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March 31, 2023

The Honorable Anne Milgram
Administrator
United States Drug Enforcement Administration
800 K Street, NW Suite 500
Washington, DC, 20001

Re: Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation (RIN: 117-AB40) (March 1, 2023)

Dear Administrator Milgram:

The Association of American Medical Colleges (the AAMC) welcomes this opportunity to comment on the Drug Enforcement Administration (DEA) proposed rule on telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation, published March 1, 2023 (*88 Fed. Reg. 12875*). It is critical that patients have continued access to care, including clinically appropriate controlled substances, especially in the face of a growing overdose epidemic, which has been exacerbated by the COVID-19 pandemic. We recognize that the DEA plays an important role in preventing drug diversion and ensuring the legitimate prescribing of controlled substances. We urge the DEA, the Department of Health and Human Services (HHS) and Congress to work collaboratively to break down barriers to care post-COVID-19 public health emergency (PHE), while limiting drug diversion and preventing illegal drug sales.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S.

membership and expanded its reach to international academic health centers. Learn more at aamc.org. Through their missions of education, research, and clinical care, our teaching hospitals, faculty physicians and other providers have been actively responding to this public health crisis and preparing the next generation of health care professionals to address the opioid crisis.

During the COVID-19 PHE, the DEA used its public emergency authority to waive the requirement that providers conduct an in-person evaluation prior to prescribing controlled substances via telemedicine.¹ This waiver has increased access to clinically appropriate medications, including for mental health and substance use disorder treatment, by enabling providers to safely prescribe controlled substances remotely using telemedicine.

This telemedicine waiver has been especially important given the shortage of qualified behavioral health and primary care providers. According to data from the Health Resources and Services Administration (HRSA), as of March 23, 2023, 160 million people currently reside in a Mental Health Professional Shortage Area (HPSA) and there are 8,039 fewer practitioners than are needed.² Currently, 99 million people reside in a Primary Care Shortage Area and there are 17,097 primary care practitioners that are needed.³ Additionally, a June 2021 report from the AAMC predicts a shortage of up to 124,000 physicians by 2034.⁴ These shortages have a real impact on patients, particularly those living in rural, frontier, island, or non-contiguous settings, and other already underserved communities.

The AAMC is concerned that when the public health emergency ends, many patients will be left without access to care, especially given the ongoing drug overdose crisis, the growing mental health crisis precipitated by the pandemic, and the shortage of behavioral health care providers. Requirements for in-person visits to receive controlled substances will particularly have an impact on individuals who reside in rural areas, those with transportation barriers, and those suffering from mental health and addiction issues. While we understand the DEA's important role in protecting the public from false prescribing and overprescribing, we do not believe the proposed rules strike the appropriate balance between this goal and the critical need to access safe and effective care.

Our specific comments in response to the proposals in this rule are below.

In-Person Visit Requirement Before Prescribing Requirement and the 30-day time frame

Under the proposed rule, a practitioner would be required to conduct an in-person visit before prescribing schedule II medications (e.g., Adderall, oxycodone) or Schedule III-V narcotic medications (with the sole exception of buprenorphine). Practitioners would be able to prescribe

¹ See <https://www.deadiversion.usdoj.gov/coronavirus.html>

² HRSA data on health professional shortage areas by discipline can be found here: <https://data.hrsa.gov/topics/health-workforce/shortage-areas>

³ Id.

⁴ AAMC, The complexities of physician supply and demand: projections from 2019-2034 (June 2021) can be found here <https://www.aamc.org/media/54681/download>

a 30-day supply through telemedicine without the initial in-person visit for buprenorphine and non-narcotic schedule III, IV, V drugs (e.g., Ambien, Valium, Xanax). The practitioner could continue prescribing after the 30-day window if the practitioner performs an in-person evaluation with the patient, the practitioner performs a synchronous audio-video telemedicine encounter with the patient while the patient is located in the physical presence of another DEA registered practitioner, or the practitioner receives a qualifying telemedicine referral from a DEA registered practitioner who has conducted an in-person exam of the patient.

