



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-407]

RIN 1117-AB40 and 1117-AB78

Practice of Telemedicine: Listening Sessions

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of meeting.

SUMMARY: The Drug Enforcement Administration (DEA) is conducting public listening sessions to receive additional input concerning the practice of telemedicine with regards to controlled substances and potential safeguards that could effectively prevent and detect diversion of controlled substances prescribed via telemedicine. Specifically, DEA is inviting all interested persons, including medical practitioners, patients, pharmacy professionals, industry members, law enforcement, and other third parties to express their views at the listening sessions concerning the advisability of permitting telemedicine prescribing of certain controlled substances without any in-person medical evaluation at all, the availability and types of data that would be useful in detecting diversion of controlled substances via telemedicine that are either already reported or could be reported, and specific additional safeguards that could be placed around the prescribing of schedule II controlled substances via telemedicine.

DATES: The listening sessions will be held on Tuesday, September 12, 2023, and Wednesday, September 13, 2023, from 9 a.m. to 5:30 p.m at DEA Headquarters, 700 Army Navy Drive, Arlington, VA 22202; (202) 307-1000. Check-in will begin at 8 a.m.

MEETING ATTENDANCE: Persons wishing to attend the listening sessions in person, space permitting, must complete and submit the attendance form available at DEA's Diversion Control Division website, <https://apps.deadiversion.usdoj.gov/ListeningSession>, no later than August 21, 2023. There is no fee to submit the attendance form or to attend the listening sessions. In-person

attendance requests will be granted via random lottery among those who have submitted timely attendance forms. The listening sessions will also be livestreamed online.

MEETING PRESENTATIONS: DEA is accepting requests to make limited oral presentations during the listening sessions, as discussed further in this document. Oral presentations may be given in-person or by video teleconference. Persons wishing to give an oral presentation at the listening sessions, space and time permitting, must complete and submit the attendance form available at DEA's Diversion Control Division website

<https://apps.deadiversion.usdoj.gov/ListeningSession>, check the box indicating the desire to present at the listening sessions, and provide a summary of the presentation in the appropriate form field. This form must be submitted no later than August 21, 2023. Persons and groups having similar interests may wish to consider consolidating their information for an oral presentation through a single representative. After reviewing the requests to present, DEA will respond to all persons who request to provide an oral presentation to notify them of the status of their request. DEA will exercise its discretion to select a cross-section of persons and organizations to present at the listening sessions based on: (1) the person or organization's ability to respond to the specific questions presented below with new information, including the capacity to provide data responsive to the questions; and (2) the person or organization's ability to represent stakeholders on a given issue, position, or interest as raised by the requests. If selected to give an oral presentation, DEA will notify the presenting person or organization of the amount of time available to present and the approximate time the participant's presentation is scheduled to begin.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776-3882.

SUPPLEMENTARY INFORMATION:

Background

Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Ryan Haight Act), a prescribing practitioner—subject to certain exceptions—may prescribe controlled substances to a patient only if the practitioner has, at some point previously, conducted an in-person evaluation of that patient.

The Ryan Haight Act and DEA’s implementing regulations do not limit a practitioner’s ability to prescribe controlled substances for a patient after the practitioner has conducted at least one in-person medical evaluation of the patient. The Ryan Haight Act applies only where the prescribing practitioner wishes to prescribe controlled substances and has not conducted an in-person medical evaluation prior to the issuance of the prescription. In addition, the Ryan Haight Act and DEA’s implementing regulations do not apply to telemedicine, telehealth, or telepsychiatry not involving the issuing of prescriptions for controlled substances or to other aspects of telemedicine, telehealth, or telepsychiatry that are not otherwise specified in the Controlled Substances Act (CSA).

In response to the COVID-19 Public Health Emergency (COVID-19 PHE) as declared by the Secretary of the Department of Health and Human Services (HHS) on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), DEA granted temporary exceptions to the Ryan Haight Act and DEA’s implementing regulations under 21 U.S.C. 802(54)(D),¹ thereby allowing the prescribing of controlled substances via telemedicine encounters—even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient—in order to prevent lapses in care.

