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March 31, 2023

Scott A. Brinks
Diversion Control Division
Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

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

Mr. Brinks,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback on DEA's proposed rule: *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation*.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Overview

The proposed rules would provide safeguards for a narrow subset of telemedicine consultations—those telemedicine consultations by a medical practitioner that has: 1) never conducted an in-person evaluation of a patient; AND 2) that result in the prescribing of a controlled medication. For these types of consultations, the proposed telemedicine rules would allow medical practitioners to prescribe: 1) a 30-day supply of Schedule III-V non-narcotic controlled medications; and 2) a 30-day supply of buprenorphine for the treatment of opioid use disorder without an in-person evaluation or referral from a medical practitioner that has conducted an in-person evaluation, as long as the prescription is otherwise consistent with any applicable Federal and State laws.

Concerns with Timing of Enforcement

NCPA has concerns about the very narrow timeframe for pharmacies to prepare for implementation of this proposed rule, and that our members will not have time to be able to

become fully compliant. The DEA will receive comments on this proposed rule up until March 31. This is 41 calendar days before the May 11 deadline of the expiration of the PHE. In a best-case scenario, DEA will respond to all public comments in a final rule in three weeks from March 31, so this will leave approximately 20 days before the expiration of the PHE for all stakeholders to implement the final rule. This is not a workable deadline.

Alternatively, the proposed rule includes a provision that suggests a six-month transition of doctor-patient relationships from the use of telehealth prescribing flexibilities established during the COVID–19 public health emergency to the use of the prescribing authority set forth in this proposed rule. However, NCPA believes this six-month window will still be insufficient for members to be able to comply with the finalized rule. Several information systems updates will need to take place in pharmacy, and six months' time is insufficient.

Concerns on How Pharmacies and Pharmacists are Implicated

NCPA is unclear as to what, if anything, the DEA is asking pharmacists to do to comply with this rule, both technically and professionally. We ask DEA to be clear if the proposed rule creates new criteria for determining that a prescription is legitimate and that a pharmacist should refuse to fill any prescription issued from a telehealth visit not in compliance with this proposed rule. NCPDP's SCRIPT Implementation Recommendations should be adopted by e-prescribing stakeholders for identifying when a prescription is a telehealth prescription. We request NCPDP's SCRIPT Implementation Recommendations for identifying when a prescription is a telehealth prescription (excerpts that follow are from pages 27-28). It states that "The <*PrescriberPlaceOfService*> should be used to identify the prescriber/patient encounter…It is highly recommended that <*PrescriberPlaceOfService*> always be populated regardless of the place of service." Further, when a valid practitioner-patient relationship is required for prescribing via Telehealth, NCPDP recommends how it should be noted in an electronic prescription: "The <*PrescriberPlaceOfService*> should be used to identify the prescriber/patient encounter, values 02 and 10 are specific to Telehealth. Additionally, to help establish that practitioner/patient relationship exists, the date of the last in-person office visit should be placed in the <*MedicationPrescribed*> <*Note*> element as follows: "LastOfficeVisit:MMDDCCYY." CMS maintains the code set of place of service codes, including 02 (Telehealth provided other than in patient's home) and 10 (Telehealth provided in patient's home).

That being said, few *NewRx* or *RxRenewlResponse* messages populate the <*PrescriberPlaceofService*> field. This indicates that EHRs and prescribers will have significant workflow changes to provide the information the pharmacy needs to determine that a telemedicine visit occurred and that it complied with the proposed rule. Pharmacy systems receive this information, when sent, but may need time to build workflow alerts based on the medication prescribed. For example, if <*PrescriberPlaceOfService*> value of 10 is received, the system would need to alert the pharmacy to look at the date of last office visit in the <*MedicationPrescribed*> <*Note*>, or contact the prescriber and document that additional information, when the medication prescribed is a Schedule III-V non-narcotic controlled medications or buprenorphine for the treatment of opioid use disorder.

NCPA requests clarity on what is expected of pharmacies and pharmacists in this proposed rule, as the proposed rule is unclear. NCPA requests clarification on the following:

- Are pharmacies responsible for verifying that provider visits are being conducted via telemedicine and via in-person consultation? How do pharmacies do this? What is the documentation standard? Are pharmacies at risk of being audited by PBMs for failing to verify?
- Will pharmacies be responsible for verifying prescribers' and referring physicians' DEA registrations?
- Will a pharmacy be required to decline to fill a covered prescription and if the prescription cannot be filled is it deemed invalid and not eligible for forwarding to another pharmacy?
- Will a pharmacy be required to report the prescriber to DEA? What will be the manner of the report?

