AAFP
AMERICAN ACADEMY OF FAMILY PHYSICIANS

March 29, 2023

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

Re: RIN 1117-AB40; 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 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) entitled "Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation" as posted in the March 1, 2023 version of the Federal Register.

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. Congress also directed the Drug Enforcement Agency (DEA) to promulgate regulations establishing a special registration for the prescribing of controlled substances via a telehealth encounter but these regulations were not developed before the COVID-19 pandemic. During the COVID-19 PHE, the DEA established flexibilities to allow for virtual prescribing of controlled substances without an in-person visit requirement. This helped ensure timely access to care for patients while also helping to keep primary care practices open and minimizing patient and clinician exposure to COVID-19. This NPRM proposes new federal regulations for the prescribing of controlled substances via telehealth encounters after the end of the PHE, which will end on May 11, 2023.

The AAFP appreciates DEA proposing regulations to permanently enable telehealth prescribing of controlled substances and buprenorphine for the treatment of opioid use disorder (OUD). **We agree that a continuous care relationship enables clinicians to provide patient-centered care and can help guard against misuse and diversion. However, we are concerned that these proposed regulations will restrict access to care, exacerbate health disparities, and inappropriately interfere in clinical decision making. In the final rule, the AAFP recommends the DEA:**

- **Increase the 30-day maximum supply for "virtual first" telehealth prescriptions of schedule III-V controlled substances to a six-month supply before an in-person exam is required;**
- **Remove overly burdensome documentation requirements and duplicative licensing requirements for prescribers;**

1133 CONNECTICUT AVE., N.W., STE. 1100 | WASHINGTON, DC 20036-4305 | (800) 794-7481 | (202) 232-9033

- **Rescind the proposal to limit prescriptions to a seven-day supply if the prescriber cannot access Prescription Drug Monitoring Program (PDMP) data;**
- **Finalize the proposal to implement a 180-day grace period for prescribers to conduct a qualified in-person examination on patients for which they established a relationship during the COVID-19 PHE; and**
- **Focus efforts to prevent diversion primarily on law enforcement tactics instead of establishing specific standards of care through DEA rulemaking.**

General Comments

Family physicians are trained to provide high-quality, person-centered, continuous primary care for patients across the lifespan. Family physicians' broad scope of practice is both unique and valuable, as they are able to modify their personal focus and scope of practice to meet the needs of their communities. Family physicians practice in a wide variety of settings, from primary care practices, to hospitals, skilled nursing facilities, emergency departments, urgent care centers, and hospice facilities. As such, family physicians prescribe a wide variety of controlled substances to patients for the treatment of a broad range of conditions. They have also experienced first-hand the profound impact of the opioid and overdose epidemics on their patients and communities. The AAFP has advocated to improve safe prescribing guidelines, improve access to substance use disorder treatment, and offers a plethora of continuing medical education opportunities on these topics.

Family physicians rapidly implemented telehealth in their practices during the COVID-19 pandemic. A recent AAFP survey found that 90 percent of family physicians are providing telehealth services, with more than 80 percent providing audio-only telehealth services. Patients and clinicians agree – and the latest available evidence confirms – that telehealth is a valuable modality of care that should be available and accessible after the end of the PHE. Family physicians are more likely than other physicians to practice in rural and other underserved areas and they have repeatedly shared that telehealth has removed barriers to care for many patients during the PHE.

The AAFP has advocated to permanently expand coverage and payment of telehealth services and shared our support for policies that facilitate the use of telehealth from patients' usual source of continuous primary care. We have repeatedly shared concerns that services provided by direct-to-consumer telehealth companies may drive care fragmentation. However, we have also advocated for the removal of in-person visit requirements for Medicare beneficiaries seeking tele-mental health services due to the well-documented dearth of behavioral health professionals.

Patients increasingly rely on their primary care physicians to address mental and behavioral health concerns. Some family physicians have integrated behavioral health services into their practice to comprehensively meet their patients' needs, noting that many struggle to find this care elsewhere in their communities. Family physicians are often some of the only OUD treatment providers in their communities. However, many of our members report significant barriers to integrating mental health care into the primary care setting, noting the lack of available behavioral health clinicians and significant upfront costs. Evidence indicates behavioral health workforce shortages also prevent primary care physicians from referring patients to behavioral health specialists.[1] While the AAFP has advocated to address primary care and behavioral health workforce shortages and bolster supports for practices integrating behavioral health care, data suggest patients will continue struggling to access in-person behavioral health care.

