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March 28, 2023

Anne Milgram

Administrator

Drug Enforcement Administration

8701 Morrisette Drive

Springfield, VA 22152

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

Dear Administrator Milgram:

The American Academy of Child and Adolescent Psychiatry (AACAP) appreciates the opportunity to comment on the U.S. Drug Enforcement Administration's proposed rule for "Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation."

AACAP is the medical professional home to more than 10,000 child and adolescent psychiatrists, fellows, residents, and medical students with a mission to promote the healthy development of children, adolescents and families through advocacy, education, and research. Child and adolescent psychiatrists are a highly trained workforce of medical doctors who have extensive specialized training in both adult and child psychiatry whose patients have benefited greatly from increased access to telemedicine visits during the Public Health Emergency (PHE). As such, we are uniquely qualified to comment on the impact this proposed rule will have on children and adolescents' access to specialty mental health care, including pharmacological treatment.

The United States is in the midst of a children's mental health crisis. In fact, in October 2021, three national major healthcare organizations including AACAP, the American Academy of Pediatrics and the Children's Hospital Association, declared a national emergency in children's mental health to shine a light on years of deteriorating pediatric mental health.ⁱ Rates of children and adolescent mental health and substance use disorders remain unacceptably high, while rates of access to treatment remain low.ⁱⁱ Suicide is currently the second leading cause of death for youth ages 10-18 in the United States, with rates increasing among minoritized populations.ⁱⁱⁱ The COVID-19 pandemic exacerbated this crisis and put additional pressure on an already weak pediatric mental health system and overburdened workforce.

In declaring COVID-19 a PHE, the federal government waived requirements across public health programs that enabled healthcare providers to maintain Americans' access to healthcare throughout the pandemic. Telehealth flexibilities were critical in maintaining patients' access to care, including DEA's waiver to allow DEA-registered prescribers to prescribe a controlled substance to patients diagnosed with a mental health or substance use disorder for whom the prescriber had not first examined in person. Despite historical concerns that telepsychiatry, including the electronic prescription of controlled substances, would lead to substandard care and diversion of controlled substances, telepsychiatry proved to be a safe and effective way to deliver high-quality mental health care. Moreover, telepsychiatry extended the reach of child and adolescent psychiatrists and other behavioral health specialists already in short supply to patient populations in underserved areas, and into less traditional healthcare settings like schools and homes.

Proposed Rule Restricts Pediatric Access to Mental Health Care

AACAP is concerned that the DEA's proposed rule will restrict children and adolescents' access to vital mental and substance use disorder care.

AACAP appreciates that the proposed rule creates a "telemedicine relationship established during the COVID-19 public health emergency" that extends the in-person exam waiver an additional 180 days. The PHE in-person exam waiver enabled many pediatric patients in behavioral health crises to initiate treatment via telepsychiatry and establish meaningful and long-term patient-physician relationships. In many cases, telepsychiatry created access to mental health care for patients who would not otherwise have had access due to geographic, healthcare, financial or other limitations. Requiring patients who, before the pandemic, had no access to healthcare to now connect with their provider in-person (or via a telemedicine referral) will likely result in disruptions in their care or loss of access altogether. This requirement will only further entrench existing access issues in rural areas, as well. Consideration must be given to reducing barriers to care for patients who reside in rural areas, in the final rule. The limitations that precluded them from accessing care prior to the pandemic remain a barrier today. AACAP asserts that frequency of an in-person exam should be a matter of clinical discretion, based on their judgment of a patient's diagnosis and condition. AACAP members want to practice medicine safely, but there must be some compromise in the final rule that will not harm access to needed care. ***To maintain continuity of care for patients for whom a "telemedicine relationship [was] established during the COVID-19 public health emergency," AACAP asks the DEA to amend the proposed rule to extend the PHE in-person exam waiver indefinitely.***

AACAP also appreciates the DEA creating a pathway for providers to issue an initial prescription of no more than thirty days for non-narcotic schedule III-V controlled substances without having first conducted an initial in-person exam. Further, we understand that the patient must have an in-person exam with the prescriber before additional prescriptions can be issued. Unfortunately, the child and adolescent psychiatry workforce is insufficient to meet the current demand for this subspecialty. Patients often wait months to see a child and adolescent psychiatrist.^{iv} ***AACAP recommends that the DEA amend the proposed rule to allow the provider to issue a prescription (or prescriptions) for no more than a ninety-day supply of the controlled medication.*** Ninety days would better align with current wait times and facilitate continuity of care for patients who require these medications for the treatment of their mental health or substance use disorder.

