rule will pose substantial—and sometimes insurmountable—barriers to care.

As described in detail above, for many trans and gender diverse individuals, any requirement for an in-person visit presents a significant obstacle for accessing care, or even makes accessing care impossible. Many trans and gender diverse patients live very long distances from gender-affirming care providers.[34] For some trans people, especially trans youth, who live in rural areas and/or who are experiencing poverty, travel to a gender-affirming provider even for a single visit is unrealistic.[35] And even for trans and gender diverse individuals who can *physically* reach care providers, they face mistreatment when physically present in health care facilities, including overt discrimination and systemic bias.[36] This can pose a major barrier to care for trans and gender diverse individuals, especially for those who also suffer from other mental and behavioral health challenges that can be seriously exacerbated by mistreatment in health care facilities. The result of the Proposed Telemedicine Rule will be that many trans and gender diverse people will face significant barriers to making even a single in-person appointment, and some people simply won't be able to—and thus will lose access to testosterone.

Additionally, the large influx of patients needing in-person appointments after the end of the public health emergency is likely to disrupt and delay care even for those trans and gender diverse individuals who are willing and able to attend in-person appointments. This is true even with the proposed 180-day delayed implementation of the rule for individuals already receiving telemedicine care. As discussed in the previous section, the number of trans and gender diverse individuals treated via telemedicine has rapidly increased over the past three years. Boston's Fenway Health roughly doubled the number of trans and gender diverse patients it treated in 2020 via telemedicine compared to 2019 in-person,[37] and telemedicine provider Plume supported 16,000 patients via telemedicine as of October 2022.[38] These numerous patients who began telemedicine during the public health emergency and who have not previously had an in-person appointment will need to arrange for an in-person appointment during the 180-day grace period, or lose access to care. They will face bottlenecks at health care providers who suddenly need to support a large number of in-person appointments, during a time when many health systems are already understaffed and overwhelmed. This will be exacerbated by the needs of trans and gender diverse individuals who are seeking to start therapy after the end of the public health emergency, but who need an in-person appointment to do so. And the problem will be further aggravated in states like Massachusetts that offer broad gender-affirming care, as trans and gender diverse individuals relocate to these states in increasing numbers to avoid discriminatory laws in other states. In sum, the Proposed Telemedicine Rule will very likely result in delays in treatment for new

[34] *See, e.g.*, Li Lock et al., *Transgender Care and the COVID-19 Pandemic*, *supra* note 6.

[35] *See, e.g.,*, Apple, *Acceptability of Telehealth for Gender-Affirming Care in Transgender and Gender Diverse Youth and Their Caregivers*, *supra* note 8 at 163.

[36] *See, e.g.*, Renner, *Barriers to Accessing Health Care in Rural Regions by Transgender, Non-Binary, and Gender Diverse People: A Case-Based Scoping Review*, *supra* note 14 at 7.

[37] Grasso, *Gender-Affirming Care Without Walls*, *supra* note 25.

[38] *2022 Colorado Inno Awards Winner Plume Takes Gender-Affirming Care Nationwide*, *supra* note 29; Cuadra, *How Plume Is Making Gender-Affirming Care Accessible Across the U.S.*, *supra* note 29.

patients, and disruptions in treatment for previously telemedicine-exclusive patients, even amongst those who are ready, willing, and able to go to an appointment in person.

The disruption, delay and outright denial of testosterone for trans and gender diverse individuals will greatly harm those individuals who require this care. Long-term deprivation of gender-affirming care can lead to severe health consequences. This includes "poor mental health outcomes," such as "depression, non-suicidal self-injury, and suicidal ideation and behavior," and "a decreased life expectancy."[39] Disruptions in access to hormone therapy can also lead to physical health consequences, including "symptoms of hypogonadism, such as osteoporosis and cardiovascular disease,"[40] if individuals are forced to ration or stop taking their hormones entirely. This is particularly concerning in the context of patients who have had some gender-affirming surgeries, in which patients lose the ability to produce sex hormones on their own. Some studies indicate that trans people with masculinized hormone profiles may even have an increased risk of severe COVID if they are denied access to testosterone.[41] Even with limited disruptions to this course of treatment, some patients report more difficulty engaging in activities of daily living, including showering, exercising, and moving through public spaces.

