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Dispensing Naltrexone without a Prescription

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<u>Section 4729.283 of the Ohio Revised Code</u> authorizes a pharmacist to dispense naltrexone without a prescription under certain conditions.

For questions regarding this provision, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <u>http://www.pharmacy.ohio.gov/contact.aspx</u>.

NOTE: Nothing in this provision affects a pharmacist's ability to dispense a drug without a prescription in accordance with <u>section 4729.281 of the Revised Code</u>. Guidance document: <u>www.pharmacy.ohio.gov/emergency</u>. **See Q6 of this document for how this provision differs from section 4729.281 of the Revised Code**.

Q1) Under what circumstances am I permitted to dispense naltrexone without a prescription?

A pharmacist is authorized to dispense naltrexone without a written or oral prescription from a prescriber if all the following conditions are met:

(1) The pharmacist can verify a record of a prescription for the injectable long-acting or extended-release form of naltrexone in the name of the patient who is requesting the drug, but the prescription does not provide for a refill or the prescription on file has expired.

(2) The pharmacist is unable to obtain authorization to refill the prescription from the prescriber who issued it or another prescriber responsible for the patient's care.

(3) In the exercise of the pharmacist's professional judgment:

(a) The naltrexone is necessary to continue the patient's therapy for substance use disorder.

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(b) Failure to dispense the drug to the patient could result in harm to the health of the patient.

Q2) What are the requirements for verifying a record of a prescription?

Verification of a record of prescription that meets the requirements in Q1 of this document include, but are not limited to, the following:

- 1. Verification of the record in the pharmacy's computer system (or a shared computer system).
- If the prescription is not on file at the pharmacy, the pharmacist or an agent of the pharmacist should contact the dispensing pharmacy to verify the prescription record. Such verification must be documented in the patient profile.
- 3. OARRS now tracks the dispensing of naltrexone products for the treatment of substance use disorder. If a patient (must be the patient) requests an emergency fill of naltrexone, the pharmacist may rely on the information reported into OARRS to verify a record of a prescription.

Q3) Does the patient have the option to choose between the oral or injectable longacting or extended-release naltrexone?

Yes. The law states that prior to dispensing naltrexone, the pharmacist is required to offer the patient the choice of receiving either the oral form or injectable long-acting or extended-release form, but only if both forms of the drug are available for dispensing at the time of the patient's request or within one day after the request.

IMPORTANT: A patient who normally receives a long-acting or extended release naltrexone injection can obtain up to a five-day emergency supply of oral naltrexone pursuant to this section of law. This is intended to address any possible gaps in care.

If a patient already receives an oral prescription for naltrexone but does not have any refills, then a pharmacist may also dispense the oral supply without a prescription in accordance with <u>section 4729.281 of the Revised Code</u>. Guidance document: <u>www.pharmacy.ohio.gov/emergency</u>.

Q4) What are the limitations on the dispensing of an emergency supply of the oral form <u>naltrexone?</u>

For the oral form of naltrexone, a pharmacist is not permitted to dispense an amount that exceeds a five-day supply. The law specifically states that the pharmacist must exercise professional judgment in determining the amount of the drug dispensed.

IMPORTANT: If the patient has a previous script for oral naltrexone, the pharmacist has the option to dispense an emergency refill in accordance with <u>section 4729.281 of the Revised</u> <u>Code</u>. Guidance document: <u>www.pharmacy.ohio.gov/emergency</u>.

Q5) If dispensing the long-acting or extended-release naltrexone, am I permitted to administer the drug?

A pharmacist that dispenses the long-acting or extended release naltrexone injectable is permitted to administer the drug but must meet the requirements of <u>section 4729.45 of the</u> <u>Revised Code</u> and <u>rule 4729-5-40 of the Administrative Code</u>. A guidance document on this requirement is available by visiting: <u>www.pharmacy.ohio.gov/injections</u>.

If a pharmacist is unable to meet the administration requirements previously stated, the pharmacist may still, using their professional judgement, dispense the long-acting or extended release injectable drug to the patient.

Q6) How does this section of law differ from the pharmacist's ability to dispense emergency refills per ORC 4729.281?

The primary difference is that a patient who normally receives a long-acting or extended release injectable naltrexone prescription can obtain up to a five-day supply of oral naltrexone. This is intended to address any possible gaps in care.

Additionally, while there is a one-time restriction for emergency refills (<u>ORC 4729.281</u> (A)(4)(b)(ii)), there is not stated limit for naltrexone (see Q7).

Q7) How many times may a patient receive naltrexone per this provision of law?

There are no specific limitations. Rather, <u>ORC 4729.283</u> states the following:

A pharmacist shall exercise professional judgment in determining the number of times naltrexone may be dispensed under this section to the same patient.

Q8) In addition to the record keeping requirement of the Ohio Administrative Code, does the law require me to maintain additional records?

The law requires a pharmacist to maintain a record of the drug dispensed, including the amount and form dispensed, the original prescription number, the name and address of the patient and, if the individual receiving the drug is not the patient, the name and address of that individual.

Q9) Are there any notification requirements?

Yes. The dispensing pharmacist (or an agent of the pharmacist) must do the following:

- Notify the prescriber who issued the prescription that is no longer valid or another prescriber responsible for the patient's care not later than five days after the drug is dispensed. Such notification must be documented in the patient's profile.
- If applicable, obtain authorization for additional dispensing from the health professional who issued the original prescription or another health professional responsible for the patient's care.

Q10) Do I create a new prescription document when dispensing an emergency supply of naltrexone?

Yes. A pharmacist should create a new prescription document. Be advised, there is no provision requiring insurance to cover an emergency dispensing conducted under this section of the Ohio Revised Code.

Q11) Am I required to report naltrexone dispensed to OARRS?

Yes. It must be reported to OARRS.