NCPA believes that pharmacists will be hesitant to fill controlled substance prescriptions in the absence of such clarity which delays initiation of MOUD. Further, NCPA believes that pharmacists should be allowed to assume that prescribers meet the requirements of this proposed rule, and that responsibility for compliance should fall exclusively on the prescribers. NCPA requests clarity that this proposed rule does not add any additional obligations for pharmacists. Rather, pharmacists should continue to use existing professional judgment and corresponding responsibility.

Logistical Issues of Pharmacists Obtaining Information

For pharmacists to comply with the rule, NCPA assumes (and requests DEA provide clarification on this) that pharmacists need to know: 1) a verification from the provider that a telemedicine visit has occurred; 3) provider licensure information for the state where the patient is located; 4) the patient's location; 5) who performed the in-person exam, where applicable; and 6) when and where the in-person exam was located, where applicable.

NCPA believes that these logistical challenges will create significant hesitancy among pharmacists to dispense controlled substances. **NCPA requests feedback from DEA on these logistical concerns.**

Further Clarifications or Provisions to Ensure Appropriate Access to Care

DEA invites comments concerning whether any clarifications or other regulatory provisions are warranted to ensure appropriate access to care, consistent with effective controls against diversion and otherwise consistent with public health and safety.

NCPA believes there is a need for some patients to have access to greater than 30-day supplies of Schedule III-V non-narcotic controlled medications without an in-person evaluation or referral from a medical practitioner that has conducted an in-person evaluation, as long as the prescription is otherwise consistent with any applicable Federal and State laws via telemedicine.

Telemedicine continues to evolve, and some companies are now providing continuity of care and making the same physicians available to the same patients each encounter. Patients in rural areas would benefit from continued medical care in this manner. In these instances, continued care should be allowed and prescriptions should be allowed to be refilled. However, for the majority of patients, NCPA recommends that there be incentives for patients to find in-person, local providers when they need greater than the 30-day supply of these medications.

As stated above, NCPA believes that it is not the responsibility of pharmacists to police prescribers for purposes of this proposed rule. Such policing would contribute to an unfunded mandate and significant administrative burden on pharmacy.

Limitations of Prescriptions to FDA-Approved Indications

DEA is requesting comments on whether the rule should limit the issuance of prescriptions for controlled medications to the FDA-approved indications contained in the FDA-approved labeling for those medications. **NCPA opposes limiting prescriptions for controlled medications to the FDA-approved indications contained in the FDA-approved labeling for those medications, as off-label use is permitted.**

If the patient has demonstrated non-adherence, refills may need to be restricted. There needs to be a way for the pharmacist to communicate with the prescriber in these instances, which may be difficult with some telemedicine providers, especially if they have multiple virtual or brick-and-mortar practice sites. NCPA suggests that DEA and HHS incentivize patients to seek out local providers for treatments of these medications lasting longer than 30 days.

Practitioner Recordkeeping Obligations

This proposed rule would require a practitioner to maintain a written or electronic log for each prescription issued pursuant to a telemedicine encounter indicating the date the prescription was issued; the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; if issued through a qualifying telemedicine referral, the name and NPI of the referring practitioner, a copy of the referral and any communications shared pursuant to § 1306.31(d)(3)(i)–(iii); and all efforts to comply to access the PDMP system (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database). DEA invites comments on the proposed practitioner recordkeeping obligations.

Practitioner and patient location. This proposed rule would require a practitioner to maintain a written or electronic log for each prescription issued pursuant to a telemedicine encounter indicating, among other things: the address at which the practitioner, and the city and State in which the patient, are located during the telemedicine encounter.

NCPA requests that these same addresses are provided to the pharmacy in order to determine compliance with this rule as well as state and other applicable rules and health plan reimbursement policies. Members have told NCPA that Optum is auditing pharmacies on whether prescriptions have full addresses for both the prescriber and the patient. Specifically, a

prescriber should not transmit as their location for the telemedicine encounter on an e-prescription:

1. Fabricated addresses
2. Proxy addresses, e.g., rented post office boxes
3. Telemedicine practitioners', or their EHR vendor's, corporate address

Our members recognize that the first of these three categories is unquestionably inappropriate and impermissible, and when they encounter such instances, they inform those who are responsible that what they have done is unacceptable and admonish them that they should cease said practice. The second and third categories, however, have proven to be more difficult for our members to deal with.

However, NCPA also recognizes that in some limited instances, telemedicine providers are in marginalized communities, and the address of the telemedicine provider is their home. So there may be a safety concern for these providers to disclose their actual address.

