

March 30, 2023

**Submitted electronically on regulations.gov**

Scott A. Brinks, Diversion Control Division  
Drug Enforcement Administration  
Attention: DEA Federal Register Representative/DPW  
8701 Morrissette Drive  
Springfield, Virginia 22152  
(571) 776-3882

Re: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407) & Expansion of Induction of Buprenorphine via Telemedicine Encounter (Docket No. DEA-948)

Dear Mr. Brinks:

Foley & Lardner submits these comments in connection with the Drug Enforcement Administration (DEA)'s proposed rules regarding telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation. The views and opinions expressed in this letter are those of Foley & Lardner and do not necessarily reflect the views or positions of any clients Foley & Lardner represents.

For a decade, Foley & Lardner's Telemedicine and Digital Health Industry Team has been at the forefront of providing strategic legal and regulatory compliance advice to the industry on the appropriate deployment and use of telemedicine across a wide variety of provider specialties and health care settings. Based on our experience, telemedicine services can immensely improve access to patient care and enhance the quality of health care for all patients.

We commend the DEA's enforcement discretion during the COVID-19 public health emergency (PHE), which facilitated the access and delivery of essential telemedicine services to patients across the United States. We recognize the DEA's intent to curb substandard, illegal, and dangerous prescribing of controlled substances by promulgating regulations that will provide effective controls against diversion and protect public health and safety. However, we believe the proposed rules as written will limit access to legitimate health care while not promoting the public health and safety goals of DEA. In this comment letter, we provide reasonable suggestions and solutions that will allow DEA to appropriately address diversion concerns while safeguarding patient access to essential telemedicine services including for the treatment of mental health and substance use disorder.

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In this letter, we recommend revising the DEA's proposed rule in several sections using the following method:

- Deleted text has a ~~strikethrough~~.
- New text has an underline.

**1. The DEA's regulatory requirement for an in-person medical evaluation prior to prescribing controlled substances should be removed.**

Mandating an in-person medical evaluation prior to prescribing controlled substances will negatively impact access to patient care and infringe on states' traditional exercise of their police powers to promote public health and safety. During the PHE, the DEA waived the in-person medical evaluation requirement prior to prescribing controlled substances requirement under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act). The waiver of this in-person requirement has increased access to healthcare services including for the treatment of mental health and substance use disorder by the use of telemedicine. Moreover, health care providers were able to safely prescribe controlled substances remotely to patients for legitimate medical purposes. We have seen no reports or information available that indicate there was an increase in diversion or illegal activity involving controlled substances due to the suspension of the in-person evaluation requirement during the PHE. It is not, therefore, clear that waiving the in-person medical evaluation requirement will lead to increased diversion or that requiring an in-person medical evaluation curbs diversion.

What is clear is the regulatory mandate of an in-person medical evaluation will restrict access to essential healthcare services, resulting in negative patient outcomes such as non-adherence and in some instances serious adverse health consequences such as continued substance use abuse or even death. Patients are currently facing challenges in obtaining in-person visits with health care providers. A report found that the average wait time in 2022 for an appointment with a new primary care provider was 26 days.<sup>1</sup>

States generally grant sole authority to their medical boards to adopt regulations and standards to protect the public and promote patient safety including in the practice of telemedicine. States also determine the provisions of delivering appropriate health care services such as the requirements for establishing a physician-patient relationship and whether an in-person medical evaluation is required prior to prescribing controlled substances. Currently, only 13 states expressly require an in-person evaluation prior to prescribing controlled substances. Furthermore, a practitioner who uses telemedicine must meet the same standard of care and professional conduct as a practitioner who uses an in-person encounter. The failure to follow the appropriate standard of care or professional conduct while using telemedicine can result in discipline by the state medical board. The DEA must defer to state law and clinical practice standards rather than create its own medical practice policies.

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<sup>1</sup> Merritt Hawkins, *AMN Healthcare Survey: Physician Appointment Wait Times Up 8% from 2017, Up 24% from 2004*, <https://www.merrithawkins.com/physician-appointment-wait-times-up-from-2017/> (last visited March 16, 2023).

