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IMPORTANT DEA CHANGES AND UPDATES FOR ALL LICENSED HEALTHCARE PROVIDERS THAT PRESCRIBE CONTROLLED SUBSTANCES (INCLUDING TESTOSTERONE, KETAMINE, ETC.)

Below are important changes, some or all of which will affect you if you prescribe any controlled substances. *I have tried to call out which may apply to you with the headings.*

APPLICABLE TO ALL LICENSED PROVIDERS WHO PRESCRIBE ANY CONTROLLED SUBSTANCES: Please read if you prescribe any controlled substances and therefore have a DEA registration.

Starting June 2023, there is a new requirement to apply for or renew a DEA registration to prescribe controlled substances. In order to apply for or renew your DEA registration, you must have completed a **one-time, eight hours of education and training on addiction treatment and management of patients with opioid or other substance use disorders**. This is required even if you cannot or do not prescribe opioids. It is required for all DEA registrants. The DEA's letter outlining the new requirement is also attached. The DEA also clarifies which courses and trainings qualify.

- **Who must satisfy this new training requirement?**
 - All DEA-registered practitioners, except for practitioners that are solely veterinarians. This is not dependent on state scope. It is required even if the practitioner cannot or does not prescribe opioids.
- **How will practitioners be asked to report satisfying this new training requirement?**
 - Beginning on June 27, 2023, practitioners will be required to check a box on their online DEA registration form—regardless of whether a registrant is completing their initial registration application or renewing their registration—affirming that they have completed the training requirement.
- **What is the deadline for satisfying this new training requirement?**
 - The deadline for satisfying this new training requirement is the date of a practitioner's next scheduled DEA registration submission—regardless of whether it is an initial registration or a renewal registration—on or after June 27, 2023.
 - This one-time training requirement affirmation will not be a part of future registration renewals.
- **What if I am a Naturopathic Doctor? I don't see any approved trainings for NDs.**

- The AANP is working to get AANP on the list of "approved organizations" to provide NDs with addiction education and training that is compliant with the new requirement. Until then, the AANP is working on compiling a list of accredited organizations or programs that offer an 8-hour addiction education and training curriculum that are open to NDs.

APPLICABLE TO ANYONE WHO PRESCRIBES BUPRENORPHINE FOR OPIOID USE DISORDER:

Congress has eliminated the DATA-Waiver Program – In the past, a provider was required to have a DATA-Waiver registration in order to prescribe buprenorphine for opioid use disorder, and there was a limit on the number of patients a provider could treat for opioid use disorder with buprenorphine. *Going forward:*

- A DATA-Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder. Of course, you still must have a DEA registration.
- All prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescriptions.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.
- This change does not change any existing state laws or regulations that may be applicable to prescribing controlled substances or buprenorphine.

APPLICABLE TO ANY DEA REGISTERED PRACTITIONERS WHO HAVE OR WILL PRESCRIBE ANY CONTROLLED SUBSTANCES VIA TELEMEDICINE:

Your ability to prescribe controlled substances without at least one in-person examination will be limited.

Telemedicine Updates and DEA Proposed Regulations with the End of the COVID Public Health Emergency

With the upcoming end of the Public Health Emergency (PHE) on May 11, 2023, the DEA has published two proposed regulations to address how telehealth may be used to prescribe controlled substances following the end of the PHE.

Starting May 12, 2023, the rules regarding prescriptions of controlled substances via telemedicine will be changing. Beginning on May 12th, your ability to prescribe controlled substances without conducting at least one in-person visit with the patient will be limited.

Prior to March 2020, the federal Ryan-Haight Act required that all DEA registered and licensed providers must conduct at least one in-person examination of a patient prior to the first prescription of a controlled substance. (After which, a practitioner may use telehealth to prescribe that patient any prescription for a controlled substance medication that the practitioner deems medically necessary.) This requirement that the practitioner conduct at least one in-person examination was

waived when the PHE was declared in March 2020, and the waiver has been in place for the last three years. Additionally, once the practitioner has conducted the in-person medical examination, the Ryan Haight Act does not set an expiration period on that exam or a minimum requirement for subsequent in-person exams.

