AMA
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The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I write to thank you for your leadership in working to end the national epidemic of opioid-related overdose and death. As the largest professional association for physicians and the umbrella organization for state medical associations and national medical specialty societies, the AMA especially commends your Department's focus on increasing access to medication-assisted treatment (MAT) for patients with opioid use disorder (OUD). Together, these initiatives represent an unprecedented Department-wide effort to close the OUD treatment gap, including:

- Medicare bundled payments established by the Centers for Medicare & Medicaid Services;
- Scientific recommendations from the Food and Drug Administration to encourage innovation and development of novel drugs for MAT;
- Studies supported by the National Institute on Drug Abuse (NIDA) to advance the science demonstrating the effectiveness of MAT;
- Telehealth flexibilities for MAT put in place by the Substance Abuse and Mental Health Services Administration during the COVID-19 public health emergency; and
- Outreach to the physician community by the Assistant Secretary for Health and the Surgeon General encouraging physicians to become certified to provide MAT with buprenorphine to their patients.

Notwithstanding our strong support and appreciation for all of these important initiatives, the truth of the matter is that the wide gap between the number of patients with OUD who would benefit from MAT and the number who are receiving it has persisted, and abundant barriers remain to closing this gap. Foremost among them is the requirement for physicians to obtain a special registration from the U.S. Drug Enforcement Administration (DEA) and subject themselves to what has been an overly burdensome and stigmatizing regulatory and recordkeeping regime in order to prescribe buprenorphine to their patients.

To eliminate this barrier, the AMA strongly recommends that the Administration support and work to enact H.R. 2482, the "Mainstreaming Addiction Treatment Act." This legislation, referred to as the MAT Act, would eliminate the need for physicians to obtain a waiver from the DEA to provide MAT in their practices. They would no longer need to take an 8-hour training course, limit the number of patients to whom they can provide MAT, maintain special records of those patients, and be subject to DEA audits of their compliance with the MAT waiver regulatory requirements. Physicians working with

their patients to manage other medical conditions could also treat them for OUD without being subjected to a separate and burdensome regulatory regime. Physicians could have other physicians who are covering for them when they are away from the office manage their patients being treated with buprenorphine whether or not these physicians also have a special waiver to provide this care.

The effectiveness of long-term treatment with MAT in allowing patients with OUD to lead satisfying, productive lives means that many opioid-related deaths could be prevented if more patients received evidence-based therapy. It is estimated that more than two million Americans need treatment for OUD, but fewer than 90,000 practitioners have met the federal requirements to prescribe office-based buprenorphine to their patients, and only a small percentage of those 90,000 practitioners actively provide buprenorphine in-office for the treatment of OUD. According to NIDA, fewer than 20 percent of those who need treatment for OUD are receiving it. A 2019 National Academies of Sciences, Engineering and Medicine (NASEM) report, "Medications for Opioid Use Disorder Save Lives," highlights key barriers to expanding the use of MAT under current law.

Barriers to Increasing Physician Provision of MAT

Stigma: There are high levels of stigma toward individuals with OUD and medications that treat OUD among the public and health professionals. Negative public attitudes toward patients with OUD exceed those for other medical conditions, including mental illness. A 2016 national survey found that more than three-quarters of respondents blamed people with OUD for their substance use. Stigma toward people with OUD is intertwined with other stigma based on race and social class. Stigma toward medications used to treat OUD is grounded in a false narrative that they substitute one drug for another. Stigma leads to feelings of shame and curtails treatment-seeking, and erodes support for patients who do seek treatment. It also makes some health professionals less willing to offer treatment or to be listed in MAT provider directories. Increasingly, physicians are employees, and they may have little leverage with employers such as health care systems and private equity firms to overcome the stigma associated with individuals with OUD and the medications that treat OUD in order to devote practice resources to compliance with DEA waiver requirements, be listed on MAT provider directories and attract more patients with OUD to the practice, and invite special audits by the DEA. Instead of helping to eliminate stigma, the waiver requirements may reinforce and amplify it because they place people with OUD, medications to treat OUD, and physicians who provide MAT into a special DEA category seemingly at exceptionally high risk for abuse.

Fear: Physicians are extremely reluctant to invite the scrutiny of the DEA by pursuing a waiver to treat OUD patients with buprenorphine. They fear that the DEA would take punitive action in response to innocent mistakes, and that DEA agents with weapons would enter their practices and frighten patients and staff. The DEA is a law enforcement agency, not a health care agency. Waivered physicians who have experienced DEA audits have expressed concerns that DEA auditors do not understand medical records and do not conduct audits appropriately. They have also described the DEA's approach as "threatening." These concerns have been heightened by raids and criminal investigations of waivered physicians by the DEA and state attorneys general. Recently, to its credit, the DEA has conducted outreach to physicians in an effort to mitigate these fears, and the AMA has assisted DEA in this effort as part of a much larger effort by the AMA to remove stigma from OUD treatment. Removing the DEA requirements would help allay physicians' concerns and, in our view, increase the number of physicians treating patients with OUD.

