



U. S. Department of Justice
Drug Enforcement Administration
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Practitioner Registrants and Pharmacists

Dear Practitioner Registrants and Pharmacists:

The Drug Enforcement Administration (DEA) is providing the following guidance regarding the issuance of oral schedule II prescriptions in light of the nationwide public health emergency (“Public Health Emergency”) declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, pursuant to section 319 of the Public Health and Service Act, 42 U.S.C. 247d, as a result of the Coronavirus Disease 2019 (COVID-19). The term “oral schedule II prescription” means a prescription for a schedule II controlled substance that a practitioner conveys to a pharmacist via a telephone call or other oral form of communication – as opposed to via a written or electronic prescription. DEA is aware that during this pandemic there are obstacles to practitioners meeting with their existing patients and providing these patients with written prescriptions for schedule II controlled substances. As a result, practitioners and pharmacists have asked DEA to clarify the circumstances under which oral schedule II prescriptions are permitted. DEA provides the following guidance on this topic and announces temporary exceptions. These exceptions shall remain in place for the duration of the Public Health Emergency (unless modified or withdrawn by DEA).

Background

The Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, states that a pharmacist may not dispense a schedule II controlled substance without a written prescription of a practitioner, “except that in emergency situations... such drug may be dispensed upon oral prescription...” 21 U.S.C. 829(a). The criteria for identifying an emergency situation are found in a Food and Drug Administration (FDA) regulation, 21 CFR 290.10, which provides that an emergency situation is one in which the prescribing practitioner determines that immediate administration of the schedule II controlled substance is necessary for the proper treatment of the intended user, that no appropriate alternative treatment is available, and that it is not reasonably possible for the prescribing practitioner to provide a written prescription to the pharmacy prior to dispensing the substance.

Whether an emergency situation exists is a determination made by a practitioner based on the individual facts of a particular medical situation. Thus, an emergency situation does not necessarily exist with regard to every prescription of a schedule II controlled substance issued during the Public Health Emergency: this determination must still be made by practitioners on a case-by-case basis. DEA acknowledges, however, that the Public Health Emergency is likely creating emergency situations, as defined by 21 CFR 290.10, in some cases.

The regulation that permits emergency schedule II prescribing is contained in 21 CFR 1306.11(d).¹ That regulation further describes the requirements for issuing an emergency oral prescription. A pharmacist may dispense a schedule II controlled substance upon receiving oral authorization of a prescribing individual practitioner, provided that:

- (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner);
- (2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in [21 CFR] 1306.05, except for the signature of the prescribing individual practitioner;
- (3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and
- (4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of [21 CFR] 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

21 CFR 1306.11(d)(1)-(4).

Temporary Exceptions

DEA is announcing today two temporary exceptions to the criteria to enable greater flexibility in oral prescribing.²

¹ These provisions do not authorize central fill pharmacies to prepare prescriptions of controlled substances listed in schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner. 21 CFR 1306.11(d)(5).

² Please note that controlled substances in schedules III-V may always be prescribed by oral prescription. *See* 21 U.S.C. 829(b), (c).

First, in light of the Public Health Emergency, DEA recognizes that 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 7 days as required by 21 CFR 1306.11(d)(4). Therefore, exercising its authority under 21 CFR 1307.03 to grant an exception to the application of any provision in its regulations,³ DEA hereby grants practitioners 15 days within which to provide that prescription to the pharmacy. This exception is granted from March 16, 2020, through the duration of the Public Health Emergency (unless modified or withdrawn by DEA).

Second, DEA recognizes that, during the Public Health Emergency, there may be times when providing the pharmacy with a paper prescription as a follow up to an emergency oral prescription may prove very challenging or impossible.⁴ Thus, for the duration of the Public Health Emergency, DEA hereby allows the practitioner to send the follow-up prescription to the pharmacy 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. It is the responsibility of the practitioner to ensure that, whichever method the practitioner uses, the prescription contains all of the required information outlined in 21 CFR 1306.05 and 1306.11(d), including the statement that the prescription is “Authorization for Emergency Dispensing.” As a condition of this exception, the practitioners who choose to send this specific type of prescription to the pharmacy via facsimile, photograph, or scan must maintain the original paper prescription in the patient file. Regardless of any exceptions that DEA has made in response to COVID-19, pharmacists continue to have a corresponding responsibility to ensure that any controlled substance prescription for they fill was issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice. 21 CFR 1306.04(a).

Please note that DEA does not assign a numerical limit to the amount of schedule II controlled substance to be prescribed. Instead, DEA recognizes that these are medical decisions within the prescribing practitioner’s sound medical discretion, as guided by any limitations imposed by the state medical board and state law. Practitioners with questions on the amount and duration of emergency oral schedule II prescriptions should consult their state medical board. Nevertheless, as stated above, the regulations at 21 CFR 1306.11(d)(1) limit emergency oral prescriptions to “the amount adequate to treat the patient during the emergency period.” As with all prescriptions for controlled substances, emergency oral prescriptions must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice. *See* 21 CFR 1306.04(a).

³ The DEA Administrator is permitted by 21 CFR 1307.03 to grant an exception to the application of any provision in 21 CFR, Chapter II. This authority has been re-delegated to the Assistant Administrator of the Diversion Control Division.

⁴ Please note that the practitioner already has the authority to submit this follow-up prescription using EPCS.

We hope this information is helpful. For information regarding DEA's Diversion Control Division please visit www.DEAdiversion.usdoj.gov. Please contact the Diversion Control Division, Policy Section at (571) 362-3260 if you seek additional assistance regarding this or any other matter.

Sincerely,

WILLIAM
MCDERMOTT

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William T. McDermott
Assistant Administrator,
Diversion Control Division.

DEA073 – March 27, 2020