James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
james.madara@ama-assn.org

February 27, 2025

Mr. Derek S. Maltz
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Subject: Docket No. DEA-948; Expansion of Buprenorphine Treatment via Telemedicine Encounter

Dear Acting Administrator Maltz:

On behalf of the medical student and physician members of the American Medical Association (AMA), I write in strong support of implementing the final rule issued by the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration expanding buprenorphine treatment for opioid use disorder (OUD) via telemedicine encounters. Implementing this final rule without further delay will provide physicians and patients with important confirmation that they can rely on telemedicine services to support OUD treatment and help prevent potentially dangerous disruptions in continuity of care. The AMA views the final rule as a significant improvement from the 2023 notice of proposed rulemaking. It expands the proposed initial 30-day prescription limitation to six months, removes the proposed requirement for an in-person medical evaluation to issue additional prescriptions, introduces reasonable safeguards to protect against diversion, and avoids the burdensome recordkeeping requirements that were initially proposed.

Whether audio-only, audio-visual, or in-person care, physicians embrace their ethical and professional obligation to provide high-quality, evidence-based care that relies on thorough assessments and sound decision-making. The federal flexibilities initiated by the Trump Administration in 2020 that underpin this final rule demonstrated beyond a doubt that physicians can thoroughly assess a patient with OUD via a telemedicine encounter. This includes determining whether a prescription would be clinically appropriate during an initial telehealth visit. For individuals with OUD, telemedicine showed multiple positive impacts, including increases in initiation with buprenorphine and treatment retention without increases in overdose.[1,2] Physicians' clinical experience also demonstrated that telemedicine allows a physician to conduct pill counts, monitor toxicology screens and ensure medication adherence, or identify aberrant behaviors requiring changes in therapy. Prescribing buprenorphine through telehealth visits provides the opportunity to reach remote and underserved communities, as well as patients who may be

[1] Hammerslag LR, Mack A, Chandler RK, et al. Telemedicine Buprenorphine Initiation and Retention in Opioid Use Disorder Treatment for Medicaid Enrollees. *JAMA Netw Open.* 2023;6(10):e2336914. doi:10.1001/jamanetworkopen.2023.36914

[2] Impact of Telemedicine on Retention in Medications for Opioid Use Disorder (MOUD) Treatment With Buprenorphine in the Times of COVID-19 Pandemic: A Retrospective Chart Review. Journal of Rural Mental Health. 2022, Vol. 46, No. 2, 75–81 https://doi.org/10.1037/rmh0000206

unable to obtain in-person care because of distance to a medical practice or opioid treatment program, transportation costs, health impairments, stigma, childcare, or employment.

Implementing the final rule expanding buprenorphine treatment via telemedicine encounters does not mean, however, that individuals with OUD will automatically secure access to evidence-based treatment with buprenorphine. The AMA continues to advocate for a reduction in all barriers to care. Some of the major barriers that continue to contribute to the nation's overdose and death epidemic include health insurance company use of prior authorization and their failure to comply with state or federal mental health and substance use parity laws.

Another barrier is fear of the DEA and its suspicious order reports (SORs) among entities that distribute and dispense buprenorphine. The AMA appreciates that the DEA has attempted to calm these fears, but additional action is needed. Last year, the AMA wrote to the DEA that state opioid litigation settlement agreements with opioid manufacturers unintentionally added to the stigma and scrutiny of buprenorphine to treat OUD and urged the previous administration to remove buprenorphine from SOR requirements. Because the agreements list buprenorphine as a potential "red flag" medication, distributors and pharmacies restrict access to buprenorphine out of fear of having to submit SORs to the DEA if the distributors or pharmacies provide or order quantities above historical averages–even if the increased prescribing is due to expanding OUD treatment to a new patient population. These fears may not be justified in the eyes of DEA, but we have received multiple reports from physicians and pharmacy colleagues that distributors are delaying or suspending orders of buprenorphine because of fear that they will be investigated by the DEA for suspicious orders. The net result is that patients with OUD suffer delays and denials of care—situations that cause harm and could lead to tragedy.

The AMA continues to urge that the DEA make clear that no action will be taken by the federal government against any party solely for not including buprenorphine products approved by the Food and Drug Administration to treat OUD in SOR threshold reporting. Non-enforcement of SOR requirements for buprenorphine products will increase access to buprenorphine for the treatment of OUD—a central tenet of the SUPPORT Act, landmark legislation signed by President Trump in 2018.

Thank you for your consideration of our recommendations to implement the final rule on buprenorphine treatment on March 21 as indicated in this notice and to further lower barriers to care for patients with OUD by removing buprenorphine from SORs. If you have any questions, please contact Margaret Garikes, AMA's Vice President of Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,

James L. Madara, MD