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HEALTH CARE UNINTERRUPTED

# Telemedicine Prescribing

## Critical Elements of the 2025 Proposed and Final Rules

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# Caution

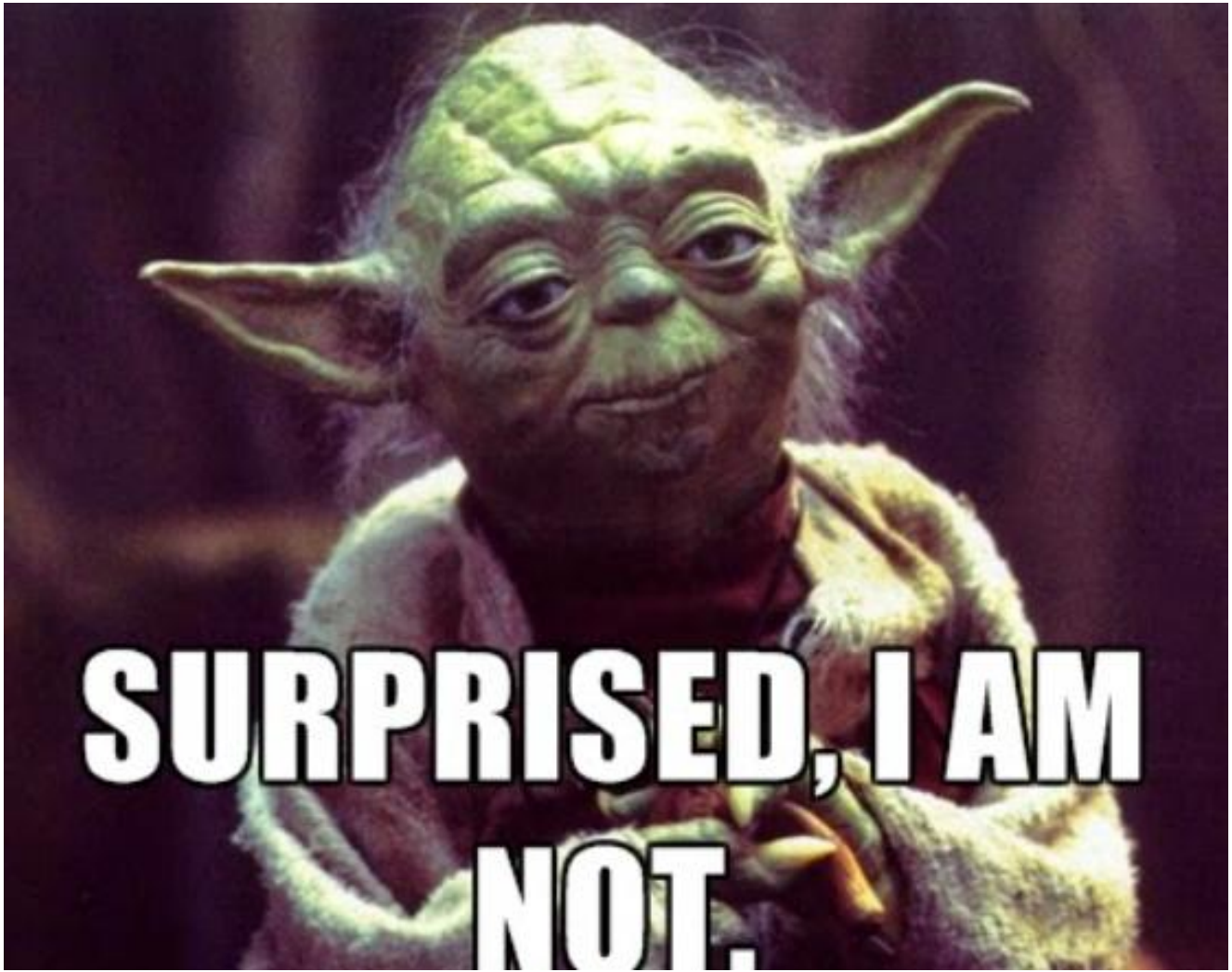
These slides were prepared on February 23, 2025. They are intended to provide talking points. The laws and regulations applicable to Virtual Care are frequently changing. What was the law yesterday, may not be the law today. Please use caution in reference to these slides, as the law may have changed.

