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TELEHEALTH | RESEARCH · POLICY · ACTION

DEA PROPOSED RULES

March 23, 2023



Background: Controlled Substances Act and Ryan Haight Act

THE CONTROLLED SUBSTANCES ACT (CSA)

The Controlled Substances Act (CSA) places all substances which were in some manner regulated under existing federal law into one of five schedules. This placement is based upon the substance's medical use, potential for abuse, and safety or dependence liability. The CSA establishes federal drug policy for the manufacturing, importation, possession, use and distribution of controlled substances.

THE RYAN HAIGHT ONLINE PHARMACY CONSUMER PROTECTION ACT OF 2008 (RHA)

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (RHA) amends CSA to prohibit distributing, dispensing or delivery of a controlled substance through the internet without a valid prescription. This act requires practitioners to conduct at least one in-person medical evaluation of the patient before prescribing a controlled substance by means of the internet or telehealth.

TELEMEDICINE EXCEPTIONS TO THE RHA'S IN-PERSON EXAM REQUIREMENT

THE ACT OFFERS SEVEN NARROW TELEMEDICINE EXCEPTIONS TO THE IN-PERSON EXAM REQUIREMENT:

- *The patient is being treated in a DEA-registered hospital or clinic.
- *The patient is being treated in the physical presence of a DEA-registered practitioner.
- The telemedicine consult is conducted by a DEA-registered practitioner for the Indian Health Service
- *The telemedicine consult is conducted during a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services.
- *The telemedicine consult is conducted by a practitioner who has obtained a DEA special registration for telemedicine. (Note** DEA decided against a special registration in rules)
- The telemedicine consult is conducted by a Veterans Health Administration (VHA) practitioner during a medical emergency recognized by the VHA.
- The telemedicine consult is conducted under other circumstances specified by future DEA regulations.

FEDERAL PUBLIC HEALTH EMERGENCY (PHE) PRESCRIBING WAIVER



During the Federal PHE, DEA adopted policies to allow DEA-registered practitioners to prescribe controlled substances without having to interact in-person with their patients.



If DEA's proposed rules, on telemedicine prescribing, do not become final the ability to prescribe controlled substances will revert back to pre-pandemic Ryan Haight Act requirements.



The Federal PHE is scheduled to end on May 11, 2023.

DEA PROPOSED RULE FOR PERMANENT TELEMEDICINE FLEXIBILITIES

★ Public Comments on the proposed rule must be submitted to the Federal Register by Friday, March 31

- The proposed rules would establish “a referral pathway” for telemedicine providers to prescribe Schedule II-Schedule V controlled substances.
- Under the proposed rules, 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.
- Under the proposed rules, registered practitioners do not need to obtain a “physical address” in each state that they practice medicine. “Practitioner using telemedicine to prescribe controlled substances may operate out of multiple locations. This to avoid any confusion and ensure that DEA investigators are able to locate the records when necessary, proposed § 1304.04(i) would specify that the records must be maintained at the registered location of the practitioner’s registration under 21 CFR 1301.13(e)(1)(iv)”.
- DEA is proposing to waive the “in-person” requirements for patients with an “established telemedicine relationship established during the COVID-19 public health emergency” for an additional 180 days after proposed rule is finalized. To continue prescribing a controlled medication to this patient beyond 180 days from the end of the public health emergency, you must conduct an in-person medical evaluation of the patient.

DEA'S PROPOSED DEFINITION OF "QUALIFYING TELEMEDICINE REFERRAL"



DEA defines qualifying telemedicine referral as, “a referral to a practitioner 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 must note the name and National Provider Identifier (NPI) of the practitioner to whom the patient is being referred.”

If the prescribing telemedicine practitioner receives a qualifying telemedicine referral for the patient, a prescription may be issued for any controlled substance the practitioner is otherwise authorized to prescribe under applicable laws and regulations, including Schedule II and narcotic controlled substances.

PROPOSED REFERRAL PATHWAYS FOR SCHEDULE II AND SCHEDULE III-V CONTROLLED SUBSTANCES

SCHEDULE II:

- ✓ In-person examination must be completed by a medical practitioner under all circumstances before a telemedicine practitioner can prescribe Schedule IIs.
- ✓ If the prescribing telemedicine practitioner receives a qualifying telemedicine referral for the patient, a prescription may be issued for any controlled substance the practitioner is otherwise authorized to prescribe under applicable laws and regulations.

SCHEDULE III-V:

- ✓ A telemedicine practitioner may prescribe up to 30-days of a schedule III-IV medication. The proposed rule generally would subject a practitioner to a 30-day supply. A practitioner would be allowed to issue multiple prescriptions for the same patient, but would only be allowed to prescribe an amount less than or equal to a total quantity of a 30-day supply of the controlled medication.
- ✓ To continue prescribing to that patient, after 30-days, the prescribing practitioner would be required to examine the patient In-person.
- ✓ Alternatively, if the prescribing practitioner receives a qualifying telemedicine referral for the patient, the practitioner may rely on the referring practitioner's in-person medical evaluation in order to prescribe the controlled substance via telemedicine.

IS MY PRESCRIPTION A CONTROLLED MEDICATION?



“QUALIFYING TELEMEDICINE REFERRAL” Map



PROPOSED TELEMEDICINE RULES SUMMARY

RELATIONSHIP BETWEEN PRESCRIBING MEDICAL PRACTITIONER AND PATIENT	PRESCRIBING A NON-CONTROLLED MEDICATION	PRESCRIBING SCHEDULE III, IV, OR V NON-NARCOTIC CONTROLLED MEDICATIONS	PRESCRIBING BUPRENORPHINE AS MEDICATION FOR OPIOID USE DISORDER	PRESCRIBING SCHEDULE II AND/OR NARCOTIC CONTROLLED MEDICATIONS
Prior in-person medical evaluation by prescribing medical practitioner	PERMITTED	PERMITTED	PERMITTED	PERMITTED
Referral under the proposed rules from medical practitioner who conducted prior in-person medical evaluation	PERMITTED	PERMITTED	PERMITTED	PERMITTED
Telehealth visits without: <ul style="list-style-type: none"> • Prior in-person medical evaluation by prescribing medical practitioner; or • Referral from a medical practitioner who conducted prior in-person medical evaluation 	PERMITTED	<ul style="list-style-type: none"> • UP TO 30 DAY INITIAL PRESCRIPTION • IN-PERSON VISIT REQUIRED FOR ADDITIONAL PRESCRIPTION 	<ul style="list-style-type: none"> • UP TO 30 DAY INITIAL PRESCRIPTION • IN-PERSON VISIT REQUIRED FOR ADDITIONAL PRESCRIPTION 	NOT PERMITTED

PROCESS TO SUBMIT COMMENTS TO CTEL

- Please email comments to CTeL's Ben Steinhafel at Ben@CTeL.org
- Comments due to CTeL by 12:00 PM ET on Wednesday, March 29
- Comments due to DEA by 12:00 PM ET on Friday, March 31

CONTACT US

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