National and regional news reports indicate that many patients are struggling to find a primary care physician or secure an appointment in a timely manner. The latest physician workforce data indicate that, not only are we facing a significant primary care physician shortage, many physicians are near retirement, with 45 percent of surveyed primary care physicians over the age of 55 reporting that they plan to stop seeing patients in the next one to three years.[2,3] A recent study also found that the number of active physicians dropped by almost 7 percent between 2019 and 2021, with disproportionate losses in rural areas.[4] The study further notes that physician work hours have continually declined over the past twenty years, causing physician workforce hours per capita to lag behind US population growth.[5] These data indicate that health care access challenges may worsen as the health care workforce and overall population age and clinicians leave the workforce as a result of the pandemic. These health care workforce challenges, as well as other barriers, like transportation, cost, childcare, and lack of paid time off, make telehealth modalities more timely, accessible and, in many cases, preferrable for some patients.

We share the above data, previous advocacy, and relevant AAFP policies as context for our comments on the NPRM. **The AAFP is strongly supportive of policies that promote patient access to continuous, evidence-based care and strengthen the patient-physician relationship. However, we also strongly urge the DEA to refrain from interfering in this relationship and in clinical decision-making, and instead focus efforts to address diversion on law enforcement activities**. Below we provide specific recommendations for how DEA can increase the flexibility in these regulations to facilitate access to evidence-based care while also preventing diversion.

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. The AAFP firmly believes that audio-only technology should be permitted for services beyond mental health services when a patient is unable or unwilling to have an audio/video telehealth visit. 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. The available data clearly indicate that the availability of audio-only services is essential to facilitating equitable access to care after the PHE-related telehealth flexibilities expire. **To facilitate equitable access to evidence-based treatments, the AAFP urges DEA to expand the acceptable use of audio-only services under these regulations.**

Documentation and Licensing Requirements

DEA proposes to require all telemedicine prescriptions include on the face of the prescription, or within the order if prescribed electronically, that the prescription was issued via a telemedicine

encounter. The AAFP does not support this proposal. Our members report that their patients often face barriers filling controlled substance prescriptions at the pharmacy, particularly as many pharmacies have instituted their own “red flag” and other programs that prevent patients from obtaining medications as a result of a prescriber’s patterns or volume of prescriptions. While we share concerns about diversion and inappropriate prescribing, these programs have resulted in significant burden (and potentially patient harm) for family physicians, particularly those that practice in underserved areas and serve as medical directors of facilities like hospice centers. **We are concerned that requiring prescribers to denote that prescriptions were issued pursuant to a telehealth encounter will only worsen these challenges for patients in accessing the courses of treatment prescribed to them by their physician.**

DEA proposes to require a prescriber to maintain a written or electronic log for each prescription issued pursuant to a telemedicine encounter indicating the date the prescription was issued, the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, and directions for use; the address at which the practitioner, and the city and state in which the patient, is located during the encounter. The AAFP supports all of these proposed requirements except for the requirement that the practitioner document the address at which they are located during the encounter. **Some physicians and other practitioners conduct telehealth visits in their homes and should be able to instead record a business address to protect their privacy and personal safety.**

DEA proposes to add regulatory language clarifying that telemedicine may only be used to issue a prescription if that prescription is issued pursuant to a telemedicine encounter and for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The prescription would need to arise out of a telemedicine communication directly between the prescribing practitioner and the patient. DEA further proposes that a practitioner cannot use telemedicine to prescribe controlled medications while that practitioner is located outside the United States (including states, territories, or possession of the United States; the District of Columbia; or the Commonwealth of Puerto Rico). The AAFP supports these proposals.

DEA proposes to require that the practitioner prescribing via a telemedicine encounter be authorized to prescribe that basic class of controlled substance under registrations in the state where the practitioner is located, as well as the state where the patient is located. **The AAFP opposes this proposal.** It is standard practice to require only that the practitioner be licensed 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.

Requiring the physician to also have a DEA license for the state in which they are located adds an unnecessary, duplicative requirement that will needlessly create barriers to care. For example, many family physicians travel regularly to professional conferences in states where they do not regularly practice and therefore are not licensed to prescribe controlled substances. This would prevent physicians from being able to provide continuous care to patients when they travel out of state.