# Overview


- Status of Proposed and Final Rules
- Telemedicine Prescribing Timeline
  - Ryan Haight Act
  - Covid 19 Waiver
- Proposed Rule - Special Registrations for Telemedicine and Limited State Telemedicine Registrations
- Final Rule - Expansion of Buprenorphine Treatment via Telemedicine Encounter
- Questions

# Status of Proposed and Final Rules

- Special Registrations for Telemedicine and Limited State Telemedicine Registrations
  - Proposed Rule
  - Published in Federal Register on January 17, 2025
  - Comments to be accepted during the following 60-day period
  - January 20, 2025 Executive Order freezing all proposed rules **still in effect**
- Expansion of Buprenorphine Treatment via Telemedicine Encounter
  - Final Rule
  - Published on January 17, 2025
  - Scheduled to become effective on February 18, 2025
  - On February 14, 2025, President announced the effective date of this final rule would be delayed to March 21, 2025, to solicit additional comments
- Expectations and context for discussion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# Telemedicine Prescribing Timeline

- **2008** – Ryan Haight Online Pharmacy Consumer Protection Act
  - "Special Registration" contemplated by original rule
- **2018** – President Trump signed into law the Special Registration for Telemedicine Act, which required the DEA to promulgate final regulations to implement use of the Special Registration
- **March 2020** – In response to the PHE, the DEA invoked its emergency authority per 21 U.S.C. § 802(54)(D) to waive certain requirements of the Ryan Haight Act
  - Permits prescription of controlled substances through telemedicine if:
    - Legitimate medical purpose by appropriate licensed practitioner;
    - Synchronous (audio and visual) technology is used; and
    - Practitioner acts in accordance with applicable federal **and state law**.

# Telemedicine Prescribing Timeline

- **May 2023** – DEA issues two proposed rules:
  - General Telemedicine NPRM and Buprenorphine NPRM
  - Additionally extends (through First Temporary Rule) Covid Waiver through 2023
- **October 2023**
  - DEA, in response to more than 38,000 comments, indicates more time will be needed to evaluate the NPRMs
  - Per Second Temporary Rule extends Covid Waiver through 2024
- **November 2024**
  - Per Third Temporary Rule, extends Covid Waiver through 2025
- **January 2025** – DEA publishes:
  - Proposed Rule - Special Registrations for Telemedicine and Limited State Telemedicine Registrations
  - Final Rule - Expansion of Buprenorphine Treatment via Telemedicine Encounter (now delayed stayed as noted above)

# Ryan Haight Act

- **Ryan Haight Online Pharmacy Consumer Protection Act**
  - Enacted in 2008 "to prevent the illegal distribution and dispensing of controlled substances by means of the internet.
  - Named after Ryan Haight, a California high school student who died in 2001 from an overdose of controlled substances that he had purchased from an online pharmacy."
- The Act requires that a qualified practitioner perform at least one (1) in-person medical examination of a patient prior to prescribing that patient a controlled substance, except:
  - When a "covering practitioner" (as defined) or
  - Engaged in "the practice of telemedicine" (as defined)
- In all instances, the prescription must be provided by an appropriately licensed/registered practitioner, in the usual course/scope of practice, for a legitimate medical purpose.

 (See, 21 U.S.C.A. § § 802 and 829)

# Ryan Haight Act

- "**In-person medical evaluation**" means "a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals."
  - Act does not specify a requisite time period for the performance of this in-person exam.
    - But see below regarding "Covering Practitioner"
  - The Act does provide that no provision in the Act "shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice."
- "**Covering Practitioner**" means "a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who:
  - Has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and
  - Is temporarily unavailable to conduct the evaluation of the patient."

