

March 27, 2023

Anne Milgram
Administrator
Drug Enforcement Administration
Attention: DEA Federal Register Representative
DPW, 8701 Morrisette Drive
Springfield, Virginia 22152

Re: Expansion of Induction of Buprenorphine via Telemedicine Encounter (Docket No. DEA-948)

Submitted electronically on regulations.gov

Dear Administrator Milgram:

On behalf of ATA Action, thank you for the opportunity to comment on the Drug Enforcement Administration (DEA)'s proposed rules regarding expansion of induction of buprenorphine via telemedicine. We appreciate DEA's responsibility to write rules that provide effective controls against diversion and protect public health and safety but believe that **the requirement that a patient see a clinician in-person is not an effective control against diversion and, instead, simply limits access to legitimate health care**. These comments elaborate further upon this theme and provide additional suggestions for ways to improve the draft rule to maintain mechanisms to prevent diversion while ensuring patients do not lose access to necessary treatments. We offered similar comments to Docket No. DEA-407, Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation.

ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, advances policy to ensure all individuals have permanent access to telehealth services across the care continuum. ATA Action supports the enactment of state and federal telehealth coverage and fair payment policies to secure telehealth access for all Americans, including those in rural and underserved communities. ATA Action recognizes that telehealth and virtual care have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

Timeline to Finalize and Implement is Not Feasible

We are gravely concerned with the timeline to finalize and implement DEA's proposed new process. Published March 1, 2023 with a 30-day comment period, the proposed rule – while not a special registration as required by law, would be a new process for provider compliance. As of March 27, there were over 2,000 filed stakeholder comments to the rule. This allows for **around 6 weeks** for DEA to review and respond to comments, write and publish a final rule, *and* for providers to read and implement the final rule before the COVID-19 public health emergency (PHE) ends on May 11. While we appreciate DEA's recognition that the pre-pandemic policy for controlled substance prescribing was untenable and that a new post-pandemic framework is necessary, we must note that compliance with new regulations will take time. To ensure that patients do not lose access to necessary services via telehealth, we strongly urge DEA to extend the existing pandemic-era flexibilities for such period of time that the rule is finalized and implementable or at least through calendar year 2023.

In-Person Mandates Restrict Access to Care

During the COVID-19 PHE from early 2020 until May 11, 2023, DEA has used its public emergency authority to waive the prior in-person requirement. This has enabled providers to safely prescribe controlled substances remotely using telemedicine, increasing access to clinically appropriate medications. After the initial experience of the pandemic, a report found that over 70% of providers surveyed reported that telehealth made patient continuity of care better or much better and that overall level of care provided via telehealth was better or equal to that of in-person care.¹

Mandating an in-person evaluation prior to prescribing a controlled substance via telemedicine only results in reduced access to care and does not enhance DEA's ability to do its job of limiting drug diversion or pursuing illegal actors. A provider seeing a patient in person does not prevent the provider from acting illegally. Nor does a provider seeing a patient via telehealth enhance the risk of illegal activity or diversion. In fact, reports and investigations during the COVID-19 public health emergency (PHE) from the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) have found cases of fraud via telehealth have been rare despite the lifting of restrictions such as in-person requirements and that fraud that does occur mirrors what is found in the in-person modality².

While in-person requirements may be intended to reduce diversion and illegal activity, they likely will result in the opposite. As access to legitimate healthcare is restricted, a consequence of these draft rules, illegal online drug sellers will fill the void. Patients who need treatment but now cannot access care via telehealth face a terrible choice: no access to care, or seek medication through unregulated, dangerous sources such as illegal online pharmacies and social media drug dealers.^{3,4} We urge DEA to reject the notion that an in-person visit is necessary prior to a telemedicine visit and instead pursue other mechanisms to prevent inappropriate access to medication via the internet. Today illegal online drug sales as well as drug diversion continues to occur and should be addressed, but we have not seen increased illegal activity related to the waiver of these requirements during the pandemic.

Every state allows a clinician and a patient to establish a valid relationship via telehealth⁵, and that relationship is just as legitimate as one established in-person. Providers routinely conduct appropriate virtual physical examinations via telehealth^{6,7,8} when indicated by the standard of care (and of note, mental and behavioral health examinations rarely require a physical component). When a practitioner is unable to obtain the data they need during a virtual physical examination, clinical best practice indicates that an in-person consultation is the logical next step. Such decisions should be based on a provider's clinical discretion rather than policy mandates. DEA should defer to the clinical authorities and allow legitimate practice to occur. Rather than attempting to regulate the circumstances under which telemedicine is appropriate, DEA should defer to state law and clinical practice standards while tracking and monitoring DEA-licensed telehealth practitioners in the same way DEA already does for in-person providers.

