March 31, 2023

Drug Enforcement Administration
Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: Desk Officer for DOJ
Washington, DC 20503

Submitted via regulations.gov

Re: Proposed Rules on Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (RIN 1117 – AB40/Docket No. DEA – 407); and Expansion of Induction of Buprenorphine Via Telemedicine Encounter (RIN 1117-AB78/Docket No. DEA – 948)

To Whom It May Concern:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP appreciates the opportunity to provide comments to the Drug Enforcement Administration (DEA) on its two Notices of Proposed Rulemaking (NPRMs) (DEA – 407; DEA – 948) specifically as they relate to requirements for controlled substance electronic prescriptions issued based on a telemedicine encounter. NCPDP recognizes the DEA's intent to permanently allow certain telemedicine prescribing practices that were temporarily authorized under a COVID-era DEA waiver. However, NCPDP seeks clarification on the applicability of new requirements for electronic telemedicine prescriptions and clarification regarding digital signature requirements of new telemedicine prescriptions as they apply to NCPDP standards.

I. Applicability of Telemedicine Prescription Requirements

DEA has communicated that the intent of these rulemakings is to not impose any new requirements on practitioners who are authorized to practice telemedicine under other statutory exceptions to 21 U.S.C. 802(54), or who have conducted an in-person medical evaluation:

- Telemedicine Proposed rule Summary

This proposed rule applies only in limited circumstances when the prescribing practitioner wishes to prescribe controlled medications via the practice of telemedicine and has not otherwise conducted an in-person medical evaluation prior to the issuance of the prescription.

- Telemedicine Proposed rule Executive Summary

  This rulemaking would authorize telemedicine pursuant to 21 U.S.C. 802(54)(G) in those instances where (1) the prescribing practitioner has not conducted an in-person medical evaluation with the patient; (2) the prescription was issued pursuant to a telemedicine encounter and (3) the telemedicine encounter results in a prescription for controlled medications. The regulatory requirements proposed in this rulemaking would only apply to practitioners who issue prescriptions pursuant to telemedicine encounters authorized under 802(54)(G).

- Telemedicine Proposed rule Legal Authority and Background

  This 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).

- Buprenorphine Proposed rule Legal Authority and Background

  As indicated above, the Ryan Haight Act generally requires an in-person medical evaluation prior to the prescription of controlled substances. Section 829(e), however, also provides an exception to this in-person medical evaluation requirement where the practitioner is "engaged in the practice of telemedicine" within the meaning of the Ryan Haight Act (21 U.S.C. 802(54)). Consistent with the Ryan Haight Act's purpose of preventing diversion of controlled substances by means of the internet, the Act's definition of "the practice of telemedicine" does not encompass all forms of telemedicine. Rather, as set forth in 21 U.S.C. 802(54), the Ryan Haight Act's definition of the "practice of telemedicine" includes seven distinct categories of telemedicine that Congress determined were appropriate to allow for the prescribing of controlled substances despite the practitioner never having evaluated the patient in person.

  The CSA and DEA's regulations only define the "practice of telemedicine" for the purpose of establishing obligations under the CSA and DEA regulations. DEA is not attempting to define what constitutes appropriate telemedicine in other contexts. Thus, the proposed rule would not determine when substances that are not controlled may be appropriately prescribed via telemedicine or the nature of appropriate remote medical treatment more generally. Moreover, this proposed rule would not create any additional regulatory requirements for other categories of telemedicine authorized by the CSA under 21 U.S.C. 802(54). Rather, it would create additional circumstances under which the use of telemedicine to prescribe controlled substances is authorized by the CSA.

- DEA Highlights for Medical Practitioners

  The proposed rules do not affect either of the following:
  • Telemedicine consultations that do not involve the prescribing of controlled medications.
  • Telemedicine consultations by a medical practitioner that has previously conducted at least one in-person medical examination of a patient.

- DEA Highlights for Medical Practitioners

  Below is information on how the proposed rules may affect you and your patients.

  II. Telemedicine consultations with a patient you have previously evaluated in person

  • The proposed rules maintain current telehealth flexibilities in place during the COVID-19 public health emergency.

  • If you have evaluated a patient in person at least once, you may prescribe that patient any scheduled controlled medication via telemedicine, so long as the prescription is otherwise authorized by applicable Federal and State law.

However, it is unclear whether one of the new requirements applies only to telemedicine prescriptions issued pursuant to 21 U.S.C. 802(54)(G), or if it applies to any prescription order issued based on a telemedicine encounter.

