AMA Statement for the Record
U.S. Drug Enforcement Administration
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- I am Dr. Jesse Ehrenfeld, an anesthesiologist and president of the AMA.
- That's J-E-S-S-E E-H-R-E-N-F-E-L-D.
- The American Medical Association appreciates the DEA hosting this public listening session to help inform DEA's regulations on prescribing controlled substances via telemedicine.
- The AMA commends the DEA for taking additional time to ensure that its rules provide appropriate balance between advancing patients' access to care via telemedicine and ensuring patient safety.

Schedule III-V

- The Covid public health emergency demonstrated that telemedicine prescribing of schedule III-V medications—with and without an in-person evaluation—helped patients with many medical conditions begin and maintain necessary care.
- Whether audio-only, audio-visual, or in-person care, physicians provide high-quality, evidence-based care that relies on thorough assessments and sound decision-making.
- For example, during the Covid PHE, audio-only and audio-visual telehealth induction with buprenorphine for opioid use disorder was extremely helpful for maintaining continuity of care and preventing relapse for those currently receiving treatment with medication for OUD.
- The AMA strongly urges the DEA to ensure that access to medications for OUD is not interrupted through new requirements that impose barriers to care.
- Many safeguards currently exist—through state law as well as the Controlled Substances Act—that provide a sufficient framework to help ensure patient safety and prevent diversion.
- The professional, ethical and legal obligations that govern the practice of medicine and pharmacy can and should be trusted to provide ample safeguards for ensuring patient safety.
- If a prescription is not issued for a legitimate medical purpose, it should not be dispensed. This applies regardless of the modality used for the patient evaluation leading to issuance of the prescription.

- Another key safeguard is that every state requires controlled substances to be entered into state prescription drug monitoring programs when they are dispensed.
- This information provides physicians and pharmacists with helpful clinical information, including whether patients are obtaining prescriptions from multiple prescribers and pharmacists.
- If the dispensing pharmacist has questions regarding whether a prescription for a scheduled medication is for a legitimate medical purpose, or has other questions, it is common for the pharmacist to talk with the patient, contact the physician, or seek other information to try and resolve the questions, or determine that the prescription should not be dispensed.
- These processes and relationships help ensure patient safety as well as protect against diversion.
- The framework for prescriptions issued based on a telemedicine encounter must also allow patients sufficient time to schedule an in-person visit when clinically appropriate.
- The AMA urges that following an initial telehealth encounter, the patient be afforded at least six months to fill and renew prescriptions before being required to have an in-person visit.
- This can help ensure that the patient is stable on the course of medication therapy so that the in-person visit can be a seamless transition.
- Having at least six months as part of the framework for prescribing Schedule III-V Controlled Substances via telemedicine addresses multiple current barriers.
- These barriers include health insurance network inadequacy, functional limitations that can make access to in-person services difficult, long travel times, racial disparities in access to buprenorphine versus methadone treatment, long wait times for treatment, the need for a caregiver to accompany the patient, stigma within the medical community regarding drug users, and patients experiencing unstable housing and lack of transportation and childcare.
- Telehealth visits for OUD have helped many patients access treatment, including buprenorphine.

Schedule II

- The AMA continues to support telemedicine prescribing of Schedule II controlled substances in the absence of an in-person medical evaluation when clinically appropriate.
- A telemedicine prescription can help ensure that the patient receives timely therapy without delay, including for patients with chronic medical conditions, cancer, in hospice, those living in remote or underserved areas or other situations.
- The AMA does not support sham practices that have no assessment, evaluation or other markers of legitimate care, but the Covid PHE demonstrated that physicians can thoroughly assess a patient via a telemedicine encounter.

- This includes determining whether a prescription would be clinically appropriate during an initial telehealth visit, or for current patients, telemedicine can allow a physician to conduct pill counts, monitor toxicology screens and ensure medication adherence or identify aberrant behaviors requiring changes in therapy.
- For situations where an in-person evaluation would result in delays in care that could lead to patient harm, the AMA urges that telemedicine prescribing of Schedule II medications be permitted.
- 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.
- It is equally true that not all care can be provided via telehealth.
- If a physician determines during a telehealth visit that the patient needs to be seen in-person, that should be the next step.
- The AMA cautions DEA about making new rules allowing only some controlled substances to be prescribed based on telemedicine visits.
- If at the end of a telemedicine visit the complexity of a patient's medical condition warrants a prescription for a medication that is not on an 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. This includes Schedule II medications.
- The AMA urges a targeted enforcement strategy to deal with illegal online practices rather than new rules that would adversely affect practices that provide high-quality, evidence-based care to patients with medical conditions benefiting from Schedule II Controlled Substances.
- Safeguards already exist in the Controlled Substances Act and state licensure governing medical and pharmacy practice.
- 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, medical boards pursue focused oversight to ensure appropriate patient care and prescribing of controlled substances.
- If there is illegal activity, law enforcement intervention may be necessary as well.
- The Covid PHE forced physicians to adopt new ways to ensure evidence-based, high-quality continuity of care—and increase access to care for patients with chronic conditions. Physicians met that challenge, and our patients benefited.
- The AMA supported the Administration's efforts to extend the PHE flexibilities, and we similarly urge DEA to not reverse practices helping patients.

Data

- The framework moving forward also should avoid new, burdensome record-keeping requirements.
- The AMA is concerned about the DEA's proposal regarding records being maintained for investigation purposes.
- Current DEA requirements for records related to prescribing and dispensing of controlled substances should be sufficient if the DEA needs to conduct an investigation.
- The DEA already receives a tremendous amount of data from manufacturers, distributors and pharmacies about controlled substances in the supply chain.
- These entities are required to provide DEA with suspicious order reports to help identify potential problem areas.
- State PDMPs contain personal health information regarding individual prescribers and patients that is clinical in nature and should not be shared or disclosed to law enforcement without probable cause.
- DEA has the ability to seek judicial approval for accessing a PDMP or conducting other surveillance activities.
- The AMA does not believe DEA needs more data to strategically target illegal activity, and we would be concerned if DEA proactively sought state PDMP data as part of data mining or routine surveillance activities.

Thank you for the opportunity to provide these comments.