Restricted Access to Telemedicine Will Increase Patient Harm and Diversion Risks

Virtual care isn't just a stopgap until patients can see their provider again in person; for some, virtual care is the only option either due to socio-economic factors, convenience or preference, or because a physical location just isn't available where they are. Accordingly, many relationships that were newly established during the pandemic were with providers who do not have a brick-and-mortar presence at all or near the patient's location. Moreover, many patients have since moved farther away from their

provider but continue the care plan with their provider of choice, who they trust and with whom they have built a relationship. With an in-person requirement in place, these patients will have nowhere to turn, and many will end up with delayed or no care, resulting in negative outcomes.

There is an ever-increasing number of patients who cannot or will not seek treatment for their conditions in person. These are the patients who will fall through the cracks under this rule, creating a significant and avoidable public health crisis. Challenges to obtaining in-person care include:

- *Provider shortages:* Nearly one-third of Americans do not have access to a usual source of primary care due to a shortage of providers in their local communities; this problem is even more acute in sparsely populated rural areas.^{9,10} The U.S. could see an estimated shortage of nearly 125,000 physicians by 2034, including shortfalls in both primary and specialty care.¹¹ And this problem is exacerbated for the mental health workforce: nearly half the U.S. population is living in a mental health workforce shortage area.¹²
- *In-person visit wait times:* The average wait time to secure an appointment with a physician in 2022 was 26 days. So once a patient finds a provider, they must wait additional weeks before seeing that provider.¹³ Telehealth providers are often much more readily accessible.
- *Sensitive conditions require culture competence and privacy:* Patients with mental health and substance use disorder conditions have historically been reticent to seek treatment due to stigma both from health care providers and from their friends, family, and communities. It may be challenging for patients to find a local provider they can trust to treat their conditions medically and with the appropriate cultural competency. Telehealth can offer a more private option for patients. Further, the ability to seek care outside of one's physical community vastly expands the opportunity to find a provider who understands your experience and can treat you in a compassionate and culturally competent way.
- *Substance use disorder (SUD) barriers and stigma:* Telehealth has been a critical access point for OUD treatment during the pandemic and has the potential to benefit underserved populations.¹⁴ Any barrier posed to a patient seeking treatment for SUD decreases the likelihood that the patient will follow through on care. Among individuals who recognize that they need opioid use disorder (OUD) care, many do not seek it. Reasons for this may include cost of care, stigma, lack of local treatment availability, lack of transportation, and inconvenience.¹⁵ Although the administration's recent action to remove the burdensome X-waiver removed a barrier on providers seeking to treat patients with OUD, we have not yet seen an influx of new providers due to historic stigma and other challenges.¹⁶
- *Nontrivial convenience issues:* Whether in a rural area or an urban area, it can be difficult to obtain transportation and arrange childcare in order to travel across town or across the state to visit a clinician in person. This burden is even more significant for low-income populations with less access to affordable transportation or childcare, creating equity issues. Given ever-increasing reliance on and comfort with technology for every aspect of life, health care should keep pace and virtual care should be an option.

We are concerned that in-person requirements will exacerbate existing inequities in the health care system, as it will only serve patients who have the ability to see an in-person provider and misses the point that telehealth provides to reach previously unreachable populations.

Additionally, requiring patients who have already established a relationship with a virtual provider to then go seek treatment from an in-person provider is duplicative not only from a clinical perspective, but also from a cost perspective. This may drive unnecessary utilization of visits without clinical need simply to satisfy the requirement, thereby generating extra cost that could have been avoided.

As an alternative, DEA could require that the telehealth clinician attest that an in-person visit wasn't necessary for the service provided and document that information in the medical record.

In-person Requirement Should be Waived During the Ongoing Opioid Epidemic PHE

Thus, we strongly recommend DEA use its existing public health emergency authority to continue to waive the in-person requirement for buprenorphine for OUD treatment for the duration of the ongoing opioid epidemic PHE, consistent with the waiver available during the COVID-19 PHE.

