



E-News May 2023

Guidance on Controlled Substance Dispensing

In light of recent drug shortages, the Board would like to provide some important reminders to pharmacists on federal and state laws related to controlled substance dispensing.

Exceptions to Ohio's Mandatory Electronic Prescribing Requirements

Under current law, prescribers are required to issue an electronic prescription when prescribing a Schedule II controlled substance. The law includes several exceptions which still allow prescribers to issue a written prescription in specified circumstances. Some examples related to patient care include:

- When the prescriber determines that an electronic prescription cannot be issued in a timely manner and the patient's medical condition is at risk.
- When the prescription is issued from a health care facility, which may include an emergency department, and the prescriber reasonably determines that an electronic prescription would be impractical for the patient or would cause delay that may adversely impact the patient's medical condition.

Please note that this law includes a "safe harbor" provision that does not require a pharmacist to verify any exceptions prior to dispensing a written Schedule II controlled substance prescription.

For additional information, the Board published a guidance document on the [electronic prescribing of Schedule II controlled substances](#), which can be accessed here: www.pharmacy.ohio.gov/C2.

Emergency Dispensing of Schedule II Controlled Substances Upon Verbal Order

In the case of an emergency situation, [federal regulations](#) permit a pharmacist to dispense a controlled substance listed in Schedule II upon receiving verbal authorization from 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 [§ 1306.05](#), except for the signature of the prescribing individual practitioner;
- (3) If the prescribing individual practitioner is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the verbal authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using the practitioner's phone number as listed in the telephone directory and/or other good faith efforts to insure the practitioner's 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 [§ 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 the pharmacist; 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.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Federal Controlled Substances Act, the term [emergency situation](#) means those situations in which the prescribing practitioner determines:

- (1) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and
- (2) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act, and
- (3) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

State law ([3719.05](#)) also permits a Schedule II controlled substance to be dispensed upon an verbal prescription in emergency situations as provided in the federal drug abuse control laws (i.e., the process outlined above).

Partial Dispensing of Controlled Substances

Due to reported drug shortages, pharmacies may have to engage in the partial fill of prescriptions. As a reminder, partial dispensing must be conducted in accordance with rule [4729:5-5-12](#) of the Ohio Administrative Code.

Transfer of Unfilled Electronic Prescriptions for Controlled Substances

Currently, unfilled electronic prescriptions for controlled substances cannot be transferred. DEA rescinded its policy that previously authorized this practice and is in the process of [writing rules](#) to formally address this issue. Only refills for drugs listed in Schedule III - V may be transferred.

New Law Permits Pharmacists to Add Drug Delivery Devices to Prescriptions

Ohio law ([4729.391](#)) permits a pharmacist to modify a drug's prescription to also include a drug delivery device, if the pharmacist determines that the device is necessary for the drug's administration.

Here are a few helpful reminders to assist pharmacists in implementing this new law:

- The device should be added to the existing prescription for the drug requiring the delivery device.
- The pharmacy should follow their standard process for amending prescription records to document the addition of a device.
- This is a modification of the current prescription, not the creation of a new prescription.
- The pharmacist should use their professional judgment to determine if adding a device is appropriate and necessary for the administration of the drug.

The law also addresses reimbursement for the device, specifically: *For purposes of reimbursement under the terms of a health benefit plan by a health care insurer, government health care program, pharmacy benefit manager, or other entity that offers health benefit plans, a prescription modified as described in this section, and in accordance with any rules adopted under it, shall be deemed a valid prescription for the drug delivery device.*

LAST CHANCE TO SUBMIT COMMENTS: Board Publishes Updated Workload Rule for Stakeholder Comment (Comments Due 5.5.23)

As part of the Pharmacist Workload Advisory Committee, the State of Ohio Board of Pharmacy is issuing a draft rule on the minimum standards for an outpatient pharmacy.

This rule was developed from the comments received from two previous draft rules (quotas and meal breaks) as well as the work of the committee. Those comments were then incorporated into a new version of the outpatient pharmacy minimum standards rule (OAC 4729:5-5-02).

Comments on the rule are due by **close of business on May 5, 2023.**

A copy of the rule can be found here: www.pharmacy.ohio.gov/minstandardsrule **(Please scroll to page 9 of the rule document to view a copy of the proposed rule text.)**

Comments on the proposed rule may be submitted using this online form: <https://www.surveymonkey.com/r/OPminstandards>.

Board Publishes Spring 2023 Rule Package for Stakeholder Comment (Comments Due 5.31.23)

The Board published a set of proposed rules for public comment as part of the five-year review process required by Ohio law. These rules cover the following topic areas:

- Continuing Education
- Pharmacists
- Pharmacy Interns
- Pharmacy Technicians
- Terminal Distributors of Dangerous Drugs
- Drug Distributors
- Pharmacy Compounding

A copy of the rules and comment submission instructions can be found here: www.pharmacy.ohio.gov/Spring23Rules

Comments on the rules are due by close of business on May 31, 2023.

Please note that if you choose to unsubscribe from receiving emails, this unsubscribes you from all emails that are sent by the State of Ohio Board of Pharmacy, including renewal reminders. If you believe you have unsubscribed in error, you may subscribe by visiting: www.pharmacy.ohio.gov/subscribe. If you would like to change your email address, please log into your [eLicense Ohio](#) account to update the email address on file.