The DEA should remove the in-person requirement and 30-day limit on prescriptions for buprenorphine

In the face of an escalating overdose crisis and the need to reach rural and underserved communities, making the current telehealth flexibility permanent is critical. More than 2 million Americans are afflicted with OUD, and on average 130 die every day due to overdose.^{5 6} OUD remains the leading cause of accidental deaths in the U.S. Patients who seek treatment of OUD continue to have significant difficulty in accessing treatment options that reflect the most current science.⁷ In 2018, for a variety of reasons, only 11.1% of people who needed treatment for substance use received it.⁸

The AAMC urges the DEA to remove the in-person requirement and 30-day limit on prescriptions for buprenorphine. At a minimum, we recommend that the DEA waive the prior in-person requirement for buprenorphine for the duration of the ongoing opioid epidemic public health emergency issued by the Department of Health and Human Services on October 26, 2017.⁹ This would allow providers offering treatment of substance use disorder and medication for opioid use disorder to continue doing so via telemedicine without their patient's care being terminated when the COVID-19 PHE waiver ends.

While we oppose the in-person requirement for buprenorphine prescribing, if the DEA does decide to institute an in-person requirement, the supply should not be limited to a 30-day allowance. Physicians should be responsible for making determinations on the supply of medication that is necessary. At a minimum, if the physician determines it is appropriate, up to a 90-day supply should be allowed, to avoid disruptions in care.

Studies have shown that buprenorphine, a MOUD that alleviates opioid withdrawal and decreases drug craving, is an effective and safe treatment for OUD. The effects of opioid

⁵ Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>

⁶ See HRSA's Opioid Crisis <https://www.hrsa.gov/opioids>. Please frequently check this webpage for further updates and guidance." (Last accessed February 2, 2023).

⁷ See CDC Injuries and Violence Are Leading Causes of Death <https://www.cdc.gov/injury/wisqars/animated-leading-causes.html>

⁸ Wilson N, Kariisa M, Seth P, et al. Drug and Opioid-Involved Overdose Deaths—United States, 2017-2018. MMWR Morb Mortal Wkly Rep 2020; 69:290-297.

⁹See https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/October_26_2017_Public_Health_Declaration_for_Opioids_Crisis.pdf

withdrawal can cause people to go back to drug use, so there is often a time pressure associated with treatment. Before the PHE, patients with OUD were often instructed to go to the nearest emergency department in the hopes that a practitioner there would prescribe buprenorphine. However, travel time, particularly in rural areas, and workforce shortages, often delayed access to care and resulted in recurrences of OUD. During the PHE, patients suffering from OUD have received buprenorphine treatment via audio-video and audio-only technology without an initial in-person visit. This has been critical to improving care by expanding access and reducing wait times to administer buprenorphine.

Allowing use of audio-only technology has also been a key step to addressing equity concerns. The lack of availability of video services or a patient's discomfort regarding the use of video may disproportionately affect certain populations, some of whom have high-risk and chronic conditions, including older adults, those with low socioeconomic status, those in rural communities, and certain races and ethnicities. In addition, patients in rural areas and those with lower socioeconomic status are more likely to have limited broadband access, making it more difficult to receive telehealth services by audio-video interactions. For these patients, their only time-effective treatment option may be to receive buprenorphine initiation services remotely by audio-only.

A recent study on two harm reduction primary care programs providing buprenorphine treatment for opioid use disorder via telehealth found that the removal of the in-person requirement greatly increased access to care and addressed health inequities.¹⁰ Studies have also shown that there are no significant differences between telehealth and in-person buprenorphine induction in the rate of continued substance use, retention in treatment or engagement in services.¹¹ One recent study showed that the pandemic-era flexibilities that were allowed for medication for opioid use disorder reduced the risk of opioid overdoses.¹²

In summary, the in-person evaluation requirement prior to prescribing via telemedicine only results in reduced access to care and does not enhance the DEA's ability to do its job of limiting drug diversion or pursuing illegal actors. The requirement would act as a significant barrier to care for those who need the potentially lifesaving treatment, buprenorphine. This barrier will disproportionately affect those in more vulnerable populations who, because of challenges such as lack of flexibility with their workplace, inability to secure care for their dependents, transportation issues or other limitations, are not able to attend an in-person visit. As previously mentioned, time is a critical component to successfully initiating buprenorphine and a delay in treatment caused by the in-person visit requirement may increase the risk of recurrence of OUD. Physicians are responsible for the quality of care delivered to their patients. As such, physicians

