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,

The Autistic Self Advocacy Network (ASAN) is grateful for this opportunity to offer information and comments for the DEA’s proposed rule, “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation”.

ASAN is a national disability rights organization that serves autistic adults. We advocate for policies that support the needs of autistic individuals, including access to health care that meets our needs. We have previously produced resources for self-advocates and families to access care that meets the needs of autistic individuals. We have also previously submitted public comments on a number of health care related concerns, including proposed changes to HIPAA privacy rule\(^1\), discriminatory practices in organ procurement and transplantation\(^2\), and on nondiscrimination in health care activities\(^3\).


Telemedicine flexibilities have helped people during the pandemic

The telemedicine flexibilities instituted during the COVID-19 public health emergency have enabled a tremendous and needed expansion of access to mental health care services and providers. While these flexibilities were a product of the COVID-19 emergency, the surge in mental health care utilization that has been facilitated by these telehealth provisions reflects the presence of a long-standing crisis in behavioral health access across many communities. 55% of counties in the US have no mental health providers⁴, while 130 million Americans – more than one-third of the country – live in areas with a shortage of mental health providers⁵. It is essential that Congress and the Biden administration preserve the benefits of expanded use of telehealth as the public health emergency ends.

We have serious concerns about the impacts the DEA’s proposed rule will have on the access of necessary telehealth-driven access to care for our community. While we recognize the statutory obligation to ensure that adequate safeguards are in place to prevent the misuse of prescription controlled substances via the internet, the DEA’s proposed rule is likely to have perverse impacts. These include reducing access to necessary telehealth care, interruptions of provider access and treatment regimens, and forcing patients to approaches to self-management that put them at even greater risk of abuse.

We object strenuously to the exclusion of non-narcotic Schedule II controlled substances from this rule. Many of our community experience challenges related to executive function and attention that are either part of our autism diagnoses or overlapping ADHD diagnoses. It has long been recognized that mental health medications are an essential

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element of treatment for many individuals with ADHD and related executive function needs. Furthermore, it is well-documented that for people with ADHD and similar conditions, lack of treatment poses a significant health risk to individuals. People with ADHD are at greater risk of accidental injury and death than people without ADHD\(^6\), and this difference is ameliorated with proper medication.\(^7\)

While it is true that there has been a notable and substantial increase in the number of prescriptions for stimulant medications during the public health emergency, we believe that this reflects greater access to appropriate mental health treatment afforded by expanded telehealth availability; according to a Kaiser Family Foundation Report, telehealth flexibilities have facilitated an expansion of behavioral health utilization across a broad range of services and diagnoses. We have not identified any evidence that the increase in stimulant medications during the pandemic reflects an increased incidence of improper prescribing practices rather than improvements to treatment access among people who were previously unable to access needed care as reflected by these improvements in mental health utilization.

Moreover, individuals who are diagnosed and prescribed medications for ADHD have reported widespread and continuing challenges accessing their prescribed medications amid a monthslong national prescription shortage of amphetamine as well as other stimulant medications such as methylphenidate. While the causes of this shortage include supply-chain issues beyond the federal government’s control, one significant contributing factor is the DEA’s own manufacturing quotas, which have been held at unsuitably low levels despite the increase in mental health utilization that could be anticipated to correspond to additional prescribing\(^8\). As a result of this shortage, many individuals have experienced extreme delays and substantial administrative and logistical burdens in accessing properly prescribed medication, often being forced to


delay, discontinue, or disrupt necessary treatments. These disruptions in medication access have led to widespread and serious adverse impacts for millions of patients nationwide.

Recommendations:
Extend the rule's telemedicine provisions to duly prescribed Schedule II medications. Failure to include provisions for the telehealth provisions schedule II mental health medications under this rule will substantially burden the mental health care of millions of individuals in an environment where access to appropriate services is already severely limited and inaccessible.

Vulnerable populations are at risk of losing access to essential medications

Members of the autistic community are disproportionately likely to be transgender or gender-nonconforming relative to nonautistic individuals. Because of the disproportionate impact experienced by the autistic community, ASAN has been monitoring the unprecedented nationwide policy assault on transgender individuals and their access to health care with increasing concern. ASAN wishes to raise additional concerns about the impacts that the proposed rule would have on transgender individuals’ access to appropriate transition-related medications in an environment where access to this care is increasingly being burdened by state policy actions.

