JAMES L. MADARA, MD



November 20, 2020

William T. McDermott Assistant Administrator for Diversion Control U.S. Drug Enforcement Administration 8701 Morrissette Drive Springfield, VA 22152

Dear Assistant Administrator McDermott:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I write to provide the U.S. Drug Enforcement Administration (DEA) with feedback from physicians about the prescribing and treatment flexibilities authorized by the DEA¹ during the COVID-19 Public Health Emergency (PHE). The AMA and the physician community have embraced these flexibilities and deeply appreciate their rapid implementation by the agency, especially the increased flexibility to prescribe controlled substances, including medications to treat opioid use disorder (OUD), based on audio-video and audio-only patient visits. The AMA is also grateful for DEA officials' ongoing outreach to our staff as we work to help physicians manage their patients' care during this PHE, and for its rapid actions to help alleviate patients' suffering, such as by increasing the manufacturing quotas for controlled substances that are needed by patients on ventilators and for which COVID-19 exacerbated supply shortages.

To learn more about physicians' use of the new DEA-authorized flexibility during the PHE and to consider the optimal policies after the COVID-19 PHE ends, the AMA conducted a survey of physicians who treat patients with painful conditions, and also assisted addiction specialty organizations on a second survey directed specifically at physicians and other health professionals who treat patients with OUD. The AMA survey included physicians specializing in pain medicine, anesthesiology, physical medicine and rehabilitation, hospice and palliative care, and others. There were 240 completed responses to the online survey, which was conducted from July 30, 2020–September 18, 2020.

A major finding of the survey is that 80 percent of physician respondents said that the flexibilities provided by the DEA during the COVID-19 pandemic have been either very helpful or somewhat helpful for treating patients with pain. The AMA strongly supports these flexibilities, including the authority "to allow DEA-registered practitioners to begin issuing prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation."²

¹ The DEA has provided several important updates, including <u>COVID-19 Prescribing Guidance</u>, <u>Registrant</u> Guidance on Controlled Substance Prescription Refills, Exception to Separate Registration Requirements Across <u>State Lines</u>, <u>Exception to Regulations Emergency Oral CII Prescription</u>, and <u>Q&A Remote Identity Proofing EPCS</u> at hospital/clinics.

² See https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19

An issue brief describing the key findings from the survey is available at the following link: https://end-overdose-epidemic.org/wp-content/uploads/2020/11/Issue-Brief-AMA-Survey-of-Pain-Management-Physicians-During-COVID-19-FINAL.pdf. In addition to support for the ability to treat patients with pain via telehealth and telephone visits, and to call in needed controlled substance prescriptions to the pharmacy, survey respondents described their concerns about barriers to care during the pandemic, including:

How concerned are you about each of the following during the	"Very"	<i>"Very"</i> +
COVID-19 pandemic?	concerned	"Somewhat"
		Concerned
Unnecessary delays caused by prior authorization	56%	77%
Unnecessary delays for patients who do not have a primary care	43%	80%
physician in accessing needed medications		
Unnecessary delays for patients receiving in-office procedures	42%	78%
Patients waiting too long before making an appointment if they	37%	78%
need treatment		
Unnecessary delays for new patients in accessing needed	34%	79%
medications		
Patients having sufficient medication so they can avoid additional	24%	67%
trips to the pharmacy		
Patients who are hesitant or afraid to go to a pharmacy to pick up	21%	58%
needed medications		
Patients' ability to fill prescriptions for controlled substances as	19%	58%
part of their pain care treatment		

We are thankful for the work of DEA to quickly recognize the need to ensure new flexibilities for physicians to help them address the above concerns. More than 90 percent of the survey respondents have been taking new patients during the pandemic, and they continue to find in-person physical examinations important for these new patients. For patients with an established relationship with a physician who is treating their pain, especially rural, elderly, and other patients who had difficulty getting to the physician's office even before the pandemic, telehealth and telephone visits are proving to be a lifeline. The increased flexibility from the DEA is particularly helpful given that the nation continues to face an increasingly complicated and deadly drug overdose epidemic.

A second survey, led by the American Academy of Addiction Psychiatry (AAAP) in collaboration with other organizations from July 15, 2020–August 15, 2020, obtained responses from more than 1,000 physicians, nurse practitioners, and physician assistants who prescribe buprenorphine and other medications that treat OUD. The survey confirmed that, during the COVID-19 pandemic, physicians and other health care professionals have adapted to quickly provide high-quality, evidence-based care to their patients with OUD, but this care was only possible due to the new flexibilities provided by the DEA, such as treating patients with OUD via audio-video or audio-only visits and issuing prescriptions based on these visits. A key finding of this survey is that more than 80 percent of X-waivered survey respondents who treat patients with OUD want virtual visits and other telehealth options to continue after the COVID-19 PHE. A report on the survey findings is available at https://www.aaap.org/wp-content/uploads/2020/10/COVID-29-Survey-Results-First-Glance_EW-10.15.pdf.

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It should be noted that the AAAP survey comes amidst a growing number of reports from more than 40 states about increasing drug overdose mortality.³ These state-level reports provide sobering context for data from the U.S. Centers for Disease Control and Prevention that nearly 74,000 Americans died from a drug-related overdose between 2019-2020, including nearly 40,000 from illicit fentanyl. The need for evidence-based care for the treatment of patients with OUD has never been greater.

The Secretary of Health and Human Services has declared two nationwide public health emergencies: the epidemic of opioid overdose deaths and the COVID-19 pandemic. Both PHE declarations were renewed in October 2020 and will continue at least into the year 2021. The opioid epidemic PHE declaration has been in effect for more than three years. The new survey data make it clear that, although the flexibilities provided by the DEA were first issued in conjunction with the COVID-19 PHE, they have become critical tools in the effort to bring an end to the opioid epidemic as well. There is an urgent need to ensure that patients with pain and patients with OUD receive evidence-based care, and this need will not cease with the end of the COVID-19 pandemic. The AMA strongly recommends, therefore, that all of the flexibilities that have been put in place by DEA during the COVID-19 PHE be kept in place at a minimum until both the COVID-19 and the opioid public health emergencies come to an end.

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

³ Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic. American Medical Association. Updated October 6, 2020. Available at https://www.ama-assn.org/system/files/2020-10/issue-brief-increases-in-opioid-related-overdose.pdf