¹⁰ Wang, L. et al. Journal of Substance Abuse Treatment January 15, 2021. [https://www.jsatjournal.com/article/S0740-5472\(20\)30529-8/fulltext](https://www.jsatjournal.com/article/S0740-5472(20)30529-8/fulltext)

¹¹ Vakkalanka, J.P., Lund, B.C., Ward M.M., Arndt, S., Field R.W., Charlton M., & Carnahan, R.M. (2022) Telehealth Utilization is Associated with Lower Risk of Discontinuation of Buprenorphine: A Retrospective Cohort Study of US Veterans. Journal of general internal medicine, 37 (7), 1610-1618 <https://doi.org/10.1007/s11602-021-06969-1>.

¹² Jones, Shoff, Hodges, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. JAMA Psychiatry 2022; 79 (10): 981-992. https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2795953?guestAccessKey=ee7219e9-7be8-4f85-bf27-6313250cfea3&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tf1&utm_term=083122

should be responsible for determining when, if at all, it is appropriate for the patient to have an in-person visit. For the reasons discussed above, the DEA should permanently allow the initiation of buprenorphine via both audio-video and audio-only technology. We would welcome the opportunity to discuss other approaches to addressing illegal actors.

For Other Controlled Substances, DEA Should Allow Exemptions to the In-person Visit for Certain Clinical Conditions and Factors

In addition to buprenorphine, we are concerned that the requirements for the in-person visit and the 30-day telemedicine supply for other controlled substances may interfere with clinical decision-making, limit patient's access to clinically appropriate medications, and will be devastating to certain patients. For these other controlled substances, we urge the DEA to allow for exceptions if the patient cannot be seen in person before prescribing due to his/her clinical condition and other factors. In such instances, the practitioner should use his/her clinical judgment to determine if the risks and burdens of the in-person visit outweigh the benefits. For example, prescriptions for the palliative treatment of symptoms related to life-limiting illness should be permitted without an in-person visit for patients who are physically homebound and unable to come in person to the provider's office due to their illness.

Qualified Telemedicine Referral and Three-Party Visit Requirements

The proposed rule would allow practitioners to prescribe controlled substances (including Schedule II controlled substances and narcotics) based on telemedicine encounters without personally conducting an in-person medical evaluation of the patient where there has been a "qualifying telemedicine referral". In such a case, the prescribing practitioner can prescribe any controlled substance (including Schedule II controlled substances and narcotics) via telemedicine that they are otherwise authorized to provide under federal and state law and there is no requirement that the prescription be limited to a thirty-day supply. As proposed, a qualifying telemedicine referral is a referral from a DEA registered practitioner who has conducted at least one in-person medical evaluation of the patient. The referral must specifically include the name and National Provider Identifier ("NPI") of the DEA registered practitioner to whom the patient is being referred and the name and NPI of the referring practitioner. The referral must be issued in writing, communicate the results of the evaluation by sharing the relevant information in the medical record, which includes at a minimum the diagnosis, evaluation, and treatment of the patient prior to the prescribing practitioner issuing the prescription. The proposed rule would also allow the in-person visit requirement to be satisfied by qualified telemedicine referral through a three-party visit. A three-party visit requires that the prescribing practitioner, the DEA registered practitioner on site with the patient, and the patient participate in an audio-video conference simultaneously.

Flexibilities Should be Allowed for Practitioners in Group Practices When Prescribing Controlled Substances

We urge the DEA to allow a practitioner to prescribe controlled substances via telemedicine to a patient who has received an in-person medical evaluation (for a condition related to the need for

the prescription) from another practitioner who is in the same group practice at the time of the in-person evaluation without requiring a qualified telemedicine referral. Practitioners in the same group practice have access to the patients' complete medical record in the electronic medical record (EHR) system. Access to the EHR would provide key information about the patient's condition, including the in-person medical evaluation, medical history and medication history to allow practitioners in the same group practice to safely determine whether to prescribe the controlled substances or to conduct a telehealth/in-person visit for further evaluation. Therefore, there is no need for a separate telemedicine referral in order to provide a telemedicine exam and prescribe the controlled substance.

