The Prescribing of Controlled Substances via Telemedicine and
The Impact on Tribal Communities
U.S. Department of Justice Consultation Framing Paper

BACKGROUND

In March 2020, in response to the COVID-19 Public Health Emergency (COVID-19 PHE) declared by the Secretary (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 used its authority under 21 U.S.C. 802(54)(D) to grant temporary exceptions to the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (the *Ryan Haight Act*) and its implementing regulations, allowing authorized practitioners to generally prescribe controlled substances in Schedules II-V through telemedicine.

On March 1, 2023, DEA in concert with HHS promulgated two Notices of Proposed Rulemakings (NPRMs) (the General Telemedicine Rule and Buprenorphine Rule) pursuant to 21 U.S.C. 802(54)(G), which collectively proposed to expand patient access to prescriptions via telemedicine relative to the pre-COVID-19 PHE landscape. *See Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Evaluation,* 88 Fed. Reg. 12875 (March 2023); *Expansion of Induction of Buprenorphine via Telemedicine Encounter,* 88 Fed. Reg. 12890 (March 2023). The General Telemedicine Rule generally proposed to allow a DEA-registered practitioner to prescribe non-narcotic Schedule III-V controlled substances to a patient via telemedicine for an initial 30-day supply. However, ongoing prescriptions for the same patient would require an in-person examination by the prescribing practitioner or a "qualifying telemedicine referral" from another practitioner who has conducted an in-person evaluation of the patient.

The Buprenorphine Rule generally proposed to allow a DEA-registered practitioner to prescribe any Schedule III-V narcotic drug approved by the Food and Drug Administration (FDA) specifically for use in the maintenance or detoxification treatment of opioid-use disorder (OUD) via telemedicine, including through audio-only telemedicine. Currently, buprenorphine is the only FDA-approved drug in this category. Buprenorphine is a Schedule III narcotic. 21 C.F.R. 1308.13 (e)(2)(i). Like the General Telemedicine Rule, controlled substance prescriptions would be limited to a 30-day supply, and subsequent prescriptions would require an in-person examination by the prescribing practitioner or a "qualifying telemedicine referral" from another practitioner who has conducted an in-person evaluation of the patient. As an additional safeguard, both proposed rules required Prescription Drug Monitoring Program (PDMP) checks, specific notations on the face of the prescriptions, and certain recordkeeping requirements.

In the General Telemedicine Rule NPRM, DEA asserted that the "rulemaking would not impose any new requirements on practitioners authorized to practice telemedicine under other statutory exceptions in 21 U.S.C. 802(54), such as Indian Health Service (IHS) and Tribal practitioners, who are authorized to engage in the practice of telemedicine under a different statutory paragraph, 802(54)(C)." 88 Fed. Reg. 12875, 12877-78. The regulatory analyses of the NPRMs of both the General Telemedicine Rule and the Buprenorphine Rule asserted that the proposed rules would not have substantial direct effects on the Tribes, on the relationship between the national government and the Tribes, or the distribution of power and responsibilities

between the Federal Government and Indian Tribes, and therefore would require no Tribal consultation pursuant to Executive Order 13175. However, in response to the two March 2023 NPRMs, DEA received at least six comments from Alaskan Native and American Indian (AN/AI) organizations expressing concerns about the proposed telemedicine regulations. Among their concerns was DEA's assertion that there would be no direct impact on Tribal communities, which they argued was inaccurate. They contended that despite the telemedicine exception for certain Indian Health Services and Tribal practitioners there would still be a substantial direct effect on Tribal communities given the limited practical and legal scope of the exception under 21 USC 802(54)(C). Further, they argued that DEA was obligated to engage and consult with Tribal officials as mandated by Executive Order 13175.

On May 10, 2023, to prevent the lapse of care with the expiration of the COVID-19 PHE, DEA, jointly with HHS, promulgated a rule (the First Temporary Rule) pursuant to 21 U.S.C.802(54)(G) to extend the temporary exceptions originally authorized under the COVID-19 PHE through November 11, 2023 for all telemedicine relationships, and through November 11, 2024 for such telemedicine relationships that were established on or before November 11, 2023. *See Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications*, 88 Fed. Reg. 30037 (May 2023).

