March 27, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: RIN 1117-AB78/Docket No. DEA-948 - Expansion of Induction of Buprenorphine via Telemedicine Encounter

Dear Administrator Milgram:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction and co-occurring conditions, thank you for the opportunity to comment on the Drug Enforcement Administration's (DEA) notice of proposed rulemaking (the NPRM) regarding the expansion of induction[1] of buprenorphine via telemedicine encounter.

ASAM is deeply committed to ensuring every person with substance use disorder (SUD) has access to high-quality, full-spectrum addiction care and to closing the addiction treatment gap.[2] This commitment includes advocating for optimizing telehealth access and utilizing it to advance health equity in addiction medicine. With the illegal drug supply becoming increasingly lethal,[3] and the COVID-19 pandemic's exacerbation of challenges faced by people with SUD,[4] racial and ethnic health disparities have widened with record numbers of drug overdose deaths.[5] Although telehealth for addiction care grew more slowly than it did for other types of medical care before the onset of COVID-19,[6] the pandemic catalyzed sweeping changes that brought the use of telehealth for addiction care beyond where it was previously underutilized or prohibited.

The emergency administrative actions of the DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA) during the COVID-19 public health emergency

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(PHE), which allowed for greater flexibilities in the treatment of opioid use disorder (OUD) via telemedicine encounters, have been critical tools for expanding access to OUD treatment.

ASAM applauds the NPRM to the extent it preserves ongoing flexibility for physicians and other prescribers of controlled medications to initiate prescriptions of Schedule III-V narcotic[7] medications approved for SUD treatment, such as buprenorphine for OUD, via telemedicine encounter. However, ASAM opposes other elements of the NPRM to the extent they devolve into the regulation of the practice of addiction medicine without a strong public health justification; represent poorly tailored controls against diversion; or constitute actions that threaten public health and safety. In summary, ASAM strongly encourages the DEA to:

- **Eliminate the proposed <u>in-person</u> evaluation requirement[8] for prescribing more than a 30-day supply (across prescriptions) of Schedule III-V medications approved for SUD treatment (including buprenorphine for OUD) while engaging in the practice of telemedicine, as defined in 21 U.S.C. 802(54)(G), and, instead, reinforce the long-standing precedent and the DEA's expectation that services and procedures rendered, including for the evaluation and management of OUD, be for a legitimate medical purpose by a practitioner acting in the usual course of professional practice and adequately documented in the patient's medical record;**
- **Finalize its proposal for continued flexibility in telehealth initiation format (i.e., audio-only or audio-visual), including its flexible understanding of the term "home," for prescribing buprenorphine for OUD via audio-only telehealth initiation;**
- **Exclude <u>all</u> prescriptions of Schedule III-V medications approved for SUD[9] treatment via telemedicine encounters from the definition of "telemedicine prescription;"[10] revisit its proposed definitions of (1) "telemedicine prescription" and (2) "qualifying telemedicine referrals" in the proposed rule at Docket No. DEA-407 and consider if there are less burdensome (and confusing) ways for the DEA to define such terms;**
- **Consider whether its recordkeeping proposals are consistent with the significant public health interest in expanding appropriate access to addiction medications and if there are less complex mechanisms to achieve the DEA's goals without requiring prescribers of addiction medications to alter their practice workflows;**
- **Delay, at a minimum, any enforcement of new recordkeeping requirements to a time sufficient for practitioners who prescribe addiction medications to comply with a new regulatory environment; and**
- **Continue the COVID-19 PHE telehealth flexibilities for buprenorphine for OUD using its authorities under the opioid PHE to avoid disruptions to addiction care, which may increase overdose deaths, while the DEA works towards an improved, final rule, if a final rule incorporating this letter's recommendations cannot be issued by the end of the COVID-19 PHE.**

In addition, ASAM notes that the Consolidated Appropriations Act, 2023 (CAA 2023), eliminated the DATA 2000 waiver program. Thus, ASAM urges the DEA to eliminate all references related to the former DATA 2000-waiver program, including any related separate recordkeeping

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requirements under the DATA 2000-wavier program, prior to finalizing its rule. ASAM offers further detailed comments below on these recommendations.

Requirement of a Medical Evaluation In Person Or in the Presence of Another DEA Registrant

DEA Proposal

In its NPRM, the DEA proposes new circumstances in which individual practitioners treating OUD may prescribe buprenorphine via telemedicine encounters, following the conclusion of the COVID-19 PHE. Specifically, the DEA proposes to add a new paragraph (e) to 21 CFR 1306.04 to clarify when, and for what purpose, an individual practitioner may issue prescriptions pursuant to a telemedicine encounter under the authority of the proposed 21 CFR 1306.34. Under the NPRM, such purpose is limited to "maintenance or detoxification treatment,"[11] and the proposed §1306.34 adds requirements for prescribers who initiate prescriptions for Schedule III-V "narcotic" medications approved for SUD treatment via telemedicine encounters and who have never conducted an in-person medical evaluation with the patient and are not otherwise authorized to engage in the "practice of telemedicine," as defined in 21 CFR 1300.04(i).