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Nevertheless, should DEA determine to maintain the in-personal medical evaluation as part of its final rule, as described further below, we believe there are alternative steps DEA may take to reduce the potential for delayed care or patient harm by requiring in-person evaluations. These include lengthening the 30 day period for an initial prescription prior to an in-person medical evaluation and undertaking further rulemaking to implement a special telemedicine registration for practitioners where no in-person evaluation should be required for practitioners who go through this special registration process.

## **2. The DEA's regulatory requirement for an in-person medical evaluation prior to prescribing buprenorphine should be removed.**

Should DEA retain the in-person requirement generally, there are compelling reasons for removing the in-person medical evaluation requirement for buprenorphine. Mandating an in-person medical evaluation prior to prescribing buprenorphine for the treatment of opioid use disorder (OUD) will impede patients' access to legitimate care in the ongoing opioid public health emergency.

Buprenorphine, because of its partial opioid receptor agonist activity, causes less euphoria compared to full agonists such as methadone or morphine.<sup>2</sup> Therefore, buprenorphine is less likely to be abused or diverted.<sup>3</sup> Multiple studies have shown that a majority of individuals who use nonprescribed buprenorphine do so to prevent withdrawal symptoms or to self-detox rather than to experience euphoria.<sup>4</sup>

The in-person medical evaluation requirement prior to prescribing buprenorphine for the treatment of OUD will obstruct patients' access to necessary care and increase the risk of negative patient outcomes for these individuals. The removal of the in-person medical evaluation requirement to prescribe buprenorphine for the treatment of OUD will likely result in decreased overdose and emergency room visits, improved medication adherence, reduced patient stigma, and increased patient privacy. Moreover, an in-person requirement may actually increase the risks of diversion, because patients without access to a practitioner, including those in rural areas, may instead seek drugs from the black market, which will increase the likelihood of overdose deaths from opioids and tainted fentanyl illegally shipped into the United States from overseas.

We believe that DEA possess authority to undertake this change with respect to buprenorphine specifically, as a result of the still ongoing public health emergency for the opioid crisis. Thus, DEA may

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<sup>2</sup> Kumar R, Viswanath O, Saadabadi A. Buprenorphine. StatPearls [Internet] 2022, <https://www.ncbi.nlm.nih.gov/books/NBK459126/> (last visited March 16, 2023).

<sup>3</sup> *Id.*

<sup>4</sup> Wayne State University, School Of Social Work: Center for Behavioral Health and Justice, *Buprenorphine Diversion in the Treatment of Opioid Use Disorder* (June 2020), [https://behaviorhealthjustice.wayne.edu/ote/diversion\\_brief\\_7\\_20.pdf](https://behaviorhealthjustice.wayne.edu/ote/diversion_brief_7_20.pdf) (last visited March 16, 2023).

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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.

For these reasons we believe DEA should remove the requirement for an in personal evaluation entirely.

To implement this change, we recommend the following revisions to the DEA’s proposed rule:

§ 1306.31 Circumstances under which the practice of telemedicine may be conducted pursuant to 21 U.S.C. 802(54)(G).

\* \* \* \* \*

(d) Such a medical evaluation for the purposes of this section may be one of the following except for the prescribing of buprenorphine for the treatment of opioid use disorder in which case such medical evaluation is not required:

§ 1306.36.34 Requirements for individual practitioners who conduct the induction of maintenance or detoxification treatment via telemedicine encounter.

~~(4) Upon completing the review described in paragraph (b)(2) of this section, the practitioner may issue prescriptions authorizing the dispensing of no more than a 30-day supply across all such prescriptions, including any prescriptions issued pursuant to paragraph (b)(3)(i) of this section, for Schedule III, IV, or V narcotic drugs approved by the Food and Drug Administration specifically for maintenance or detoxification treatment until the practitioner has conducted a medical evaluation as described in paragraph (b)(5) of this section.~~

~~(5) For the purposes of this section, the required medical evaluation may either be:~~

- ~~(i) An evaluation during which the patient is treated by, and in the physical presence of, the prescribing practitioner; or~~
- ~~(ii)(A) An evaluation during which the patient is treated by, and in the physical presence of, a DEA-registered practitioner (other than the prescribing practitioner);~~
- ~~(B) This practitioner in the physical presence of the patient is acting in the usual course of professional practice;~~
- ~~(C) The evaluation is conducted in accordance with applicable State law; and~~
- ~~(D) The remote prescribing practitioner, the patient, and the DEA-registered practitioner on site with the patient participate in a real-time, audio video conference in which both the practitioners and the patient communicate simultaneously; or~~
- ~~(iii) An evaluation that was conducted by a DEA-registered practitioner who:~~