In some circumstances, the need for a telemedicine visit to prescribe should be left to the discretion of the practitioner in the same group practice. For example, a patient who has been stable on Adderall for several months and needs a refill, may not need to have a telemedicine visit with the practitioner if another practitioner in the same group practice has had the in-person visit with the patient and prescribed the Adderall. This would reduce burden for group practices and improve access for their patients who are treated via team-based care.

The DEA Should Remove the Requirement that the Name and NPI of Prescribing Practitioner be Included on the Telemedicine Referral

In some circumstances, the qualifying telemedicine referral can help in enabling access to care. However, barriers to care will still exist since many providers do not have an existing relationship in place with other referring providers and electronic medical record systems that would enable the seamless exchange of these referrals. Upgrades to electronic medical record systems take time and are costly.

We urge the DEA to remove the requirement that the telemedicine referral include the name and the NPI of the other practitioner to whom the patient is referred. It is impractical for a practitioner from an outside practice to have advanced knowledge of another practitioner's name and NPI to whom they are referring the patient. There would also be no certainty that the particular practitioner identified in the telemedicine referral would be available for a visit with the patient in a timely manner. Identifying one specific practitioner in the telemedicine referral would limit the ability of other qualified practitioners in the same practice to provide the telemedicine visit and prescribe the medications. At a minimum, the referral should be at the group practice Taxpayer Identification Number level rather than the individual practitioner NPI level.

We recommend that the DEA remove the requirement that a "qualified telemedicine referral" must be from a DEA registered practitioner. In the setting of the 3-party exam option (patient, in-person practitioner, and telemedicine practitioner, simultaneously), we also recommend that the DEA remove the requirement that the in-person practitioner is a DEA-registered practitioner. Both requirements would significantly restrict access without providing a compelling benefit to law enforcement.

During the PHE, to reduce barriers to accessing addiction treatment and physical and mental health care, some practices developed programs specifically for populations such as those

experiencing homelessness, polysubstance abuse, and concurrent behavioral health conditions or that live in rural locations. These programs are built upon a licensed nurse/behavioral health care manager model that allows an expanded care team to safely extend access to care. The nurse or behavioral health specialist case manager (who are not DEA registered) conduct an in person clinical assessment with the patient in community settings such as the patient's home, shelters, community centers, and harm reduction agencies. The case manager then facilitates a referral to the appropriate specialist, or a telemedicine visit among the patient, care manager, and a DEA prescriber who develops a care plan and prescribes the controlled substance. These case managers who see the patient may not be DEA registered; however, they are able to evaluate the patient and communicate safely and effectively with a DEA registered practitioner regarding the patient's condition and their need for medication. We recommend that the DEA allow a licensed practitioner (e.g., an RN), provide the in-person visit and refer the patient to a DEA registered practitioner. Requiring only the prescribing practitioner to be DEA-registered would provide protection to the patient and an audit trail for the DEA, while ensuring that patients continue to have timely access to care, especially in rural locations and for populations who have significant barriers to accessing medical care.

Prescription and Record Keeping Requirements

The rule provides a number of requirements that a practitioner must satisfy to issue a prescription for a controlled substance following a telemedicine encounter. In addition, the rule imposes certain additional recordkeeping requirements for these telemedicine encounters to enhance the DEA's ability to detect and investigate the potential misuse of telemedicine to prescribe controlled substances. As discussed in more detail below, we believe that some of these requirements are overly burdensome and would interfere with access to care.

Consider Other Mechanisms for Tracking Telemedicine Prescriptions to Avoid Unintended Consequences

The DEA proposes to require all telemedicine prescriptions include on the face of the prescription or within the prescription order if prescribed electronically, that the prescription was issued via a telemedicine encounter. The rule states that when reviewing pharmacy prescription records, DEA investigators would be able to readily distinguish prescriptions issued pursuant to telemedicine encounters from those issued using their dispensing registrations for non-telemedicine prescriptions- giving investigators greater ability to detect abusive patterns in the use of telemedicine.

