AMERICAN ACADEMY OF FAMILY PHYSICIANS

March 29, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Agency
600 Army Navy Dr
Arlington, VA 22202

RE: RIN: 1117-AB78; Expansion of Induction of Buprenorphine via Telemedicine Encounter

Dear Administrator Milgram:

On behalf of the American Academy of Family Physicians (AAFP), representing 129,600 family physicians and medical students across the country, I write in response to the notice of proposed rulemaking (NPRM) titled "Expansion of Induction of Buprenorphine via Telemedicine Encounter" as posted in the March 1, 2023 version of the Federal Register.

The AAFP shares the Drug Enforcement Agency's (DEA) concern about rising overdose rates involving illicit and prescription drugs across the U.S and goal of improving access to opioid use disorder treatment. Family physicians provide comprehensive health care to patients of all ages, are tuned in to the needs of their community, and form long-standing relationships with their patients. As a result, they are often the first line of defense for primary care, chronic care management, acute illness, and, increasingly, mental health care. Family physicians also play a crucial role in safe pain management prescribing practices, screening patients for opioid use disorder (OUD), and prescribing and maintaining treatment of medications for OUD (MOUD).

To preserve the progress achieved in improving equitable access to MOUD during the PHE, the AAFP recommends the DEA:

- **Remove in-person examination requirements for telehealth prescribers of buprenorphine for maintenance or detoxification treatment,**
- **Remove overly burdensome documentation and licensing requirements for prescribers or clinicians providing an in-person exam through one of the proposed alternate pathways;**
- **Rescind the proposed 7-day supply restriction for prescriptions provided during a telehealth visit during which the prescriber was unable to access Prescription Drug Monitoring Program (PMDP) data; and**
- **Implement a grace period for complying with record keeping requirements while EHR systems are updated to comply with this measure.**

Prior to the COVID-19 public health emergency (PHE), the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 required patients to receive an in-person medical evaluation to receive a prescription for a controlled medication. While this requirement was put in place to prevent illegal distribution and diversion of controlled substances over the internet, it also prevented physicians and

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other clinicians from prescribing MOUD and other controlled substances during a telehealth encounter. Family physicians were also required to obtain an x-waiver to prescribe buprenorphine to treat OUD, which included several restrictions like how many patients a physician could treat, what training they must complete for renewal, and certain record-keeping requirements. The AAFP long-advocated for and applauded the recent removal of the x-waiver, and we appreciate the DEA taking action to quickly implement this change.

During the PHE, the DEA and the Substance Abuse and Mental Health Administration (SAMHSA) implemented temporary flexibilities to make prescribing buprenorphine more accessible and to prevent the spread of COVID-19 while ensuring patients could continue with MOUD treatment. The AAFP applauded these steps, which allowed physicians to prescribe buprenorphine and initiate treatment via telehealth and audio-only visits and advocated for these flexibilities to be made permanent.

Evidence published during the PHE confirmed that the new telehealth flexibilities improved access to and retention to buprenorphine treatment. Some programs saw a sharp increase in buprenorphine initiation once telehealth flexibilities were in place during the PHE.[1] Studies also showed that telehealth-only treatment of OUD using buprenorphine, including audio-only, increased treatment retention and reduced illicit opioid use when compared to those using in-person treatment options.[2, 3] This was true across demographics and geographic locations.[4] Telehealth and audio-only initiation of and continued treatment with buprenorphine was also associated with higher patient satisfaction, lower health care costs, and improved access to treatment.[5]

In response to this evidence, SAMHSA recently released and the AAFP supported a proposed rule that would allow registered opioid treatment programs (OTPs) to permanently continue telehealth and audio-only prescribing of buprenorphine after the PHE ends on May 11, 2023. The AAFP appreciates that the DEA is also taking action to clarify how the current flexibilities will change for physicians not practicing at an OTP once the PHE ends.