The DEA proposes to require clinicians review and consider prescription drug management program (PDMP) data from the state the patient is located in (or the comparable Veteran’s Health Administration portal) prior to prescribing controlled substances via a telehealth encounter. 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 encourages physicians to attempt to access their state PDMP before prescribing any potentially misused pharmaceutical product, and we agree these requirements should apply to telehealth prescribing of controlled substances. 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. As detailed further below, some schedule III-V medications carry patient safety risks if a course of treatment is improperly or abruptly stopped. Limiting prescriptions to a 7-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.

Finally, the AAFP notes that electronic health record (EHR) and other system updates will be required before physicians can comply with new documentation and other administrative requirements. **DEA must allow at least a 12-month grace period after regulations are finalized to allow for upgrading and configuration of EHRs before physicians are subject to audits or other enforcement actions related to these provisions.**

<u>Extend the 30-day Supply Limit</u>

DEA proposes to impose a one-time 30-day supply limit for prescriptions of schedule III-V non-narcotic controlled substances prescribed through a telehealth encounter with a prescriber that has never performed an in-person exam on the patient (or received a qualified exam or referral through the pathways discussed later). DEA refers to these as "virtual-first prescriptions." Prescribers who have performed an in-person medical exam on the patient previously are not subject to these restrictions and are free to prescribe any controlled substance to patients as long as they are complying with state and federal requirements and acting in their usual course of professional practice.

The AAFP is appreciative that the DEA did not propose a supply limit for prescribers that have previously performed an in-person exam on the patient. We strongly agree that all prescribers who have performed an exam and therefore have an established relationship with the patient should be able to prescribe controlled substances without arbitrary restrictions, provided they are otherwise licensed and permitted to do so under state and federal laws and regulations.

This appropriately leaves clinical and shared decision making up to the prescribing clinician and patient.

Care continuity is a cornerstone of family medicine: family physicians develop and maintain long-term relationships with their patients and are well-equipped to determine appropriate prescribing. Enabling family physicians to prescribe these treatments via telehealth encounters will advance equitable access to evidence-based care, particularly for patients who face barriers obtaining in-person services. Our members have repeatedly emphasized the importance of maintaining telehealth access, coverage, and payment for their patients living in rural and other health professional shortage areas, patients with disabilities, homebound patients, and those who regularly travel outside of their community, like college students and snowbirds.

The AAFP is concerned that the proposed 30-day supply limit for virtual-first schedule III-V prescriptions will create operational and logistical challenges for both physicians and patients and could ultimately risk patients' safety. As we mentioned previously, many patients are reporting challenges finding and securing a timely appointment with both primary care physicians and subspecialists. Family physicians confirm months-long wait times for new patient appointments in their practices are common. Imposing a 30-day supply restriction will force patients to scramble to find a local physician or referring clinician within a matter of weeks to have their prescription refilled. This will increase appointment wait times for patients, as well as add to physicians' already overwhelming administrative and regulatory burdens as they try to fit more and more patients in their schedule to avoid disruptions in treatments. Many practices are scheduling new patient appointments several months out, meaning most patients will be unable to secure an appointment and medication refill, potentially worsening their condition and overall health. **Some schedule III-V medications can cause seizures and other dangerous side effects and outcomes if patients abruptly stop a course of treatment.[9] Patients that are unable to secure appointments within the 30-day timeframe could experience significant discomfort and even patient harm.**

Patients faced challenges obtaining timely in-person care and refilling medications after recent crackdowns by pharmacies and regulators on some telehealth companies' prescribing practices.[10] While the prescribing practices of these companies may have been inappropriate, patients should not be left without access to the care they need. These operational and logistical challenges will be particularly overwhelming for physician practices who provide, and patients who need, certain types of care that are only provided by a small proportion of clinicians across the country. For example, one family physician noted that they provide gender affirming care to transgender patients that would have to travel hours to have an in-person visit. **The AAFP is therefore concerned that the 30-day timeframe will exacerbate existing health access and outcome disparities for already vulnerable patient populations.**

