March 31, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
800 K Street N.W., Suite 500
Washington, D.C. 20001

Dear Administrator Milgram,

On behalf of the nation's Medicaid Directors and Medicaid Medical Directors, the National Association of Medicaid Directors (NAMD) and National Medicaid Medical Directors Network (MMDN) are pleased to offer comments on the proposed rule, Expansion of Induction of Buprenorphine via Telemedicine Encounter [DEA–948].

The proposed rule would allow providers to prescribe a 30-day supply of buprenorphine for opioid use disorder (OUD) without an in-person evaluation; patients would need to receive an in-person evaluation to continue their prescription beyond 30 days. We appreciate that this rule represents an expansion of telehealth flexibilities compared to the time before the COVID-19 public health emergency but are concerned about the access issues that may be caused by requiring an in-person evaluation after 30 days. We also have concerns about potential enforcement liability for Medicaid agencies, as it would take significant time and resources to establish a process for ensuring providers have met the requirements in the proposed rule before approving claims.

NAMD is a bipartisan, nonprofit, professional organization representing leaders of all Medicaid agencies across the country. NAMD represents, elevates, and supports state and territorial Medicaid leaders to deliver high value services to the millions of people served by Medicaid and CHIP so they can achieve their best health and thrive in their communities.

The Medicaid Medical Directors Network (MMDN) works to advance the health of Medicaid beneficiaries across the country by providing a nexus for senior clinical leaders to discuss their most pressing needs and share best practices. The MMDN conducts multistate projects on pressing topics, builds on research and quality improvement efforts, and leverages collective experience to support and advance both state and national work.

Requiring an In-Person Visit After 30 Days May Restrict Access

Our nation is in the midst of an overdose crisis, with the CDC estimating approximately 108,000 overdose deaths from October 2021 to October 2022. Despite significant work at the federal, state, and community level to stem the tide, overdose deaths have almost

doubled since 2019, representing a tragic backsliding during the COVID-19 pandemic. This crisis has largely been fueled by the rise of fentanyl and other opioids.

Buprenorphine has consistently been shown to be one of the most effective treatments for opioid use disorder (OUD), with a recent study showing a 76 percent reduction in overdose risk at three months and a 59 percent reduction at 12 months for individuals who received buprenorphine or methadone, compared to individuals who did not receive treatment. Still, many people with OUD lack access to this medication.

During the COVID-19 pandemic, the DEA temporarily lifted the Ryan Haight Act's requirement that providers conduct an in-person evaluation before prescribing a controlled substance. Research during the pandemic suggests that these flexibilities significantly reduced the risk of overdose and did not lead to increased misuse of buprenorphine.

In this rule, the DEA proposes to allow providers to prescribe a 30-day supply of buprenorphine without an in-person evaluation, following the end of the COVID-19 public health emergency in May. Patients would need to receive an in-person evaluation to continue their prescription beyond 30 days. While this proposal represents increased flexibilities as compared to the time before the pandemic, **Medicaid Directors and Medicaid Medical Directors are concerned that the resumption of the in-person visit requirement will restrict access, especially for patients in rural and frontier areas.**

Medicaid Directors report that the many of their members live in areas without providers who prescribe buprenorphine, meaning that patients often must travel long distances to receive an in-person evaluation. This represents a major barrier to care, especially for individuals who lack access to affordable transportation options, and may discourage Medicaid members from pursuing buprenorphine treatment.

Through the Consolidated Appropriations Act of 2023, Congress removed the "X-waiver" requirement for providers to prescribe buprenorphine. Medicaid agencies have also taken steps to increase access to medications for opioid use disorder (MOUD). Paradoxically, this proposed rule would restrict access to buprenorphine when overdose deaths are at all-time high, as legislators and clinicians are pushing to remove barriers to MOUD.

The DEA is statutorily required to create a special registration process to waive the in-person requirement for registered prescribers but has not yet done so. If the DEA moves forward with this special registration process, **NAMD and MMDN urge the DEA to ensure this process is as streamlined as possible and does not include training requirements beyond what is already required through the MATE (Medication Access and Training Expansion) Act.** Research suggests that overdose mortality risks associated with buprenorphine are low and that most people who use

diverted buprenorphine do so to avoid or ease withdrawal symptoms, maintain abstinence from other drugs, or to reduce their use of other drugs. As an alternative to establishing this special registration process, **the DEA could consider other strategies to increase access to buprenorphine which ensuring providers are legitimate, such as allowing a video-assisted visit in lieu of an in-person visit and checking the credentials of prescribers.**

Medicaid Agencies Should Not Be Held Liable for Enforcement

This rule would establish a complex regulatory construct in which providers could prescribe a 30-day supply of buprenorphine before an in-person visit but must conduct an in-person evaluation before refilling that prescription. The DEA also proposes new recordkeeping requirements for buprenorphine prescribers, including a requirement that prescribers document their attempts to check Prescription Drug Monitoring Program (PDMP) databases and whether the encounter was audio-only, audio-visual, or in-person. The DEA asserts that these recordkeeping requirements are essential for proper oversight.

If the DEA moves forward with this proposed rule, they should clarify that Medicaid agencies will not be held liable for enforcing these provisions during the claiming process. Medicaid agencies may not currently distinguish between audio-only, audio-visual, and in-person visits in their claiming systems, which would make it very difficult to check if a provider has conducted the required in-person visit before approving a claim for a refill. It may also be challenging to ensure providers are complying with the PDMP and recordkeeping requirements. Building out these processes would require significant time and resources on the part of Medicaid agencies, so the DEA should clarify that Medicaid agencies will not be held liable for ensuring providers are compliant with this proposed rule before approving claims.

Thank you for the opportunity to provide comments on this proposed rule. NAMD and MMDN look forward to continuing to work with the DEA to ensure Medicaid members have access to medications for opioid use disorder, including buprenorphine.

Sincerely,

Allison Taylor

Cynthia Beane, MSW, LSCSW

Allison Taylor
NAMD Board President
Director of Medicaid
Indiana Family and Social Services Administration

Cindy Beane
NAMD Board President-Elect
Commissioner
West Virginia Department of Health and Human Resources

Mohammad Dar, MD
MMDN Chair
Senior Medical Director
MassHealth