Once all proposed requirements are met, the DEA's proposal would permit prescribing up to a 30-day supply (across all prescriptions) of buprenorphine for OUD via telemedicine encounters under the authority of the proposed 21 CFR 1306.34, but prohibit additional telemedicine prescribing of the such medication unless and until an in-person evaluation has been conducted. As currently proposed, it appears that the required in-person evaluation could be satisfied if one or more of the following conditions are met: (1) the prescriber conducts a medical evaluation while the patient is in the physical presence of the prescriber; (2) the patient is in the physical presence of a DEA-registered practitioner[12] while the remote prescriber, patient, and on-site DEA-registered practitioner participate in real-time, audio-video conference allowing for simultaneous communication;[13] or (3) the prescriber received a "qualifying telemedicine referral"[14] based on the diagnosis, prognosis, or treatment that occurred as a result of the in-person medical evaluation that was conducted by the referring practitioner. Notably, these requirements would limit the supply of buprenorphine prescribed pursuant to an audio-only telemedicine encounter with a patient in their "home"[15] to a maximum 30-day supply.[16]

ASAM's Response

During the COVID-19 PHE, telehealth became a valuable tool for more addiction clinicians,[17] providing greater access[18] and convenience for patients,[19] and was associated with improved retention in addiction treatment.[20,21] It is well-established that receipt of medications for OUD lowers the odds of overdose; a recent study found reduced medically treated overdoses among a cohort of patients who received medications for OUD during the COVID-19 pandemic, with high rates of telehealth use.[22] **ASAM supports DEA's proposal to the extent it preserves ongoing flexibility for physicians and other prescribers to initiate prescriptions of Schedule III-V narcotic medications approved for SUD treatment via telemedicine encounters. ASAM also appreciates**

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the DEA's proposal to continue telehealth format flexibility - e.g., audio-visual telehealth or audio only telephone care - for establishing a clinician-patient relationship for initiating buprenorphine for OUD under certain circumstances. ASAM further appreciates the proposal's flexible definition of "home" for the location of the patient in the context of audio-only initiation of buprenorphine for OUD.

However, ASAM opposes the proposal to the extent it calls for the codification of a fixed period[23] (i.e., 30 days) within which the proposed *in-person* evaluation must take place before any additional prescribing beyond that 30-day supply of a Schedule III, IV, or V medication approved for SUD treatment (such as buprenorphine for OUD) can occur- when the initiation of the prescription is by an individual practitioner who engages in the practice of telemedicine, as defined in 21 U.S.C. 802(54)(G). Such an *in-person* evaluation requirement should be based upon the clinician's determination of clinical need, and the references to this requirement within the proposed rule should be eliminated. Instead, the DEA should reinforce the long-standing precedent and the DEA's expectation that services and procedures rendered, including for the evaluation and management of OUD, be for a legitimate medical purpose by a practitioner acting in the usual course of professional practice and adequately documented in the patient's medical record.

Rationales for ASAM's opposition to the DEA's proposed in-person evaluation requirement in the NPRM are as follows:

(1) The Appropriate Use of Telemedicine Technologies in the Practice of Addiction Medicine

The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder 2020 Focused Update (ASAM's NPG),[24] which predates the COVID-19 PHE telemedicine flexibilities, provides that, prior to (or soon after) treatment of a diagnosed OUD[25] with pharmacotherapy, the prescriber should ensure that a current *physical*[26] [i.e., in-person versus virtual is not specified] examination is contained within the patient medical record. Note that HHS has acknowledged that some physical exams can be conducted virtually.[27] While not all potential components of a physical exam can be conducted via telehealth, it is up to the prescribing practitioner to determine what is appropriate based on the individual patient's clinical presentation. Further, in 2022, the Federation of State Medical Boards (FSMB), which supports its member boards in their mandate to protect the public's health, safety and welfare through the proper licensing, disciplining, and regulation of physicians, concluded in its white paper that a *"physician patient relationship may be established via either synchronous or asynchronous telemedicine technologies without any requirement of a prior in-person meeting, so long as the standard of care is met."*[28] The FSBM paper goes on to state that a medical evaluation and treatment of the patient via telemedicine are appropriate, so long as the physician or other practitioner can maintain the standard of care.

According to reviewed literature, incorporation of telehealth technology with treatment for OUD is associated with higher patient satisfaction, comparable rates of retention, an overall reduction

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in health care costs, and an increase in both access to and uptake of buprenorphine.[29] Preliminary research also suggests that the use of telemedicine to treat OUD during the COVID-19 PHE was a comparable alternative to in-person OUD care.[30,31] Indeed, consistent with ASAM's NPG and FSMB's 2022 white paper, the DEA's proposal would permit the initiation of buprenorphine for OUD via telemedicine encounter, thus triggering the establishment of a legitimate clinician-patient relationship. Therefore, the DEA, in consultation with the Department of Health and Human Services (HHS), concedes that, for purposes of the CSA, a legitimate clinician-patient relationship *can* be established prior to an in-person visit for the purposes of diagnosing and treating OUD, and furthermore, the DEA concedes that related prescribing *can* meet the standard of care and *can* constitute prescribing for a legitimate medical purpose while acting in the usual course of professional practice.[32] As a result, ASAM contends that the proper role of the DEA and HHS, thereafter,[33] is limited to promulgating rules that are consistent with effective controls against diversion and otherwise consistent with the public health and safety, as articulated under 21 U.S.C. 802(54)(G).

