National Organization of
State Offices of Rural Health

March 30, 2023

Comments on Proposed Rulemaking for Expansion of Induction of Buprenorphine via Telemedicine Encounter

Introduction

On March 1, 2023, the Drug Enforcement Administration (DEA) of the Department of Justice released, for comment, a notice of proposed rulemaking addressing the *Expansion of Induction of Buprenorphine via Telemedicine Encounter* (Docket No. DEA–948). This proposed guidance supplements related proposed guidance in Docket No. DEA–407 and provides specific requirements for the telemedicine prescribing of buprenorphine. In this communication, the National Organization of State Offices of Rural Health (NOSORH) makes specific comments and recommendations related to the proposed rulemaking.

NOSORH was established in 1995 to assist State Offices of Rural Health (SORHs) in their efforts to improve access to, and the quality of, health care for over 60 million rural Americans. All 50 states have a SORH, and each SORH helps their state's rural communities to build effective health care delivery systems.

NOSORH knows that the severity of the opioid epidemic in rural communities has reached crisis levels. NOSORH understands that the needs of non-metropolitan communities are distinct from those of urban communities, and that effective approaches to opioid use disorder (OUD) prevention and treatment will be different. NOSORH believes that several of the provisions contained in DEA's proposed rulemaking would create unnecessary barriers for effective medication treatment of opioid use disorder (MOUD) in rural communities. NOSORH is particularly concerned with provisions in the proposed rulemaking which would restrict telemedicine practice that has been permitted throughout the three years of the COVID-19 Public Health Emergency (PHE).

NOSORH's comments and recommendations are detailed below.

Discussion

The opioid epidemic in the United States has had an inordinate impact on rural communities. At the same time, the availability of treatment services for OUD in rural areas is limited:

- https://pubmed.ncbi.nlm.nih.gov/25905856/

Telemedicine approaches to the provision of MOUD in rural areas have been shown to be an effective intervention for rural communities:

- https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783548

During the COVID-19 PHE, telemedicine, including interstate telemedicine practice, was facilitated by flexibilities under the PREP Act and its subsequent amendments.

- https://telehealth.hhs.gov/licensure/licensure-during-covid-19-public-health-emergency

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44648 Mound Road, #114 | Sterling Heights, MI 48314-1322 | TEL 586-336-4627 | FAX 586-336-4629

Under these declarations, providers were allowed to conduct a broad telemedicine practice to ensure continued access to health care during the COVID-19 pandemic. Some of these flexibilities have been made permanent, while others have been temporarily extended through December 31, 2024.

- https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/policy-changes-after-the-covid-19-public-health-emergency

Of particular importance are the flexibilities extending provision of behavioral telemedicine.
NOSORH believes that the flexible telemedicine rules of the COVID-19 pandemic with respect to buprenorphine prescribing and dispensing have shown to be effective in both improving access to MOUD, improving patient outcomes, and preventing diversion of this medication:

- https://www.cms.gov/newsroom/press-releases/increased-use-telehealth-opioid-use-disorder-services-during-covid-19-pandemic-associated-reduced'

NOSORH believes that the telemedicine flexibilities of the COVID-19 PHE have improved access of rural communities to MOUD, and that these flexibilities should be extended, to the degree possible, into the post-PHE era.

NOSORH notes that *interstate* telemedicine practice is a complex issue. Many states permit interstate medical practice through interstate licensure compacts and appropriate in-state licensing. Of particular importance is the Interstate Medical Licensure Compact, subscribed to by more than 30 states:

- https://www.ama-assn.org/system/files/issue-brief-licensure-telehealth.pdf

Studies have shown that, in general, flexible telemedicine policies have not increased provider practice problems:

- https://ciceroinstitute.org/wp-content/uploads/2023/02/Few-Disciplinary-Issues-with-Out-of-State-Telehealth-Report.pdf

With the end of the COVID-19 PHE, some of the interstate practice permissions, both Federal and state, will be withdrawn. NOSORH believes that, after the end of the PHE, interstate telemedicine buprenorphine visits and prescribing should be permitted to the maximum possible under state and federal requirements.

The proposed rules would significantly restrict the provision of telemedicine-based MOUD compared to what was permitted during the three years of the COVID-19 PHE. The restrictions will particularly affect MOUD in rural communities and have deleterious impact on the health of rural residents with opioid use disorders. NOSORH finds that two provisions in the proposed guidance are particularly concerning:

- **Face to face visit requirement**: The proposed rule requires a face-to-face encounter with a health care provider within 30 days of prescribing buprenorphine. This provision is problematic for many rural communities. A 2022 study indicated that the average wait time for an appointment with a new primary care provider was 26 days:
    - https://patientengagementhit.com/news/average-patient-appointment-wait-time-is-26-days-in-2022

  Wait times in non-metropolitan areas were substantially longer. In addition, many rural areas are Federally designated Health Professional Shortage Areas (HPSAs), locations with less than half the primary care providers needed by the local community. These shortages could delay access

to a provider even longer. A 30-day requirement for a face-to-face visit would, in many cases, be impractical.

- **Telemedicine prescription labeling requirement**: The proposed rule requires special labeling of telemedicine-based prescriptions. This could also create difficulties for both providers and patients. There have been reports indicating that patients have been stigmatized by this type of labeling. Further, some pharmacies have refused to fill prescriptions labeled in this manner, fearing potential exposure to liability.

Recommendations

NOSORH recommends that the DEA continue the flexibilities granted for telemedicine-only based buprenorphine prescribing that were in effect during the COVID-19 Public Health Emergency. More specifically, NOSORH recommends that DEA:

- Maintain existing rules adopted during the pandemic *permitting telemedicine only visits* for buprenorphine prescription and refills.
- Permit prescription of *more than 30 days' supply of buprenorphine*.
- Permit use of *audio-only telemedicine visits* for prescription refill.
- *Prohibit the labeling of* prescriptions and refills ordered after a telemedicine visit as "*telemedicine prescriptions*".
- *Require that telemedicine prescriptions be conditioned upon consultation with Prescription Drug Monitoring Program (PDMP) systems*. If, for any reason, these systems are not available at the time of prescription, permit prescription of a limited supply of medication, to be supplemented when PDMP consultation has been completed.

NOSORH also recommends that DEA not create any additional restrictions on the interstate telemedicine prescribing of buprenorphine but permit such prescribing to be conducted as permitted by state interstate agreements and other Federal guidance.

We appreciate the opportunity to submit comments. Please reach out to me at tammyn@nosorh.org or 919.215.0220 with questions, for discussion or for additional information.

Thank you.

Tammy Norville, CEO
National Organization of State Offices of Rural Health
Phone: (888)391-7258 ext. 105
Mobile: (919) 215-0220
tammyn@nosorh.org | www.nosorh.org