

Dispensing of an Emergency Refill of Medication Without a Prescription

Updated 7/14/2022

<u>Section 4729.281 of the Ohio Revised Code</u> authorizes a pharmacist to dispense medications without a prescription under certain conditions. On June 1, 2022, this law was further amended to make the following changes:

- Increases from one to three the number of times that a pharmacist may dispense certain refills without a prescription to a specific patient within a 12-month period.
- Requires a health insurer to cover prescription drugs dispensed under the act if those drugs are already covered under the insurer's health benefit plan, and prohibits the insurer from imposing a cost-sharing requirement that is greater than that imposed on a drug dispensed with a prescription.

NOTE: In addition to this guidance, there is additional guidance on dispensing naltrexone without a prescription: <u>www.pharmacy.ohio.gov/EmergencyNaltrexone</u>.

For questions regarding the dispensing of an emergency refill, please review this guidance document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Q1) What are the requirements for a pharmacist to dispense an emergency refill of medication without a prescription?

A pharmacist is permitted to dispense medication, other than a schedule II controlled substance, without a written or oral prescription if all the following conditions are met:

- The pharmacy at which the pharmacist works has a record of a prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted for providing refills has elapsed. Refills are good for one year from the date the prescription was written on a non-controlled schedule V controlled substance prescription and six months for a controlled substance prescription for drugs in schedules II-IV (see OAC <u>4729:5-5-15</u>).
- 2. The pharmacist is unable to obtain authorization to refill the prescription from the health care professional who issued the prescription or another health professional responsible for the patient's care.

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- 3. In the exercise of the pharmacist's professional judgment:
 - (a) The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient.
 - (b) Failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

Q2) What are the days' supply limits for dispensing a medication without a prescription?

The law generally limits to a 72-hour supply the amount of a drug that a pharmacist may dispense to a patient without a prescription. It further restricts a pharmacist from doing so more than once per drug and prohibits the dispensing of schedule II controlled substances without a prescription.

An exception exists, however, when the patient has been on a consistent drug therapy with a noncontrolled substance. In those circumstances, a supply greater than 72 hours may be dispensed. Under prior law, the exception permitted dispensing only once per drug in any 12-month period. The law now authorizes dispensing not more than three times during any 12-month period. The dispensing may not be consecutive in time.

The table below summarizes dispensing limits for patients on a consistent drug therapy under the new law as compared to prior law.

Dispensing limits for consistent drug therapy without a prescription*		
Frequency	New Law (Effective 6.1.22)	Previous Law (Prior to 6.1.22)
First time in a 12- month period	Authorizes a pharmacist to dispense a 30-day supply of the drug based on the original prescription or, if the drug's standard dispensing unit is greater than a 30-day supply, not more than the standard unit.	Same.
Second or third time in a 12-month period	Authorizes a pharmacist to dispense a seven day supply or, if the drug is packaged in a manner that provides more than a seven-day supply, the lowest available supply.	Dispensing not authorized.

*Does not apply to drugs where there is no consistent drug therapy or controlled substances. In those situations, a pharmacist is limited to a **<u>one-time</u>** 72-hour supply (except for schedule II controlled substances).

Q3) Am I required to dispense a full thirty-day supply of a non-controlled dangerous drug?

No. The Board would like to remind all pharmacists that they are not required to dispense a full thirty-day supply and should use their professional judgment to determine what supply is in the best interest of the patient.

Q4) Do I create a new prescription document when dispensing an emergency refill of medication?

Yes. A pharmacist should create a new prescription document for the emergency refill.

Q5) What documentation am I supposed to maintain following the dispensing of an emergency refill?

For one year after the date of dispensing, a pharmacist is required to maintain a record of the drug dispensed, including the amount dispensed, the original prescription number, the name and address of the patient and the individual receiving the drug, and, if the individual receiving the drug is not the patient, the name and address of that individual.

Q6) Will insurance cover the emergency refill of medication?

If a health insurer covers a prescription drug under its health benefit plan, the law requires the insurer to cover that drug when it is dispensed by a pharmacist without a prescription in accordance with the law's provisions.

Additionally, the health insurer is prohibited from imposing cost-sharing requirements on a drug dispensed without a prescription that are greater than those imposed on that drug when dispensed under a prescription. Preexisting law defines "cost-sharing requirement" as the cost to a covered person under a health benefit plan according to any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket expense requirement.

Q7) Are there any additional requirements following the dispensing of an emergency refill?

Yes. A pharmacist is required to do all the following:

- Notify the prescriber who issued the original prescription or another prescriber responsible for the patient's care no later than seventy-two hours after the drug is dispensed; and
- 2. If applicable, obtain authorization for additional dispensing from the prescriber who issued the original prescription or another health professional responsible for the patient's care.

Q8) The commercially available size of the product will last only 10-days (i.e. patient is on a high dose of insulin). Am I limited to dispensing only one unit (i.e. the 10-day supply) or may I dispense enough to last up to the full thirty-day supply?

You are permitted to dispense up to a thirty-day supply of drugs for patients on a consistent drug therapy. However, as stated in Q3, pharmacists are not required to dispense a full thirty-day supply and should use their professional judgment to determine what supply is in the best interest of the patient.

Q9) The law only addresses prescriptions for which I have a record at my pharmacy. Does this include pharmacies that share a real-time database or does the record have to be from the same physical store which filled the prescription?

The law states that the pharmacy must have a record of the prescription. However, it does not specify that the record must be specific to that pharmacy. Therefore, pharmacists may utilize a real-time database to access patient records in order to determine whether it is appropriate to dispense an emergency refill.

Q10) Does the law cover me for a patient who is not my regular patient but is the patient of a pharmacy which is not open that day (i.e. closed on Sundays) and to go without might cause patient harm?

The law specifically requires that a pharmacist must have a record of a prescription for the drug in the name of the patient who is requesting it.

Q11) What about the dispensing of an emergency supply of schedule II controlled substance medications?

The Ohio Revised Code does not permit the dispensing of a schedule II controlled substance without a valid prescription. If an emergency situation arises, the prescriber has the authority under 21 CFR 1306.11(d) to phone in an emergency supply of a C-II which must be followed up with a hard copy prescription with the prescriber's original signature.