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The DEA's Adjustment to Schedule II Rules Amid COVID-19

Announcer:

You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:

Welcome to *The Drug Report* with a special focus on the COVID-19 epidemic.

The Drug Enforcement Administration has just issued a new guidance for the issuance of oral Schedule II prescriptions in light of the COVID-19 pandemic and nationwide public health emergency. William T. McDermott Assistant Administrator, DEA Diversion Control Division issued the guidance on March 27, 2020.

An "oral schedule II prescription" is defined as a prescription for a schedule II controlled substance that a practitioner communicates to a pharmacist via a telephone call or other oral method – as opposed to a written or electronic prescription. DEA realizes that stay at home directives nationwide are preventing practitioners from 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.

Here is some further background.

According to The Controlled Substances Act 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." An emergency situation is defined by the FDA as 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. Note: Not every situation in which a prescribed schedule II controlled substance is issued during the pandemic constitutes an "emergency." Emergency status is determined by practitioners on a case by case basis.

The regulation that permits emergency schedule II prescribing 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 the regulation, except for the signature of the prescribing individual practitioner;
- (3) If the prescribing individual practitioner is not known to the pharmacist, a reasonable effort must be made to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using the phone number as listed in the telephone directory and/or other good faith efforts to insure identity; and
- (4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall write the prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements, the

prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written 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 DEA if the prescribing individual practitioner fails to deliver the written prescription; failure of the pharmacist to do so shall void the authority to dispense without a written prescription of a prescribing individual practitioner.

There are two temporary exceptions to the criteria to enable greater flexibility in oral prescribing during the pandemic.

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. Therefore, exercising its authority under the regulation to grant an exception to the application of any provision, the DEA grants practitioners 15 days within which to provide that.

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. DEA 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, 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 they fill was issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice.

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 previously stated, the regulations 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.

For *The Drug Report*, I'm pharmacist, Dr. Linda Bernstein.

Announcer:

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