

E-NEWS UPDATE FEBRUARY 2017 EDITION

Senate Bill 319

On January 4, 2017, SB 319 was signed by Governor Kasich. This law includes the following provisions:

- **90-day Supply:** The law limits the authority of a pharmacist, pharmacy intern, or terminal distributor of dangerous drugs to dispense or sell an opioid analgesic pursuant to a prescription for a drug to be used on an outpatient basis. It prohibits dispensing or selling more than a 90-day supply of the drug, as determined according to the prescription's instructions for use of the drug, regardless of whether the prescription was issued for a greater amount. This provision takes effect on **April 6, 2017.** The Board is in the process of developing guidance regarding this provision that will be disseminated by March.
- **14-day Prescriptions for Opioid Analgesics:** The law generally prohibits a pharmacist, pharmacy intern, or terminal distributor from dispensing or selling an opioid analgesic pursuant to a prescription if the drug is to be used on an outpatient basis and more than 14 days have elapsed since the prescription was issued. This provision takes effect on **April 6, 2017.** The Board is in the process of developing guidance regarding this provision that will be disseminated by March.
- **TDDD Requirements for Controlled Substances:** All locations that possess controlled substances are required to obtain licensure as a category III terminal distributor of dangerous drugs. Please be advised that this requirement takes effect on **April 6, 2017.** More information on this provision can be found by visiting: <u>www.pharmacy.ohio.gov/TDDDcs</u>.
- **Office-Based Opioid Treatment:** Effective **August 4, 2017**, all locations that treat more than 30 individuals for opioid dependence or addiction using a controlled substance are required to obtain a license as a terminal distributor of dangerous drugs with an office-based opioid treatment classification. Please be advised that there are some exemptions to this requirement. More information on this provision can be found by visiting: www.pharmacy.ohio.gov/OBOT.
- Registration of Pharmacy Technicians: The law requires the registration of pharmacy technicians by April 6, 2018. While the deadline for registration is not until next year, the Board plans to open the registration process well in advance to allow enough time for individuals to register. The opening of technician registration is not known at this time, as the Board needs to finalize rules regarding the registration process. More information on this provision can be found by visiting: www.pharmacy.ohio.gov/technicians.

Terminal Distributor Requirements for Prescribers and Compounded Drugs

Effective **April 1, 2017,** all prescribers that possess compounded drugs or engage in the compounding of dangerous drugs (i.e. prescription drugs) must obtain a license as a terminal distributor of dangerous drugs (ORC 4729.541). More information on this provision can be found at: <u>www.pharmacy.ohio.gov/prescribercompound</u>.

On or after April 1, 2017, any facility possessing compounded drugs or engaging in drug compounding without being properly licensed as a terminal distributor will be in violation of Ohio law. In addition, a facility that is not licensed as a terminal distributor will not be able to purchase any compounded medications or drugs used for the purpose of compounding from any wholesaler or pharmacy.

OARRS 2.0 Update

After ten years of faithful service, it is time for OARRS 1.0 to retire. In the coming months, OARRS will be upgraded to a brand new software platform. While this means lots of new and exciting features, it also means change. The Board staff and its software vendor, Appriss, are doing everything possible to make this transition smooth and seamless. You will receive multiple emails from Appriss and the Board along the way to ensure you are kept well-informed. Please read these communications carefully. If you have questions, please use the contact information provided in the e-mail. Continue reading below for a timeline of events, followed by further details of what you may need to do during each event.

<u>Timeline</u>

- Now Create new data upload accounts
- March 15, 2017 Begin sending dispensing reports to Appriss PMP Clearinghouse
- April 25, 2017 OARRS 2.0 goes live

Create New Data Upload Accounts

Those responsible for uploading dispensing information to OARRS should have already received communication regarding creating their new data upload accounts. If your vendor or home office reports for you, please check with them to ensure this information was received. The PMP Clearinghouse began accepting registrations for Ohio data uploaders on January 31. Data upload accounts from OARRS 1.0 will not be transferred to the PMP Clearinghouse. If you submit dispensing data to the Appriss PMP Clearinghouse for another state, you do not need to register for a new account. You simply need to create a folder for Ohio in your existing PMP Clearinghouse account.

If you need technical assistance related to PMP Clearinghouse, please contact the Appriss helpdesk at 844-464-4767, or create a support request at <u>https://apprisspmpclearhinghouse.zendesk.com/hc/en-us/requests/new</u>. Technical assistance is available 24 hours a day, 365 days a year.

Begin Sending Dispensing Reports to Appriss PMP Clearinghouse

Effective March 15, 2017, OARRS 1.0 will no longer accept dispensing uploads. All dispensing data uploads will be required to be sent to the Appriss PMP Clearinghouse. The PMP Clearinghouse will provide the records to both OARRS 2.0 for testing as well as to OARRS 1.0 until the OARRS 2.0 go-live date. Again, please direct any technical support issues to the Appriss helpdesk using the information above.

OARRS 2.0 Goes Live

The target go-live date for OARRS 2.0 is April 25, 2017. We are still working out the details on this process. Please stay tuned for future updates.

February 2017 Rules Update

A summary of rule changes taking effect in February can be found at: <u>www.pharmacy.ohio.gov/Feb2017Rules</u>.

Controlled Substance Inventory Disposal

Effective February 1, 2017, <u>rule 4729-9-06</u> will no longer require approval from the Board prior to the disposal of a licensee's controlled substance inventory. Instead, the rule will require adherence to all Drug Enforcement Administration (DEA) disposal requirements set forth in <u>21 C.F.R. 1317</u> and all recordkeeping requirements set forth in 21 C.F.R. 1304. A complete copy of the new rule along with frequently asked questions can be found by visiting: <u>www.pharmacy.ohio.gov/InventoryDisposal</u>.

Please note: This rule also applies to disposal by emergency medical service organizations.

Physician Assistant Prescribing of Buprenorphine Products for Office-Based Treatment of Opioid Addiction

The Substance Abuse and Mental Health Services Administration (SAMHSA) recently announced that physician assistants (PAs) can train and apply to become DATA-2000 waived practitioners. PAs who have completed the required training and seek to become DATA waived for up to 30 patients will be able to apply to do so beginning in early 2017.

Beginning in January 2017. Buprenorphine products will be listed on the Ohio Physician Assistant Formulary as "may prescribe" for office-based treatment of opioid addiction.

The PA formulary may be accessed here: <u>http://med.ohio.gov/Applicants/PhysicianAssistant(PA).aspx</u>.

Changes to CTP Number for Physician Assistants

Please be advised that the Medical Board no longer issues separate Certificate to Prescribe (CTP) numbers for physician assistants (PA). Instead, a PA's authority to prescribe is now designated by their license number with an "RX" at the end (for example, 50.xxxxxxRX). The "RX" at the end of a PA license number meets the requirements for the CTP pursuant to rule 4729-5-30 of the Ohio Administrative Code.

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