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- ~~(A) Issued a written qualifying telemedicine referral under 21 CFR 1300.04(k) for the patient to the prescribing practitioner;~~
- ~~(B) Communicated the results of the evaluation by sharing the electronic medical record which includes, at a minimum, the diagnosis, prognosis, and treatment of the patient prior to the prescribing practitioner issuing the prescription; and~~
- ~~(C) Has issued the written referral based on the diagnosis, prognosis or treatment that occurred as a result of the medical evaluation.~~

**3. The DEA’s regulatory requirement for a “telemedicine stamp” on prescriptions issued by means of telemedicine for controlled substances should be removed.**

The notation requirement of a “prescription issued in a telemedicine encounter” on legitimate prescriptions issued by means of telemedicine for controlled substances will result in fewer pharmacies filling such prescriptions due to the fear of criminal and professional liabilities. There has been a rise in blanket denials of telemedicine prescriptions for controlled substances by pharmacies.<sup>5</sup> Adding a “telemedicine stamp” on prescriptions will likely result in increased denials due to increased stigma and scrutiny surrounding prescriptions for controlled substances issued by the means of telemedicine. As a result, the denial of these prescriptions will negatively impact patient care and limit patient access to essential medications.

In addition, it will be unfeasible to require health care entities including medical practices and pharmacies to add a notation feature to their e-prescribing systems in order to issue a “telemedicine stamp” to electronic prescriptions issued by the means of telemedicine. A majority of these electronic prescribing systems do not contemplate the addition of this “telemedicine stamp” feature. To implement such a feature into the current electronic prescribing systems will require adequate time and resources, which will result in widespread disruption of care.

Even with removal of this “stamp” requirement, DEA will still have access to these records, as the rule mandates prescribers to maintain such records. Should DEA wish to inspect such records, it can do so by inspecting prescribers registered practice locations. Therefore, we recommend that DEA remove this requirement in the final rule.

To implement this change, we recommend the following revisions to the DEA’s proposed rule:

§ 1306.05 Manner of issuance of prescriptions.

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<sup>5</sup> Anastassia Gliadkovskaya, *Walmart has a new policy denying some telehealth prescriptions for controlled drugs. It's implicating patients in recovery*, Fierce Healthcare (August 9, 2022), <https://www.fiercehealthcare.com/digital-health/new-policy-walmart-denies-telehealth-prescriptions-without-person-visit> (last visited March 16, 2023).

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~~(i) In addition to the requirements of this section, the practitioner shall note on the face of any telemedicine prescription, or within the prescription order if prescribed electronically, that the prescription has been issued based on a telemedicine encounter.~~

**4. The DEA regulatory requirement should be revised to allow the referring provider to refer the patient to a medical group, health system practice, or collaborative agreement practice rather than a single health care provider.**

Due to health care provider shortages and significant wait times for in-person appointments, the referring provider should be able to refer the patient to a medical group, health system practice, or collaborative agreement practice in addition to only a single health care provider. Oftentimes, it will be impractical to require the referring provider to identify which health care provider will see the patient while preparing the referral form. The referring provider should instead be able to refer the patient to a medical group, health system practice, or collaborative agreement practice. In addition, we would recommend that DEA permit the receiving practitioner of the referral also be able to transfer the referral if they are unable to provide the necessary care or to do so in a timely manner.