See, 21 U.S.C.A. § § 802 and 829

# Ryan Haight Act

- In-person examination is not required when a practitioner is engaged in the "practice of telemedicine" and using an appropriate "telecommunications system"
- However, the "practice of telemedicine" is narrowly defined to include:
  - Treatment in a DEA registered hospital or clinic
    - The practice of telemedicine is being conducted while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f)…..
    - By a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located….
  - Treatment in the physical presence of a DEA registered practitioner
    - The practice of telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a health care practitioner who is:
      - acting in the usual course of the health care practitioner's professional scope of practice,
      - is acting in accordance with applicable State law, and
      - who is himself/herself registered with the DEA to prescribe controlled substances under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located

# Ryan Haight Act

- Practice of Telemedicine, continued:
  - Indian Health Service or tribal organization
    - The practice of telemedicine is being conducted by a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act
  - Department of Veterans Affairs Medical Emergency
    - In a "medical emergency" (as defined) by a practitioner who is "an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract…."
  - **Special Registration**
    - The practice of telemedicine is being conducted by a practitioner who has obtained from the Administrator a special registration
  - **Public Health Emergency**

# PROPOSED RULE:
# SPECIAL REGISTRATIONS FOR TELEMEDICINE

# The New (Proposed) Special Registrations

- Three (3)Types of Special Registrations for Telemedicine have been introduced:
  - **Telemedicine Prescribing Registration**
    - Authorizes qualified **"clinician practitioners"** to prescribe Schedule III-V controlled substances via telemedicine
  - **Advanced Telemedicine Prescribing Registration**
    - Authorizes qualified **"specialized clinician practitioners"** to prescribe Schedule II-V controlled substances via telemedicine
  - **Telemedicine Platform Registration**
    - Authorizes **"covered online telemedicine platforms"** in their capacity as **"platform practitioners"** to dispense Schedule II-V controlled substances

# What Does Not Change

- Although the proposed rule creates three (3) new special registration pathways, the proposed rule does not otherwise modify the Ryan Haight Act
  - The current/default rule in relation to requisite in-person visit applies
    - Notably, the NPRM states, "In other words, the regulations implemented under the Ryan Haight Act would not be applicable to practitioner-patient relationships in which there has ever been a prior in-person medical evaluation of the patient by the practitioner."
  - The current (limited) "telemedicine" exceptions apply
- Practitioners must meet the requisite in-person standard of care

# What Does Not Change

- Practitioners must comply with applicable state law (which may be more restrictive than the DEA's requirements)
  - What may/may not be prescribed through telemedicine
  - What technology is permitted to conduct telemedicine visits
  - Other professional practice requirements (consent, documentation, registration, etc.)
- Understand the professional practice rules applicable telemedicine visits/prescribing may be (and often are) different than the rules/conditions for reimbursement

# Telemedicine Prescribing Registration

- This initial pathway is more broadly applicable to “clinician practitioners” who have a “legitimate need” to for such special registration
  - “Physicians and board-certified mid-level practitioners (defined under 21 CFR 1300.01) have a legitimate need to prescribe Schedules III through V controlled substances when they anticipate that they will be treating patients for whom requiring in-person medical evaluations prior to prescribing Schedule III-V controlled substances could impose significant burdens on bona fide practitioner-patient relationships.”
  - “For example, practitioners may have a legitimate need for the Special Registration when their patients face significant challenges in attending in-person medical evaluations, such as severe weather conditions, living in remote or distant areas, or having communicable diseases, which make in-person appointments difficult or even unadvisable.”

# Advanced Telemedicine Prescribing Registration

- This advanced pathway only applies when certain practitioners “have a legitimate need to prescribe Schedule II controlled substances in addition to Schedules III through V.”
- Only the following practitioners are permitted to apply/obtain this registration:
  - Psychiatrists;
  - Hospice Care Physicians;
  - Palliative Care Physicians;
  - Physicians rendering treatment at long term care facilities;
  - Pediatricians;
  - Neurologists; and
  - Mid-level Practitioners and Physicians “from other specialties who are board certified in the treatment of psychiatric or psychological disorders, hospice care, palliative care, pediatric care, or neurological disorders unrelated to the treatment and management of pain”