Under a companion proposed rule (telehealth prescribing proposed rule), the DEA would restrict "virtual first" prescribing of controlled medications to only those that are schedule III-V non-narcotics. The AAFP submitted comprehensive comments on this companion rule, applauding DEA for enabling clinicians with established in-person relationships to continue prescribing controlled substances via telehealth after the PHE and recommending a number of improvements to ensure ongoing, equitable access to care. This proposed rule, "Expansion of Induction of Buprenorphine via Telemedicine Encounter," would create an exception to the telehealth prescribing proposed rule to allow schedule III-V narcotics used for OUD treatment to be prescribed via telehealth and audio-only visits with certain restrictions. To date, buprenorphine is the only schedule III-V narcotic approved to treat OUD.

Definition of Telehealth

DEA proposes to define several terms in reference to existing CMS regulatory definitions for telehealth and interactive telecommunications system. This includes specifying that interactive telecommunications systems include systems using two-way, real-time audio/video communications technology. CMS also allows the use of two-way, real-time audio-only technology for the provision of mental health services, provided to patients in or near their home, and when the patient is unable or does not want to use audio/video technology.

The AAFP appreciates and supports efforts to align and harmonize federal regulations, as it eases compliance burden for physicians. We strongly support DEA proposing to allow the use of audio-only encounters to prescribe buprenorphine for MOUD. The lack of modern broadband infrastructure has

proven to be a primary barrier to equitable telehealth and digital health access for rural Americans, who are 10 times more likely to lack broadband access than their urban counterparts, leading to fewer audio/video visits.[6,7,8] A report from the Assistant Secretary for Planning and Evaluation (ASPE) also found that Black, Latino, Asian, and elderly patients, as well as those without a high-school diploma, were more likely to rely on audio-only telehealth visits. As mentioned above, the available evidence also confirms buprenorphine prescriptions via audio-only encounters are safe and effective.

In-Person Evaluation Requirement

As proposed, the DEA would limit telehealth and audio-only prescribing of buprenorphine to 30-days if the patient has not received an in-person evaluation by either the prescribing clinician or through one of the approved pathways discussed further below. Prescribers that have ever performed an in-person evaluation or are comfortable with relying on an in-person evaluation from another clinician through one of the alternative pathways would no longer be subject to this restriction.

The AAFP shares DEA's concerns about the substance use and overdose crisis in the U.S. and we agree that an ongoing relationship with a physician is often vital for patients receiving OUD treatment. **The in-person connection between a physician and patient can provide a valuable touchpoint for patients receiving MOUD and other OUD treatment services. However, existing shortages of clinicians prescribing buprenorphine for OUD, as well as numerous other barriers faced by patients with OUD, will prevent many patients from being able to obtain an in-person visit, particularly within the 30-day timeframe.** Nearly 160 million individuals live in a mental health professional shortage area, and many more have mental health professionals in their area that do not accept the patient's insurance or require unfeasible cost sharing.[9] Nearly 99 million individuals live in a primary care health professional shortage area and would be unable or challenged to receive MOUD without telehealth and audio-only visits.[10] This difficulty in access to care for patients is compounded by transportation, time, and child-care challenges, as well as trauma and stigmatization from past experiences with the health care system. All of which makes virtual visits critically important for initiating and maintaining OUD treatment.

While an in-person evaluation may be necessary for other primary care treatment, the data cited previously shows that buprenorphine prescribing is particularly well-suited for virtual-only visits. As previously mentioned, telehealth initiation of and continued treatment with buprenorphine has shown greater treatment retention, reduced illicit opioid use, improved access to treatment, greater patient satisfaction, and reduced healthcare costs. We note that telehealth management of buprenorphine does not preclude a physician from obtaining urine drug screenings or referring patients to other services and supports, such as counseling.

Given the evidence in support of telehealth, limited access to OUD treatment prescribers, relatively lower rate of buprenorphine diversion, and the other measures to limit diversion as proposed in this regulation, the AAFP strongly encourages the DEA to rescind the proposal to require any in-person exam for prescribers of buprenorphine for treatment of OUD.