To implement this change, we recommend the following revisions to the DEA's proposed rule:

1300.04 Definitions relating to the dispensing of controlled substances by means of the internet.

\* \* \* \* \*

(k) A qualifying telemedicine referral means a referral to a practitioner, medical group, health system practice or collaborative agreement practice that is predicated on a medical relationship that exists between a referring practitioner and a patient where the referring practitioner has conducted at least one medical evaluation in the physical presence of the patient, without regard to whether portions of the evaluation are conducted by other practitioners, and has made the referral for a legitimate medical purpose in the ordinary course of their professional practice. A qualifying telemedicine referral to an individual practitioner must note the name and National Provider Identifier of the practitioner to whom the patient is being referred, however, a referral to a medical group, health system practice or collaborative agreement practice need only list the corporate entity name. A practitioner, medical group, health system practice or collaborative agreement practice receiving a qualifying telemedicine referral may forward the referral to another practitioner, medical group, health system practice or collaborative agreement practice if they are unable to provide

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telemedicine services to the patient at that time. The entity receiving the referral must provide notice to the original referring practitioner.

**5. Patients treated during the PHE should be “grandfathered in” in order to prevent disruption in continuity of care or the alternative, the 180 day period should be extended to a full year.**

Patients treated during the PHE should be exempted from the in-person medical evaluation requirement and “grandfathered in” to prevent disruption in continuity of care. As discussed earlier, an in-person medical evaluation requirement will likely lead to more negative patient outcomes especially for patients who are currently being treated for various medical conditions such as OUD that require treatments involving controlled substances. This patient group has already demonstrated during the PHE that telemedicine evaluation, prescribing and treatment can occur without an in-person evaluation requirement. Requiring an in-person visit not deemed medically necessary by the practitioner is impractical and unnecessary and will only add greater burden to patients and practitioners alike at a time when seeing new patients will increase burdens on practitioners and lengthen wait times for scheduling in person visits.

We recognize that the proposal includes a 180 day extension for patients seen and prescribed during the PHE, however, consistent with the above reasons, we recommend such patients be exempted entirely or at a minimum extend the 180 day period to a full year to give practitioners and patients addition time during what will be a difficult transitional period for patients and practitioners alike.

To implement this change, we recommend the following revisions to the DEA’s proposed rule:

1300.04 Definitions relating to the dispensing of controlled substances by means of the internet.

(o) An individual practitioner and a patient have a *telemedicine relationship established during the COVID-19 public health emergency* if:

(1) The practitioner has not conducted an in-person medical evaluation of the patient;

(2) The practitioner has prescribed one or more controlled substances based on telemedicine encounters during the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 and pursuant to the designation pursuant to that public health emergency on March 16, 2020, by the Secretary of Health and Human Services, with concurrence of the Acting DEA Administrator, that the telemedicine allowance under section 802(54)(D) applies to all schedule II-V controlled substances in all areas of the United States; ~~and~~

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~~(3) No more than 180 days have elapsed since [EFFECTIVE DATE OF RULE] or the end of the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019, whichever is later.~~

**6. The DEA should state explicitly in the final rule that a DEA registration for a telemedicine prescribing practitioner is only required in the location where the practitioner's practice is located.**

The requirement that a practitioner obtain and maintain DEA registrations in each state in which the practitioner is located as well as where the patient is located had been waived during the PHE.<sup>6</sup> As described further below, based on language in the preamble we believe that DEA intends only to require a telemedicine practitioner to have a DEA registration in the state in which their practice is located where they do not see any patients in person outside that state. We applaud this policy change as multi-state DEA registrations with the attendant physical location is a significant hindrance to patient care, especially with the referring physical aspects of the rule which do not require the telemedicine provider to be geographical located near the patient. We request that DEA address this explicitly in the final rule.

Specifically, we reference the following language which states that practitioners must possess an active DEA registration “in the State in which the practitioner is located (“unless exempted”) but does not state that they must possess a DEA registration where the patient is located.

The preamble in relevant part states that a telemedicine practitioner need only possess a DEA registration “in the State in which the practitioner is located”:

Pursuant to this authority, and in concert with the Department of Health and Human Services (“HHS”), DEA and HHS are hereby proposing to amend 21 CFR parts 1300, 1304, and 1306 to specify the circumstances under which practitioners may prescribe controlled medications, pursuant to 21 U.S.C. 802(54)(G), to patients whom the practitioner has never evaluated in person, including that (1) such prescriptions be in accordance with applicable Federal and State laws; and (2) **such practitioners possess an active DEA dispensing registration issued pursuant to 21 CFR 1301.13(e)(1)(iv) in the State in which the practitioner is located (unless exempted).**

88 Fed. Reg. 12,875R,12,876 (March 1, 2023) (emphasis added).

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<sup>6</sup> See DEA Policy Dated March 25, 2020, Exception to Separate Registration Requirements Across State Lines available at [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-018\)\(DEA067\)%20DEA%20state%20reciprocity%20\(final\)\(Signed\).pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf)



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Elsewhere in the preamble it states that the practitioner must be “authorized to prescribe” controlled substances “under registrations in the State where the practitioner is located, as well as the State where the patient is located.

