AMA
AMERICAN MEDICAL ASSOCIATION

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Mr. Derek S. Maltz
Acting Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA-407; Special Registrations for Telemedicine and Limited State Telemedicine Registrations; Notice of Proposed Rulemaking

Dear Acting Administrator Maltz:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to comment on the U.S. Drug Enforcement Administration's (DEA) proposal to establish several categories of special DEA telemedicine registrations for physicians who prescribe controlled substances to patients with whom they have not had an in-person medical evaluation. The AMA views several aspects of the new proposed rule as significant improvements from the 2023 proposal.

In response to the original 2023 proposal, AMA comments and our testimony at the September 2023 DEA Listening Session expressed concern that physicians prescribing Schedule III-V medications based on telemedicine encounters would be required to have an in-person evaluation with the patient to prescribe controlled substances beyond a 30-day period. We are pleased that the current proposal eliminates this requirement. Also, the original proposal did not have any provision for Schedule II medications to be prescribed to patients who had not had an in-person medical evaluation. As the AMA recommended, the current proposal provides a special registration process for Advanced Telemedicine Prescribing for use in certain circumstances, such as hospice care, where Schedule II medications may be indicated for appropriate patient care. Finally, previous AMA comments noted some limited, but concerning, reports of rogue online prescribing practices and encouraged 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. We believe the current proposal and the establishment of a special registration for online telemedicine platforms strikes a better balance between the need to allow access to medically necessary medications while also preventing illegal practices that can harm patients.

The AMA also has several concerns about the proposed rule. The DEA should withdraw both proposals that set arbitrary quantitative limits on telemedicine prescribing: one limits prescribing of controlled substances based on telemedicine to 50 percent for clinician special registrants with in-person medical practices and the other limits monthly telemedicine prescriptions for Schedule II controlled substances to 50 percent of clinicians' total Schedule II prescriptions.

Whether providing care in-person or via telemedicine, physicians embrace their ethical and professional obligation to provide high-quality, evidence-based care that relies on thorough assessments and sound decision-making. The federal flexibilities initiated by the Trump Administration in 2020 that underpin this proposed rule demonstrated beyond a doubt that physicians can thoroughly assess patients via telemedicine encounters, including determining whether a prescription for a controlled substance would be clinically appropriate. Physicians' clinical experience also demonstrated that telemedicine allows them to conduct pill counts for adherence, monitor toxicology testing and ensure medication safety and efficacy to determine changes in therapy, or identify aberrant behaviors indicating diversion risk. Prescribing controlled medications through telehealth visits provides the opportunity to reach remote and underserved communities as well as patients who may be unable to obtain in-person care because of distance to

a medical practice, transportation costs, physical and mental health impairments, need for an accompanying caregiver or being a caregiver for others, employment, or other factors impeding in-person access to care.

The AMA appreciates the DEA's explanation of the provisions of the Ryan Haight Act and its statement that the special telemedicine registrations only apply to circumstances where the physician prescribing the controlled medication has not had at least one in-person medical evaluation of the patient. We believe this is a critical point and that there has been significant confusion about it. More detailed comments on the proposed rule follow.

Telemedicine Prescribing Registration (Schedules III-V)

The AMA agrees with the DEA's emphasis on the importance of state law and its requirement that the special registration only be issued if the practitioner has a DEA registration in the state in which the patient will be located when receiving the telemedicine service. A special registrant under the proposed framework would need to continue to comply with the laws and regulations of the state in which they are registered with the DEA and in which they are issuing special registration prescriptions via telemedicine encounters. The DEA further emphasizes that clinician practitioners under this rule "must establish and maintain a bona fide doctor-patient relationship in order to act 'in the usual course of…professional practice' and to issue a prescription for a 'legitimate medical purpose.'" The AMA strongly supports state boards of medicine to play the primary role in regulating the practice of medicine.

The DEA proposes that all physicians who are registered to prescribe controlled substances in Schedules III-V would be eligible to obtain a Telemedicine Prescribing Registration when they anticipate that they will treat patients for whom requiring in-person medical evaluations prior to prescribing these medications could impose significant burdens on bona fide practitioner-patient relationships. The AMA supports this proposal.

Mid-level practitioners who are "board-certified" are also proposed to be eligible to register as telemedicine prescribers for Schedules III-V controlled substances. Although 21 CFR 1300.1 includes a definition of mid-level practitioners "who are authorized to dispense controlled substances by the State in which they practice," the proposal does not define what a "board-certified" mid-level practitioner would be, nor does it explain how this board certification would qualify them to prescribe controlled substances to patients who have not had an in-person evaluation. The AMA does not support this proposal.