While substantial negative media and law enforcement attention have been devoted to buprenorphine diversion, use of non-prescribed buprenorphine (NPB) is commonly observed among individuals trying to reduce opioid use or those struggling to access treatment^{17,18,19}. Qualitative research suggests that adults with a history of NPB do not seek or experience euphoric effects^{20,21} and studies indicate that approximately 70% to 90% of people who use “street Suboxone” report using it to prevent craving and withdrawal, suggesting use of NPB may be a stepping stone to formal treatment.^{22,23,24,25} These findings are consistent with pre-clinical human trials that have found no preference for buprenorphine over other opioids for rewarding effects.²⁶

Rules Should Create Less, Not More, Confusion for Pharmacies and Pharmacists

The rule proposes that the prescriber include a notation on the face of the prescription that the prescription has been issued via a telemedicine encounter, which we are referring to as a telemedicine “stamp”. Clinically, a valid prescription is a valid prescription and the fact that one was issued via telemedicine makes it no less so. Unfortunately, such a stamp will likely result in confusion and frequent denials to dispense legitimate prescriptions.

As access to telehealth has increased during the pandemic, and accordingly, prescriptions written as a result of a telehealth visit have increased, we have already seen a rise in denials of legitimate prescriptions at the pharmacy counter.^{27,28} This is due to a confluence of concerns stemming from unclear guidance and a resulting overabundance of caution on the part of both pharmacy chains and individual pharmacists. Every part of the pharmaceutical supply chain was implicated in the overprescribing and over-dispensing of prescription opioids that led to the opioid epidemic. Legal settlements have held many of these actors accountable and laws and rules have been changed to ensure more flagging of suspicious orders, doctor shoppers, and unscrupulous providers. However, the reaction to be more diligent around opioid prescribing, while appropriate, has often overzealously been applied to the treatment of opioid use disorder and other necessary controlled substance treatments. Pharmacies and pharmacists do not want to repeat the mistakes of the past, and have thus erred on the side of restricting access rather than risk over-dispensing. Inconsistent guidance and enforcement by DEA has fueled this fire. Unfortunately, telehealth often falls into the category of perceived potential

risk, and thus we see blanket denials of legitimate prescriptions. This has true impact on patients who are unable to access necessary medications.

There is an existing mechanism called electronic prescribing of controlled substances (EPCS) that is used to determine the legitimacy of a prescription for controlled substances. The multi-step mechanism ensures that only “authorized” providers who meet a series of criteria have the ability to safely transmit a controlled substance prescription electronically. In fact, there is an entire registration process they are required to undergo every time they work with a new practice. The SUPPORT Act, passed into law in 2018, required the use of EPCS and most prescribers and pharmacies are equipped to do so.²⁹ DEA should work with partners at HHS and the Centers for Medicare and Medicaid Services (CMS) to ensure these requirements balance the need to prevent diversion and allow for legitimate access to controlled substances. Rather than add a telehealth “stamp”, prescription requirements could be updated to include more relevant information such as the diagnosis date or the most recent consult/appointment date.

The proposed rules as drafted focus on the requirements around the telehealth prescribers, but do not adequately contemplate the next step in the process as those prescriptions reach the pharmacy. Under the rules, the pharmacist has no way of knowing – other than calling each individual prescriber and asking for documentation – if the prescriber followed all of the rules. The pharmacist has no way to know if the prescriber saw the patient in-person and even less way to know that information about a referring provider as “referring provider” is not typically a field included in an e-prescription. Pharmacies and pharmacists also have no guidance on what their responsibility is to verify this information. Given the existing inclination to err on the side of caution and the heavy administrative burden posed by this framework, the telemedicine stamp will simply result in denials and reduced access. As discussed below, a Special Registration process could have been an opportunity for pharmacists to easily identify legitimate telemedicine prescribers.

Proposed Provider Referral Pathway is Important, But Fixes are Needed

While we are gravely concerned about the patients who will fall through the cracks due to inability to obtain in-person care, we appreciate that the draft rule expands pre-pandemic access by allowing patients to receive ongoing telehealth care from a referring in-person provider. This referral pathway is welcome and creates a means of access for those patients who can receive care from an in-person provider who is willing to refer the patient to either their existing telehealth provider or a new one for ongoing treatment. We commend DEA for creating this option and, if in-person requirements are not removed entirely, urge DEA to maintain this option in the final rule.