AACAP also urges the DEA to create a similar pathway to issue prescriptions for non-narcotic schedule II medications (including stimulants such as Adderall) for children and adolescents diagnosed with Attention-Deficit Hyperactivity Disorder (ADHD). Roughly ten percent of American children (ages 3-17) are diagnosed with ADHD and more than half who have an ADHD diagnosis have at least one other mental, emotional, or behavioral disorder.^v While treatment for ADHD can include behavioral therapy and/or medication, research shows that [stimulant] medication is the most effective treatment when compared to other treatments.^{vi} Untreated ADHD can lead to mental and behavioral disorders, including mood and substance use disorders, unintended injuries resulting from ADHD-related impulsivity, and long-term impacts on relationship-building, educational achievement, and professional success. Yet access to stimulant medication varies widely across different socioeconomic and geographic groups, with some states reporting that fewer than forty percent of patients diagnosed with ADHD receiving ADHD medication. Access to ADHD medication is further diminished by an inadequate supply of child and adolescent psychiatrists, and ongoing stimulant supply shortages acutely felt today by psychiatrist and families across the country. ***Given the ongoing national children's mental health emergency, AACAP urges the DEA to amend proposed section 1306.31 (c)(2) to allow providers to prescribe non-narcotic schedule II medications approved for the treatment of ADHD without an initial in-person exam for a treatment period of no more than ninety days.***

Proposed Rule is Incompatible with Current Practice of Medicine

Throughout the COVID-19 Public Health Emergency, 85% of psychiatrists provided telepsychiatry and reported lower no-show rates, improved patient satisfaction with treatment, and improved patient access to treatment.^{vii} Telepsychiatry is a mode of treatment delivery with outcomes comparable to in-person service delivery and is increasingly being integrated into providers' standard practices. The proposed rules include requirements that are inconsistent with the current practice of medicine.

Telemedicine prescriptions are commonly understood to be any prescription that results from a telemedicine exam, including those that are conducted under current Ryan Haight Act telemedicine exceptions. The proposed rule ties the term "telemedicine prescription" only to those prescriptions that result from the newly proposed options within the rule and the additional administrative burdens associated with these prescriptions. AACAP is concerned that the newly defined "telemedicine prescription" will cause confusion related to any telemedicine-based prescriptions, at the provider, pharmacist and health plan level. Additionally, requiring that "telemedicine prescriptions," as defined in the proposed rule, be annotated as such may trigger reluctance among pharmacists worried that filling such prescriptions puts them at greater risk of DEA infractions. ***AACAP requests that the DEA remove the proposal that would require a practitioner to annotate a prescription issued pursuant to a telemedicine encounter as a "telemedicine prescription."***

Patient referrals across specialties and/or practice settings are routine and conducted for a variety of reasons including for labs and x-rays, for specialty consultation, and for placement in higher levels of care. Patients may also be temporarily referred to other providers to provide coverage for maternity leave, sick leave, and vacation. The requirements and limitations associated with the proposed rule's "telemedicine referral" do not reflect current medical practice wherein a patient may be referred by the pediatric or emergency department within a health system (e.g., a hospital) to the psychiatry department within the same health system. There are also many reasons why a provider may need a "covering" provider to temporarily accommodate their patients. In either of these scenarios, a referring

physician may not be able to refer a patient to a particular DEA-registered psychiatrist at the point of referral. It is likely that an emergency room physician or pediatrician needing to refer to a DEA-registered psychiatrist may not have access to an available psychiatrist, may not know what type of psychiatrist the patient needs (i.e., subspecialty experience), and have no way of knowing in which insurance network the other provider may participate or their availability to see the patient. Additionally, referred patients may be seen by a resident or fellow who rotates to a new training placement. ***AACAP proposes that the DEA amend the proposed rule to allow for telemedicine referrals to clinics, medical groups, facilities or other similar settings types instead of tying the referral to a specific DEA-registered provider.***

Proposed Rule Creates Unnecessary and Duplicative Burdens

AACAP appreciates the DEA's efforts to safeguard our patients and their communities from unlawfully prescribed controlled substances. However, many of the safeguards promulgated by the Ryan Haight Act and the proposed rules duplicate safeguards that currently exist within medical standards of care, health plan medical management requirements, and/or state law. In particular, the record-keeping and multi-state registration requirements are burdensome and expensive and disincentivize providers from practicing in underserved communities outside of their own.

