

Expedited Licensure of Drug Distributors

Updated 8/31/2020

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This guidance shall remain in effect until rescinded by the Board.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