Nurse practitioners, physician assistants and other non-physicians are important members of the care team, but their skillsets are not interchangeable with those of fully educated and trained physicians. Physicians complete four years of medical school plus a three-to-seven-year residency program, including 12,000-16,000 hours of clinical training. By contrast, nurse practitioners complete only two to three years of education, have no residency requirement, and only 500-720 hours of clinical training. The current physician assistant education model is two years in length with only 2,000 hours of clinical care and no residency requirement. Other non-physician health care professionals authorized to prescribe controlled substances similarly have much less education and training than physicians.

During medical school, students receive a comprehensive education in the classroom and in laboratories, where they study the biological, chemical, pharmacological, and behavioral aspects of the human condition. This period of intense study is supplemented by two years of patient care rotations through different specialties, during which medical students assist licensed physicians in the care of patients. During clinical rotations, medical students continue to develop their clinical judgment and medical decision-making skills through direct experience managing patients in all aspects of medicine. They then must pass a series of examinations to assess a physician's readiness for licensure. At this point, medical students "match" into a three-to-seven-year residency program during which they provide care in a select surgical or medical specialty under the supervision of experienced physician faculty. As resident physicians gain experience and demonstrate growth in their ability to care for patients, they are given greater responsibility and independence. Programs for non-physicians do not have high-quality, time-tested, standardized requirements and they should not be eligible for the proposed special registrations.

Advanced Telemedicine Prescribing Registration (Schedules II-V)

As the AMA recommended in our comments on the 2023 proposed rule, we deeply appreciate the proposed establishment of a special registration that would allow physicians to prescribe Schedule II medications for patients who have not had an in-person evaluation. Our previous letter cited patients who require hospice or palliative care as among those who may face barriers to obtaining in-person medical care and for whom telemedicine could be especially beneficial. The AMA generally agrees with the types of patient care circumstances that the DEA has listed for whom the advanced telemedicine prescribing registration may be most helpful: psychiatric care, hospice care, palliative care, long term care, pediatric care, and neurologic care. The AMA agrees with the DEA that the advanced special registration should not be limited to physicians who can demonstrate specialization in these areas, such as through specialized training and/or board certification. We support the proposal to also allow physicians to qualify by having a certain percentage of their overall practice in this specialty area. In addition, there are physicians who specialize in primary care, geriatrics, medical oncology, or other specialties who provide a continuum of whole-person care to patients that may include palliative and hospice care, for example, even though that is not their designated specialty. To ensure that patients who rely on telemedicine for care do not suffer potentially harmful interruptions in care, the AMA urges that DEA accept other means for physicians to demonstrate that their practices include addressing these types of patient care so that they can qualify for the advanced registration if needed for their patients.

As described in detail in our above comments regarding eligibility for the special registration for Schedules III-V, the AMA does not agree that "board-certified" mid-level practitioners should be eligible for the advanced special registration to prescribe Schedules II-V medications. Only physicians should be qualified for the advanced special registration.

Telemedicine Prescribing Frequency Limits

The proposed rule includes two policies that would constrain the frequency of controlled substance prescriptions based on telemedicine encounters. First, in defining a "local in-person medical practice" for purposes of eligibility for a clinician special telemedicine registration, the DEA states that the medical practice has all its offices located within 100 miles of each other and less than 50 percent of the total prescriptions for controlled substances collectively issued by the practice's physicians and mid-level practitioners are issued via telemedicine in any given calendar month. Second, the average number of special registration prescriptions for Schedule II controlled substances constitutes less than 50 percent of the total number of Schedule II prescriptions issued by the clinician special registrant in their telemedicine and non-telemedicine practice in a month.

Since 2012, the number of opioid prescriptions has fallen by more than half, and the decline in prescribing of these medications continued throughout the COVID-19 Public Health Emergency when the telemedicine flexibilities that remain in effect today began. The ability to prescribe Schedule II medications based on telemedicine encounters has not increased prescribing of these drugs. The misapplication of policies resulting from the 2016 opioid prescribing guideline issued by the Centers for Disease Control and Prevention (CDC) showed the patient harm that results when arbitrary quantitative prescribing limits are imposed. Even though the 2022 revised CDC guideline emphasized that these quantitative metrics were removed as part of the revision and that dosage and duration of prescriptions should be decided on an individual basis reflecting the patient's needs, many of the prescribing and dispensing limits that were imposed by law and by pharmacies and health plans based on the 2016 guideline remain in place.

The AMA strongly urges the DEA to withdraw these metrics from the special registration policies. We are very concerned that they could lead to serious unintended consequences for patient care that, once included in a final regulation, will be difficult to impossible to reverse. For example, patients could be denied any controlled medication prescriptions in a month or denied medically necessary Schedule II medications due to fear of exceeding the percentage in a month and risking loss of their DEA registration. We are also concerned that pharmacists may interpret as a new aspect of their corresponding responsibility the need to verify these percentages each month and that this could also lead to inappropriate denials. The AMA knows that while DEA does not intend to cause

interruptions in care, we have seen time and time again that state legislatures, pharmacies, health plans, and health care professionals commonly misinterpret DEA's intention out of significant fear of investigation and prosecution.