Coverage: Despite clear evidence of the benefits of MAT to reduce cost, improve patient outcomes, reduce crime, and other public health benefits, insurance plans have placed restrictions on prescription drugs used in MAT and, even though some of them have been eliminated in recent years, the limitations in federal law for waivered physicians lend false credence to prior authorization, formulary exclusions, and other restrictions. A 2018 study cited by NASEM identified 14 state Medicaid programs as lacking a single facility that offers MAT and also accepts Medicaid coverage for OUD. Fragmentation in health care delivery and coverage compounds these effects. For example, continuity of Medicaid coverage can play a key role in supporting MAT coverage for people with OUD who are transitioning from the criminal justice system back to the community, a period of time that, absent continued MAT coverage, places individuals at extremely high risk of overdose death. Similarly, women who have Medicaid coverage for MAT during the perinatal period may be at high risk for maternal mortality once they lose their Medicaid coverage. A 2017 study of marketplace plans found that 14 percent did not cover any formulations of buprenorphine/naloxone. Plans were also more likely to require prior authorization for office-based buprenorphine or naloxone than for short-acting opioid pain medications. As the epidemic continues to worsen, **the AMA strongly urges HHS' support to help remove all administrative and other barriers to MAT.**

Disparities: Health care disparities that exist throughout the U.S. health care system are magnified in the lack of access to MAT. Rural communities have been hit hard by the epidemic of opioid overdose deaths, yet a 2019 *JAMA* article found that 71 percent of rural counties lacked a single waivered practitioner. Many of these counties are underserved in other respects as well, with many rural hospitals having closed and scarce access to primary care physicians, mental health and maternity care. Disparities in MAT access based on race and ethnicity have also been identified, with non-Hispanic white patients being more likely to receive MAT than other patients (also see *JAMA Psychiatry*).

Diversion: Untreated OUD can be lethal for patients, with the Centers for Disease Control and Prevention (CDC) reporting as many as 130 people per day dying from opioid overdoses in recent years, and recent media reports indicating that the COVID-19 pandemic has increased overdose rates in some states. Medications that treat OUD substantially reduce the risk of overdose and death, even in patients that previously experienced a nonfatal overdose, according to a NIDA study. Despite its effectiveness in treating OUD and lowering opioid-related mortality, concerns about diversion of buprenorphine have persisted. One aim of the DEA waiver process is to ensure that physicians who provide MAT also take steps to reduce diversion, but restrictions on MAT arising from the waiver requirement may actually increase the likelihood of diversion. Diversion of buprenorphine, where it exists, is more likely to be a symptom of inadequate access to MAT than due to a behavioral pattern of compulsive drug use in the face of continued harm that characterizes addiction.

Training Requirements for Provision of MAT

Some have argued that the training that is required under current law for physicians to obtain the DEA waiver that allows them to provide MAT to patients with OUD should be required for all physicians who are registered with the DEA to prescribe controlled substances as a condition of this registration. Although the AMA strongly agrees it is beneficial for physicians to become educated about prevention and treatment of OUD, the AMA disagrees that all physicians should be required by federal law to take an eight-hour course on this subject as a condition of DEA registration.

In 2015, the AMA made a commitment along with many of our partners in the state and specialty medical societies to help increase the number of physicians who become educated on OUD treatment, safe opioid

prescribing, pain management, and similar topics. Hundreds of these courses are accessible through the AMA-maintained website at https://www.end-opioid-epidemic.org/ and the AMA educational site at https://edhub.ama-assn.org/pages/opioid-cme-course. In 2018, more than 700,000 physicians and other health professionals accessed continuing medical education and other training resources provided by the AMA and state and medical specialty societies.

During the COVID-19 public health emergency, physicians have been clamoring for education on how to screen for, diagnose, and manage care for patients who may have the novel coronavirus. This is appropriate and it is what the medical profession does. When physician practices experience increases in patients with diabetes, they take courses to learn the current best practices in diabetes care, they consult with their colleagues, and make sure that they understand how to best ensure their patients' safety and well-being. Primary care and family physicians, for example, have done this as a regular part of their professional practice as new treatments become available for HIV, cardiovascular disease, diabetes, obesity or other chronic conditions.

It is difficult to understand the rationale for taking a costly educational requirement and imposing additional administrative burdens that have been a barrier to more physicians becoming certified and then providing MAT in their practices. **The AMA does not support extending that same requirement to all physicians who register with the DEA to prescribe controlled substances.** This could extend the scarcity of physicians providing MAT to being a scarcity of physicians to treat many other conditions for which patients benefit from controlled substances, including patients with COVID-19 who need to be ventilated, patients with cancer pain, patients with mental illness, and many others.

Conclusion

The best way to improve care for patients with OUD is to pass the MAT Act and start truly mainstreaming care for OUD patients instead of stigmatizing their care with additional training requirements and regulations that have no evidentiary basis. OUD is a life-threatening disease that leads to a 20-fold greater risk of early death due to overdose, infectious diseases, trauma, and suicide. As with any other disease, effective medications should not be withheld from people with OUD without any medical justification, yet current law is effectively rationing these medications so that they are only available to a small fraction of those who need them. The only remedy for this rationing of care is to change the law.

The AMA strongly urges the Administration to support and work to enact H.R. 2482, the "Mainstreaming Addiction Treatment Act." Thank you for your consideration.

Sincerely,

James L. Madara, MD