

March 30, 2023

The Honorable Merrick B. Garland
Attorney General
Department of Justice

Comments in response to RIN 1117-AB78: Expansion of Induction of Buprenorphine Via a Telemedicine Encounter

Dear Honorable Garland:

On behalf of the American Academy of Addiction Psychiatry (AAAP), thank you for the opportunity to comment on the proposed modifications for the prescribing buprenorphine via telepsychiatry. AAAP is the preeminent professional organization representing specialists in Addiction Psychiatry who treat patients with substance use disorders (SUDs) and co-occurring mental illness. We appreciate the balance the proposal works to strike to ensure patient access to medications for opioid use disorder (MOUD), specifically buprenorphine, while reducing non-medical use of the medication. However, research does not support concerns about substantial medication diversion or non-medical use associated with prescribing of buprenorphine via telemedicine.¹ **We are concerned the proposal, as written, would lead to more overdose deaths by severely limiting access to buprenorphine for those in need and cause disruption for people who started the medication during the COVID-19 Public Health Emergency.**

We support the steps the Administration is taking to provide flexibility for physicians and other clinicians to initiate prescriptions of controlled substances for addiction treatment via telehealth modalities and the flexible definition of “home” for the location of the patient to improve access. **However, we strongly urge for a repeal of the 30-day in-person requirement for those on buprenorphine who have never received an in-person evaluation.** We are in an active opioid public health emergency with overdose deaths claiming the lives of nearly [108,000 Americans for the year ending October 2022](#). Black, American Indian and Alaska Native people have experienced the [highest rates of overdose](#) and the [most limited access](#) to lifesaving medications for OUD. Among the [2.5 million individuals with opioid use disorder](#), only 1 in 5 (533,000 people) received MOUD in 2021. In addition, the COVID-19 pandemic will have long-lasting effects on the mental health of all youth and adults.

COVID flexibilities have allowed practitioners to make more patient-centered decisions, tailoring the use of telemedicine to an individual’s circumstances and determining whether, when and how often to see a patient in person.² They have also allowed for a reexamination of the value of in-person examinations, the optimal frequency of toxicology screens, alternatives for monitoring medication use, and ability to counsel patients via telemedicine about buprenorphine and other drug use.³ Practitioners must be allowed to make these care decisions without the imposition of arbitrary in-person evaluation requirements that have proven to be unnecessary for effective and safe care. The existing healthcare workforce that has provided MOUD, to date, is far too limited and geographically inaccessible in many

¹ Tanz LJ, Jones CM, Davis NL, et al. Trends and Characteristics of Buprenorphine Involved Overdose Deaths Prior to and During the COVID-19 Pandemic. JAMA Netw Open. Jan 3 2023;6(1):e2251856. doi:10.1001/jamanetworkopen.2022.51856

² Lori Usher-Pines, et al., “Treatment of Opioid Use Disorder During COVID-19: Experiences of Clinicians Transitioning to Telemedicine,” JR. OF SUBSTANCE ABUSE TREATMENT (2020) [https://www.isatjournal.com/article/S0740-5472\(20\)30380-9/fulltext](https://www.isatjournal.com/article/S0740-5472(20)30380-9/fulltext).

³ Christopher J. Frank and Lewei (Allison) Lina, Defining and Supporting High-Quality Telehealth for Patients with Opioid Use Disorder: The Promise and Potential Pitfalls of Telehealth Expansion, SUBSTANCE ABUSE (Oct. 12, 2022) <https://pubmed.ncbi.nlm.nih.gov/36222798/>.

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parts of the country to allow for an in-person evaluation within 30-days.⁴ Research shows that during the COVID-19 pandemic, the 90-day retention rates were better for those who received telehealth treatment services.⁵ Better treatment retention leads to more successful patient outcomes. Rolling back the accessibility of telehealth treatment will disrupt care for a population of people who need stability and consistency.

Research that examines the effect of the COVID telehealth flexibilities demonstrates – as the proposed rule recognizes – that buprenorphine was involved in a very small portion of overdose deaths (2.2%) and the proportion of buprenorphine-involved overdose deaths did not increase during the peak of the pandemic.⁵ The research also confirms that non-medical use of buprenorphine is motivated primarily by the need to self-treat cravings and withdrawal symptoms, which would be most effectively addressed through expanded – not reduced – access to treatment.⁶

The in-person evaluation prior to prescribing controlled substances via telemedicine does not enhance the DEA’s ability to do its job of limiting drug diversion or pursuing illegal actors. We welcome the opportunity to work with the DEA on mechanisms that can be used to prevent illegal online drug sales. Such sales as well as drug diversion does continue to occur and should be addressed, but we have not seen increased illegal activity related to the waiver of these requirements during the pandemic. Again, we strongly urge you to repeal the 30-day in-person requirement.