DEA recognizes the importance of telemedicine in providing Americans with access to needed medications, and DEA has been, and remains, committed to expanding access to telemedicine in a way that puts patients—and their safety—first, is simple to understand and

¹ William T. McDermott, DEA Dear Registrant letter, Drug Enforcement Administration (March 25, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-018\)\(DEA067\)%20DEA%20state%20reciprocity%20\(final\)\(Signed\).pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf); Thomas W. Prevoznik, DEA Dear Registrant letter, Drug Enforcement Administration (March 31, 2020), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf).

apply, reflects technological advancements, and is consistent with lessons learned during the COVID-19 PHE and the ongoing opioid epidemic.

Accordingly, on March 1, 2023, prior to the expiration of the COVID-19 PHE and with the intent to make permanent some of the telemedicine flexibilities established during the COVID-19 PHE, DEA, in concert with HHS, promulgated two notices of proposed rulemaking (NPRMs) in the Federal Register – *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*² (the “General Telemedicine NPRM”) and *Expansion of Induction of Buprenorphine via Telemedicine Encounter*³ (the “Buprenorphine NPRM”).⁴ These proposed rules sought to expand patient access to prescriptions for controlled substances via telemedicine encounters relative to the pre-COVID-19 PHE landscape, when consistent with public health and safety, while maintaining effective controls against diversion. More specifically, the General Telemedicine NPRM would allow for the telemedicine prescription of non-narcotic⁵ schedule III-V controlled substances when certain circumstances are met, and impose an initial limit on telemedicine prescriptions for a controlled substance to a 30-day supply.⁶ To prescribe an additional supply to that patient (either within that initial 30 days or after the completion of the initial 30-day supply), the prescribing practitioner would generally be required to evaluate the patient in person. The Buprenorphine NPRM would impose the same initial 30-day supply limit and in-person medical evaluation requirements. The comment period for the two NPRMs closed on March 31, 2023.

² 88 FR 12,875 (Mar. 1, 2023).

³ 88 FR 12,890 (Mar. 1, 2023).

⁴ The NPRMs were promulgated under authority granted to DEA and HHS pursuant to 21 U.S.C. 802(54)(G).

⁵ Under the CSA, narcotic drugs are drugs that contain opiates, cocaine, or ecgonine, as well as certain related plant material. 21 U.S.C. 802(17). This definition includes buprenorphine, a narcotic drug that has been approved by the Food and Drug Administration for maintenance and detoxification treatment of opioid use disorder.

⁶ The regulations proposed in the General Telemedicine NPRM would also allow a practitioner employed by the Veterans Health Administration or who has received a qualifying telemedicine referral from a practitioner who has conducted an in-person medical exam of the patient to prescribe via telemedicine any controlled substance (including schedule II controlled substances and narcotics) that the practitioner is otherwise authorized to prescribe, subject to the same circumstances and initial 30-day limit as telemedicine prescriptions for schedules III-V non-narcotic controlled substances.

DEA received a total of 38,369 public comments in response to the NPRMs – 35,454 comments on the General Telemedicine NPRM and 2,915 comments on the Buprenorphine NPRM. When combined, these were among the highest number of public comments received on an NPRM in DEA’s history. DEA thanks all commenters for their input and has been considering the comments carefully. On May 10, 2023, DEA and HHS temporarily extended the telemedicine flexibilities in place during the COVID-19 PHE to permit further consideration of the comments and avoid lapses in care.⁷

Among the 38,369 comments submitted in response to the NPRMs, a significant majority expressed concern, with respect to at least some controlled substances, that the proposed regulations placed limitations on the supply of controlled substances that could be prescribed via telemedicine prior to an in-person medical evaluation. In addition, several hundred comments specifically raised the possibility of a separate Special Registration for those practitioners who seek to prescribe controlled substances without conducting an in-person medical evaluation of patients at all.