On September 12 and 13, 2023, DEA hosted live, in-person Telemedicine 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. DEA invited the public to express their views 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, and specific additional safeguards that could be placed around the prescribing of Schedule II controlled substances via telemedicine.

On October 10, 2023, in light of the need to further evaluate the best course of action, given the comments received in response to the March 2023 NPRMs and the presentations at the September 2023 Telemedicine Listening Sessions, DEA, jointly with HHS, issued a second temporary rule (the Second Temporary Rule) to further extend the temporary exceptions originally authorized under the COVID-19 PHE through December 31, 2024. *See Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications*, 88 Fed. Reg. 69879 (October 2023).

QUESTIONS FOR CONSIDERATION

The following questions are not intended to limit discussion; the Department welcomes any question or topic of interest to consultation participants.

Tribal Health Systems

1. What key aspects of Tribal health systems should DEA consider when developing regulations and policies related to telemedicine and controlled substances?

2. Are there existing regulatory frameworks or best practices from Tribal health systems that could be leveraged to enhance the monitoring and oversight of telemedicine to prescribe, or otherwise dispense, controlled substances?

3. Can you provide information about the integration of telemedicine into the hub-and-spoke model[1] within Tribal health systems, including any challenges and successes encountered in this integration?

4. Can you provide information about how AN/AI communities residing in **rural areas** access healthcare services, and in what ways has telemedicine affected the delivery and accessibility of healthcare within these rural areas?

5. Can you provide information about AN/AI communities residing in **urban areas** access healthcare services, and in what ways has telemedicine affected the delivery and accessibility of healthcare within these urban areas?

6. What experiences or observations can you share about telemedicine practiced *by Internet Eligible Controlled Substance Providers* designated by the Secretary of the Health and Human Services pursuant 21 USC 831(g)(2)?

7. Are there cultural or jurisdictional considerations that DEA should be mindful of when implementing regulations related to telemedicine and controlled substances in AN/AI communities?

Diversion of Controlled Substances

8. What are the specific challenges or vulnerabilities related to diversion of controlled substances in telemedicine within the AN/AI communities, and how can they be addressed?

9. How can DEA effectively monitor and regulate telemedicine practices to prevent and detect diversion of controlled substances while still ensuring access to necessary medications for remote communities?

[1] In healthcare settings, the hub-and-spoke model organizes services with a central hub providing extensive medical resources and specialized care, while satellite spokes offer limited services closer to patients. Local, but limited, healthcare needs are met at satellite facilities, while more intensive medical interventions are referred to the main hub for treatment. Elrod JK, Fortenberry JL Jr. *The Hub-and-Spoke Organization Design Revisited: A Lifeline for Rural Hospitals*. BMC Health Serv Res. 2017 Dec 13;17(Suppl 4):795. doi: 10.1186/s12913-017-2755-5. PMID: 29297334; PMCID: PMC5751794.

10. How can DEA work with Tribal governments and healthcare organizations to establish reporting mechanisms for suspicious activities related to telemedicine and controlled substances?

DEA Registration

11. In your opinion, how can DEA ensure that registration requirements for telemedicine providers do not impede access to healthcare services for AN/AI communities?

12. What safeguards should be established to ensure that any telemedicine flexibilities specifically extended to AN/AI communities do not compromise patient safety or exacerbate risks of diversion of controlled substances?

Buprenorphine for Treatment of OUD

13. In general, what considerations should DEA consider regarding prescriptions via telemedicine for Schedule III-V controlled substances for the use in the treatment of opioid use disorder (OUD)? And specifically, what issues or limitations may arise from requiring audio-visual telemedicine versus audio-only telemedicine encounters?

14. In areas where no telemedicine services for the treatment of OUD are available, what are some of the burdens on AN/AI communities to access in-person treatment?

15. As mentioned above, the previous Buprenorphine Rule limited prescriptions to a 30-day supply before an in-person medical evaluation would be required. Considering the potential for diversion and the need for some prescription limitations or safeguards, should there be a limitation on the duration a buprenorphine prescription can be issued via telemedicine?

16. What other safeguards should DEA impose to allow for continued access to OUD treatment while also ensuring buprenorphine is not diverted for illicit purposes?