Prescribing Psychotropic Medications Subject to Ryan Haight Act Via Telemedicine

We are also concerned about similar telehealth prescribing restrictions the DEA has proposed placing on important psychotropic medications. At a time of heightened mental health needs – with key national associations and the U.S. Surgeon General having declared a crisis in youth mental health – these restrictions fail to strike the right balance between sustaining and increasing access to medically necessary treatment and preventing inappropriate prescribing of controlled medications.

The rule must consider the fact that 55% of U.S. counties have no psychiatrists,⁷ and 130 million people live in areas with a shortage of mental health providers.⁸ Access to mental health treatment, including medications, via telehealth has been critical to overcoming these barriers. Among specialties, psychiatry has the highest telehealth utilization for outpatient office visits, with half of all appointments occurring via telehealth in February 2021.⁹ Furthermore, other data suggests that the percentage of telehealth claims associated with a mental health diagnosis has remained steady with the need for virtual care continuing (roughly 60%).¹⁰

This is not surprising given both the shortage of providers in many areas and, as the proposed rule itself notes, the fact that CMS has recognized the unique ability of mental health services to be provided via telehealth (including audio-only); these services “are different from other services because they principally involve verbal exchanges between patient and practitioner.”¹¹ Thus, we believe the proposed rule’s restrictions on telehealth prescribing will cut off access to needed treatment at a time when we are finally making progress in increasing access to care.

We are of course concerned about high-profile reports of inappropriate prescribing of certain controlled medications, yet the proposed rule takes a harmful, unnecessary, and blunt approach. Rather than adopting the proposed rule, we urge the Administration to prevent inappropriate prescribing by putting in place safeguards relating to patient assessments and

⁴ James R. Langabeer, *et al.*, “Geographic Proximity to Buprenorphine Treatment Providers in the U.S.,” *DRUG AND ALCOHOL DEPENDENCE* (2020) <https://www.sciencedirect.com/science/article/pii/S0376871620302969?via%3Dihub>

⁵ Lauren J. Tanz, *et al.*, “Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic,” *JAMA NETWORK OPEN* (Jan. 20, 2023) <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.

⁶ Beth Han, *et al.*, “Trends in and Characteristics of Buprenorphine Misuse Among Adults in the US,” *JAMA NETWORK OPEN* (Oct. 15, 2021) <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785011>.

⁷ “Mapping Supply of the U.S. Psychiatric Workforce,” School of Public Behavioral Health Workforce Research Center, University of Michigan. October 2018.

⁸ Chris Larson, “Where the Mental Health Clinician Shortage Is at Its Worst.” *Behavioral Health Business*. June 24, 2022. <https://bhbusiness.com/2022/06/24/where-the-mental-health-clinician-shortage-is-at-its-worst/>.

⁹ Oleg Bestsenyy, *et al.*, “Telehealth: A quarter-trillion-dollar post COVID-19 reality?” McKinsey & Company. July 9, 2021. <https://www.mckinsey.com/industries/healthcare/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality>.

¹⁰ See “FAIRHealth telehealth data from December 2022 as compared to November / December 2021”: <https://s3.amazonaws.com/media2.fairhealth.org/infographic/telehealth/dec-2022-national-telehealth.pdf> (December 2022) and <https://s3.amazonaws.com/media2.fairhealth.org/infographic/telehealth/dec-2021-national-telehealth.pdf> (November / December 2021).

¹¹ Drug Enforcement Administration, *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*, 88 Fed. Reg. 12875, 12878 (March 1, 2023).


prescriber training.

Common-sense safeguards that align with the standards of care for mental health treatment can help prevent inappropriate prescribing of psychotropic medications. The proposed rule's extraordinarily restrictive approach is inconsistent with the standard of care, which does not require an in-person appointment in order to access needed treatment. **We also recommend a final rule include that after the Opioid Public Health Emergency ends, a patient is to receive an in-person evaluation within 180 days after receiving a supply of controlled medication scheduled III-V (non-narcotic).**

Rather than set back access to substance use disorder and mental health care at a time of national crisis, we urge the Administration to withdraw the proposed rule restricting access to the lifesaving medication buprenorphine and modify the proposed rule to allow telehealth prescribing of all other medications, including mental health medications, with safeguards.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Larissa Mooney". The signature is written in a cursive, flowing style.

Larissa Mooney, MD