It is important to note that under the Ryan Haight Act, failure to conduct this in-person medical evaluation prior to prescribing a controlled substance can constitute a per se violation of the Controlled Substances Act and result in civil and criminal penalties.

During the Public Health Emergency (for the last 3 years), a DEA registered and licensed healthcare provider, licensed in the state where the patient is located, was able to prescribe Schedule II-V controlled substances to the patient without an in-person medical evaluation so long as the following requirements were met.

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system (i.e., not just telephone or an online questionnaire); and
- The practitioner is acting in accordance with applicable Federal and State laws.

The term "practitioner" in this context includes a physician or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which s/he practices to prescribe controlled substances in the course of his/her professional practice.

Changes following the end of the PHE:

The following is a summary of the new rules that go into effect when the Public Health Emergency ends on May 11, 2023:

The DEA's proposed rules will discontinue the ability for telemedicine prescribing of controlled substances where the patient has never had any in-person exam – with the exception of an initial prescription period of no more than 30 days' supply, AND, if the patient requires a Schedule II medication or a Schedule III-V narcotic medication (with the sole exception of buprenorphine for opioid use disorder (OUD) treatment), an initial in-person exam with a DEA-registered practitioner is required *before* any prescription can be issued. In case this sounds confusing (because unfortunately there are a lot of details and requirements), I have tried to provide more clarification below:

Existing Patients (i.e., patients you have seen either in-person or via telemedicine prior to May 12, 2023):

- **For patients with whom you have conducted at least one in-person exam in the past and now see only via telehealth,** you may continue to conduct telehealth visits and write prescriptions for controlled substances for that patient indefinitely (you must still be registered with the DEA of course, and licensed in the state where the patient is located

and have the ability to prescribe controlled substances under that license). You have done the one in-person exam, and you are set.

- **For patients with whom you conducted at least one telehealth visit between March 16, 2020, and May 11, 2023 (the PHE period), and prescribed a controlled substance based on the telemedicine encounter but never conducted an in-person exam of the patient** -- you may continue to prescribe controlled substances for that patient without an in-person exam *until November 7, 2023 (180 days after the official end of the public health emergency)*.
 - For any prescribing after that date, the practitioner must either conduct an in-person exam of the patient (or have another DEA registered practitioner do the in-person exam and refer them back to you for the prescription) or stop prescribing for the patient. *If a controlled substance was not prescribed before May 12, 2023, a controlled substance should not be started but may be continued until November 2023.*
 - This 180 day extension for telemedicine relationships established during the PHE applies to all Schedule II-V controlled substances.

New Patients (i.e., patients seen for the first time on or after May 12, 2023):

- **Limited “Telemedicine Prescription”:**
 - For patients first seen via a telemedicine consultation, you may prescribe an initial prescription for a controlled substance via telemedicine so long as it is:
 - **(1) a non-narcotic Schedule III, IV or V controlled substance (or buprenorphine for treatment of OUD), AND**
 - **(2) the prescribed amount does not exceed 30 days.**
 - After the 30 calendar days from the date the initial telemedicine prescription is issued, additional prescriptions (e.g., refills beyond 30 days or any new prescriptions of a controlled substance), can be submitted ONLY after you have an in-person consultation with the patient OR another DEA-registered prescriber sees the patient in-person and you participate in the exam via telemedicine or that other DEA-registered practitioner refers the patient back to you for the prescription (referred to as “qualified telemedicine referral” as discussed below).
 - In other words, after 30 calendar days from the date the initial telemedicine prescription is issued, the practitioner cannot issue any more telemedicine prescriptions of controlled substances to that patient until one of the following occurs (all of which require some type of in-person exam with the patient):
 - The prescribing telemedicine practitioner conducts an in-person exam of the patient; or