DEA is open to considering—for some controlled substances—implementation of a separate Special Registration for telemedicine prescribing for patients without requiring the patient to ever have had an in-person medical evaluation at all. DEA also observes that making permanent some telemedicine flexibilities on a routine and large-scale basis would potentially create a new framework for medicine that fundamentally expands access to controlled substances in a way that warrants a new framework for accountability based, in part, on increased data

⁷ On May 10, 2023, DEA and HHS jointly promulgated a temporary final rule (Temporary Rule) that extended the telemedicine flexibilities in place during the COVID-19 PHE to avoid lapses in care given the then-pending May 11, 2023 expiration of the COVID-PHE. The Temporary Rule extends the full set of telemedicine flexibilities regarding prescription of controlled substances that were in place during the COVID-19 PHE through November 11, 2023. In addition, for any practitioner-patient relationships that have been or will be established on or before November 11, 2023, the full set of telemedicine flexibilities regarding prescription of controlled substances in place during the COVID-19 PHE will continue to be permitted via a one-year grace period through November 11, 2024. In other words, if a patient and a practitioner have established a telemedicine relationship on or before November 11, 2023, the same telemedicine flexibilities that have governed the relationship to that point are permitted until November 11, 2024. *Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications*, 88 FR 30037 (May 10, 2023) (to be codified at 21 CFR 1307 and 42 CFR 12).

collection and visibility into prescription practices in order to ensure patient safety and prevent diversion in near-real-time.⁸

Accordingly, DEA has decided to hold the aforementioned public listening sessions to gather new information from interested persons. While DEA welcomes all relevant information or opinions regarding telemedicine, DEA is particularly interested in the following questions:

- If telemedicine prescribing of schedule III-V medications were permitted in the absence of an in-person medical evaluation, what framework, including safeguards and data, with respect to telemedicine prescribing of schedule III-V medications do you recommend to help DEA ensure patient safety and prevent diversion of controlled substances?
- Should telemedicine prescribing of schedule II medications never be permitted in the absence of an in-person medical evaluation? Are there any circumstances in which telemedicine prescribing of schedule II medications should be permitted in the absence of an in-person medical evaluation? If it were permitted, what safeguards with respect to

⁸ Under the Ryan Haight Act, as a general matter, prescriptions for controlled substances may not be issued without a prior in-person medical evaluation of a patient. *See* 21 U.S.C. 829(e)(1), 2(A)(i). This reflects a background presumption that, when an in-person touchpoint has not occurred, it may be more likely that there has not been “adequate medical oversight” underlying the issuance of a prescription for a controlled substance. *See* H.R. Rep. No. 110-869, pt. 1, at 12 (describing the general performance goals and objectives of the Ryan Haight Act as “counter[ing] the growing sale of controlled substances over the Internet without adequate medical oversight”). Notwithstanding the Ryan Haight Act’s general prohibition, the law’s provisions also created an exception to the prior in-person medical evaluation requirement for practitioners who engage in the practice of telemedicine under a special registration framework. *See* 21 U.S.C. 829(e)(3)(A), 831(h).

telemedicine prescribing of schedule II medications specifically would you recommend to help DEA ensure patient safety and prevent diversion of controlled substances?

- If *practitioners* are required to collect, maintain, and/or report telemedicine prescription data to DEA, what pieces of data should be included or excluded? What data is already reported to federal and state authorities, insurance companies, and other third parties?
- If *pharmacies* are required to collect, maintain, and/or report telemedicine prescription data to DEA, what pieces of data should be included or excluded? What data is already reported to federal and state authorities, insurance companies, and other third parties?

Meeting Participation

These listening sessions are open to the public. DEA registrants (i.e., practitioners, pharmacies, manufacturers, distributors, and reverse distributors), ultimate users of controlled substances (i.e., patients and members of their households), persons and organizations representing state and local governments, law enforcement agencies, long term care facilities (i.e., hospices, nursing homes, and in-home care groups), and other concerned organizations may be particularly interested in these listening sessions.

Persons wishing to attend in person or provide a limited oral presentation must register on the Diversion Control Division website at <https://apps.deadiversion.usdoj.gov/ListeningSession>, as outlined above. These listening sessions will also be livestreamed. DEA will publicize instructions for accessing the livestream at a later date. A copy of the transcript from the listening sessions will be made available at the DEA Diversion Control Program Web site, <https://www.deadiversion.usdoj.gov>. That transcript will be considered part of the rulemaking record.

Persons needing any accommodations for a disability (e.g., sign language interpreter) are asked to notify DEA with their accommodation request no later than August 21, 2023. Such notification should be made to Scott A. Brinks, Regulatory Drafting and Policy Support Section,

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As these listening sessions are open to the public, confidential business information or other proprietary information should NOT be shared.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on August 2, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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