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-407, Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

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 controlled substances in schedules III-V based on telemedicine encounters when the physician and patient have not had an in-person visit. The AMA appreciates the prescribing and treatment flexibilities that the DEA authorized during the COVID-19 Public Health Emergency (PHE), especially allowing "DEA-registered practitioners to begin issuing prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation." The AMA is also grateful for the DEA's rapid action to increase manufacturing quotas in response to concerns that we raised early in the pandemic about supply shortages for controlled medications that were needed by patients on ventilators.

The AMA generally agrees with the DEA proposal to continue to allow non-narcotic controlled substances in Schedules III-V to be prescribed based on telemedicine encounters after the end of the COVID-19 PHE. We recommend that the DEA make several important changes to this proposal before it is finalized:

1. **For patients receiving controlled substances under an existing patient-physician relationship, the in-person requirement should be extended to one year; new patients should be able to fill and renew prescriptions for at least six months before an in-person visit is required.**
2. **All medications in Schedules III-V should be able to be prescribed based on legitimate telemedicine visits, including medications defined as narcotics.**
3. **DEA should ensure continuity of care with an exceptions process for patients with certain conditions or a special registration that would allow qualified physicians to prescribe Schedule II medications based on telemedicine visits when medically necessary for their patients.**
4. **DEA should target more rigorous enforcement to outlier practices such as those addressed in the Ryan Haight Act that allow controlled substances to be prescribed based on a form with no meaningful patient-physician relationship.**
5. **Recordkeeping requirements should be modified.**

Each of these recommendations is discussed below.

Thirty-day Limitation

The AMA strongly supports hybrid models of health care delivery that include a mix of telemedicine, in-person care, and remote monitoring. In this specific instance involving a new patient visit via telemedicine, however, we stress that it is critically important that the DEA extend significantly the proposed required timeframe for patients to receive in-person visits. The proposal requiring an in-person visit within 30 days for patients being treated with controlled substances to gain access to a refill is far too short and ultimately, is unrealistic. **The AMA recommends that this timeframe be extended to at least six months for new patients and consideration be given that for patients receiving controlled substances under an existing patient-physician relationship, the in-person requirement be extended to one year.**

The AMA has participated in several research studies to better understand how the wide availability of telehealth services during COVID-19 has affected medical practice and patient care. This research is described in materials submitted to the Agency for Healthcare Quality and Research (AHRQ) Center for Evidence and Practice Improvement in July 2021 in response to its key questions on utilization and effectiveness of telehealth services during the pandemic. The AMA collaborated with other organizations on surveys of patients and physicians conducted by The Telehealth Initiative and in the COVID-19 Health Coalition Telehealth Impact Study. The AMA also partnered with Manatt Health on research to develop a "Return on Health" framework. The Return on Health research goes beyond examining telehealth services in isolation to articulate the value of digitally enabled care that combines virtual and in-person services to increase overall health and generate positive impacts for patients, physicians, payers, and society.

Even before the pandemic, many patients had trouble getting in to see physicians for in-person visits. Health care workforce shortages and inadequate health insurance networks make wait times even longer. In addition to capacity constraints for physician practices, patients may need a caregiver to accompany them or have their own caregiver responsibilities; they may face transportation barriers, difficulty in getting time off from work, and have health-related social needs, physical and mental health challenges, or disabilities that make it hard to get to in-person visits. Patients in rural and underserved communities face even more hurdles to access in-person care.

We have grave concerns that requirements for an in-person visit within 30 days would prevent many patients from beginning medication therapy due to the barriers described above; the negative consequences for these individuals could be significant, yet are easily avoided with a more feasible time allowed to access in-person care. For patients currently being treated for serious medical conditions, we are also concerned that a rigid, 30-day rule would result in the lapse of their prescriptions, leading to complications from those conditions, emergency department visits, and hospitalizations. Physicians prescribing controlled substances based on telemedicine visits are afforded many opportunities to assess patients' medication adherence and other aspects of their treatment management prior to an opportunity for an in-person visit. These physicians can observe patients via video, order laboratory tests and review results, and engage in remote monitoring of patients' vital signs and symptoms.

Extend Telemedicine to All Schedule III-V Medications

The AMA is also concerned about the proposed rule's limitation to non-narcotic drugs in schedules III-V. **Prescriptions for all controlled substances should be permitted based on legitimate telemedicine**

visits with DEA-registered physicians. In 2020, to learn more about physicians' use of the DEA-authorized flexibilities during the PHE and, using this information, to subsequently optimize health care policies, the AMA conducted a survey of physicians who treat patients with painful conditions, including those specializing in pain medicine, anesthesiology, physical medicine and rehabilitation, hospice and palliative care, and others. Of the 240 completed responses to the online survey, 80 percent of the physicians said that the flexibilities provided by the DEA during the COVID-19 pandemic were either very helpful or somewhat helpful for treating patients with pain.