In addition, the first proposal is unclear. As noted earlier in this letter, the DEA has taken care to explain in the rule's text and illustrated in accompanying flow charts that this proposed rule does not apply to all controlled substance prescribing based on telemedicine encounters, but rather that it applies when the physician has not had any in-person evaluation of the patient. The proposed definition of a local in-person medical practice, however, appears to apply the 50 percent limitation to total prescriptions issued via telemedicine, not just those telemedicine prescriptions for which a clinician would need to have a special registration because they had not had an in-person visit with the patient. The AMA encourages greater clarity on this proposal to avoid confusion both by physicians and others charged with implementing and following the rule. For example, if a pharmacy or payer does not interpret this properly, a patient could be denied medication at the point of care and experience undue pain and suffering.

Prescription Drug Monitoring Program (PDMP) Check

For a period of three years, the DEA proposes to require that, before issuing any special registration prescription, clinician special registrants check the PDMPs for (1) the state where the patient is located; (2) the state where the physician is located; and (3) and state with PDMP reciprocity agreements with the state where the patient is located and where the physician is located. After three years, clinician special registrants would be required to check the PDMPs of all 50 states. If there is no mechanism to check every PDMP in the country after three years, then the initial requirements for PDMP checking would continue. In addition, physicians with advanced special registration would only be able to issue Schedule II prescriptions to patients within their same state.

The AMA's 2024 Overdose Epidemic Report stated that physicians and other authorized users queried state PDMPs more than 1.4 billion times in 2023 and more than 5.3 billion times in the past five years. The AMA continues to support the refinement and use of state PDMPs, including privacy protections for patients and how PDMPs can support the clinical decision-making of physicians and other health care professionals on an individualized basis. We appreciate the DEA's acknowledgement in this proposed rule that the fragmented nature of PDMPs across states and territories has created challenges for physicians in obtaining comprehensive patient data and that enhanced interoperability is needed. The AMA supports the use of PDMPs, but we emphasize that their proper role is to provide potentially useful clinical information about uncoordinated patient care. PDMPs are not and should not be used as law enforcement tools.

The DEA proposals should also consider practice workflows and the feasibility of integrating any new requirements into practice in a way that will not be overly burdensome nor impede patient access to medically necessary care. Before they are implemented, the proposed PDMP checking requirements should be further evaluated to assess their impacts in this regard, especially the proposed requirement to check every state PDMP. Imposing new requirements to check the PDMP will increase the burdens medical practices already face from other administrative rules. The AMA emphasizes that there is no convincing data showing how the billions of PDMP queries have improved patient outcomes or reduced mortality. The AMA, therefore, urges that any additional requirements to check state PDMPs be delayed until such time that it can be shown PDMPs help improve outcomes and reduce drug-related mortality.

Patient Verification Photographic Record

The DEA proposes that clinician special registrants verify the identity of patients seeking treatment via telemedicine by requiring them to present a state or federal government-issued photo identification card through the camera of the audio-video telecommunications system. At the first telemedicine encounter, the clinician special registrant would also be required to capture a photographic record of the patient presenting their federal or state-issued photo identification card or other acceptable documents and use the photographic records to confirm the patient's identity in subsequent telemedicine encounters.

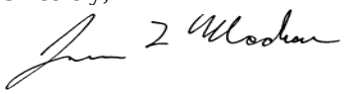
We appreciate that the DEA received testimony that it is common practice to verify patient identities during telemedicine encounters. It is not clear, however, if this specific verification method is commonly used. As this

would be a new requirement, we do not know if physicians' electronic medical record (EMR) systems currently permit this photo verification process and, if not, how feasible it would be for them to do so and for physicians to integrate this step into their telemedicine practice workflows. The AMA encourages the DEA to obtain from the EMR vendors and provide the registrant community more information about this element of the proposed policy.

Alternatively, the DEA could permit patients to self-register using an application (app) of their choice—such as verifying their identity through a personal medical record app or uploading identification documents via an online portal before their telemedicine appointment. Allowing this flexibility could reduce administrative burdens on physicians and staff while better accommodating patient needs and providing the needed identity verification. We encourage the DEA to reconsider its current proposal and, at a minimum, to allow additional time for vendors to develop and special registrants to come into compliance with this verification requirement.

Thank you for issuing this new proposed rule and for your consideration of our comments and recommendations. If you have any questions, please contact Margaret Garikes, AMA's Vice President of Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,



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