- The patient participates in a 3-party exam (patient, in-person practitioner, and telemedicine practitioner simultaneously) where the patient is being treated by, and in the physical presence of, the in-person DEA registered practitioner, and the telemedicine DEA-practitioner participates simultaneously in this exam using interactive real-time audio-video (no audio-only); or
 - Qualified Telemedicine Referral: The patient goes to a different DEA-registered practitioner for an in-person exam, and that DEA-registered practitioner sends the prescribing telemedicine practitioner a qualifying telemedicine referral for the patient.
- Under the 30 day rule, technically, the practitioner is allowed to issue multiple prescriptions for the same patient, but only prescribe an amount less than or equal to a total quantity of a 30-day supply. This supply may include dosages that are titrated up or down depending on the patient’s response to the medication and the practitioner’s medical judgment, but may not exceed a supply sufficient to treat the patient for more than 30 days.
- The practitioner must put a note on the face of the prescription, or within the prescription order if prescribed electronically, that the prescription has been issued via a telemedicine encounter.
- All prescribing of course must be done for a legitimate medical purpose in the usual course of professional practice, and in compliance with applicable state and federal laws.
- **“Qualified Telemedicine Referral” (more details):**
 - If the patient has an initial in-person exam with a DEA-registered practitioner, who subsequently refers the patient to you, you can have a telemedicine exam of the patient via video and prescribe a controlled substance without personally conducting an in-person exam of the patient. (Put differently, you may prescribe a controlled substance following a telehealth consultation and without seeing a patient in-person if the patient was properly referred to you by another DEA-registered practitioner who conducted an in-person examination with the patient before referring that patient to you for the prescription.)
 - Under this referral process, the telemedicine practitioner can prescribe Schedule II-V and narcotic controlled substances. Unlike the 30 day supply which is limited to non-narcotic Schedule III-V medications.
 - The qualifying telemedicine referral must note the name and NPI of the DEA registered practitioner to whom the patient is being referred for prescription and that should be maintained in the patient’s record by both practitioners.

In plain English, a qualifying telemedicine referral process would work as follows:

1. A DEA-registered practitioner conducts at least one in-person exam of the patient in accordance with applicable state law.
2. That practitioner refers the patient to a second DEA registered practitioner for a legitimate medical purpose in the ordinary course of their professional practice. The in-person practitioner must make a written referral (containing specific content) and send it to the second DEA registered practitioner.
3. The second DEA registered practitioner conducts a telemedicine exam of the patient. This telemedicine exam need not occur simultaneously with the first in-person exam. The second practitioner need not conduct an in-person exam.
4. The second DEA registered practitioner must review and consider the PDMP database in the state where the patient is located (if the state has a PDMP) for data regarding any controlled substance prescriptions issued to the patient in the last year, or, if less than one year of data is available, in the entire available period.
5. The second DEA registered practitioner can prescribe a controlled substance, including Schedule II and narcotic controlled substances.
6. The second DEA registered practitioner must impose a notation on the face of the prescription, or within the prescription order if prescribed electronically, that the prescription has been issued via a telemedicine encounter.

There is no requirement for the patient to undergo a subsequent in-person exam by either the first or second practitioner, nor must the patient obtain subsequent referrals in order for the telemedicine practitioner to prescribe again in the future. Of course, if an in-person exam is required by state law, other applicable federal law, or standards of clinical practice, such in-person exam must be conducted.

If, for some reason, multiple DEA-registered practitioners were physically present during the patient's in-person exam, each of those practitioners would have the ability to issue a qualifying telemedicine referral. Referrals predicated exclusively on a telemedicine exam do not constitute a qualifying telemedicine referral.

The qualifying referral process requires special documentation and timing. The written referral must be based on the diagnosis, evaluation, or treatment that occurred as a result of the in-person medical evaluation. Along with the written referral form, the referring practitioner must communicate the results of the in-person evaluation by sharing the relevant information in the patient's medical record which includes, at a minimum, the diagnosis, evaluation, and treatment of the patient. All of this must occur and be received by the second practitioner before a prescription is issued by the second practitioner.