# Advanced Telemedicine Prescribing Registration

- Clinician Practitioners are required to furnish information on their Special Registration applications that would demonstrate their specialized training.
  - "For example, the clinician practitioner could cite or provide information on board certification in a specialty, specialized training, or the percentage of the clinician practitioner's overall practice that falls within one of the specialized practices.
- Mid-level practitioners are, however, required to be board-certified
- DEA has invited feedback/comments regarding the list of approved providers in this category
- DEA notes: "The heightened specificity of these limited circumstances is intended to strike a balance between ensuring access to necessary medications for vulnerable patients while controlling the prescribing of Schedule II controlled substances that have a higher potential risk of abuse and dependence…"

# Telemedicine Platform Registration

- Applies to "**Covered Online Telemedicine Platforms**" who desire to "dispense" Schedule II through IV controlled substances
  - DEA notes that many of these entities currently "dispense" controlled substances (and therefore should be registered)
- Must have a "legitimate need" for a Special Registration.
- A legitimate need exists when the Covered Online Telemedicine Platform (through attestation on the registration application):
  - anticipates providing necessary services to introduce or facilitate connections between patients and clinician practitioners via telemedicine for the diagnosis, treatment, and prescription of controlled substances,
  - is compliant with federal and state regulations
  - provides oversight over clinician practitioners' prescribing practices and takes measures to prioritize patient safety and prevent diversion, abuse, or misuse of controlled substances.

# Telemedicine Platform Registration

- **Covered Online Telemedicine Platform** means an entity that facilitates connections between patients and clinician practitioners, via an audio-video telecommunications system, for the diagnosis and treatment of patients that may result in the prescription of controlled substances, **but is not** a hospital, clinic, local in-person medical practice, or insurance provider, **and meets one or more of the following criteria**:
  - the entity explicitly promotes or advertises the prescribing of controlled substances through the platform;
  - the entity has financial interests, whether direct incentives or otherwise, tied to the volume or types of controlled substance prescriptions issued through the platform, including but not limited to, ownership interest in pharmacies used to fill patients' prescriptions, or rebates from those pharmacies;
  - the entity exerts control or influence on clinical decision-making processes or prescribing related to controlled substances, including, but not limited to: prescribing guidelines or protocols for clinician practitioners employed or contracted by the platform; consideration of clinician practitioner prescribing rates in the entity's hiring, retention, or compensation decisions; imposing explicit or de facto prescribing quotas; directing patients to preferred pharmacies; and/or
  - the entity has control or custody of the prescriptions or medical records of patients who are prescribed controlled substances through the platform.

# Special Registration Application Process

- A new form will be created to apply for the Special Registrations – Form 224S
- The application fee for any one of the Special Registrations is $888.
- Applicants must apply/reapply every (3) years
- All applicants must:
  - have “regular” DEA registration as a prerequisite to the addition of the Special Registration
  - designate one of their existing registered locations as the registered/physical address (which will serve as the physical point of contact for the DEA
- All applicants must provide certain disclosures and attestations:
  - Must attest to their legitimate need for the Special Registration and that they have devised, and are committed to maintaining, anti-diversion policies and procedures

# Special Registration Application Process

- All applicants must provide certain disclosures and attestations (cont.):
  - Platforms must “attest to all employment, contractual relationships, or professional affiliations with any clinician special registrant and Online Pharmacy and their respective registration numbers…”
  - Similarly, clinician practitioners:
    - “must attest to all employment, contractual relationships, and professional affiliations, including but not limited to those with covered online telemedicine platforms (and the respective online telemedicine platform's Telemedicine Platform Special Registration number, if applicable)” and
    - when applying for the Advanced Special Registration, must disclose their practice specialties (e.g., hospice care, palliative care, etc.)
- All applicants must update their application within (14) business days when there is a change (including, but not limited to employment and contractual relationships)

# Additional State Registration

- In addition to the Special Registration requirements, applicants must also obtain a DEA registration in **each state** where they intend to issue prescriptions or dispense medications to patients via telemedicine
  - Limited exemptions for VA and certain military scenarios
- This state registration will be contingent on applicable state requirements for licensure and registration
- Additional fees apply:
  - Platforms pay additional $888 for each state where state registration is required
  - Clinicians pay additional $50 for each state where state registration is required

# Additional Requirements and Limitations

- **Geographic Location**
  - Clinician special registrants must be physically present in the United States or a US Territory when conducting a telemedicine encounter and issuing a special registration prescription
- **Licensure**
  - Clinical special registrants must be "authorized and licensed to practice" **in both** the jurisdiction where the clinician is located **and** the state where the patients is located
- **Electronic Prescribing**
  - All special registration prescriptions must be issued through Electronic Prescribing for Controlled Substances
  - Must contain (in addition to routine information) the Federal and State Special registration numbers, as applicable

# Additional Requirements and Limitations

- **Technology**
  - Clinician special registrations must utilize both audio and video components of an audio-video telecommunications system
  - Limited exception for medication assisted treatment through buprenorphine
- **Prescription Drug Monitoring Program**
  - During the first (3) years following the new rule becoming effective, clinicians must query (a) the PDMP for the state/territory where the patient is located, (b) the state/territory where the clinician is located, and (c) all other states/territories that have reciprocity agreements with (a) and (b)
  - After the first (3) years, the clinician must query all PDMPs
    - DEA notes that this may be modified/delayed further depending on the technology/availability of an all-jurisdiction search function

# Additional Requirements and Limitations

- **Schedule II Controlled Substances**
  - Clinician must be physically located **in the same state as the patient**
  - Each clinician's total telemedicine prescriptions for a Schedule II in a calendar month **must be less than 50%** of all such prescriptions by the clinician
  - Approved pediatric specialists (who are advanced special registrants) must require the presence of a minor's parent or guardian during the visit
- **State law**
  - Special registrants must comply with applicable state law:
    - where the clinician is located;
    - where the patient is located; **and**
    - in any other states where a registrant maintains a registration to dispense controlled substances, to the extent such laws apply to such telemedicine encounters

# Additional Reporting Requirements

- **Patient Verification**
  - Photographic documentation of patient presenting federal or state issued identification is required
  - Other acceptable documents permissible if no ID is available (must maintain record)
  - Must verify patient identify at each visit
- **Telemedicine Encounter Record**
  - Date and Time of Encounter
  - Location of patient
  - Home address of patient
  - Must maintain for a minimum of (2) years at registered location of clinician

# Additional Reporting Requirements

- **Credential Verification and Conduct-Related Documentation**
  - Platform special registrants must maintain documentation of relationships with clinician registrations
    - Verification of special registration credentials, "including but not limited to records on education, training, board or specialty certifications" and special registration numbers
    - The applicable employment contract or other applicable contract
    - Any "disciplinary actions or sanctions, or documentation of complaints, disputes, or incidents involving the practice of telemedicine"
    - Must maintain and update this information every (2) years and it must be readily available for DEA inspection if requested
  - "[B]y requiring that platform special registrants maintain such records, they are compelled to assume responsibility for the conduct and prescribing practices of the clinician special registrants whose telemedicine prescribing is facilitated by their platform…"

# Additional Reporting Requirements

- **Centralized Recordkeeping**
  - All required records must be maintained at the physical location that is provided as part of the registration process
- **Annual Special Registrant Reporting**
  - All special registrants must report annual data related to:
    - Total number of new patients in each state for which they issued at least one special registration prescription for a Schedule II controlled substance or certain other Schedule III-V controlled substances (including Ketamine, Tramadol, and any benzodiazepine)
    - Total number of special registration prescription for Schedule II controlled substances and certain other Schedule III-V controlled substances in aggregate and across all states

# Additional Reporting Requirements

- **Pharmacy Reporting**
  - Within first seven (7) days of the start of every month, reporting required for the special registration prescriptions filled during the preceding month for each Schedule II controlled substance and certain Schedule III-V controlled substances

# FINAL RULE:
# EXPANSION OF BUPRENORPHINE TREATMENT VIA TELEMEDICINE ENCOUNTER

# Special Rules for Treating Opioid Use Disorder: Induction of Buprenorphine

- **Opioid Use Disorder, MAT, & Buprenorphine**
  - Opioid use disorder (OUD) is a chronic health condition characterized by a problematic pattern of opioid use (e.g., fentanyl, heroin, oxycodone, etc.) use that leads to serious impairment or distress
  - Estimated that over 6.1 million people aged 12 or older have OUD
  - Buprenorphine is one of three medications approved by the FDA for the treatment of OUD
    - It is the only Schedule III–V controlled substance approved for this purpose
  - For individuals with OUD, buprenorphine prevents withdrawal symptoms and reduces drug cravings without producing euphoric sensations

# Special Rules for Treating Opioid Use Disorder: Induction of Buprenorphine

- **Final Rule**
  - Expands the circumstances under which DEA-registered practitioners are authorized to prescribe Schedule III–V controlled substances approved by the FDA for the treatment of opioid use disorder (OUD) via telemedicine, including audio-only telemedicine encounters
  - Publication Date: January 17, 2025 (90 Fed. Reg. 6504)
  - Effective Date: March 21, 2025
    - Date delayed by DEA/HHS pursuant to 90 Fed. Reg. 9841 (February 14, 2025) & Regulatory Freeze (January 20, 2025)
  - DEA is soliciting comments on the extension of the effective date and on issues of fact, law, and policy raised by the rule
    - Comments Due: February 28, 2025

# Evolution of DEA Requirements for Buprenorphine Treatment via Telemedicine

| COVID-19 Telemedicine Flexibilities | March 2023 Proposed Rule | 2025 Final Rule |
|---|---|---|
| • Permit DEA-registered practitioners to prescribe buprenorphine **without having conducted an in-person medical evaluation** if:<br>  • The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;<br>  • The telemedicine communication is conducted using an audio-visual or audio-only, real-time, two-way interactive communications system; and<br>  • The practitioner is acting in accordance with applicable federal and state law.<br>• 3rd Temporary Rule (89 Fed. Reg. 91253) extends flexibilities through December 31, 2025 | • Permit DEA-registered practitioners to prescribe patients a **30-day supply** of buprenorphine without an in-person medical evaluation<br>• Requires patients to be examined in person by the prescriber **within 30 days to receive additional prescriptions of buprenorphine**<br>• Require practitioners to **keep records of** all **qualifying telemedicine referrals**<br>• Require practitioners to **review/consider PDMP data** prior to issuing prescriptions | • Expands the initial 30-day prescription supply limitation via audio-only telemedicine to a **six-month supply** limitation<br>• Eliminates certain burdensome **recordkeeping requirements**<br>• **Removes the requirement for an in-person medical examination** to prescribe more than the initial supply of buprenorphine |

# Finalized Buprenorphine Telemedicine Prescribing Requirements

- DEA-registered practitioner may prescribe an **initial six-month supply** of buprenorphine via telemedicine, including audio-only encounters, to treat a patient with opioid use disorder:
  - The prescribing practitioner must review the applicable Prescription Drug Monitoring Program (PDMP) prior to issuing a prescription
  - The pharmacist filling the prescription must verify the patient's identity
  - The prescription complies with all other relevant DEA regulations
- After the initial six-month period, a follow-up evaluation must be conducted via an in-person exam or through "*any form of telemedicine authorized under the Ryan Haight Act*"

# Key Consideration for Telemedicine Based OUD Treatment with Buprenorphine

- New rules permit prescriptions of ***up to*** a six-month supply of buprenorphine without first conducting an in-person evaluation or obtaining Special Registration
  - COVID-19 Telemedicine Flexibilities (as extended by Third Temporary Rule) remain in effect until December 31, 2025
- The framework applies only to prescriptions issued for the treatment of OUD
- State and payor-specific prescribing requirements still apply
- The new rule takes effect on March 21, 2025

Please visit the Hall Render Blog at http://blogs.hallrender.com for more information on topics related to health care law.

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