We are also concerned that the 30-day timeframe is not evidence-based and does not take into account the patient's condition or prescriber's assessment and treatment plan. Family physicians note that many schedule III-V medications can be safely prescribed and managed via telehealth for periods much longer than 30 days. For example, current law enables clinicians to prescribe Depo-Testosterone, a schedule IIIN medication, for up to six months before the prescription has to be reordered by the prescribing practitioner. Further, some mental health conditions can be safely treated without ever performing a physical exam.[11,12,13] Family physicians also note that they would be comfortable refilling some schedule III-V medications via telehealth encounters for new patients who have been taking these medications for several years and would experience

unnecessary withdrawal if their prescriptions lapsed. For example, as many primary care physicians retire, many elderly patients are proficient at using telehealth and may have a telehealth appointment to refill longtime prescriptions, such as lorazepam, as they await a new patient in-person appointment.

For these reasons, we urge DEA to allow prescribers to manage a patient's condition via telehealth visits for six months before requiring an in-person visit. While this timeframe is still somewhat arbitrary for some medications, it will provide patients and physicians with needed time and flexibility to secure a new patient visit and plan around transportation, work, and other challenges. We note that prescribers would still have to adhere to state laws throughout this time period. Family physicians indicate that they would continue to adhere to standards of care and prescribing guidelines, including scheduling telehealth follow-up visits with patients when appropriate or needed. **If DEA disagrees with our recommendation, the agency must provide at least a 90-day timeframe before an in-person exam is required. Failing to do so will create significant disruption across the health care system.**

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. We provide comments on each pathway.

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. DEA proposes to require the prescribing practitioner to document the date and time of the evaluation, the National Provider Identifier (NPI) of the DEA-registered practitioner physically present with the patient, the address at which the prescribing practitioner is located during the telemedicine encounter, and the address at which the other DEA-registered practitioner is physically present with the patient during the encounter. DEA proposes to require the practitioner physically with the patient to maintain similar documentation.

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 referring practitioner must communicate the results of the evaluation to the prescribing practitioner before the prescribing practitioner can issue a prescription. The prescribing practitioner would have to maintain documentation the NPI of the referring practitioner and the referral.

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. For example, we believe many family physicians caring for patients with 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 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.

<u>Grace Period for Telemedicine Relationships Established During the COVID-19 PHE</u>

DEA proposes to define "telemedicine relationship established during the COVID-19 public health emergency" as a relationship in which the practitioner has not conducted an in-person medical evaluation of the patient and has prescribed one or more controlled medications based on telemedicine encounters during the nationwide COVID-19 PHE. DEA proposes prescribers with such relationships would have a six month grace period after the end of the COVID-19 PHE to perform an in-person medical evaluation before the provisions of this rule would apply.

The AAFP supports this proposal and urges DEA to finalize it. As mentioned previously, we believe requirements for patients to quickly obtain in-person evaluations to continue on a course of treatment will create significant disruption in the health care system. This proposed grace period will provide patients and clinicians with several months to obtain an in-person medical evaluation before

being required to comply with these new regulations, lessening the operational and logistical disruption and avoiding unnecessary interruptions in patients' treatment plans.

Requests for Comment

DEA seeks comment on whether these regulations should limit the issuance of prescriptions for controlled medications to the FDA-approved indications contained in the FDA-approved labeling for those medications. The AAFP strongly urges DEA not to apply this limitation. Medications are often prescribed for off-label indications, particularly for certain populations like children and pregnant patients. Limiting prescribing to the FDA-approved indications will create unnecessary barriers to care for these and other patients who can safely use medications to treat other conditions. We again urge the FDA to refrain from interfering in clinical decision making and leave determinations about appropriate prescribing up to physicians and other licensed clinicians.

DEA also seeks comments on whether the companion NPRM addressing telemedicine prescribing of buprenorphine should be combined with this rulemaking or kept separate. There is some confusion about which of the policies in this rule would apply to prescribing buprenorphine via telehealth. Combining the rules would likely provide needed clarity.

Thank you for the opportunity to provide comments on the NPRM. The AAFP looks forward to partnering with DEA to ensure continuous, equitable access to care after the end of the PHE. Should you have any questions or wish to set up a meeting, please contact Meredith Yinger, Manager of Regulatory Affairs, at myinger@aafp.org or (202) 235-5126.

Sincerely,

Sterling N Ransone, Jr MD FAAFP

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

Cc: The Honorable Xavier Becerra, Secretary, Department of Health and Human Services

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