However, we anticipate some operational complications and, therefore, recommend the following changes:

- **Group referrals:** Allow the in-person referring provider to refer the patient to a medical group, health system practice, or collaborative agreement, not a single specifically named clinician. Given provider shortages – especially in highly-specialized practices which often utilize controlled substances (e.g. child psychiatry) – and standard wait times for even telehealth appointments, it is unworkable to require the referring provider to know with specificity which clinician the patient will ultimately end up seeing at the moment of making the referral. Instead, the referring provider should be able to refer the patient to a medical group, health

system practice, or collaborative agreement (“group”). From there, the group should have the authority to assign the patient to a clinically appropriate, available provider for ongoing telehealth treatment. That provider would receive access to the referring provider’s records just as contemplated under the draft rule. This approach would be consistent with how provider referrals work in the real world.

- **E-Prescribing issues:** Remove the requirement that the referring provider be named on the e-prescription. Today’s e-prescribing platforms do not have a way to list the referring provider in the allotted fields. If this requirement is maintained, the proposed referral pathway will be non-functional – or at least executed in a non-compliant way – for most healthcare providers using standard e-prescribing platforms. See also aforementioned issues with pharmacists’ inability to verify that processes in this rule were followed.

Further recommendations to improve the proposed rule

While we appreciate DEA’s intention to allow some access to care by allowing a clinician to treat a patient via telemedicine with buprenorphine for OUD without having seen the patient in-person for 30 days, we do not believe it is appropriate for DEA to create an arbitrary time limit on the patient-provider relationship nor do we believe that 30 days is a clinically appropriate amount of time for a provider to treat a patient. In fact, in many cases, a 30-day prescription could do more harm than good.

A limited 30-day prescription of buprenorphine without guaranteed prescription refills is tremendously risky for a person struggling with opioid addiction. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), “patients who discontinue OUD medication generally return to illicit opioid use” and “arbitrary time limits on the duration of treatment with OUD medication are inadvisable”.³⁰ The potential consequences of being unable to continue buprenorphine treatment beyond 30 days are relapse, overdose, and death, which puts providers at risk of medical malpractice if they write these prescriptions. The average wait time to receive an appointment with a new provider in 2022 was 26 days.³¹ Thus if a patient initially seeks treatment from a telehealth provider, it is highly unlikely that they would be able to continue their prescription seamlessly after 30 days. Any barrier to access in that critical window is extremely dangerous: 93% of OUD patients returned to active opioid use following a 4-week course of buprenorphine according to a 2011 study³² and 87% of OUD patients returned to opioid use within three months of a 28-day course of buprenorphine, according to a large multi-site study in 2009.³³ In contrast, telehealth access to MOUD during the COVID-19 pandemic improved retention in care and reduced odds of medically treated overdose for Medicare beneficiaries according to recent landmark research.³⁴ The authors from the Centers for Disease Control and Prevention (CDC), National Institute on Drug Abuse (NIDA) and Centers for Medicare and Medicaid Services (CMS), all called for strategies to increase – not hinder – telehealth access.

This data is specific to buprenorphine, but we believe the same is true for other conditions and treatments. Another vulnerable population affected by this rule is those receiving palliative or hospice care. These patients may be at home or in a facility and cannot wait for an in-person provider with controlled substances prescribing authority to be able to visit them in-person before continuing to receive their necessary medications.

Telehealth enhances access and the requirement to see a provider in-person within 30 days is, best case, a barrier, and worst case impossible. Especially for vulnerable populations and those who may be

distrustful of the health care system, the requirement to see a provider in person creates a risk that the patient will discontinue care.

Thus, in the absence of removing in-person requirements completely, below are recommendations to improve the rule:

- We strongly suggest that telehealth providers be allowed to offer a **minimum 180-day supply** to give patients more time to find and see another provider in-person. Providers will also need time to update their models of care to comply with these new rules starting May 11.
- We appreciate the opportunity for patients who have established a relationship with their clinician via telehealth during the pandemic for 180 days post-pandemic. However, as these patients have established a relationship with a trusted clinician with a treating relationship lasting up to 3 years during the pandemic, we recommend **extending this flexibility for existing patients from 180 days to at least one year if not in perpetuity**. It does not make sense to jeopardize care for existing patients with an arbitrary requirement to see a new provider.