Rather than requiring that the prescriptions include a notation that they were issued via a telemedicine encounter, we urge the DEA to consider other mechanisms to study prescribing patterns to avoid unintended consequences. Pharmacists have a responsibility to ensure prescriptions are legitimate and the U.S Department of Justice has sought to hold pharmacies that dispense controlled substance prescriptions despite the presence of "red flags" accountable. We have heard reports of pharmacists declining to dispense some medications due to fear of setting off triggers. This has been a particular concern for college students trying to fill Adderall prescriptions, patients in rural areas who have to drive long distances for medical care, and

hospice providers that rely on local pharmacies to fill their orders. Given the fact that there are already reports of difficulties obtaining medically necessary controlled substances from pharmacies, we have serious concerns that there could be an unintended consequence that pharmacies will limit distribution of clinically appropriate telehealth prescriptions out of fear of DEA action, resulting in significant access problems. We urge the DEA to put strategies in place to avoid any unintended consequences.

Remove Requirement that Practitioners be DEA registered in State Where Located When Issuing Prescription

During the PHE, the DEA granted a temporary exception to its regulations to allow practitioners to prescribe controlled substances in states in which they are not registered if the practitioner is registered with DEA in at least one state and has permission under state law to practice using controlled substances in the state where the dispensing occurs. The rule would end this waiver and replace it with a requirement that the prescribing practitioner be DEA registered where they are located and where the patient is located.

We urge the DEA to change its proposal to remove the requirement that the prescribing practitioner be registered in the state where they are located when they are issuing the prescription as it will limit access to care. Instead, a requirement that the prescriber be DEA-registered and is legally authorized to practice in the state the patient is located is a reasonable approach to ensuring patient protection. If the DEA prescriber is traveling out of state temporarily when the patient needs a refill of their prescription, the practitioner would be unable to fill the prescription if the practitioner had to be DEA registered in his/her current location.

We further recommend that these rules adopt language from the Ryan Haight Act, which states that the practitioner may prescribe from a state in which the practitioner is not registered if the practitioner is temporarily out-of-state. This would help address provider shortages by increasing clinician availability, including extended weekday and weekend hours to address urgent patient needs.

Remove Requirement to Include Practitioner's Physical Address During Telemedicine Encounter in Record

The rule proposes that practitioners shall maintain for each telemedicine prescription they issue, records that include the address at which the DEA-registered prescribing practitioner is located during the telemedicine encounter. We recommend that the DEA remove the requirement for the practitioner to report their physical address during the telemedicine encounter. Instead, practitioners should be able to always report a business address. It is possible that the practitioner is at his/her home during the telemedicine encounter at the time when a prescription is written and sharing this information publicly with patients could pose safety risks for practitioners.

180-day grace period for existing telemedicine relationship established during PHE.

The DEA proposes to extend the in-person waiver an additional 180 days (until November 2023) for patients that have already received their prescriptions via telemedicine during the PHE (i.e., the practitioner prescribed a controlled substance based on a telehealth encounter and the practitioner never conducted an in-person exam during the PHE). This 180-day extension would apply to all schedule II-V controlled substances. We commend the DEA for allowing a grace period; however, we remain concerned that 180 days is not a sufficient time frame.

We recommend that the grace period be extended to a minimum of one year. Given the significant shortages and geographic distribution of behavioral health providers across the United States, it will be very difficult for patients to obtain in-person appointments in the 180-day time frame. Both new and existing patients are currently experiencing extremely long wait times for appointments. Patients who have been receiving controlled substances via telehealth for the last three years during the PHE and new patients will be trying to obtain a limited number of in-person appointments from providers. A 180-day grace period is insufficient given this increased demand.

Conclusion

The AAMC appreciates the DEA's consideration of the above comments. Should you have any questions, please contact Gayle Lee at galee@aamc.org or Ki Stewart at kstewart@aamc.org.

Sincerely,



Jonathan Jaffery, MD, MS, MMM
Chief Health Care Officer

cc: David Skorton, MD, AAMC President and CEO