NCPA requests that DEA recognize in the final rule that greater disclosure and increased transparency of practitioner and patient addresses is needed, while at the same time recognizing when rare exceptions could be warranted.

PDMP Data. This proposed rule would require all practitioners prescribing pursuant to § 1306.31 to review the PDMP data for the State in which the patient is located, where available, for the last year. DEA estimates many practitioners already check PDMP prior to issuing a prescription for a controlled substance for a variety of reasons, so DEA believes that any additional administrative cost is minimal. **NCPA supports this requirement. However, NCPA is wary of creating additional administrative burden for providers if DEA is considering a federal PDMP.**

Thirty-Day Supply

Additionally, based on the available information, to balance benefits and risks to individual and public safety, DEA is proposing a 30-day maximum supply under proposed § 1306.31(c)(2) for the controlled substance being prescribed via telemedicine prior to an in-person evaluation being conducted. DEA seeks comment that provides evidence that an alternate maximum day supply would be more appropriate than the one proposed in this rulemaking.

While NCPA agrees that there is a need for touchpoints with buprenorphine treatment, several patient populations, like those living in rural areas or those without access to transportation, will find getting a provider visit every 30 days challenging. Further, while NCPA understands that DEA's intention is to protect access to medically necessary buprenorphine, requiring a maximum 30-day supply for telemedicine encounters may be arbitrary and restrict needed access for certain patient populations, like those living in rural areas or those without access to transportation. Further, requiring a maximum 30-day supply may create an unintended consequence of patients seeking controlled substances through the black market.

NCPA requests that DEA remove the provisions of the proposed rule that apply to buprenorphine. NCPA has been unable to find evidence of diversion of buprenorphine, and supports continued access of this medically necessary drug. We are concerned that this proposed rule does not address concerns with the criminal market, but would instead serve to deter patients from ultimately seeking care within the legitimate supply chain, and instead turn to online solutions and potentially illegal online pharmacies.

NCPA supports DEA and HHS using the opioid PHE to preserve access to buprenorphine, and to remove the in-person requirement for use of buprenorphine in this proposed rule. The additional compliance and verifications challenges associated with this proposed rule are outweighed by the need for those suffering from opioid use disorder to be able to access buprenorphine.

Long-term care and hospice. **NCPA also supports Long Term Care residents and hospice patients being carved out of the thirty-day supply proposal.** There could be scenarios where patients at the end of life need these drugs and orders may need to come from a member of a practice who has not personally conducted an evaluation.

Additional Safeguards

DEA also seeks comments about additional safeguards or flexibilities that should be considered with respect to this rule.

NCPA believes that DEA should not interfere with clinically appropriate prescribing and dispensing of controlled medications within practitioners' and pharmacists' scope of practice. While the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 amended the Controlled Substances Act (''CSA'') in part by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the internet, its intent was not to limit necessary care and burden community pharmacies and their patients.

Pharmacist as referring provider

NCPA recommends that pharmacists be allowed to be referring providers for purposes of this proposed rule. Ten states (California, Idaho, Massachusetts, Montana, New Mexico, North Carolina, Ohio, Tennessee, Utah, and Washington State)[1] have given controlled substances prescribing authority to pharmacists, and pharmacists can prescribe buprenorphine in those states as well. Pharmacists can also conduct an in-person evaluation for these patients within their scope of practice and as permissible within state law.

Pharmacists as providers for opioid abuse services

Pharmacists are key players in counseling treatment for SUDs and provide many opioid abuse services, such as drug management and referral to counseling treatment. But negative reimbursement pressure from insurers and pharmacy benefit managers and the inability of

[1] See "Mid-Level Practitioners Authorization by State," *Department of Justice.* December 2, 2022. Available at: https://deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf

pharmacists to bill Medicare Part B as providers limits the positive impact pharmacists can provide to help combat the opioid crisis.

Due to independent pharmacists' expertise in medication management and frequent interaction with their patients, they are equipped to educate patients about their use of controlled substances. Further, independent pharmacists can alert patients to possible consequences and, if needed, begin to motivate them to take steps to change their behavior. Patients currently choose to seek medication-related services from their community pharmacist for many reasons, as they have established relationships with their community pharmacists. Allowing a patient to seek these services from their pharmacist increases the odds that medication adherence will occur. **Therefore, we ask that DEA advise CMS to formally recognize pharmacists as providers eligible to furnish those opioid abuse reduction services in their scope of practice and claim reimbursement under Medicare Part B.**[2]

Conclusion

NCPA thanks DEA for the opportunity to provide feedback, and we stand ready to work with DEA to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association

[2] 42 U.S.C. 1395w-4.