Patients with painful conditions may be prescribed narcotic drugs in schedules III-V. Restricting access to care for patients who benefit from these medications, including those who have benefited during the PHE through telemedicine, should be avoided. The AMA recommends that the ability to prescribe these controlled substances based on telemedicine visits should be extended beyond the PHE. It is important to note that when a telemedicine visit is scheduled or started, the physician does not know how complex the patient's illness or injury is or what medication(s) may be most appropriate to treat the illness and/or manage its symptoms, until the visit has been completed. If the DEA determines that only some controlled substances may be prescribed based on these visits, then if at the end of a telemedicine visit the complexity warrants a prescription for a medication that is not on the approved telemedicine list, the physician's options will be to prescribe a nonoptimal treatment or to attempt to arrange an in-person appointment so that they can prescribe the appropriate medication. We strongly advise against creating regulations with a high potential to infringe on the practice of medicine.

The DEA should refrain from imposing new and discriminatory restrictions on the use of telemedicine, such as restricting the manner in which a physician-patient relationship can be established. AMA policy states that a valid physician-patient relationship may be established virtually face-to-face via real-time audio and video technology, if appropriate for the service being furnished. It also allows for the relationship to be established in a variety of other ways such as meeting standards of care set by a major medical specialty society. All 50 states and the territories allow a physician-patient relationship to be established virtually or through other means.

Ensuring Continuity of Care through Exceptions or a Special Telemedicine Registration for Schedule II Controlled Substances

The Ryan Haight Act gives the DEA authority to establish a special DEA registration for telemedicine. The AMA appreciates that the current proposal would allow all DEA-registered physicians to prescribe certain controlled medications based on telemedicine visits with patients without requiring a special telemedicine registration. There are circumstances, however, when patients may need to be prescribed Schedule II controlled substances based on telemedicine evaluations. The AMA recommends that the DEA support a good faith exception process or establish a special registration for those physicians who need the ability to prescribe Schedule II controlled substances based on telemedicine visits alone. These options have the ability to help physicians that treat patients with pain, cancer, or those who require hospice or palliative care, for example. Such an exception or special registration process would also align with the full scope and authority of the Controlled Substances Act in providing that a prescription must be issued for a legitimate medical purpose in the usual course of professional practice.

One example where this approach would be helpful is for complex homebound patients with multiple morbidities, who have annual mortality rates of 20-25 percent and may require a form of controlled substance as part of treatment. In this scenario, a patient experiencing an exacerbation of their symptoms or new, concerning symptoms may prefer an audio-video visit for an assessment with the physician with whom they have an existing relationship. Following a virtual assessment, with family members virtually

participating along with the patient, the care goals could be identified and the patient and their family may opt not to go to the hospital. In a severe case, a hospice referral may be subsequently initiated and medications prescribed, all without requiring the compromised, and possibly contagious, patient to leave their home unnecessarily. If not for the available telemedicine option in this case, the patient or family would likely need to call an ambulance for care to be delivered in an emergency department instead of the patient being able to remain in their home, which is a foundational element of hospice and palliative care.

Outlier Practices

The pandemic-era waivers allowing for the prescribing of controlled substances via telemedicine without any in-person visit requirement have led to some limited, but concerning, reports of rogue online prescribing practices. The AMA strongly supports DEA enforcement efforts to stop illegal practices that harm patients. However, we encourage the DEA to consider focusing its enforcement activities on these problematic outlier practices rather than applying new restrictions that may cause unnecessary barriers to care. For example, the pandemic saw a rapid increase in the number of telemedicine startup companies taking advantage of new business opportunities provided by waivers. While many of these companies provide valuable health care services and increase access to quality medical care, others rely heavily on patient self-screening or self-diagnosis with little attention paid to ensuring thorough patient assessment and diagnostic accuracy. Thorough examination of patient medical histories and an in-depth evaluation of patient symptoms can be accomplished via legitimate telemedicine encounters, but they may fall by the wayside if the service is merely a front to encourage easy access to prescriptions by larger numbers of patients. Access to appropriate follow-up care in such illegitimate practices can be anemic or non-existent. The AMA shares DEA's concern about services that rely primarily on patient self-assessments, particularly if they are fueled by social media trends. We also are familiar with reports that these trends may have played a role in ongoing and persistent nationwide drug shortages of critical therapeutics. The AMA recommends that, where it is suspected that the standard of care is not being met and diagnostic integrity and accuracy may be compromised, the DEA consider focused enforcement activities to ensure appropriate patient care and prescribing of controlled substances.