Testosterone for gender-affirming hormone therapy is safe, effective, and endorsed as medically necessary, evidence-based care by many professional organizations, including the World Professional Association of Transgender Health, the Endocrine Society, the American Academy of Family Physicians, the American Medical Association, and the American Psychological Association. Upwards of 80 percent of

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transgender individuals in the US seek hormone therapy, including testosterone, as part of their overall health care. The flexibility to prescribe testosterone therapy via telemedicine without an in-person visit during the COVID-19 PHE has meaningfully increased access to lifesaving care for transgender individuals. Clinics serving transgender individuals are clustered in only a few major cities across the U.S. and frequently have lengthy waiting periods to secure an appointment. A recent study found a demonstrable increase in new transgender patient visits specifically for gender-affirming hormone therapy with the adoption of telehealth during the pandemic. Telehealth has greatly reduced the barriers experienced by transgender individuals receiving care.

Moreover, transgender individuals increasingly face state policy environments that are extremely hostile to gender-affirming care, often leaving individuals with few options other than telehealth to secure access to care. According to policy analysis by the Human Rights Campaign, nearly 25% of youth live in states that have already passed legislation restricting care, while over 50% live in states where access to this care is under threat from pending or already-passed legislation. Several states— including Texas, Florida, and Oklahoma— have additionally proposed restrictions or bans on the provision of care that would extend into adulthood, further putting access to services at tremendous risk. For an increasing number of transgender individuals, this means the rule would require travel out of state for an in-person appointment within 30 days—an insurmountable barrier for many individuals, particularly given the long waits for care for gender-affirming services.

**Recommendations**

The rule should ensure that the barriers imposed on transgender individuals seeking gender-affirming care are minimal. If the final rule includes a provision similar to this

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proposed rule permitting a limited prescription prior to an in-person visit, that prescription period should be extended from 30 days to 90 days to reflect the profound burdens many vulnerable individuals will face in securing in-person assessments in a timely manner, particularly in circumstances where access to care is already burdened by excessive wait times and limited provider availability in many geographic areas.

Continued Access to Telemedicine is essential for continuity of care

As discussed above, the availability of telehealth has greatly expanded access to care for people who would have previously been excluded from care due to a combination of local provider inadequacy and burdens related to geography and access to transportation resources. It is critical that following the public health emergency, telehealth continues to be provided in ways that ensure continuity of care for individuals who have newly been able to access this care. The transition period from emergency flexibilities to any post-PHE telehealth regime will strain existing provider networks already burdened by inadequacy to need, as providers will have a limited time period to transition to in-person assessment practices for patients established during the public health emergency.

Moreover, the risks of patient harm from disruption of necessary care are profound, particularly with regard to the management of medically necessary controlled substances, including opioids. We affirm the comments submitted separately on this rule from the National Pain Advocacy Center on this topic, which notes numerous studies identifying additional patient risk of overdose, mental health crisis and death incident to interruption and destabilization of opioid medications in pain patients.¹⁴ ¹⁵ ¹⁶.

¹⁶ Larochelle MR, Lodi S, Yan S, Clothier BA, Goldsmith ES, Bohnert ASB. Comparative Effectiveness of Opioid Tapering or Abrupt Discontinuation vs No Dosage Change for Opioid
They further note that individuals with disabilities that impact communication, such as many autistic individuals and those with intellectual disabilities, are at greater risk of experiencing interruptions of care due to barriers to communication. It is essential that the DEA’s approach to regulation of controlled substances does drive further risk of overdose and harm due to disruptions of medically necessary care.

**Recommendations:**
Extend the proposed transitional period for patient relationships established during the Covid-19 PHE from 180 days to 1 year. Requiring a too-rapid transition for patients established during the public health emergency will overwhelm provider networks and disrupt continuity of care for individuals who are not able to obtain a qualifying in-person appointment in the provided time period.

The telehealth flexibilities afforded during the Covid-19 public health emergency have provided a path forward to address the long-standing and deepening mental health care crisis in America. Yet, rather than continuing to build on the successes of the pandemic response, the proposed DEA rule threatens to layer another crisis on top of this existing one. The impacts of the proposed rule would fall most heavily on those who already face substantial burdens interfacing with the medical system to receive needed treatment, whether due to disabilities that are particularly burdened by additional administrative and logistical barriers to accessing medication, because they are members of a vulnerable and highly marginalized community whose health access is being targeted by a hostile public policy environment, or—as is the case for many of us—when we are impacted by many of these factors simultaneously.

Thank you for the opportunity to provide comments on this topic. We hope that the DEA will seriously consider the impacts that this proposed rule will have on communities that already experienced substantial burdens in accessing lifesaving care. Instead of blunt and restrictive approaches that threaten to reverse the improvements to health care delivery made during the public health emergency, we strongly support a revised rule

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that does more to continue the successes of telehealth in reaching underserved communities. If there are any questions concerning these comments or to discuss this matter further, please contact our Deputy Director of Public Policy, Gregory Robinson, at grobinson@autisticadvocacy.org