Many child and adolescent psychiatrists work within multi-state geographic areas, e.g., New England; the "greater New York area"; Washington, D.C. "metro area," where patients may live and work in different states. Given the undersupply of child and adolescent psychiatrists, many work across state lines to bring access to patients who would otherwise have none. Under the proposed rule, a practitioner using telemedicine to prescribe a controlled substance must have a DEA registration in the state where the practitioner is located and in the state where the patient is located. Physicians are already required to be licensed by the state medical boards where their patients are located. Additionally, every state requires their own controlled substance license. ***To avoid unnecessary registration duplication and expense, AACAP recommends that the DEA consider adopting one national registration requirement instead of duplicative licenses across all states wherein the provider may be practicing.***

The proposed rule also imposes extensive additional record-keeping requirements for prescriptions issued under these new exceptions. AACAP understands the need to track a controlled substance prescription effectively and efficiently. However, AACAP has concerns regarding patient and provider confidentiality that may be at risk under the proposed requirements. For example, requiring that a provider document their prescribing location would capture private home addresses and vacation locations that can put the provider at risk of harm. Requiring all providers involved in a "telemedicine referral" to document and store the same information may also increase the likelihood that this sensitive patient information can be breached and misused. ***AACAP requests that the DEA revisit these record-keeping obligations in light of nearly ubiquitous physician adoption of state prescription drug monitoring programs as well as electronic medical records that have auditing capability.***

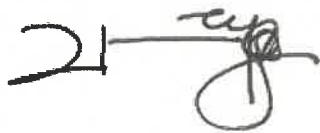
Proposed Rule Does Not Create a Special Registration for Telemedicine

This proposed rule authorizing "telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation" appears to be authorized by the seventh "practice of telemedicine" exception as outlined by the Ryan Haight Act. ***AACAP encourages***

the DEA to promulgate regulations specifying the “special registration for telemedicine” exception that could create special circumstances whereby a practitioner could prescribe controlled substances to patients with whom they have not had an in-person exam and that would not require a telemedicine referral but would require satisfying certain safeguards. For example, the special registration could be used by a child and adolescent psychiatrist to initiate a controlled substance prescription for a patient who is unable to access another prescriber due to specified limitations that could be geographic, lack of mobility, or emergency in nature and with safeguards in place including mandatory PDMP checks, mandatory routine telepsychiatry visits, and a requirement that an in-person exam be conducted within twenty-four months of the first prescription.

AACAP is grateful for the opportunity to offer its comments on this proposed rule. AACAP recognizes the challenges inherent in attempting to balance patient access to critical medications and threats to public safety due to illegal or illegitimate prescribing of controlled substances and appreciates the DEA’s thoughtful approach to updating and improving the Ryan Haight Act regulations. We intended our comments to strengthen these proposals by eliminating unnecessary burdens, aligning them with the current practice of medicine, and adding additional flexibilities that, altogether, supports the delivery of timely, safe and evidence-based pharmacological mental health care.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. Ng', with a stylized flourish at the end.

Warren Y.K. Ng, President

ⁱ [Declaration National Crisis Oct-2021.pdf \(aacap.org\)](#)

ⁱⁱ [CHILD AND ADOLESCENT MENTAL HEALTH - 2022 National Healthcare Quality and Disparities Report - NCBI Bookshelf \(nih.gov\)](#)

ⁱⁱⁱ [Changes in Suicide Rates — United States, 2019 and 2020 | MMWR \(cdc.gov\)](#)

^{iv} [Workforce Maps by State \(aacap.org\)](#)

^v [Data and Statistics About ADHD | CDC](#)

^{vi} [ADHD Medication Guide-web.pdf \(aacap.org\)](#)

^{vii} [Psychiatrists Use of Telepsychiatry During COVID-19 Public Health Emergency](#)