By reducing access to testosterone for trans and gender diverse individuals, the Department's proposed rule will compound the harm that has already been visited on trans people across the country, as state legislatures increasingly pass laws banning gender-affirming care. Members of the medical community have noted that such laws "threaten to deepen pre-existing inequities, leading to increased morbidity and mortality among [transgender and gender diverse, or TGD] youth and disproportionately harming TGD people of color and those living in poverty."[42] Even in states where care is not banned outright, some health care providers have become less willing to provide gender-affirming care, and some trans and gender diverse individuals may reasonably fear outing themselves to local doctors.[43] Trans and gender diverse individuals may face outside threats when visiting in-person providers as well, as can be seen in the recent bomb threat and anti-trans protests at Boston Children's Hospital.[44] Given all these factors, many trans and gender diverse individuals may feel they have no choice but to forego care if they cannot access it directly via telemedicine. The current climate of hostility towards trans and gender

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[39] Lock et al., *Transgender Care and the COVID-19 Pandemic*, supra note 6, 165-66; *see also* Jarrett, *Gender-Affirming Care, Mental Health, and Economic Stability in the Time of COVID-19*, *supra* note 3 (loss of access to gender-affirming resources associated with "poorer mental health," including depression, anxiety, and increased suicidal ideation).

[40] Jarrett, *Gender-Affirming Care, Mental Health, and Economic Stability in the Time of COVID-19*, *supra* note 3.

[41] Johnny S. Younis et al., *The Double Edge Sword of Testosterone's Role in the COVID-19 Pandemic*, Front. Endocrinol., March 16 2021, https://www.frontiersin.org/articles/10.3389/fendo.2021.607179/full#h5.

[42] Ames Simmons, *What Will It Take to Reduce Suicide Among Transgender North Carolinians by 2030?*, 83 North Carolina Medical Journal 182, 187 (2022) (quoting Jessica Kremen, *Addressing Legislation That Restricts Access to Care for Transgender Youth*, Pediatrics, May 2021, https://doi.org/10.1542/peds.2021-049940).

[43] *See* Kcomt, *Healthcare Avoidance Due to Anticipated Discrimination Among Transgender People*, *supra* note 18 at 6 (noting that trans people who are not fully out to everyone about their identity are more likely to avoid seeking health care, leading to missed treatment opportunities).

[44] *Trans Rights Activists, Protesters Outside Boston Children's Hospital Prompt Police Presence*, CBS Boston (Sept. 18, 2022), https://www.cbsnews.com/boston/news/trans-rights-activists-protesters-outside-boston-childrens-hospital-prompt-police-presence.

diverse people creates an "urgent" need for policymakers to *maintain* open access to gender-affirming care via telemedicine, not take it away.[45]

b. In-person examinations are not necessary for safe prescribing of testosterone as a gender-affirming care treatment or to prevent testosterone's diversion.

Trans and gender diverse patients have greatly benefitted from telemedicine access to testosterone, and face significant health risks if that access is reduced. Moreover, the past three years have shown that testosterone can be safely prescribed via telemedicine without a significant risk of diversion.

The last three years have demonstrated that gender-affirming hormone therapy (including testosterone) can be safely prescribed after a telemedicine assessment, and that an in-person examination is not medically necessary.[46] Even as patients and providers alike welcome a return to having in-person *options* for health care, telemedicine still offers advantages "as an additional modality for gender-affirming care," both "in geographic areas that may not have appropriately trained providers,"[47] and for individuals who are simply not able to access in-person services. For patients who wish to continue receiving gender-affirming care via telemedicine and do not want (or are not able) to come to an in-person care appointment, gender-affirming hormone therapy, including testosterone, can be safely prescribed after a telemedicine assessment.[48] In the absence of a physical exam, the treating provider can still use the telemedicine appointment effectively to provide needed care and gather needed information, including "carefully ask[ing] about symptoms concerning side effects of testosterone therapy, and continu[ing] this crucial treatment in their absence," even when a physical exam is not possible.[49] "While performing a full physical examination is not possible through telemedicine, in most cases, a physical examination does not change the hormonal approach," because the indication for hormone therapy is simply the patient's gender identity—which is "established by patient report."[50] Further, "contraindications to hormonal therapy are rarely identified by physical examination," making telemedicine prescription an equally safe option.[51]

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[45] Mary Kathryn Stewart, *Outcomes Research on Telemedicine-Delivered Gender-Affirming Health Care for Transgender Youth Is Needed Now: A Call to Action*, 8 Transgender Health 1 (2023), https://pubmed.ncbi.nlm.nih.gov/36824385/. Early in the pandemic, many states eased their licensure requirements to permit access to interstate telehealth, but many of those easements have now expired, including in many rural southern states such as Alabama, Mississippi, Louisiana, Florida, and Georgia. The fact that trans individuals living in some states may no longer be able to access telemedicine across state lines makes it even more essential to preserve their ability to do so within their own states. *See* Carmen Kloer, *Delays in Gender Affirming Care due to COVID-19 Are Mitigated by Expansion of Telemedicine*, 225 American Journal of Surgery 367, 372 (2023).