ASAM further maintains that when and whether any such in-person evaluation occurs should remain a clinical decision between the prescriber of the addiction medication and the patient.[34] It should not be rigidly dictated by DEA regulations, which will inevitably result in the continuation of some clinically appropriate prescriptions of buprenorphine for OUD via telemedicine encounters constituting a federal crime. Rather, ASAM agrees with FSMB that *"prescribing medications via telemedicine, as is the case during in-person care, is at the professional discretion of the physician."*[35]

Therefore, ASAM urges the DEA to eliminate the proposed <u>in-person</u> evaluation requirement for the prescribing of more than a 30-day supply (across prescriptions) of Schedule III-V medications approved for SUD treatment, including buprenorphine for OUD, while engaging in the practice of telemedicine, as defined in 21 U.S.C. 802(54)(G). Instead, with respect to these medications, the DEA should finalize its rule in a manner that allows for the decision about when and whether treatment is to be provided via an in-person evaluation to remain a clinical decision left to the treating practitioner, governed by what (1) constitutes a clinician-patient relationship under applicable state law and (2) is within the confines of the Controlled Substances Act (CSA) (which does not require the proposed *in-person* evaluation, but a *bona fide* evaluation, where the practitioner is "engaged in the practice of telemedicine" within the meaning of the Ryan Haight Act (21 U.S.C. 802(54), as further detailed below).

(2) Diversion and Public Health and Safety in the Unique Context of Buprenorphine for OUD

The DEA's concerns over buprenorphine diversion appear to be driving the proposal to require an in-person evaluation within a specified time. To support such concerns, the DEA cites the deaths of a very small number of individuals in Tennessee in 2018 without providing figures for other states, additional years, or whether these deaths were associated with people appropriately treated for OUD. The DEA also lists three federal cases as evidence for the need to balance expanded legal, medical access to buprenorphine with controls against diversion. **ASAM**

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is extremely concerned about the disproportionate weight the DEA, in consultation with HHS, appears to be giving buprenorphine diversion concerns, even when it may mean reducing appropriate access to OUD treatment that benefits public health and safety, as detailed herein. Indeed, rates of and disparities in overdose deaths have been increasing due to a lack of access to treatment with addiction medications.[36]

Although the DEA has previously stated that *"[p]rescribing a controlled substance without conducting an in-person medical evaluation has always been, and remains under the Act [CSA], a strong indication (or "red flag") of likely diversion,"*[37] ASAM maintains that the decision of (1) when to require an in-person evaluation still should be made by the prescriber within a context that balances the urgency for an in-person evaluation, the urgency of initiating buprenorphine for OUD, and the urgency for managing the risk of diversion and (2) when and for how long to defer in-person evaluation components should be a clinical decision, not a regulatory one.

Furthermore, the most common reason for buprenorphine diversion is likely self-treatment due to a lack of access to legitimate treatment.[38] Considering the unique profile of a partial agonist like buprenorphine for OUD,[39] a clinician manages the risks around its diversion differently than when they evaluate potential diversion risk and public harm of Schedule II medications approved for indications other than SUD.[40] The DEA acknowledges itself the benefits of expanded access to medications for OUD, as well as no increase in the percentage of opioid overdose deaths involving buprenorphine in the months following related COVID-19 PHE telemedicine flexibilities.[41] Yet, without providing any substantiated evidence for such a decision in the context of buprenorphine for OUD, the DEA appears to believe that its diversion concerns now warrant significantly more restrictive post COVID-19 PHE regulations. Additionally, the DEA's proposal does not provide analysis to the public as to whether more direct methods at the DEA's disposal to control buprenorphine diversion are failing to protect against buprenorphine diversion that threatens public health or safety.

The DEA's arbitrary use of authority runs in direct opposition to the Biden-Harris Administration's goal of significantly expanding access to effective medications for treating OUD. The proposed regulations, if finalized as written, may deter practitioners from treating new patients with buprenorphine for OUD via telemedicine encounters, even when clinically appropriate. The patients who have benefited most from the DEA's expanded flexibilities, including individuals experiencing homelessness, with disabilities,[42] without reliable transportation, or who may live in US counties that do not have an active prescriber of buprenorphine, stand to first lose access to lifesaving treatment if this rule is finalized as proposed. Furthermore, while numbers extend into the millions for those who need SUD treatment, but do not receive it,[43] disproportionate weight has been given to the data and concerns about buprenorphine diversion, which is simply not commensurate with the sheer rates of people who need medical access to effective medications for OUD. Moreover, the DEA has demonstrated it has other tools at its disposal to address diversion in the past. Should the DEA finalize its untimely rule, as written, ASAM maintains there will likely be deadly consequences for patients from vulnerable populations during an elevation in opioid-related overdose deaths, and an opioid public health emergency remains declared.

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(3) The Ryan Haight Act's Practice of Telemedicine Exceptions

The DEA states in the NPRM that the proposed in-person requirement "*…is necessary because the CSA generally requires each prescription for a schedule II through V controlled substance to be predicated upon at least one in-person medical evaluation. Although the proposed regulations would create an exception to this requirement, they must still maintain the CSA standard that prescriptions be tied to a medical evaluation in the physical presence of a DEA-registered practitioner. Without this provision, practitioners could theoretically prescribe buprenorphine without ever conducting a thorough medical evaluation of the patient.*"

ASAM does not concur with the DEA's interpretation of the CSA in the NPRM and points out that requiring prescriptions to be tied to a medical evaluation in the physical presence of a DEA-registered practitioner in no way guarantees that practitioners are prescribing buprenorphine with thorough medical evaluations of the patient. Although the CSA does predicate initial prescriptions for controlled substances upon at least one in-person medical evaluation (21 U.S.C. 829(e)), the statute also specifically provides at 21 U.S.C. 829(e)(3) that "nothing in this subsection [21 U.S.C 829(e)] shall apply to—(A)the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the **practice of telemedicine**…" According to the DEA's statements in a prior interim rule,[44] the definition of "practice of telemedicine":

