Reporting Naltrexone Products to OARRS

Effective March 19, 2019

Updated 7/22/2019

Effective March 19, 2019, section 4729.75 of the Ohio Revised Code will require the reporting of certain naltrexone products to OARRS. An upcoming OARRS rule change (see 4729:8-2-02), which will be effective prior to law's effective date, further specifies the following:

1. The only naltrexone drug products that must be reported are those indicated for the treatment of alcohol dependence or the prevention of relapse to opioid dependence, as indicated on the product labeling. Combination products such as bupropion/naltrexone (CONTRAVE) **SHOULD NOT*** be reported to OARRS.

   NOTE: While the rule only requires the reporting of naltrexone products indicated for the treatment of alcohol dependence or the prevention of relapse to opioid dependence (as indicated on the product labeling), pharmacy systems that cannot separate these products, or are having difficulty, may report all naltrexone products to OARRS.

2. The rule also limits the reporting of naltrexone drug products to those that are dispensed pursuant to an outpatient prescription. This includes patient-specific doses that are sent to prescriber offices for administration. The following entities **WILL NOT** be required to report naltrexone data to OARRS:

   a. Prescribers who personally furnish naltrexone products.

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b. Wholesale distributors, virtual wholesalers, manufacturers, and outsourcing facilities conducting wholesale sales of naltrexone in Ohio.

c. All pharmacies licensed as terminal distributors of dangerous drugs that conduct occasional wholesale sales (i.e. non-patient specific) of naltrexone to other pharmacies or to a prescriber.

To assist licensees with this law change, the Board has developed the following frequently asked questions. If you need additional information on reporting naltrexone to OARRS, please contact the OARRS department at support@pharmacy.ohio.gov.

Q1) I am a pharmacy. How do I report the dispensing of naltrexone to OARRS?

This handbook (Ohio PMP Handbook (ASAP 4.2A) - Instructions for reporting dispensed drugs to OARRS) outlines the steps pharmacies need to take to upload the dispensing of all reportable drugs to OARRS. The software vendor's support line is available at 844-464-4767 for questions.

Q2) I am a Ohio licensed drug distributor* or pharmacy that conducts wholesale transactions to pharmacies and prescribers. Am I required to report the sale of naltrexone to OARRS?

No. Rule 4729:8-2-02 limits the reporting of naltrexone drug products to those that are dispensed pursuant to an outpatient prescription. This includes patient-specific doses that are sent to prescriber offices for administration.

**Drug distributor includes the following license types: manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, and wholesale distributor of dangerous drugs (includes broker and virtual wholesaler).*

Q3) Is naltrexone now a controlled substance?

No. The collection of naltrexone information is intended to assist prescribers and pharmacists in identifying individuals who may be receiving treatment for substance use disorder. This information can be useful for healthcare providers who are considering the use of controlled substances to treat patients.

Q4) Am I required to check OARRS prior to dispensing or personally furnishing products containing naltrexone?

No. Unlike the rules requiring pharmacists and prescribers to request and review an OARRS report prior to dispensing controlled substances, there is no requirement to request and review an OARRS report prior to the prescribing or dispensing of a product containing naltrexone.

Q5) I am a pharmacy that has a prior exemption to reporting because I did not dispense controlled substance medications or gabapentin. Does this change impact my exemption?

For pharmacies that have an exemption **AND** are not dispensing naltrexone products, there is no need to reapply for a reporting exemption.

For pharmacies which were exempt but are no longer because they dispense naltrexone products, they must start reporting **effective March 19, 2019**.

Q6) Can I begin reporting prior to March 19, 2019?

Yes. A pharmacy may begin reporting prior to the law's effective date.