Proposed § 1306.31(a)(3)(i) would require that a practitioner using telemedicine to prescribe a controlled substance 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.**

*Id.* at 12,880 (emphasis added).

We interpret this not to be inconsistent with the language above, because we interpret the phrase “authorized to prescribe” as meaning the practitioner has the appropriate medical licensure in the State in order to practice and prescribe controlled substances, but does not mean to suggest that DEA registration is required in the state where the patient is located.

We request that the final rule clarify this position and make it clear to practitioners that DEA registrations are not required in the state where the patient is located, only in the state in which the practitioner’s practice is located.

To implement this change, we recommend the following revisions to the DEA’s proposed rule:

1306.31(a)(3)(i): Authorized under their registration under 21 CFR 1301.13(e)(1)(iv) (and such registration shall only be required in the State in which the practitioner’s practice is located, and registration is not required in the State in which the patient is located) to prescribe the basic class of controlled substance specified on the prescription; or

**7. The DEA should create a special registration process for telemedicine providers as directed by the Ryan Haight Act.**

Under the Ryan Haight Act, Congress directed the DEA to create a special registration process by which telemedicine providers could register with the DEA. For nearly 14 years, patients, clinicians, industry stakeholders, and federal elected officials have asked the DEA to activate the special registration. Moreover, DEA has been mandated, by both the Legislative and Executive Branches of the United States government, to publish final regulations activating the special registration. The statutory requirement is contained in the SUPPORT for Patients and Communities Act, and the DEA was required to promulgate such regulations by October 24, 2019. Nonetheless, no rule has been published.

In the proposed rule, DEA explained that this rule is intended to meet its obligation of creating a special registration process. DEA also further explained that creating a process would only create more administrative burden for providers and would not expand access to care. We strongly disagree that the

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rule meets DEA's Congressional mandate to create a special registration pathway under 21 U.S.C. 802(54)(5) and in fact DEA notes that this rule is issued pursuant to its authority under 21 U.S.C. 802(54)(7) and not pursuant to the special registration category at 802(54)(5). Thus, we strongly encourage DEA to utilize this authority to create a special registration process for telemedicine providers as directed by the Ryan Haight Act.

The failure to create a special registration process for health care providers will likely lead to limited access to care and for less effective methods of identifying legitimate providers. Under a special registration process, DEA can easily monitor legitimate providers as opposed to bad actors. Furthermore, this process can assist pharmacists in dispensing of telemedicine prescriptions for controlled substances by identifying legitimate providers certified by the DEA.

With implementation of the special registration rule, DEA can both exempt the in person medical evaluation requirement as is explicit in the Ryan Haight Act<sup>7</sup> and streamline the process for a single nationwide DEA registration.

**8. The DEA regulatory requirement should include an exemption for United States licensed doctors who are temporarily out of country to prevent disruption of patient care.**

Currently, the DEA's proposed rule requires health care providers who wish to engage in the practice of telemedicine to be located in the United States. We request that DEA amend this regulatory requirement to include an exemption that would allow United States licensed providers to practice telemedicine while temporarily out of the United States to prevent disruption of patient care. For example, these providers may be temporarily out of the United States due to vacation or family matters.

To implement this change, we recommend the following revisions to the DEA's proposed rule:

§ 1306.31 Circumstances under which the practice of telemedicine may be conducted pursuant to 21 U.S.C. 802(54)(G).

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<sup>7</sup> This is acknowledged in the rule's description of the Act:

While the Ryan Haight Act amended the CSA to generally require that the dispensing of controlled substances by means of the internet be predicated on a valid prescription involving at least one in person medical evaluation, it also established seven distinct categories of telemedicine **pursuant to which a practitioner may prescribe controlled medications for a patient despite never having evaluated that patient in person**, provided that, among other things, such practice is in accordance with applicable Federal and State laws.