The written referral form must also include: 1) the name and NPI of the referring practitioner (i.e., the one who conducted the in-person exam) *and* 2) the name and NPI of the telemedicine practitioner (i.e., to whom the patient is being referred). ***This means the referring practitioner cannot simply refer a patient to a business entity, medical group, facility, or specialist practice, but instead must name a specific practitioner on the referral form.***

Both the referring practitioner and the receiving practitioner must maintain copies of all qualifying telemedicine referrals they issue or receive.

If you are issuing a telemedicine prescription through a qualifying telemedicine referral, the following must be maintained in the patient's record:

1. The name and NPI of the referring practitioner;
2. A copy of the referral document and other communications from the referring practitioner (e.g., the results of the evaluation by sharing the relevant information in the patient's medical record which includes, at a minimum, the diagnosis, evaluation, and treatment of the patient); and

The following additional records must be maintained when using the 3-party exam option under the virtual first "telemedicine prescription" process:

1. The local in-person practitioner physically present with the patient must maintain, for each such medical evaluation:
 - a. The date and time of the evaluation;
 - b. The address at which the in-person practitioner is physically present with the patient during the exam;
 - c. The address at which the prescribing telemedicine practitioner is located during the telemedicine encounter; and
 - d. The NPI of the prescribing telemedicine practitioner.
2. The prescribing telemedicine practitioner must maintain, for each such medical evaluation:
 - a. The date and time of the evaluation;
 - b. The address at which the prescribing telemedicine practitioner is located during the telemedicine encounter;
 - c. The address at which the in-person practitioner is physically present with the patient during the exam; and
 - d. The NPI of the in-person practitioner physically present with the patient.

OTHER IMPORTANT NOTES AND CHANGES:

How does the proposed rule work with state laws? If a state law allows telemedicine prescribing of controlled substances without an in-person exam, does the more permissive state law preempt the Ryan Haight Act?

No. The Ryan Haight Act preempts state law on telemedicine prescribing of controlled substances, but only to the extent the federal provisions are more restrictive/stringent than the state law. If the federal Ryan Haight Act is more restrictive than the state law, the more restrictive federal

provisions apply. If the state law is more restrictive than the federal Ryan Haight Act, the more restrictive state law provisions apply. Therefore, the prescribing practitioner must comply with both state and federal laws, and can do so by following the most restrictive provisions under each.

As a general matter, the federal Ryan Haight Act in-person exam requirement is more stringent than most state laws or state telemedicine requirements. In some states, an in-person examination is not a prerequisite to prescribe controlled substances. Instead, the state law permits a practitioner to treat a patient through telemedicine, provided the practitioner creates a valid doctor-patient relationship, conducts a sufficient examination of the patient via telemedicine, and meets other state requirements.

Can a practitioner issue a “telemedicine prescription” when the practitioner is located outside the United States?

No. Under the proposed rule, a practitioner who wishes to issue a “telemedicine prescription” must be located in a State, Territory, or possession of the United States; the District of Columbia; or the Commonwealth of Puerto Rico at the time of the telemedicine encounter. Note: this geographic restriction applies to the new options for “telemedicine prescriptions”.

Does the proposed rule alter current DEA controlled substance practice location registration requirements?

Yes. Under the proposed rule, if a practitioner wishes to issue a “telemedicine prescription,” they must have a DEA registration in *both* the state where the patient is located and the state where the practitioner is located (i.e., even if the practitioner does not prescribe to patients located in the state where the practitioner is located, such as a vacation home). In other words, you would not be able to prescribe a controlled substance via telemedicine from vacation unless you have a DEA registration in that state where you are vacationing, and not if you are outside of the US.

However, this requires more clarification because it is unclear how this applies to the 180 extension for existing patients.

The above information regarding the proposed rules for telemedicine prescriptions of controlled substances is accurate as of April 1, 2023. There may be more rules and changes to come. Stay tuned.

If you would like to schedule a legal consultation to discuss how this affects your practice, please email sberg@stephanieberglaw.com.