DEA has proposed adding the following requirement in 21 CFR 1306.05:

> *(i) In addition to the requirements of this section, the practitioner shall note on the face of any telemedicine prescription, or within the prescription order if prescribed electronically, that the prescription has been issued based on a telemedicine encounter.*

In 21 CFR 1300.04, DEA is proposing defining "telemedicine encounter" as follows:

> *(m) The term telemedicine encounter means a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3).*

In 21 CFR 1300.04, DEA is proposing defining "telemedicine prescription" as follows:

> *(n) The term telemedicine prescription means a prescription issued pursuant to § 1306.31 by a physician, or a "mid-level practitioner" as defined in § 1300.01(b), engaging in the practice of telemedicine as defined in § 1300.04(j).*

While it is clear the requirement in 21 CFR 1306.05 states "the practitioner shall note on the face of any telemedicine prescription" applies only to "a prescription issued pursuant to § 1306.31", the language "or within the prescription order if prescribed electronically" does not have a formal definition. Furthermore, "telemedicine encounter" is defined as "a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3)" which is not limited to only prescriptions issued pursuant to the exception 21 U.S.C. 802(54)(G). The definition could be interpreted to mean any prescription order prescribed electronically based on a telemedicine encounter shall have a note indicating it was issued based on a telemedicine encounter.

NCPDP requests clarification whether the new requirement being added to 21 CFR 1306.05(i) applies to prescription orders prescribed electronically under other statutory exceptions in 21 U.S.C. 802(54) or after the practitioner conducted an in-person medical evaluation. If the intent is that 21 CFR 1306.05(i) only applies to telemedicine prescriptions issued pursuant to the exception 21 U.S.C. 802(54)(G), NCPDP requests the language "or within the prescription order if prescribed electronically" be removed from 21 CFR 1306.05(i) to clearly state that the requirement applies to telemedicine prescriptions based on a telemedicine encounter according to DEA definitions. The language as proposed could cause delays in patient care. For example, there could be confusion on behalf of the pharmacist should they receive a

telemedicine prescription for a 90-day supply that is written by a prescriber who has an in-person relationship with a patient, is conducting what is considered a telemedicine encounter and writes a prescription with the notation that it is being issued via telemedicine encounter.

Should the DEA intend to move forward with this new proposal that would impact electronic prescribing standards, NCPDP recommends the DEA allow adequate time after the publication of the final rule for all stakeholders to develop and implement system changes necessary to adopt the requirement across the industry prior to any type of enforcement. This would allow for adequate time for the industry to evaluate the successful transportation and exchange of such information, make any needed adjustments and identify any additional changes that may be needed for successful implementation. Without adequate time to prepare and implement this requirement, there would likely be disruption to the use of electronic prescriptions, resulting in delays in patient care.

II. Digital Signature Requirements

21 CFR 1311.120 and 21 CFR 1311.205 for prescriber and pharmacy systems, respectively states that digitally signed electronic prescriptions must digitally sign at least the information required by part 1306 of this chapter. The DEA has proposed adding a new requirement within 21 CFR 1306.05(i) that the practitioner shall note on the telemedicine prescription that the prescription has been issued based on a telemedicine encounter.

The NCPDP SCRIPT Standard Version 2017071, which is in use by the industry today to transmit the majority of digitally signed controlled substance electronic prescriptions, has a discrete element called PrescriberPlaceOfService[1] where a practitioner can indicate a prescription was part of a telemedicine encounter. However, this element according to the NCPDP SCRIPT Standard Version 2017071 is not part of the set of digitally signed elements. If the note for the new requirement in 21 CFR 1306.05(i) must be digitally signed, implementers of the NCPDP SCRIPT Standard Version 2017071 must use the free text Note element, which is part of a set of digitally signed items and will be more burdensome for prescribers and pharmacists.

NCPDP requests clarification from the DEA that the intent of this new requirement is the note stating the prescription was issued based on a telemedicine encounter must be digitally signed when electronically transmitting prescriptions in accordance with 21 CFR 1311.

NCPDP and its members appreciate the opportunity to provide comments to the DEA on its rulemaking. From a standards perspective, clarification from the DEA on the topics provided above are necessary so NCPDP can ensure our standards are able to support the DEA's proposals. NCPDP thanks the DEA for their consideration of our comments. We welcome the opportunity to work with the DEA on these issues that involve or impact NCPDP standards and their use in retail pharmacy practices.

[1] National Council for Prescription Drug Programs. SCRIPT Implementation Recommendations. February 2023. Available at https://www.ncpdp.org/NCPDP/media/pdf/SCRIPT-Implementation-Recommendations.pdf.

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Respectfully,

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