Lastly, we commend DEA for not creating restrictions around the location of the patient receiving telemedicine in this rule. Arbitrary restrictions on the location of the patient only reduce access to care and are not clinically necessary or logical in modern times.

Operational Challenges with Proposed Location and Registration Requirements

During the pandemic, the requirement for a prescriber to register with DEA in every state where they practice was lifted. The rule proposes that post-pandemic, prescribers must register with DEA both in the state where the patient is and where the provider is located. Additionally, the documentation requirements indicate that prescribers will have to list their location. These requirements are burdensome, unnecessary, and will be nearly impossible to comply with immediately. Registration can take weeks or months to complete and registration may be difficult or impossible where the provider does not have a physical location. If this rule were to go into effect, every provider intending to practice telemedicine would have to immediately pursue multiple new DEA registrations to satisfy all the possible locations where they and their patients are located. It is unlikely DEA has the existing capacity to process many registrations per provider, which will contribute to further confusion and delays. Registering based on the exact location of the patient and provider also prevents clinicians from seeing patients in an urgent situation if the clinician or patient is traveling and wants to take care of the patient with whom they've established a care rapport. This will lead to missed visits and gaps in care.

DEA acknowledges that practitioners with a multi-state practice could be prescribing in states where they might not retain a physical office location. ATA Action recommends that, at a minimum, in the absence of a special registration process, DEA should:

- Extend the registration flexibility for 180 days consistent with the other extension;
- Require prescribers to register with DEA only once;

- Require that prescribers provide a physical location for their practice, but not require that such a location exist in every state where the clinician practices and not require the prescribers' home addresses be listed publicly or in the patient's medical record; and
- Provide further clarity to how telemedicine practitioners with a multistate practice can meet the registration requirement.

Operational Challenges with Privacy Regulations for Substance Use Disorder Treatment

Substance use disorder providers are subject to privacy and confidentiality regulations separate and apart from typical privacy requirements of health care providers under HIPAA. These rules are referred to as 42 CFR Part 2 regulations or "Part 2", and are administered by SAMHSA.³⁵ Part 2 significantly restricts how SUD providers can communicate with referral partners and other practitioners. DEA's proposed rules do not appear to consider how SUD providers can simultaneously comply with both the proposed rules and Part 2. For example, a telemedicine prescriber of buprenorphine for OUD would not be able to communicate with a referring practitioner for the referral or subsequent care without a Part 2 compliant release of information from the patient. If it is granted, such explicit consent generally takes discussion and time with the patient as it is more complex than standard consent included in a HIPAA release. This added layer of time makes the 30-day window for telehealth before an in-person visit or referral all the more challenging. Part 2 also requires separation of SUD records from general medical records, implicating both documentation and communication requirements. Therefore, ATA Action recommends the rules be modified such that the requirements of the two federal laws are not in conflict and such that patient care is not interrupted.

The Special Registration Process Would Be an Appropriate Guardrail

When Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act in 2008, it directed DEA to create a special registration process by which telemedicine providers could register with the DEA. More than 10 years later, when the special registration rule had not yet been proposed, Congress again required DEA to create the process via the SUPPORT Act, with a deadline of October 2019. DEA indicates that this proposed rule on telemedicine is intended to meet its obligation of creating a special registration process and indicates that it determined creating a process would only create more administrative burden for providers and would not expand access to care.

While we agree that layering additional administrative burden on top of restrictive in-person requirements would not be productive, we believe that not creating a special registration process for providers wanting to practice legitimate telemedicine is a missed opportunity for both expanded access to care and for DEA's ability to identify providers operating legally and appropriately from those that are not. Under a special registration regime, DEA could track and manage legitimate providers and therefore more easily identify illegitimate ones. This could also solve the issue for pharmacists if they were able to access a list of prescribers who had registered with DEA. One course of action to support the removal of the in-person requirements in this rule would be to replace the in-person requirements with the statutorily required special registration process.

Thank you for your careful consideration of these rules and for consulting with HHS and its subagencies on the clinical impacts of this rule. We stand ready to assist in the efforts to finalize this rule in a way that appropriately balances the need to prevent diversion and to increase access to health care. If you

have any questions, please contact Kyle Zebley, Executive Director, ATA Action at kzebley@ataaction.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Kyle Zebley".

Kyle Zebley
Executive Director
ATA Action

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