> *[I]ncludes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act's in-person medical evaluation requirement, yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. In these circumstances, provided certain safeguards are in place to ensure that the practitioner who is engaged in the practice of telemedicine is able to conduct a **bona fide medical evaluation** of the patient at the remote location, and is otherwise acting in the usual course of professional practice, the Act contemplates that the practitioner will be permitted to prescribe controlled substances by means of the Internet despite not having conducted an in-person medical evaluation. The Act defines these categories, through the definition of "practice of telemedicine," which is set forth in 21 U.S.C. 802(54).*

The DEA specifically notes in the NPRM that it is using the last exception for "practice of telemedicine" defined at 21 U.S.C. 802(54)(G), which allows telemedicine to be "*…conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.*"

In other words, even though the CSA requires prescriptions for a controlled substance to be predicated on at least one in-person medical evaluation, the CSA is clear there is no application of such requirement for an *in-person* medical evaluation in cases where a practitioner is engaged

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in the practice of telemedicine, including pursuant to regulations promulgated under 21 U.S.C. 802(54)(G). Indeed, in the same prior interim rule,[45] the DEA acknowledges such an interpretation where it states:

> *[t]he Act [CSA] simply made the failure to perform an in-person medical evaluation in certain circumstances an automatic violation of the CSA, while leaving it as a factor indicative of possible diversion in all other circumstances"* and further *"[s]pecial registration for telemedicine—A practitioner who is engaged in the practice of telemedicine within the meaning of the Act is not subject to the mandatory in-person medical evaluation requirement of 21 U.S.C. 829(e) (although such practitioner remains subject to the requirement that all prescriptions for controlled substances be issued for a legitimate medical purpose).*

While ASAM acknowledges that the CSA requires a *bona fide* medical evaluation, practitioners can conduct *bona fide virtual* medical evaluations of patients with OUD without an in-person evaluation (by either the prescribing practitioner or another DEA-registered practitioner in the physical presence of the patient), as is illustrated in ASAM's NPG and FSMB's recent telemedicine paper, as well as in the DEA's own proposal in the NPRM to allow telehealth initiation of buprenorphine for OUD. ASAM maintains that a bona fide evaluation (whether in person or via a telemedicine encounter) is one that is sufficient for the prescriber to make/confirm[46] the diagnosis of OUD. Clinicians have, at their disposal, the opportunity to (1) review their state's prescription drug monitoring program (PDMP), (2) access other collateral information and informants, (3) obtain toxicology data remotely, and (4) evaluate how a patient sounds and appears when considering when to require their patients present for an in-person encounter for their next prescription for buprenorphine for OUD. Therefore, a *bona fide virtual* medical evaluation for prescribing buprenorphine for OUD occurs when the prescriber obtains sufficient information from the patient, based on their examination of the patient through audio and/or visual means, and collateral sources including checking the PDMP – to make/confirm a diagnosis of OUD and determines that the benefits of prescribing buprenorphine for OUD via a telemedicine encounter outweigh the risks. Importantly, the latter determination is made on a patient-by-patient basis, which factors in the extraordinary risk to the patient's health and well-being of untreated OUD,[47] and the buprenorphine diversion risks in the community where the patient resides. Such a risk-benefit analysis is quite different in the comparative contexts of prescribing buprenorphine for OUD via telemedicine encounters and prescribing Schedule II stimulants via telemedicine encounters (by way of one example) for conditions other than SUD, in part given buprenorphine's unique safety profile when prescribed for a diagnosed OUD.

ASAM concurs that on the continuum of standard of care,[48] it is *best practice* for the prescribing clinician to ensure that there's an in-person evaluation that includes a history, physical, and confirmation from collateral sources including the PDMP, either before (or soon after) a patient is started on pharmacotherapy. The DEA's proposal, on the other hand, provides anecdotal evidence to support it constituting a *per se federal crime* for continuing telemedicine prescribing of buprenorphine for OUD in the absence of its required in-person evaluation within an arbitrary time period, creating criminal legal interference with the appropriate clinical decision-making of

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DEA registered practitioners prescribing lifesaving addiction medications for a legitimate medical purpose in the usual course of professional practice.

Definitions of (1) "Telemedicine Prescription" and (2) "Qualifying Telemedicine Referral" in Docket No. DEA-407

In a separate proposed rule found in Docket No. DEA-407 - governing telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation - the DEA proposes to define the new term "telemedicine prescription" as "a prescription issued pursuant to § 1306.31 by a physician, or a "mid-level practitioner" as defined in 21 CFR 1300.01(b), engaging in the practice of telemedicine as defined in 21 CFR 1300.04(j)."[49] A prescription of a *non-narcotic* controlled substance in schedules III–V issued via telemedicine encounter by a practitioner who has not conducted an in-person medical evaluation; a controlled medication prescription via a "qualifying telemedicine referral;" and a controlled medication prescription by a practitioner for a patient with a "telemedicine relationship established during the COVID-19 public health emergency," appear to be covered by the proposed definition of "telemedicine prescription."

By way of contrast, (1) prescription(s) issued via telemedicine encounters for buprenorphine for OUD that do not cumulatively exceed a 30-day supply, without an in-person evaluation, issued under the authority of the proposed 21 CFR 1306.34 and (2) such prescription(s), followed by prescription(s) via an in-person evaluation in which the patient is in the physical presence of another DEA-registered practitioner and the remote prescriber, patient, and other DEA-registered practitioner on site with the patient can participate in real-time, audio-video conference in which they can communicate simultaneously, do not appear to fall within the proposed definition of "telemedicine prescription." The proposed term "telemedicine prescription" would also not apply to practitioners who issue a prescription via telemedicine encounter permissible under one of the other six "practice of telemedicine" exceptions under the Ryan Haight Act (i.e., not under 21 U.S.C. 802(54)(G)). Thus, this single definition of "telemedicine prescription" has the potential to create enormous confusion for pharmacies, pharmacists trying to fulfill their corresponding responsibilities under law, health plans, prescribers, and patients as they may erroneously assume that all prescriptions issued via telehealth encounters are "telemedicine prescriptions."