Additionally, the pandemic waivers have given rise to several telemedicine startup ventures aimed at offering psychedelic "therapies" to treat a range of mental health conditions. While some of these treatments are showing promise for these uses, they have generally not yet been approved by the Food and Drug Administration (FDA) for use in the treatment of psychiatric disorders. For example, ketamine is a psychedelic with FDA approval for use in anesthesia but is also used experimentally for the treatment of treatment-resistant depression and post-traumatic stress disorder, among others. The pandemic has seen significant increases in the number of telemedicine businesses offering ketamine to patients for administration at home, instead of pursuing administration at an outpatient clinic setting where the patient experience on the psychedelic can be carefully monitored. When the formulation, dosage, and method of administration is changed in the manner it is for home administration of ketamine, significant risks to patients can arise. Ketamine not only has significant street value and risk of diversion, but patients with unsupervised at-home use are at higher risk of abuse and developing dependence. The FDA has issued specific alerts to health professionals about some of the risks associated with certain ketamine products. AMA policy strongly supports "that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion." Given that the evidence base for use of drugs like ketamine is still under development and that the drug poses significant potential risks to patients when administered in unsupervised settings, this seems to be an example of the type of outlier practice that warrants scrutiny by the DEA.

Recordkeeping Requirements

The AMA is concerned that the many recordkeeping requirements in the proposed rule may make physicians overly apprehensive about the likelihood of DEA investigations that they will no longer be willing to prescribe controlled substances based on telemedicine encounters. Under the proposed rule, physicians would be required to maintain records indicating that they checked the prescription drug monitoring program before issuing a prescription, the date and time of the patient evaluation and the location of the prescriber during the telemedicine encounter, 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 unless the pharmacist has access to them, as well as information about whether the patient had an in-person evaluation within the required timeframe. The AMA encourages the DEA to adopt a more flexible approach. **Current DEA requirements for records related to prescribing and dispensing of controlled substances should be sufficient if the agency needs to conduct an investigation.**

In addition, the DEA is proposing to require all telemedicine prescriptions to specifically note that the prescription was issued via a telemedicine encounter. It is not clear whether all EHR or electronic prescribing vendors are currently able to streamline this new requirement or if the electronic prescribing technical standards themselves could facilitate the notation or exchange of this information. The AMA is concerned that if a patient goes to the pharmacy to have his or her prescription dispensed, and the electronic prescription does not notate that it was issued via telemedicine, the pharmacist would be prevented from dispensing the medication, putting the patient at risk for lapsed care. The AMA urges flexibility with implementing this proposal to include, for example, the pharmacist being allowed to note on the prescription that it was issued via a telemedicine encounter.

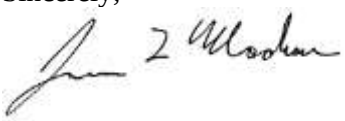
Conclusion

The AMA believes that the proposed rule presents an opportunity to harness the advances made in telemedicine during the PHE, while addressing problems and abuses that came to light during this period. Thoughtfully crafted regulations can further the public health goals of enhancing equitable access to care while alleviating physician burnout. Conversely, overly restrictive barriers to accessing care will leave marginalized patient populations stranded and vulnerable, while onerous recordkeeping requirements and the ongoing threat of DEA investigation could further drive already overburdened physicians to discontinue a practice in which prescribing a controlled substance is essential to patient care. **The AMA urges DEA to further the goals espoused by multiple federal agencies in recent guidance,[1] to remove barriers to care rather than erecting new ones which threaten to disrupt physician practice and patient care.**

[1] *See, e.g.*, Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6446, (proposed January 1, 2021). *See also,* Grady, J., *New Regulations Have Potential to Remove Barriers to Care*, Behavioral Health Executive, January 17, 2022, available at https://www.hmpgloballearningnetwork.com/site/bhe/perspectives/new-regulations-have-potential-remove-barriers-care, (noting also the CARES Act Revisions to 42 CFR Part 2, proposed in Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74216, 74253 (proposed December 2, 2022), and SAMHSA Methadone Take-Home Flexibilities Extension Guidance, November 18, 2021, available at https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance, among others.

Thank you for the opportunity to provide comments on this proposal. Please contact Margaret Garikes, Vice President, Federal Affairs at margaret.garikes@ama-assn.org or 202-789-7409 with any questions or concerns.

Sincerely,



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