The special registration is one of these seven categories.

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(2) At the time of the telemedicine encounter that gives rise to the issuance of the telemedicine prescription, the practitioner is located in a State, Territory, or possession of the United States; the District of Columbia; or the Commonwealth of Puerto Rico unless such practitioner is temporarily abroad for a period not to exceed six months.

**9. The DEA's final rule should allow health care providers to prescribe Schedule II stimulants in the similar manner as Schedule III-V non-narcotic medications.**

The DEA's final rule should allow health care providers to prescribe Schedule II stimulants in the similar manner as Schedule III-V non-narcotic medications. This similar flexibility for Schedule II stimulants would prevent disruption in continuity of care for patients currently receiving these medications for the treatment of various mental conditions.

To implement this change, we recommend the following revisions to the DEA's proposed rule:

§ 1306.31 Circumstances under which the practice of telemedicine may be conducted pursuant to 21 U.S.C. 802(54)(G).

\* \* \* \* \*

(1) A telemedicine prescription may only be for a:

(i) A Schedule IIN stimulant, III, IV, or V nonnarcotic controlled substance;

**10. The Prescription Drug Monitoring Program (PDMP) querying requirement under the DEA's proposed rule needs to be simplified to avoid confusion and disruption in continuity of care.**

Currently, the DEA's proposed rule creates a complex PDMP querying process that would require health care providers to limit their prescriptions to patients to no more than 7-day supply until the providers can access the PDMP. Health care providers are generally required by state laws to query PDMP before prescribing and dispensing controlled substances under specified conditions. Therefore, the PDMP provision under the DEA's proposed rule would lead to unnecessary confusion and disruption in continuity of care if patients do not receive the entire course of necessary medication.

To implement this change, we recommend the following revisions to the DEA's proposed rule:

§ 1306.31 Circumstances under which the practice of telemedicine may be conducted pursuant to 21 U.S.C. 802(54)(G).

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(2) If the practitioner is unable to obtain the PDMP (or, if employed by the Department of Veterans Affairs, the Department of Veterans Affairs internal prescription database) data due to the PDMP (or Department of Veterans Affairs internal prescription database) system being non-operational or otherwise inaccessible as a result of a temporary technological or electrical failure, then:

~~(i) The practitioner may issue the prescription for no more than a 7-day supply;~~

~~(ii) The practitioner must obtain the PDMP (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database) data and conduct the review described in paragraph (e)(1) of this section within 7 days of the telemedicine encounter; and~~

(iii) The practitioner must record the attempts to obtain the PDMP and (if applicable) the Department of Veterans Affairs internal prescription database data. If the practitioner fails to obtain the PDMP (or, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database) data as described in paragraph (e)(1) of this section, the dates and times that the practitioner attempted to gain access, the reason why the practitioner was unable to gain access, and any follow-up attempts made to gain access to the system.

**11. Healthcare providers are exceedingly fearful of DEA enforcement actions surrounding the prescribing and dispensing of controlled substances, which is resulting in limited access to patient care including in the treatment of mental health and substance use disorder.**

The DEA laws, regulations, and policies pertaining to prescribing and dispensing of controlled substances are often times complex and difficult to comprehend. Therefore, we believe it would be constructive for DEA to issue guidance that will assist practitioners in understanding these new requirements and publicly announce that after the final rule is implemented and for the first year that DEA intends to take an educational approach to guide individuals on how to comply rather than directing through aggressive enforcement actions for alleged violations. The vast majority of practitioners want to fully comply with DEA requirements and are looking to be good partners with DEA to minimize diversion while providing needed care to patients. We encourage DEA to take a measured enforcement approach with the implementation of these complex and at times confusing rules.