ASAM is particularly concerned about how pharmacists will interpret or practically implement the proposed definitions of "telemedicine prescription" and "qualifying telemedicine referral." ASAM fears that they will impede access to OUD treatment with buprenorphine. Patients and prescribers encountering difficulties filling prescriptions for buprenorphine for OUD, particularly prescriptions issued via telemedicine encounter, have been extensively documented by ASAM,[50] research studies,[51] and media outlets.[52] ASAM notes that should these proposed definitions be finalized, patients and prescribers may encounter increased difficulties at pharmacies continuing telemedicine prescribing of buprenorphine for OUD and filling those prescriptions for buprenorphine for OUD. In essence, these definitions will create uncertainty, frustration, impede the desire of clinicians to engage in the treatment of new patients with OUD via telehealth encounters, and ultimately leave some patients without access to lifesaving treatment. **ASAM**

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strongly encourages the DEA to revisit its proposed definitions of "telemedicine prescription" and "qualifying telemedicine referral" and consider if there are less burdensome (and confusing) ways for the DEA to define such terms and still accomplish the DEA's objectives. For starters, a foreseeable alternative to the definition of "telemedicine prescription," is to finalize a definition that explicitly excludes prescriptions of all Schedule III-V medications approved for SUD treatment. Such an explicit exclusion would (1) streamline the appropriate dispensing of such medications to the extent initiated and maintained via telemedicine encounters; (2) account for the possibility of future developments and approvals of new Schedule III- V, non-narcotic, controlled medications for addiction treatment; and (3) align the final rule with the enactment of Section 1262 of the Consolidated Appropriations Act, 2023, which eliminated the concept of differential, heightened treatment for Schedule III-V "narcotic" medications for "maintenance or detoxification treatment." Finally, all requirements applicable to prescriptions of Schedule III-V medications approved for SUD treatment via telemedicine encounters authorized under 21 U.S.C. 802(54)(G) should be consolidated in one place and set forth in the proposed 21 CFR 1306.34.

Recordkeeping

The DEA also proposes new recordkeeping requirements for prescribers of controlled substances via telemedicine encounters, including buprenorphine for OUD. The DEA notes that the proposed, new requirements only apply to the "practice of telemedicine" exception at 21 U.S.C. 802(54)(G) and would not apply to prescribers practicing under any of the other "practice of telemedicine" exceptions under the Ryan Haight Act. Apart from instituting a new, complex regulatory scheme, ASAM is extremely concerned that this proposal does not comport with the objectives of Section 1262 of the Consolidated Appropriations Act, 2023, which eliminated the requirement that practitioners obtain a separate registration to prescribe certain controlled medications for SUD, including buprenorphine. ASAM reiterates that the goal of this reform was to make it easier for prescribers to treat addiction with Schedule III-V narcotic medications. Now, the proposal set forth by the DEA intends to add an additional layer of requirements - some of which are unlikely to further public health and safety or serve any meaningful purpose in the context of prescribing buprenorphine for OUD - that may further dissuade practitioners from engaging in the practice of treating addiction via telemedicine encounters. Additionally, neither does the DEA justify the need for these new requirements in the context of prescribing buprenorphine for OUD, nor does it consider whether these obligations are feasible for practitioners prescribing addiction medications, nor does it proffer whether less burdensome alternatives were considered to acquire the information sought. On their face, the burden that these requirements will place on prescribers of addiction medications do not appear aligned with the goal of expanding appropriate access to addiction medications. **While ASAM concurs with the proposals to require certain documentation and recordkeeping with respect to (1) audio-only telemedicine encounters resulting in the initiation of a prescription for a controlled addiction medication and (2) required PDMP checks,[53] ASAM strongly encourages the DEA to consider whether its other documentation/recordkeeping proposals align with the significant public health interest in expanding appropriate access to addiction medications, and if there are**

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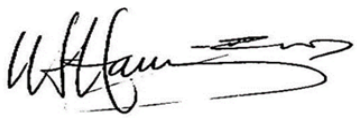
less complex mechanisms to achieve the DEA's goals without requiring prescribers of addiction medications to alter their practice workflows. At a minimum, the DEA should delay any enforcement of new recordkeeping requirements to a time sufficient for practitioners who prescribe addiction medications to comply with a new regulatory environment.

