

Remote Prescribing of Controlled Substances

Ryan Haight Online Pharmacy Consumer Protection Act

- The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 requires a telemedicine provider to perform an **in-person medical evaluation** of a patient **prior to prescribing a controlled substance** to that patient, unless an exception applies (21 U.S.C. § 829(e)(1)).
- The Act includes an exemption to the in-person medical evaluation requirement for the delivery, distribution or dispensing of a controlled substance by a practitioner engaged in the “**practice of telemedicine**” (21 U.S.C. § 829(e)(3)).
- However, the “practice of telemedicine” is defined quite narrowly. Specifically, it is defined as an encounter that is provided in one of **seven circumstances**.

Seven “Practice of Medicine” Circumstances

- A. The patient is being treated in and is physically located in a hospital or clinic.
- B. The patient is being treated by and in the physical presence of another practitioner.
- C. The patient is being treated by a provider employed by the Indian Health Services.
- D. The treatment is occurring **during a PHE**...as designated by HHS and the US Attorney General.
- E. The patient is being treated by a practitioner who holds a **special registration**....
- F. There is a medical emergency and the patient is being treated by an employee of the Veterans Health administration....
- G. The patient is being treated under **other circumstances as set forth in regulation** as determined jointly by the HHS Secretary and the US Attorney General....

“Special Registration”

- The “special registration” could establish a criteria, process or other circumstances under which controlled substance prescribing could occur without a prior in-person visit.
- The DEA has not defined “special registration” in **14 years**.
- In the 2018 SUPPORT for Patients and Communities Act, Congress imposed a deadline of October 2019 for the DEA to define the “special registration”

March 16, 2020: PHE Exception for Telemedicine Prescriptions

- The DEA waived the Ryan Haight Act requirement that a practitioner prescribing controlled substances over the internet must have conducted at least one “in-person medical evaluation” of the patient
- Prescribers may issue prescriptions pursuant to a telemedicine encounter for all schedule II-V controlled substances if:
 - 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
 - The practitioner is acting in accordance with applicable Federal and State laws
- Expires May 11, 2023

February 24, 2023: DEA Proposed Rules

- DEA publishes two Proposed Rules on Friday, February 24, 2023
 - The Telemedicine Controlled Substance Proposed Rule
 - The Telemedicine Buprenorphine Proposed Rule
- Includes **three new options** for telemedicine prescribing of controlled substances without a prior in-person medical exam
 - The options are more limiting than the DEA's PHE waiver
 - The proposed rules still do not address "special registration" for telemedicine
 - Instead, the DEA relied on subparagraph G (i.e., the 7th circumstance)
- The Proposed Rules closed for public comment on March 31, 2023

New Options under Proposed Rules

- Option 1: Telemedicine Encounter for a Limited Supply of Schedule III, IV or V Controlled Substances
- Option 2: Qualifying Telemedicine Referral
- Option 3: Buprenorphine via Telemedicine Encounter

Definition of “Telemedicine Encounter”

- Means an encounter conducted as defined by 42 CFR 410.78(a)(3):

“...multimedia communications equipment that includes, at a minimum, **audio and video** equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

“For services furnished for purposes of diagnosis, evaluation, or treatment of a **mental health disorder** to a patient in their home, interactive telecommunications may include two-way, **real-time audio-only** communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology.”

- The term “mental health disorder” includes “substance use disorder

Definition: “Telemedicine Relationship During the COVID-19 Public Health Emergency”

- Means:
 - When a prescriber **has not** conducted as an in-person medical evaluation of the patient,
 - But conducted a telemedicine encounter **during the PHE**, and
 - Conducted the encounter in compliance with the DEA’s waiver requirements
- Facilitates a six-month transition of doctor-patient relationships established during the PHE
 - **Expires Nov. 7, 2023**

Option 1: Telemedicine Encounter for a Limited Supply

- Allows practitioners to prescribe non-narcotic Schedule III-V controlled substances when:
 - The telemedicine encounter is for a legitimate medical purpose with a prescriber acting in the usual course of professional practice
 - The prescriber is located in the U.S.
 - The prescriber is authorized to prescribe in their state and the patient's state
 - The prescriber reviews the state's PDMP records for the past 12 months
 - The prescriber notates the prescription to indicate it was issued pursuant to a telemedicine encounter

Option 1: Telemedicine Encounter for a Limited Supply

- Excludes Schedule II controlled substances
- Limited to a 30-day supply (no renewals)
- Limited to a 7-day supply if the PDMP is nonoperational or unavailable, and the prescriber documents:
 - When they attempted to access the PDMP
 - Why they could not gain access to the PDMP
 - Any follow-up attempts to access the PDMP

Option 1: Record Keeping

- For each prescription issued pursuant to these rules, a prescriber must maintain records of the following:
 - Date the prescription was issued
 - Full name and address of the patient
 - Drug name, strength, dosage form, quantity and directions for use
 - Addresses of the prescriber and patient during the telemedicine encounter
 - All efforts to comply with the requirement of accessing the PDMP system

Option 2: Qualifying Telemedicine Referral

- What is a “Qualifying Telemedicine Referral”?
 - A referral by a practitioner who has conducted at least one in-person exam of a patient
 - To another practitioner who conducts a telemedicine exam of such patient
 - The referral is made for a legitimate medical purpose in the ordinary course of their professional practice

Option 2: Qualifying Telemedicine Referral

- Allows prescriptions of controlled substances (including beyond a 30-day supply) if:
 - The prescriber receives a “qualifying telemedicine referral”
 - From a DEA registered practitioner
 - Who has conducted **an in-person exam** of the patient

Option 2: Record Keeping (Prescriber)

- For each prescription issued pursuant to Option 2, a prescriber must maintain the same records as Option 1, plus:
 - The name and NPI of the referring practitioner
 - A copy of the referral and any communications shared

Option 2: Record Keeping (Referring Practitioner)

- For each prescription issued pursuant to Option 2, a referring practitioner must maintain records of the following:
 - The data and time of the evaluation
 - The NPI of the DEA-registered practitioner physically present with the patient
 - The address at which the prescribing practitioner is located during the telemedicine encounter
 - The address at which the DEA-registered practitioner was physically present with the patient during the medical evaluation

Option 3: Buprenorphine via Telemedicine Encounter

- Allows buprenorphine prescriptions via telemedicine encounters when:
 - For use in the maintenance and detoxification treatment of opioid-use disorder (only)
 - Prescriber maintains a DEA registration in prescriber's state
 - Prescriber is authorized to practice telemedicine in the patient's and the prescriber's state (i.e., complies with state law, including modality limitations)
 - Prescriber must comply with DEA and Controlled Substances Act requirements applicable to maintenance and detoxification treatment
 - Prescriber must be capable of using synchronous audio-video
 - Prescriber must review the state's PDMP prior to prescribing buprenorphine

Option 3: Buprenorphine via Telemedicine Encounter

- Some requirements are the same as Option 1:
 - 30-day / 7-day limits (no renewals)
 - Record keeping requirements
- Audio-only permitted (if “the patient is not capable of, or does not consent to, the use of video technology”)

Takeaways

- Re-establishes many pre-pandemic barriers to care: Geographic, socioeconomic, technology
- Some telehealth providers do not have physical space to conduct in-person visits
- No Schedule II prescriptions without an in-person evaluation
- New options and grandfathering may conflict with state law
- Statutory “Special Telemedicine Registration” exception is still undefined
- Creates a “telemedicine cliff” for some patients
 - Opioid treatment
 - Pain
 - ADHD
 - Sleep Disorders
 - Panic and Anxiety
 - Epilepsy
 - Other