Absent a full removal of this in-person requirement, we recommend DEA allow six to twelve months of virtual-only prescribing and management before requiring an in-person exam. As we detailed in our comments on the companion telehealth prescribing proposed rule, a six month period would provide patients and clinicians with adequate time to find, schedule, and obtain an in-person exam from their prescriber or through one of the approved pathways. The AAFP reiterates that a 30-day supply limit will create significant operational and logistical challenges for patients and for the health care system. We are also concerned that the proposal to impose a one-time 30-day supply limit does not reflect the latest clinical evidence and could cause patient harm. It is vital that DEA provide patients with ample

time and flexibility to overcome transportation, cost, child-care, stigma, and other barriers to OUD treatment.

Alternative In-person Examination Pathways

DEA proposes two pathways that can be used to obtain an in-person physical exam from another practitioner. If either of the two pathways are used, the controlled substance prescription provided pursuant to a telehealth encounter will no longer be subject to the 30-day supply restriction.

The first option is for the prescribing practitioner to participate in a real-time audio/video telehealth visit with another DEA licensed practitioner that is physically in the presence of the patient. Audio-only technology would not be permitted. The non-prescribing practitioner would have to be acting in the usual course of professional practice. The prescriber would then remotely observe the in-person evaluation conducted by the on-site practitioner and rely on it when determining whether or not to continue prescribing to the patient.

The second option is for the prescribing practitioner to receive a qualifying telemedicine referral from a DEA registered practitioner. Under this pathway, the patient must have received a face-to-face evaluation from a DEA registered practitioner, known as the "referring practitioner." The referring practitioner may then issue a written qualifying telemedicine referral to the prescribing practitioner based on the diagnosis, evaluation, or treatment that was provided for the medical issue upon which the evaluation was predicated.

The AAFP appreciates that DEA proposed these pathways to enable patients to obtain an in-person medical evaluation with another practitioner even if they are not able to see a particular prescriber in-person. We believe the qualifying telemedicine referral could be valuable for family physicians who choose to refer their patients to other licensed clinicians with additional expertise to treat and manage certain conditions, like OUD. For example, we believe many family physicians caring for patients with OUD and/or other severe mental health conditions may wish to refer their patients to a behavioral health professional that is located outside the patient's community. The family physician is well positioned to conduct a physical exam and provide relevant clinical information to the behavioral health clinician to inform treatment and appropriate prescribing, but the behavioral health clinician may be better equipped to manage the prescribing and monitoring of the medication for treatment. This could improve access to needed behavioral health care for many patients.

However, as proposed, the documentation requirements for both pathways are overly burdensome and will prevent family physicians and patients from being able to use them regularly. **The AAFP urges DEA to remove the following requirements:**

- **The requirement that both the prescribing practitioner and the practitioner that is physically present with the patient document the address where the prescribing practitioner is physically located during the telehealth visit.** Some physicians provide telehealth services from their homes and have privacy concerns with their home address being documented and shared in patients' medical records and other locations. To avoid physicians receiving threats or experiencing harassment or violence in their homes, DEA should allow both practitioners to document a business address for the prescribing practitioner, if available.
- **The requirement that the referring or physically present practitioner be DEA licensed.** Physicians, nurse practitioners, and physician assistants who are not DEA licensed could still provide an acceptable referral and medical evaluation even if they are not DEA licensed, as long as they are licensed to practice in the state. Expanding eligibility for referral or exam to

practitioners that are not registered with the DEA could further expand access to care. DEA would have sufficient ability to audit the prescribing practices and referral through other documentation requirements.

We further note that referring clinicians should be able to refer patients to a physician by name or practice name and should not be required to include the prescriber's NPI on a qualified referral. The AAFP urges DEA to ensure that both of these pathways are as accessible and flexible as possible to ensure they meet their intended goals of improving access to care while ensuring patient safety and preventing diversion.

Grace Period for Telemedicine Relationships Established During the COVID-19 PHE

Under the telehealth prescribing proposed rule, the DEA proposes to establish a grace period for patient-physician relationships that were established during the PHE. This allows a clinician to continue prescribing schedule III-V non-narcotics for an additional 180 day after the final rule's effective date, if the patient was receiving prescriptions from this clinician via telehealth between March 20, 2020, and May 11, 2023, pursuant to the COVID-19 PHE.