Conclusion

ASAM supports DEA's proposals in the NPRM to the extent that they continue to promote appropriate access to buprenorphine for the treatment of OUD. However, ASAM has grave concerns about the DEA's factoring – with disproportionate weight – its diversion concerns in the proposed in-person evaluation requirement tied to an arbitrary day-limit for prescriptions of buprenorphine for OUD via telemedicine encounters. The DEA cited few examples of buprenorphine diversion, which appear unrelated to the proposed rule, and failed to consider whether other methods at the DEA's disposal are adequate to monitor against diversion of buprenorphine for the benefit of public health and safety. In addition, the DEA's interpretation of the CSA in the NPRM fails to recognize that a *bona fide virtual* evaluation can constitute a thorough medical evaluation of the patient with OUD for purposes of prescribing buprenorphine for OUD without the patient being in the presence of a DEA registrant. ASAM is concerned the proposals in the NPRM will have outcomes that are inconsistent with public health and safety, as the proposal in the NPRM would decrease legitimate medical access to buprenorphine for OUD via telemedicine encounters during an HHS-declared opioid PHE and the deadliest opioid-related overdose crisis of our lifetimes. **Therefore, ASAM strongly recommends that DEA not finalize these rules, as proposed, to the extent they impact prescriptions of Schedule III-V addiction medications via telemedicine encounters. Instead, the DEA should seriously consider the advice and recommendations set forth herein. In the event a revised, final rule cannot be issued by the end of the COVID-19 PHE that incorporates this letter's recommendations, then ASAM urges the DEA to continue the COVID-19 PHE telehealth flexibilities for buprenorphine for OUD using the DEA's authorities under the opioid PHE to avoid disruptions to addiction care while the DEA works towards an improved, final rule.**

Thank you for your attention to this important matter. Please contact Kelly Corredor, Chief Advocacy Officer, at kcorredor@asam.org or Corey Barton, Associate Director, Advocacy and Government Relations, at cbarton@asam.org to schedule further conversations regarding this letter, or if you have any questions or concerns.

Sincerely,



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[1] ASAM recommends that references to "induction" be changed to "initiation" in the final rule to reflect contemporary medical terminology.
[2] Saini J, Johnson B, Qato DM. Self-Reported Treatment Need and Barriers to Care for Adults With Opioid Use Disorder: The US National Survey on Drug Use and Health, 2015 to 2019. Am J Public Health. 2022;112(2):284-295. doi:10.2105/AJPH.2021.306577
[3] Brent J, Weiss ST. The Opioid Crisis—Not Just Opioids Anymore. JAMA Netw Open. 2022;5(6):e2215432. doi:10.1001/jamanetworkopen.2022.15432
[4] Mallet J, Dubertret C, Le Strat Y. Addictions in the COVID-19 era: Current evidence, future perspectives a comprehensive review. Prog Neuropsychopharmacol Biol Psychiatry. 2021;106:110070. doi:10.1016/j.pnpbp.2020.110070
[5] Centers for Disease Control and Injury Prevention. Overdose Deaths Rise, Disparities Widen. Centers for Disease Control and Prevention. Published July 19, 2022. Accessed August 10, 2022. https://www.cdc.gov/vitalsigns/overdose-death-disparities/index.html
[6] Huskamp HA, Busch AB, Souza J, et al. How Is Telemedicine Being Used In Opioid And Other Substance Use Disorder Treatment? Health Aff (Millwood). 2018;37(12):1940-1947. doi:10.1377/hlthaff.2018.05134
[7] The DEA's use of "narcotic" in the rulemaking refers to "narcotic drug" under the Controlled Substances Act 21 U.S.C. 802(17). At the time of this letter, the only controlled medications that fit the description under this NPRM is buprenorphine and combination of drugs containing buprenorphine, but no other narcotics.
[8] ASAM recognizes that the proposed requirement is for a medical evaluation in person or in the presence of another DEA registrant. For brevity, ASAM may refer to such proposed requirement simply as the "in-person evaluation requirement."
[9] Under a recent SAMHSA NPRM on Medications for the Treatment of Opioid Use Disorder, SAMHSA states that 'opioid use disorder' more precisely reflects the diagnosis for which medications are indicated. ASAM recommends that the DEA finalize this rule in a manner that uses SAMHSA's updated medical terminology. Available at https://public-inspection.federalregister.gov/2022-27193.pdf.
[10] If DEA does not remove the proposed in-person evaluation requirement for maintenance of buprenorphine following a virtual initiation of treatment, then the DEA should ensure that the 180-day, post COVID-19 PHE off-ramp discussed in the proposed rule in Docket No. DEA–407 ("Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation") will be applicable to buprenorphine for OUD.
[11] Under a recent SAMHSA NPRM on Medications for the Treatment of Opioid Use Disorder, SAMHSA states that the terms 'maintenance' and 'detoxification' reference outdated terminology that has potentially hindered adoption of evidence-based treatments for OUD. ASAM recommends that the DEA finalize this rule in a manner that uses SAMHSA's updated medical terminology. Available at https://public-inspection.federalregister.gov/2022-27193.pdf.
[12] Under the NPRM, the non-prescribing "DEA registered practitioner" who is physically present with the patient would have to be acting in the usual course of professional practice and in accordance with applicable State law. Notably, however, the NPRM does not use the defined term "individual practitioner" as defined in 21 CFR 1300.01, in such context, which would have explicitly excluded pharmacists.
[13] ASAM notes that this option may pose numerous reimbursement and billing issues, including under Medicare and Medicaid.
[14] Proposed 21 CFR 1300.04(k) in Docket No. DEA–407 ("Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation"). A "qualifying telemedicine referral" would require the referring practitioner to identify and name a specific telemedicine clinician; a general referral to a specialty group, hospital, or facility would not suffice. This seems unnecessarily burdensome and should be revised to allow for greater flexibility in implementation to the extent the DEA continues to use the term in the context of medications approved for SUD treatment.
[15] The proposal includes a flexible understanding of "home" to include temporary lodging such as hotels and homeless shelters.
[16] ASAM. Public Policy Statement on Optimizing Telehealth Access to Addiction Care. Available at https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/advocacy/2022-optimizing-telehealth-access-to-addiction-care-board-approved.pdf?sfvrsn=9c924fd1_3 (recommending that federal agencies should continue to study the impact of the use of audio-only technology for buprenorphine treatment for OUD, including the impact on health inequities and outcomes and that DEA regulations should continue to allow for the initiation and maintenance of buprenorphine with audio-only technology during the opioid overdose crisis PHE).

