Resolutions and Discussion Items

September 2020 Board Meeting

77 South High Street, 17th Floor, Columbus, Ohio 43215

T: (614) 466.4143 | **F:** (614) 752.4836 | **contact@pharmacy.ohio.gov** | **www.pharmacy.ohio.gov**

Licensed HME Services Provider Criminal Records Check Requirements

Updated X/X/2020

To address operational and statutory limitations, the employee criminal records check requirements pursuant to paragraph (F)(3)(c) of rule 4729:11-3-01 of the Administrative Code shall, until further notice, be limited to the results of a criminal records check conducted by the Ohio Bureau of Criminal Identification and Investigation.

Approval for UC Health Pharmacists to Participate in Vaccine Study

Updated X/X/2020

To support efforts to facilitate the development of a COVID-19 vaccine, the State of Ohio Board of Pharmacy hereby authorizes pharmacists employed or contracted by UC Health to participate in the following vaccine study: *"A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older."*

This resolution permits immunization trained/certified pharmacists employed or contracted with UC Health to administer the study vaccine or placebo (both referred to as "study drug") in the above-mentioned study.

This authorization was initially issued in accordance with a Board resolution adopted on May 5, 2020 and shall remain in effect until the conclusion of the trial.

Please be advised that this approval applies only to the vaccine study provided by UC Health dated July 13, 2020 and that all other provisions of the Ohio Revised Code and Ohio Administrative Code relating to the administration of immunizations by pharmacists are still applicable.

Expedited Licensure of Drug Distributors

Updated X/X/2020

In order to ensure the continuity of the drug supply chain during the COVID-19 outbreak, the State of Ohio Board of Pharmacy issued the following guidance for the expedited licensure of drug distributors, which includes any of the following license types as defined in paragraph (A) of rule 4729:6-1-01 of the Administrative Code:

(1) Wholesale distributors of dangerous drugs, including:
    (a) Brokers; and
    (b) Virtual wholesalers.
(2) Manufacturers of dangerous drugs.
(3) Outsourcing facilities.
(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

This guidance is being issued in accordance with a Board resolution adopted on March 2, 2020.

The Board is temporarily waiving the requirement for the submission of ownership/officer and responsible person criminal records checks prior to the initial issuance of a drug distributor license received on or after March 2, 2020. The drug distributor will then have 120 days from the date the application is submitted to submit fingerprints for criminal records checks to the Ohio Bureau of Criminal Investigation.

The Board reserves the right to review all applications consistent with the minimum requirements for licensure. An applicant that fails to meet the minimum standards - unrelated to its pending criminal records checks as required in ORC 4729.53(A)(7) - will be subject to the Board's regular administrative processes, including a Notice of Opportunity for Hearing Proposing to Deny the License, during which time the license will not be activated.

UPDATE: If a drug distributor licensed under this resolution cannot meet the 120 day requirement for fingerprint submission, the licensee may request an extension via email to licensing@pharmacy.ohio.gov. Extension requests will be reviewed and considered by the Executive Director's designee in consultation with the Executive Director and Board President. The licensee will be notified of the approval or denial of the request. If the request is denied, the licensee will have thirty (30) days to comply with the requirements of this resolution. Failure to comply will result in a case investigation and potential disciplinary action up to and including revocation for failure to meet the minimum requirements of ORC 4729.53.

This guidance shall remain in effect until rescinded by the Board

REMINDER: Drug Distributor Application Requirements

Applicants must complete the eLicense Ohio application – available here (www.elicense.ohio.gov) and submit payment (Category 2 - $1,900, Category 3 - $2,000) plus a $3.50 eLicense system transaction fee. The following information will be required on the application:

- Business contact and facility information
- Business ownership information
- Attestation for the submission of criminal records checks for owners/officers and responsible person (NOTE: Submission of criminal records checks must now occur within 120 days upon submission of an application)
- Answers to legal and disciplinary questions. Guidance can be found here – www.pharmacy.ohio.gov/legalbusiness
- Signed attestations by the applicant and responsible person
- Proof of home state licensure (out of state applicants only)
- Copy of DEA Registration (Category 3 only)

If you need additional information about this guidance or how to apply for a drug distributor license, the most expedient way to have your questions answered is to e-mail the Board at www.pharmacy.ohio.gov/contact.

Temporary Expansion of the Maximum Days' Supply for Multiple Drugs in Single-Dose Containers

Updated X/X/2020

To address patient access to medication during the COVID-19 outbreak, the State of Ohio Board of Pharmacy has adopted the following guidance allowing for the temporary expansion of the authorized maximum days' supply permitted under rule 4729-9-23 of the Administrative Code from 31 days to 60 days.

This guidance shall remain in effect until rescinded by the Board.