The AAFP appreciates this grace period for relationships established during the PHE. **Absent a full removal of the in-person requirement for buprenorphine for OUD prescribing, the AAFP strongly urges the DEA to provide clarification that this grace period will also apply to patients and prescribers who established a relationship via telehealth for OUD treatment during the COVID-19 PHE.**

PDMP Data Review

The DEA proposes to require clinicians review and consider PDMP data prior to prescribing buprenorphine. In circumstances where the PDMP system is non-operational, practitioners would be required to limit prescriptions to patients to no more than a seven-day supply until they are able to access the PDMP system again. The practitioner would also have to record their attempts to access PDMP data, including the date, time, and reasons for being unable to gain access.

The AAFP advocates for physicians to use their state PDMP before prescribing any potentially misused pharmaceutical product, and we support the DEA finalizing this provision. However, the success of such efforts depends on state reporting systems that are accessible, timely, interoperable, and comprehensive. State investments in their PDMP systems vary widely and directly impact the effectiveness and accessibility of PDMPs. To ensure this provision fulfills the intended goal of helping clinicians identify potential diversion risks, co-prescribing concerns, and inappropriate prescribing by other clinicians, the AAFP strongly encourages the DEA to work with states to improve the functionality, utility, and interoperability of PDMPs, and develop best practices for their use and implementation.

The AAFP does not support the requirement to limit prescriptions to a seven-day supply if the prescriber is unable to access the PDMP. Most states already require clinicians to access the PDMP prior to issuing a prescription for a controlled substance, but those states *do not* restrict access to care for the patient as a result of this requirement. PDMP systems experience outages and interoperability challenges but these outages should not disrupt patients' access to medications as long as the prescriber is documenting attempts to access PDMP data. Limiting prescriptions to a seven-day supply could create barriers to obtaining prescription refills and result in needless discomfort, frustration, and even harm. We urge DEA to rescind this policy.

Licensure and Comprehensive Recordkeeping

The DEA proposes to require that the prescriber be authorized by state law, or not otherwise prohibited by state law, to engage in the practice of telemedicine in both the state where the practitioner is located, as well as the state where the patient is located. The AAFP does not support this proposal and refers and DEA to our comments on the companion telehealth prescribing rule. As we stated in those comments, it is standard practice to require only that the practitioner be licensed and permitted to practice telehealth in the state in which the patient is located. This provides the state where the patient is located with the oversight and related authorities to ensure patient safety. Applying the same requirement to controlled substance prescribing gives DEA sufficient audit and other law enforcement abilities. We recommend DEA modify this policy accordingly.

The DEA proposes to require all clinicians to maintain comprehensive records beyond what is currently required to include:

- whether the telemedicine encounter was conducted using audio-video or audio-only technology,
- the patient's reason for requesting an audio-only encounter, if the encounter was audio-only, and
- all efforts to comply with PDMP checks.

As proposed, these records would be maintained at the registered location on the clinician's DEA-registration.

While the AAFP agrees that much of these record keeping requirements are already standard practice, some aspects of EHRs will need to be updated to accommodate these requirements. As such, the AAFP encourages the DEA to implement at least a 12-month grace period to ensure EHR system come into compliance and physicians are not penalized when awaiting an EHR update for the purpose of this statute. We appreciate the DEA taking action to reduce risk of diversion without overburdening physicians with regulatory reporting that would ultimately reduce access to affordable and timely care. With this in mind, we strongly urge the DEA to not implement additional record keeping requirements that will unduly burden physicians.

Thank you for the opportunity to provide these comments. The AAFP looks forward to working with the DEA and other agencies to uphold safe prescribing practices and improve access to SUD treatment. For additional questions, please contact Morgan Bailie, Senior Regulatory Specialist, at mbailie@aafp.org.

Sincerely,

Sterling Ransone, Jr., MD, FAAFP
American Academy of Family Physicians, Board Chair

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