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[19] Uscher-Pines L, Sousa J, Raja P, Mehrotra A, Barnett M, Huskamp HA. Treatment of opioid use disorder during COVID-19: Experiences of clinicians transitioning to telemedicine. J Subst Abuse Treat. 2020;118:108124. doi:10.1016/j.jsat.2020.108124
[20] Lin L, Kim H, Frost M. Impact of COVID-19 telehealth policy changes on buprenorphine treatment for opioid use disorder. Am J Psychiatry. Published online in press 2022.
[21] Jones CM, Shoff C, Hodges K, 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. Published online August 31, 2022. doi:10.1001/jamapsychiatry.2022.2284
[22] Ibid.
[23] The arbitrary nature of tying an in-person evaluation to any *numerical day-limit*, in the context of telehealth initiation of buprenorphine for OUD, is illustrated by the recent actions of two different parts of the Biden Administration – the DEA and SAMHSA. In December 2022, SAMHSA released its NPRM on Medications for the Treatment of Opioid Use Disorder, in which SAMHSA proposed allowing for audio-visual or audio-only telehealth initiation of buprenorphine for OUD in the opioid treatment program (OTP) setting, followed by an in-person physical evaluation within *14 days* of OTP admission. ASAM's comment letter to SAMHSA's Part 8 NPRM requested that SAMHSA consider limiting the scope of its final Part 8 rule to the dispensing of methadone for OUD, as the intent of the CAA 2023 was to carve out controlled medications in schedule III, IV, or V from Section 303(h) of the Controlled Substances Act. Thus, if ASAM's recommendation is ultimately adopted by SAMHSA (at least with respect to telehealth and buprenorphine), then it would be the DEA's telemedicine rules that would govern the legality of telehealth initiation of buprenorphine for OUD in the OTP and office-based settings. This would provide consistency across medical settings for the telehealth initiation of the same medication for the same indication. SAMHSA's Part 8 NPRM is available at https://public-inspection.federalregister.gov/2022-27193.pdf. ASAM's comment letter to SAMHSA's Part 8 NPRM is available at: https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/advocacy/letters-and-comments/23.02.13---asam-42-cfr-part-8.pdf?sfvrsn=f41fd9b6_5/%2023.02.13---ASAM-42-CFR-Part-8%20pdf.
[24] The ASAM NATIONAL PRACTICE GUIDELINE For the Treatment of Opioid Use Disorder 2020 Focused Update. Available at https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2/
[25] According to ASAM's NPG, opioid use disorder is primarily diagnosed on the basis of the history provided by the patient and a comprehensive assessment that includes a physical examination and laboratory testing, including drug testing. Corroborating information reported by significant others can be used to confirm the diagnosis, especially when there is lack of clarity or inconsistency in information. Other clinicians may make a diagnosis of opioid use disorder; however, prescriber confirmation of the diagnosis is required before medications are prescribed. ASAM's NPG also makes it clear that a comprehensive assessment of the patient is critical for treatment planning, but that completion of all assessments should not delay or preclude initiating pharmacotherapy for opioid use disorder, and, if not completed before initiating treatment, assessments should be completed soon thereafter. While the failure to follow one or more of such guidelines may not align with best practices, nothing in the CSA indicates that a failure to follow all of the guidelines in a subsequently published medical society's clinical practice guideline constitutes a per se violation of the CSA, and, thus, a federal crime.
[26] According to ASAM's NPG, as part of the comprehensive assessment of patients with OUD, a physical examination may be completed by the prescriber him/herself (the clinician authorizing the use of a medication for the treatment of opioid use disorder) or another member of the clinician's health system. The responsible clinician should assure that a current physical examination is contained within the patient medical record before (or soon after) a patient is started on a new medication for the treatment of his/her OUD. The examination should include identifying objective physical signs of opioid intoxication or withdrawal. Table 2 in the NPG lists common signs of intoxication and withdrawal. In addition, the examination should evaluate objective signs of substance use disorders. Table 3 in the NPG contains a list of physical signs of substance use disorders (including OUD). The examination should also look for common physical signs of OUD (see Table 3 in the NPG), and physical health problems associated with substance use disorders including sleep disorders, infectious diseases, pain, cardiovascular disease, and liver disease. Special attention should be given to identifying injection drug use by the presence of new or older puncture marks.
[27] HHS. Conduct a *telehealth* physical exam. Available at https://telehealth.hhs.gov/providers/preparing-patients-for-telehealth/telehealth-physical-exam

