



Alerts

DEA Waives Telemedicine and Other Rules for Controlled Substances

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Health Care Alert

The Drug Enforcement Agency (DEA) recently published guidance relating to the COVID-19 public health emergency, including the ability to prescribe controlled substances via telemedicine without a prior in-person exam; relaxation of DEA Form 222 ordering requirements; guidance on controlled substances refills; exceptions to DEA requirements for Schedule II controlled substances oral prescriptions; and exceptions to separate registration requirements for operations across state lines.

DEA Guidance: Controlled Substance Telemedicine Prescriptions

The Ryan Haight Online Pharmacy Consumer Protection Act (the "Act") imposes a federal prohibition on online prescribing for controlled substances. Under the Act, a practitioner cannot issue a "valid prescription" for a controlled substance by means of the internet (which includes telemedicine) without having first conducted at least one in-person medical evaluation, except in certain specified circumstances. One specified circumstance is when the Secretary of the U.S. Department of Health and Human Services (the "Secretary") has declared a public health emergency.

On January 31, 2020, the Secretary declared a public health emergency in response to COVID-19, and on March 16, 2020, he indicated that the telemedicine waiver imposed would apply to all schedule II-V controlled substances. Until the end of the public health emergency, the DEA will permit DEA-registered practitioners to issue prescriptions for controlled substances to telemedicine patients for whom they have not previously conducted an in-person medical evaluation if the following required conditions are 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.
- The practitioner is acting in accordance with applicable federal and state law (including state controlled substances laws unless the requisite state has issued a waiver to such requirements).

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DEA Guidance: [Exception to Regulations to Email or Fax DEA Form 222's](#)

The DEA has provided guidance that "all DEA registrants who order controlled substances are permitted to fax or scan/email a DEA Form 222 to their respective suppliers." The fax/scan/email can be treated as the original order form for purposes of the regulation. The exception is effective as of March 20, 2020, and will remain in place until the end of the public health emergency. At the conclusion of the public health emergency, the DEA registrants must send the original Form 222s to their suppliers, who are required to maintain the forms with the fax/scan/email copy.

DEA Guidance: [Registrant Guidance on Controlled Substance Prescription Refills](#)

The DEA has provided guidance that a pharmacy may provide early refill dispensing of a Schedule III-Schedule V controlled substance if such is permissible under state law (including recent public health emergency exceptions where some states have issued orders allowing pharmacies to dispense early refills of prescriptions). The prohibitions against refills of Schedule II controlled substances continue to apply. However, pursuant to 21 CFR 1306.12(b) "an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance."

DEA Guidance: [Exception to Regulations Emergency Oral Schedule II Controlled Substance Prescriptions](#)

The DEA has provided guidance that, due to the current public health emergency, it may not be feasible for a practitioner to deliver, in response to an emergency oral prescription, the follow-up paper prescription to the pharmacy within seven days as required by 21 CFR 1306.11(d)(4). Thus, the DEA has issued the following two exceptions regarding the use of oral prescriptions for Schedule II controlled substances during the public health emergency:

- The DEA is providing practitioners "15 days within which to provide [a hard copy of an emergency oral prescription] to the pharmacy."
- The DEA will permit "the practitioner to send the follow-up prescription via facsimile or to take a photograph or scan of this follow-up prescription and send the photograph or scan to the pharmacy in place of the paper prescription."

DEA Policy: [Exception to Separate Registration Requirements for Out-of-State Controlled Substance Prescribers](#)

The DEA has provided guidance that, "DEA-registered practitioners are not required to obtain additional registration(s) with DEA in the additional state(s) where the dispensing (including prescribing and administering) occurs, for the duration of the public health emergency declared on January 31, 2020, if authorized to dispense controlled substances by both the state in which the practitioner is registered with DEA and the state in which the dispensing occurs." The controlled substance-prescribing practitioner should monitor whether or not the state where the patient resides has announced similar public health emergency telemedicine exceptions to state law controlled substances permit requirements.

Questions?

Hinshaw has a [team of health care law attorneys](#) that are monitoring pharmacy law related state and federal agency policy and regulatory responses to COVID-19. Please contact your Hinshaw attorney for any questions and for additional guidance on how other COVID-19 considerations may impact pharmacies and prescription drugs. Hinshaw has also has [published additional guidance](#) regarding how companies can address other COVID-19-related business and legal issues.