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**12. If the DEA decides to retain the in-person medical evaluation regulatory provision, the limited 30-day supply of medication should be increased to a 180-day supply.**

A limited 30-day supply is not clinically appropriate for a health care provider to treat a patient. In fact, in many cases, a limited 30-day supply of necessary medication can lead to negative patient outcomes. For example, a patient who is receiving buprenorphine for the treatment of OUD would suffer negative consequences if only given a limited 30-day supply of this medication without guaranteed prescription refills. Some of these potential consequences could include relapse, overdose, and death. Furthermore, health care providers can be professionally liable for these negative patient outcomes and even accused of patient abandonment if patients are not able to receive further necessary treatment. As mentioned earlier, the average wait time in 2022 for an appointment with a new primary care provider was 26 days.<sup>8</sup> As a result, there is a high likelihood of disruption in continuity of care for this vulnerable patient population. Therefore, in the absence of removing the in-person regulatory requirements, we request the DEA to allow health care providers to offer a 180-day supply of medication to give patients adequate time to see another provider.

To implement this change, we recommend the following revisions to the DEA’s proposed rule:

§ 1306.31 Circumstances under which the practice of telemedicine may be conducted pursuant to 21 U.S.C. 802(54)(G).

\* \* \* \* \*

(2) The prescribing practitioner may issue multiple prescriptions for the patient, provided, however, that the prescriptions do not authorize the dispensing of more than a total quantity of a ~~30~~ 180 day supply of the controlled substance. This 90 ~~30~~-day limitation shall not apply to prescriptions issued by a practitioner who has a telemedicine relationship established during the COVID–19 public health emergency with the patient, as defined in § 1300.04(o), or to a practitioner employed by the Department of Veterans Affairs when prescribing to a patient of the Department of Veterans Affairs health system who has received an in-person medical evaluation from a practitioner who, at the time of the examination, was employed by the Department of Veterans Affairs. The prescribing practitioner may prescribe a supply in addition to the 180 ~~30~~ day supply if a medical evaluation is conducted pursuant to paragraph (d)(1), (2), or (3) of this section.

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<sup>8</sup> Merritt Hawkins, *AMN Healthcare Survey: Physician Appointment Wait Times Up 8% from 2017, Up 24% from 2004*, <https://www.merrithawkins.com/physician-appointment-wait-times-up-from-2017/> (last visited March 16, 2023).

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(3) Upon completing the review described in paragraph (e)(1) of this section, the practitioner may issue prescriptions authorizing the dispensing of no more than a 180 ~~30~~-day supply across all such prescriptions, unless otherwise exempted from the 180 ~~30~~-day supply limitation.

**13. Health care providers' residential addresses required to be documented should remain confidential to protect the safety of these providers.**

The proposed rule requires documentation of the address at which both the prescribing physician and referring physician are located as part of a telemedicine prescription from a referring practitioner. Often times, telemedicine practitioners operate from their homes. Such information would be reflected in a patient's medical records. With patient access to their medical records, this would allow patients to review this sensitive information. We request DEA to permit home residential addresses confidential and instead, in those instances, to permit only the DEA registration number associated with the address (and which DEA has on file) to replace it. This retains the confidentiality of the practitioners home residence, signals this fact to DEA, and allows DEA to access and review this information as needed.

There are reported instances where health care providers have been threatened or stalked on the premises of their homes by individuals who have obtained this information. Requiring this information to be documented could have a chilling effect and might drive providers away from being willing to provide these needed telemedicine services.

To implement this change, we recommend the following language change to the DEA's proposed rule:

1304.03(c)(i)

[t]he address at which the prescribing practitioner is located, (unless such location is a home or private residence, in which case the address may be omitted and the DEA registration number of the practitioner may be provided).

**14. The proposed rule does not address post-PHE practice location registrations, nor does it provide a clear framework or expectations of what elements are required to register a telemedicine-only practice location.**

The proposed rule does not state what DEA will do with the current COVID-19 PHE waivers on DEA state-by-state practice location registrations, come May 11, 2023. Will the DEA will also apply a 180 day extension to its state-by-state registration requirements? If so, is that extension limited solely to prescriptions in connection with a telemedicine relationship established during the COVID-19 public health emergency? What elements and features do DEA field investigators want to see when reviewing



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a practice location for telemedicine-only practitioners? Please provide responses to these queries in the commentary to the final rule.

\* \* \*

We appreciate the DEA's efforts in this important area of public policy and look forward to continuing the conversation as the rule process continues. Thank you for your consideration of our comments, and please feel free to contact us if you would like to discuss further.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Nathan A. Beaver', followed by a horizontal line.

Nathan A. Beaver, Esq.  
Foley & Lardner LLP