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[28] FSMB. THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE. Available at https://www.fsmb.org/siteassets/advocacy/policies/fsmb-workgroup-on-telemedicineapril-2022-final.pdf.
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[31] ASAM. Public Policy Statement on Optimizing Telehealth Access to Addiction Care. Available at https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/advocacy/2022-optimizing-telehealth-access-to-addiction-care-board-approved.pdf?sfvrsn=9c924fd1_3 (noting that telehealth should not supplant adequate in-person addiction care and that health plans need to have adequate SUD provider networks that allow beneficiaries the option to access telehealth and in-person addiction care).
[32] 21 CFR § 1306.04 ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.")
[33] According to the NPRM, " . . . the Ryan Haight Act applies only when a prescribing practitioner wishes to prescribe controlled substances via the practice of telemedicine and has not otherwise conducted an in-person medical evaluation prior to the issuance of the prescription." The "practice of telemedicine," as defined in 21 U.S.C. 802(54)(B), speaks to when the practice of telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a practitioner.
[34] In the ASAM COVID-19 TASK FORCE RECOMMENDATIONS CARING FOR PATIENTS DURING THE COVID-19 PANDEMIC: Access to Buprenorphine in Office-Based Settings, ASAM states that clinicians should carefully assess whether an in-person physical exam would change the management of a given patient. For patients maintained on buprenorphine for OUD, monitoring for signs of intoxication is recommended. This assessment can be accomplished with visual inspection alone, and partially and sufficiently evaluated through an audio-only platform as well (e.g., slurred speech might suggest use of alcohol or other opioids, while pressured speech might suggest stimulant use). For patients seeking to initiate buprenorphine, assessment of opioid withdrawal can typically be accomplished through visual inspection alone, for signs such as yawning, pupillary dilation, lacrimation, rhinorrhea, and restlessness. While an accurate COWS score may sometimes require palpation for subtle tremor or piloerection, home versions of the COWS scale or the Subjective Opioid Withdrawal Scale can be self-administered by the patient. At-home initiation of buprenorphine does not require a perfectly accurate COWS assessment and has demonstrated feasibility and safety relative to office-based buprenorphine starts. Clinicians can carefully instruct patients on at-home initiation and provide anticipatory guidance for the management of precipitated withdrawal, should it occur. Available at https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/covid-19/14-tf_access-to-buprenorphine-in-office-based-settings_updated-11132020.pdf?sfvrsn=929759c2_2.
[35] FSMB. THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE. Available at https://www.fsmb.org/siteassets/advocacy/policies/fsmb-workgroup-on-telemedicineapril-2022-final.pdf.
[36] Kariisa, Mbabazi. "Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020." MMWR. Morbidity and Mortality Weekly Report 71 (2022). https://doi.org/10.15585/mmwr.mm7129e2.
[37] DEA Interim Final Rule: https://www.federalregister.gov/documents/2009/04/06/E9-7698/implementation-of-the-ryan-haight-online-pharmacy-consumer-protection-act-of-2008#citation-30-p15603
[38] Lofwall, M. R., & Walsh, S. L. (2014). A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world. Journal of addiction medicine, 8(5), 315-326.
[39] Brandon del Pozo, Danielle Atkins, Barbara Andraka-Christou, Rachel Wightman, M H Clark, Philip Huynh, Bradley Ray, Buprenorphine involvement in opioid overdose deaths: A retrospective analysis of postmortem toxicology in Marion County, Indiana, 2015-2021, Drug and Alcohol Dependence Reports, Volume 6, 2023, 100131, ISSN 2772-7246, https://doi.org/10.1016/j.dadr.2023.100131. (https://www.sciencedirect.com/science/article/pii/S277272462300001X)
[40] Compare SAMHSA's NPRM on Medications for Addiction Treatment which proposes to allow telehealth initiation of methadone approved for OUD and available at https://public-inspection.federalregister.gov/2022-27193.pdf with the DEA's NPRM on telemedicine as it relates to all Schedule II medications and available at https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had.
[41] Tanz LJ, Jones CM, Davis NL, et al. Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic. JAMA Netw Open. 2023;6(1):e2251856. doi:10.1001/jamanetworkopen.2022.51856

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[43] Substance Abuse and Mental Health Services Administration. (2022). Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report

[44] DEA Interim Final Rule: https://www.federalregister.gov/documents/2009/04/06/E9-7698/implementation-of-the-ryan-haight-online-pharmacy-consumer-protection-act-of-2008#citation-30-p15603

[45] Ibid.

[46] Under ASAM's NPG, "[o]ther clinicians may diagnose opioid use disorder, but confirmation of the diagnosis must be obtained by the prescriber before pharmacotherapy for opioid use disorder commences."

[47] Krawczyk, N., M ojtabai, R., Stuart, E. A., Fingerhood, M., Agus, D., Lyons, B. C., Weiner, J. P., & Saloner, B. (2020). Opioid agonist treatment and fatal overdose risk in a state-wide US population receiving opioid use disorder services. *Addiction (Abingdon, England)*, *115*(9), 1683–1694. https://doi.org/10.1111/add.14991

[48] Vanderpool, Donna. "The Standard of Care." Innovations in Clinical Neuroscience 18, no. 7–9 (2021): 50–51.

[49] Consider whether this cross-reference should read: 21 CFR 1300.04(i).

[50] ASAM. Reducing Barriers to Lifesaving Treatment: Report on the Findings from ASAM's Pharmacy Access Survey Available at https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/advocacy/reports/asam-pharmacy-access-survey-report-final-11.7.22.pdf?sfvrsn=6da97680_3.

[51] Id.

[52] News stories available at: https://www.politico.com/news/2023/03/08/bidens-opioids-bureaucracy-00085968; https://time.com/6186319/buprenorphine-overdoses-pharmacy-drug-treatment/; https://www.npr.org/sections/health-shots/2021/11/08/1053579556/dea-suboxone-subutex-pharmacies-addiction; https://www.virginiamercury.com/2022/04/11/southwest-virginia-patients-struggle-with-access-to-addiction-medication/

[53] ASAM supports DEA's proposal to require prescribers to consult their state's prescription drug monitoring program (PDMP) database prior to prescribing permissible controlled medications via telemedicine. PDMPs are an important tool in encouraging safer prescribing practices and identifying patients who merit an assessment for SUD.

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