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

March 31, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA-948, Expansion of Induction of Buprenorphine via Telemedicine Encounter

Dear Administrator Milgram:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I write to respond to the notice of proposed rulemaking issued by the Drug Enforcement Administration (DEA) concerning prescribing of buprenorphine to treat opioid use disorder (OUD) based on telemedicine encounters. The AMA deeply appreciates the prescribing and treatment flexibilities that the DEA authorized during the COVID-19 Public Health Emergency (PHE), including the ability to prescribe medications to treat OUD based on audio-video and audio-only patient visits. We also appreciate the DEA's support for elimination of the X-waiver requirements and its efforts to increase access to medications for OUD.

The AMA agrees with the DEA proposal to continue to allow buprenorphine induction based on telemedicine encounters after the end of the COVID-19 PHE. The AMA also appreciates the DEA's reliance on the Centers for Medicare & Medicaid Services definition of "interactive telecommunications system," which includes audio-only technology.

During 2020, the first year of the PHE, the AMA assisted in a survey, led by the American Academy of Addiction Psychiatry in collaboration with other organizations, that obtained responses from more than 1,000 physicians and other health professionals who prescribed buprenorphine to treat OUD about their experiences with the PHE flexibilities. The survey confirmed that these physicians adapted to quickly provide high-quality, evidence-based care to their patients with OUD, but that this care was only possible due to the ability during the PHE to treat patients with OUD via audio-video or audio-only visits and issue prescriptions based on these visits. A key finding was that more than 80 percent of surveyed X-waivered physicians, physician assistants, and nurse practitioners who treat patients with OUD wanted virtual visits and other telehealth options to continue after the end of the PHE.

The AMA supports hybrid models of health care delivery that include a mix of telemedicine, in-person care, and remote monitoring. It is critically important that the DEA extend the timeframe for patients to receive in-person visits significantly, however. The proposed DEA requirement for patients being treated for OUD to have an in-person visit within 30 days of their initial buprenorphine prescription to obtain refills so that they can continue taking the medication is far too short. The AMA recommends that this timeframe be extended to at least six months.

A 2021 study in the *Journal of Substance Use and Addiction Treatment* described significant barriers that patients must overcome to obtain in-person visits for OUD treatment. These barriers include racial disparities in access to buprenorphine versus methadone treatment, long wait times for treatment, stigma within the medical community regarding drug users and lack of education about OUD treatments, and patients experiencing unstable housing and lack of transportation and childcare. The article observed that during the PHE, telemedicine allowed patients seeking buprenorphine to be rapidly started on treatment without delaying initiation until an in-person evaluation was possible. It indicated that, in upstate New York, before the PHE patients with OUD had an average wait of 12 weeks for an in-person visit. The end of the PHE will not suddenly eliminate these barriers.

A new study published in JAMA Psychiatry by researchers at the Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services, and the National Institutes of Health lends further support to the AMA recommendations. The study concluded that between September 2019 and February 2021, patients receiving treatment for OUD through telehealth had 33 percent lower adjusted odds of a fatal overdose than those receiving no medication treatment, compared with a 38 percent lower risk of a fatal overdose among patients being treated in-person and 59 percent among those in certified opioid treatment programs.

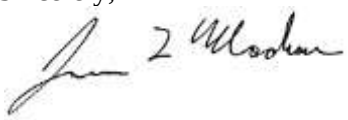
We have grave concerns that requirements for an in-person visit within 30 days would cause many patients who were started on buprenorphine to have their prescriptions lapse, leading to more overdose deaths instead of closing the treatment gap. There are many opportunities for physicians prescribing buprenorphine based on telemedicine visits to assess patients' medication adherence and other aspects of their OUD management before there is an opportunity for an in-person visit. They can observe patients administering their medication via video, order laboratory tests and review results, and engage in remote monitoring of patient care.

The AMA is also concerned that the DEA has significantly overstated the risks from buprenorphine diversion and overuse. A recent CDC study published in *JAMA* concluded that "actions to facilitate access to buprenorphine-based treatment for opioid use disorder during the COVID-19 pandemic were not associated with an increased proportion of overdose deaths involving buprenorphine."

We have serious concerns that the recordkeeping requirements of the proposed rule will diminish its effectiveness in increasing access to buprenorphine for patients with OUD. Under the proposed rule, physicians would be required to maintain records indicating that they checked the prescription drug monitoring program before issuing a prescription, whether the patient encounter was via audio-video or audio-only technology, and the reason for an audio-only encounter. The rule indicates that DEA requires that these records be maintained for "investigation purposes." We are concerned that pharmacies may demand records and may refuse to fill valid prescriptions for buprenorphine unless the pharmacist has access to them, as well as information about whether the patient had an in-person evaluation within the required timeframe. Although the DEA cites claims data from the Medicare Part D program indicating that only 0.43 percent of initial prescriptions for buprenorphine were based on telemedicine visits, demands for records on in-person or telemedicine visits could extend to a much wider patient population and serve as a significant new barrier to treatment for OUD. **Current DEA requirements for records related to prescribing and dispensing of controlled substances should be sufficient if the agency needs to conduct an investigation. The AMA encourages the DEA to adopt a more flexible approach.**

Thank you for your consideration. If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at Margaret.Garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD