February 7, 2025

Provision	Final Rule on Expansion of Buprenorphine Treatment via Telemedicine Encounter	Proposed Rule on Special Registrations for Telemedicine	Notes
Effective Date	February 18, 2025 (subject to possible postponement per an <u>Executive Order on a Regulatory</u> <u>Freeze Pending Review</u> issued on January 20th)	On or after publication of final rule in the Federal Register	Special registration for telemedicine rules are in the proposed phase and its elements would not be in effect until on or after a final rule has been published in the Federal Register.
Special registration classes	N/A	 Clinician Registrant; Advanced Telemedicine Prescribing Registrant; or Telemedicine Platform Registrant 	Eligibility restrictions. See description below.
Separate State Telemedicine Registration Required?	No	Yes, with some exemptions	All special registrants (clinician, advanced telemedicine prescribing, & platform) are required to obtain an ancillary registration for every state in which they prescribe/dispense. Registration contingent upon obtaining one of the three special registrations. Exemptions apply. See below.
DEA Registration Required?	Yes	Yes	All prescribers/dispensers of controlled substances must be registered with the DEA to do

			so. This is separate from the special registration process.
Application required?	No	Yes	If approved for a special registration, approval lasts 3 years.
Application fees	No application, no fees	\$888/category	Some exemptions. See below.
		\$888/state for telemedicine platform registrations	
		\$50/state for clinicians for state registrations	
Telemedicine format	Audio-only or audio-visual	Schedules 2-5*: Initial & subsequent RX must be issued via audio/visual encounter RX for buprenorphine: Audio-only allowed for refills, but audio-visual required for first fill Special registrants: May use audio-only for initial fill, but audio/visual encounter needed before audio-only allowed again	
		*Doesn't apply to buprenorphine/special rules for schedule 2 RX for pediatric patients	
In-person visit required?	No	No	

Time Limitation of initial Buprenorphine Prescriptions issued via telemedicine encounter	6 months	None	
Requirements for additional fills via telemedicine beyond initial time limit	In-person evaluation by prescriber or use of a telemedicine pathway outlined in 21 U.S.C. 802(54)	Continued eligibility under special registration	
Identity verification	Pharmacists must verify patient identity using state/Federal Government-issued photographic identification card, or in the absence of such identification, any other form of documentation showing that the patient is the same person as the patient listed on the prescription	Registrants required to conduct certain identity verification checks	
Recordkeeping requirements	Standard	 Patient verification photographic record (clinician) Special registration telemedicine encounter record (clinician) Credential verification and conduct-related verification (telemedicine platform) Centralized recordkeeping Annual reporting of certain prescription 	

		data (clinician and	
		telemedicine platform)	
PDMP Checks	Prescriber must review PDMP	Effective date – 3 yrs after:	
	data in the state where patient	PDMP check required in state	
	is located	where patient & clinician	
		special registrant are located,	
	Prescriber must document date	as well as PDMPs of any states	
	and time of PDMP review in	that have reciprocity	
	medical record	agreements with the state	
	(paper/electronic) before	location of patient or clinician	
	prescribing	special registrant	
	If PDMP is unavailable or	After 3 yrs: PDMP check	
	inaccessible, prescriber must	required in all 50 states, unless	
	document in medical record	no nationwide mechanism	
	(paper/electronic).	exists.	
	If PDMP is unavailable,	If none exists, schedule 2's may	
	prescriber may only prescribe a	only be issued to patients	
	7-day supply before additional	located within the same state	
	PDMP check required. May	as the registrant, and PDMP	
	issue additional 7-day	checks would revert to the	
	prescriptions up to 6-month	process outlined under	
	limit.	"effective date – 3 yrs after."	
Telemedicine RX notation	No requirement for special	Required notation on the	
	notation	prescription that it was issued	
		via telemedicine	
		Special registration & state	
		telemedicine registration	
		numbers of clinician special	
		registrant and telemedicine	
		platform (if applicable) must be	

		listed on special registration	
		prescriptions	
Electronic prescribing required?	No	Yes	

Frequently asked questions:

- 1. Do these rules apply if I've conducted an in-person evaluation of my patient in person? **No.**
- 2. If my state has a more restrictive law/regulation than the federal standard, which do I follow? You must follow the stricter state requirements. Prescribers are bound by all applicable federal and state laws/regulations regarding the dispensing (including prescribing) of controlled substances for legitimate medical use.
- **3.** As a clinician practitioner, do I need a special registration to treat this patient? **A special registration is <u>NOT</u> required if:**
 - a. You areacting in accordance with state law, are a DEA-registered in the state where the patient is located, and the patient is being treated (and located) in a DEA-registered hospital or clinic;
 - b. Your patient is being treated (and located) in a DEA-registered hospital or clinic by another practitioner who is acting in accordance with state law, and is DEA-registered in the state where the patient is located;
 - c. You are an employee of the Indian Health Service, acting within the scope of such employment, who has been designated as an Internet Eligible Controlled Substance Provider by the US Department of Health and Human Services;
 - d. There is a public health emergency (the Opioid PHE does not qualify) declared by HHS that affects that area in which the patient is located;
 - e. The patient has a medical emergency that prevents them from being in the physical presence of an employee/contractor of the Veterans Health Administration at a DEA-registered hospital/clinic and you believe in good faith that your immediate intervention is required using a controlled substance to prevent imminent and serious clinical consequences such as further injury/death; OR
 - f. The DEA and HHS have jointly promulgated a regulation authorizing telemedicine, specifically under circumstances where treating the patient would qualify as the practice of telemedicine (e.g., the expansion of buprenorphine treatment via telemedicine encounter rule).

- 4. If I need a special registration, then which special registration do I need? If you meet the definition of a "covered online telemedicine platform," then you must register as a *Telemedicine Platform Registrant*. If you want to write schedule 2 prescriptions via telemedicine, then you must be one of the clinicians eligible to write these prescriptions under the rule AND register as an *Advanced Telemedicine Prescribing Registrant*. If you seek to only prescribe schedules 3-5 via telemedicine, then you must register with as a *Telemedicine Prescribing Registrant*.
- 5. Do I need a state telemedicine registration? If you are a special registrant, intend to write prescriptions for controlled substances, and are not exempt from registration requirements, then you are required to hold a state telemedicine registration in each state where a patient resides.
- 6. Who is exempt from state telemedicine registration requirements and associated fees? **Clinician registrants who are** officials of the U.S. Army, Navy, Marine Corps, Air Force, Space Force, Coast Guard, Public Health Service, or Bureau of Prisons and who are authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties -OR- (2) clinician registrants who are employees or contractors of the Veterans Administration acting in the scope of such employment/contract, and is registered under section 823(g) in any state or is utilizing the registration of a hospital or clinic operated by the VA registered under 21 U.S.C. 823(g).
- 7. What clinicians are eligible for the clinician special registration? **DEA has proposed that eligible clinicians** demonstrate a legitimate need by being a physician or board-certified mid-level practitioner who anticipates they will be treating patients for whom an in-person medical examination prior to prescribing schedules 3-5 would impose significant burdens on the bona fide practitioner-patient relationship.
- 8. What clinicians are eligible for Advanced Prescribing? These clinicians must demonstrate a legitimate need by being a physician or board-certified mid-level practitioner who anticipates they will be treating patients for whom an in-person medical examination prior to prescribing would impose significant burdens on the bona fide practitioner-patient relationship. DEA has determined that practitioners with a legitimate need, include:

- Psychiatrists;
- Hospice care physicians;
- Palliative care physicians;
- Physicians rendering care in long term care facilities;
- Pediatricians;
- Neurologists; and
- Mid-level practitioners and physicians 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 prescribing special registrants are required to provide information on application that demonstrates their specialized training.

- 9. What are the eligibility requirements for registration as a telemedicine platform? **DEA has determined that covered** online telemedicine platforms, in their capacity as platform practitioners, have a legitimate need to dispense schedules 2-5 when they anticipate providing necessary services to introduce or facilitate connections between patients and clinician practitioners via telemedicine for the diagnosis, treatment, and prescription of controlled substances, are compliant with federal and state regulations, provide oversight over clinician practitioners' prescribing practices, and take measures to prioritize patient safety and prevent diversion, abuse, or misuse of controlled substances. Platforms would attest to their legitimate need on registration application forms.
- **10.** What is a "covered online telemedicine platform"? Per the DEA's proposal, it is 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:

(1) the entity explicitly promotes or advertises the prescribing of controlled substances through the platform;

(2) 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; (3) 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

(4) the entity has control or custody of the prescriptions or medical records of patients who are prescribed controlled substances through the platform.

- 11. I work in an opioid treatment program. Do these rules impact telemedicine services in these settings? No.
- 12. Can I use these rules in conjunction to prescribe buprenorphine via telemedicine? Yes. According to the DEA, prescribers who are acting in accordance with state law, are DEA-registered in the state where the patient is located, may use the final rule regarding buprenorphine to initiate telemedicine prescribing in cases where the patient has not had an in-person evaluation. If the prescriber determines that they have a legitimate need for a special registration following the patient's initial 6-month supply under that regulation, then they may apply for a special registration to continue prescribing if they are unable to evaluate the patient in person.
- 13. What if I do not prescribe controlled substances? Do these rules impact my practice? No.
- 14. If I am a clinician special registrant, do I need to pay the state telemedicine registration fee in every state where I prescribe to a patient? **Yes, unless you are exempt as outlined in FAQ #6.**
- 15. If I have a DEA registration to prescribe controlled substances, do I still need a special registration? If you believe that you have a legitimate need to prescribe a controlled substance via telemedicine and cannot use the regulatory flexibilities outlined in the final rule regarding buprenorphine, then you may need to apply for a special registration. This registration is not the same as a DEA registration to prescribe controlled substances.
- 16. There is a temporary rule covering expanded flexibilities for buprenorphine initiation via telemedicine that expires at the end of 2025, and now there's a final rule regarding permanent telemedicine authorities for buprenorphine. Which rule

applies? The Trump Administration has yet to issue official guidance on this point, but if the final rule takes effect prior to December 31, 2025, then we anticipate that clinicians could use either rule until the temporary rule expires at the end of 2025.

- **17.** I've determined that I don't need a special registration but want more guidance on utilizing telemedicine to prescribe buprenorphine for the treatment of OUD. Where can I find more information on that? **Check out SAMHSA's Q&A on this topic** <u>here</u>.
- 18. Are there additional special registration supplemental requirements I should know? All platform registrants are required to attest to employment, contractual relationships, or professional affiliations with any clinician special registrant and Online Pharmacy and their respective registration numbers. All clinician registrants required to disclose 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). Additionally, registrants must attest to maintaining antidiversion measures and to a legitimate need for a special registration. Clinician registrants must be physically located in the United States when conducting a telemedicine encounter and issuing a special registration prescription and hold the proper license and authorization in the state/territory where the practitioner is located when telemedicine encounter takes place. Finally, advanced Telemedicine Prescribing Registrants are required to disclose their practice specialties.
- 19. Are there any special requirements related to schedule II prescriptions? Yes, in the case of pediatricians and pediatric board-certified mid-level clinician prescribing to minors, a parent/guardian must be present for telemedicine encounters. In all cases, the Advanced telemedicine special registrant must be physically located in the same state as the patient and the average number of special registration prescriptions for schedule II's must be less than 50% of the total number of schedule II prescriptions issued by special registrant in their telemedicine and non-telemedicine practices.