Sale and Shipment of Non-Reportable Dangerous Drugs from Unlicensed Out-of-State Facilities

Updated X/X/2020

Commented [MC1]: NOTE: The Board has not received any submissions for this resolution since it was adopted.

In order to address any drug shortages during the COVID-19 outbreak, the State of Ohio Board of Pharmacy issued the following guidance on the sale and shipment of non-reportable dangerous drugs that are in shortage by unlicensed, out-of-state facilities.

As used in this guidance:

- "Non-reportable dangerous drug" means a dangerous drug, as defined in section 4729.01 of the Revised Code, that is not required to be reported to the Ohio Automated Rx Reporting System for the purposes of reporting wholesale transactions. Therefore, a non-reportable dangerous drug includes all dangerous drugs except for:
    - Controlled substances dangerous drugs; and
    - Dangerous drugs containing gabapentin.
- "Drug in shortage" or "drug shortage" means any of the following:
    - A drug on the United States Food and Drug Administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.
    - A drug on the American Society of Health-System Pharmacists drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler.

This guidance is being issued in accordance with a Board resolution adopted on March 2, 2020.

An Ohio terminal distributor of dangerous drugs may receive non-reportable dangerous drugs from an unlicensed pharmacy, wholesale distributor of dangerous drugs, third-party logistics provider, or manufacturer of dangerous drugs located in another state in order to alleviate a drug shortage if all the following apply:

1. The unlicensed location is appropriately licensed in its home state and documentation of the license verification is maintained by the Ohio terminal distributor of dangerous drugs.

2. The terminal distributor maintains documentation of the shortage of any dangerous drug received from any pharmacy, wholesale distributor, third-party logistics provider, or manufacturer not licensed in Ohio.

3. The terminal distributor complies with all record keeping requirements for each dangerous drug received from any pharmacy, wholesale distributor, third-party logistics provider, or manufacturer not licensed in Ohio.

4. All documentation and records required above shall be maintained and readily retrievable for three years following the end of the declared public health emergency.

5. The dangerous drug was produced by an authorized FDA registered drug manufacturer.

6. The pharmacy, wholesale distributor, third-party logistics provider, or manufacturer submits an Out-of-State Shipment Notification Form to the Board of Pharmacy prior to shipping any drugs to an Ohio terminal distributor of dangerous drugs. Only one form per unlicensed location must be submitted during the effective period of this guidance.

This guidance shall remain in effect until rescinded by the Board.

Sale and Shipment of Non-Reportable Patient-Specific Medications by Non-Ohio Licensed Border State Facilities

Commented [MC2]: NOTE: The Board has not received any submissions for this resolution since it was adopted.

Updated X/X/2020

In order to promote social distancing during the COVID-19 outbreak, the State of Ohio Board of Pharmacy issued the following resolution on the sale and shipment of patient-specific, non-reportable dangerous drugs by non-Ohio licensed border state facilities to patients residing in the state.

As used in this guidance:

- "Non-reportable dangerous drug" means a dangerous drug, as defined in section 4729.01 of the Revised Code, that is not required to be reported to the Ohio Automated Rx Reporting System for the purposes of reporting wholesale transactions. Therefore, a non-reportable dangerous drug includes all dangerous drugs except for:

- Controlled substances dangerous drugs; and
- Dangerous drugs containing gabapentin.

- "Border state" means the state of Kentucky, West Virginia, Pennsylvania, Indiana or Michigan.

This guidance is being issued in accordance with a Board resolution initially adopted on March 2, 2020.

A border state facility that is not licensed in Ohio may sell patient-specific, non-reportable dangerous drugs to Ohio patients if all the following apply:

1. The non-Ohio licensed location is currently licensed in its home state and in good standing. "In good standing" means the facility does not have a license, registration or certificate limited, on probation, suspended, or revoked by any public agency or licensing agency. This applies to expired or lapsed licenses that the facility may have held in other states.

2. The facility must offer counseling with every medication dispensed, shipped or sold. The offer shall be made by telephone or in writing on a separate document and shall accompany the medication. A written offer to counsel shall include the hours a pharmacist (or prescriber, if applicable) is available and a telephone number where a pharmacist (or prescriber, if applicable) may be reached. The facility shall have sufficient telephone service to provide access to incoming callers.

3. The dangerous drug sold or shipped was produced by an authorized FDA registered drug manufacturer (i.e. no compounded medications).

4. The facility submits a Border State Shipment Request Form to the Board of Pharmacy prior to shipping any medications to an Ohio patient. Only one request form per unlicensed location must be submitted during the effective period of this guidance. Once the form is reviewed and approved, the facility shall receive temporary authorization from the Board to sell or ship non-reportable, patient-specific dangerous drugs into the state.

Failure to comply with this resolution will result in an unlicensed entity being found in violation of applicable sections of the Ohio Revised Code.

This guidance shall remain in effect until rescinded by the Board.