[46] *See, e.g.*, Laura J. Mintz, *Telehealth in Trans and Gender Diverse Communities: the Impact of COVID-19*, 11 Current Obstetrics and Gynecology Reports 75, 78 (2022), https://pubmed.ncbi.nlm.nih.gov/35463051/ (discussing the growing consensus over time that gender-affirming hormones may be prescribed without a physical examination).

[47] Dowshen, *Telehealth for Gender-Affirming Care: Challenges and Opportunities*, *supra* note 10.

[48] Hamnvik, *Telemedicine and Inequities in Health Care Access*, *supra* note 12 at 114.

[49] Kaplan, *Telehealth Beyond the Pandemic*, *supra* note 9, 76.

[50] Hamnvik, *Telemedicine and Inequities in Health Care Access*, *supra* note 12 at 114 (discussing Yoram Vardi et al., *Is Physical Examination Required Before Prescribing Hormones to Patients with Gender Dysphoria?* 5 Journal of Sexual Medicine 21-26 (2008)).

[51] *Id.*

The last three years of telemedicine prescription of testosterone have also shown that testosterone does not pose a significant risk for diversion, or to public health and safety, when it is prescribed via telemedicine. Testosterone was listed as a Schedule III drug through the Anabolic Steroids Control Act of 1990 "with the aim of putting an end to 'cheating' in sports."[52] But when the Anabolic Steroids Control Act was originally passed, the Drug Enforcement Administration, along with the Food and Drug Administration and the National Institute on Drug Abuse, objected to the scheduling of testosterone on the basis that testosterone did not have the abuse potential to require additional controls.[53] Decades later, many earlier stereotypes about steroid misuse (including "roid rage") have been debunked by the medical community.[54]

Moreover, the Proposed Telemedicine Rule does not cite any evidence that diversion of testosterone has increased during the public health emergency, nor that continuing to allow telemedicine prescriptions of testosterone for gender-affirming care would endanger public health. In fact, the Department's own data shows that testosterone misuse may have *decreased* during the public health emergency, after telemedicine prescription requirements were relaxed. In 2019, the DEA's National Forensic Laboratory Information System database collected 1,945 reports of testosterone misuse from participating forensic drug laboratories. In 2020 and 2021, the same database collected only 1,290 and 1,169 reports of misuse, respectively.[55]

In contrast to the theoretical danger that testosterone could be diverted—which doesn't appear to be the case based on the Department's own data—the danger the Proposed Telemedicine Rule poses to trans people is unfortunately very real. By taking access to testosterone via telemedicine away from individuals who can't access gender-affirming and culturally competent care where they live, the Rule will cut off access to gender-affirming care for some of the most vulnerable members of the trans community.

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Trans and gender diverse individuals have benefitted enormously from access to telemedicine prescription of testosterone. A reduction in the telemedicine availability of testosterone, as proposed in The Proposed Telemedicine Rule, will cause significant harm to the physical and mental health of trans and gender diverse individuals—during a time when access to gender-affirming care is already under

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[52] Ryan McGrew, *Raising the Bar: Why the Anabolic Steroid Control Acts Should Be Repealed and Replaced*, 15 Hous. J. Health L. & Policy (2015), https://www.law.uh.edu/hjhlp/volumes/Vol_15/McGrew.pdf (citing Rick Collins, *Changing the Game: The Congressional Response to Sports Doping via the Anabolic Steroid Control Act*, 40 New Eng. L. Rev. 753, 754-55 (2006)).

[53] *See Letter from Senators Markey and Warren* (Sept. 15, 2022) at 2, https://www.markey.senate.gov/imo/media/doc/letter_on_expanding_access_to_gender-affirming_hormone_therapy1.pdf. There are ongoing efforts to deschedule testosterone from the list of controlled substances, including by Massachusetts Senators Edward Markey and Elizabeth Warren. *Id.* The Massachusetts Transgender Health Coalition agrees with and supports these efforts. However, because that question is beyond the scope of this comment, MTHC does not address that issue here.

[54] McGrew, *Raising the Bar*, *supra* note 52 at 234, 243.

[55] Drug Enforcement Administration, Diversion Control Division, Anabolic Steroids (December 2022), https://www.deadiversion.usdoj.gov/drug_chem_info/anabolic.pdf.

attack by state legislatures across the country.[56] A solution is desperately needed to provide uninterrupted access to gender-affirming care as the Public Health Emergency draws to a close: the Department should continue to allow patients to receive testosterone prescriptions without the need for an in-person examination.

Thank you for your consideration. Please contact Suzanne Davies (sudavies@law.harvard.edu) or Steph Neely (sneely@hla-inc.org) with any questions.

Sincerely,

The Massachusetts Trans Health Coalition

[56] *See* ACLU, *Mapping Attacks on LGBTQ Rights in U.S. State Legislatures*, https://www.aclu.org/legislative-attacks-on-lgbtq-rights.