



Verification of Licensure Prior to the Sale or Distribution of Drug Samples or Complimentary Supplies

Updated 1/9/2018

The Board received inquiries regarding the verification of licensure, pursuant to rule 4729-9-12 of the Administrative Code and section 4729.60 of the Revised Code, prior to the sale or distribution of drug samples or complimentary supplies. **NOTE: Samples and complimentary supplies of prescription medications have always been considered dangerous drugs for the purposes of licensure by the Board of Pharmacy.**

While the statute and rules require verification of licensure or the verification that a prescriber practice is exempt from licensure, the Board has developed guidance relating to the sale or distribution of drug samples and complimentary supplies.

This guidance is intended for the sale of **non-controlled** drug samples and complimentary supplies that are being shipped to a prescriber. To assist licensed wholesale distributors, virtual wholesalers, third-party logistics providers, manufacturers, outsourcing facilities or repackagers to comply with licensure verification requirements, the Board has developed the following frequently asked questions document.

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

Q1) What is the recommended verification process for non-controlled drug samples?

License verification prior to the sale of non-controlled dangerous drug samples or complimentary supplies, as required by section 4729.60 of the Revised Code, may be met by complying with the following:

- 1) The licensed wholesale distributor, virtual wholesaler, third-party logistics provider, manufacturer, outsourcing facility or repackager shall, prior to sale, verify from the Ohio licensing board (using the e-licensing system) that the prescriber's license is in good standing and that there are no restrictions on prescriber's license to practice and utilize dangerous drugs; and
- 2) Either of the following:



- a. If a prescriber is currently licensed as a terminal distributor of dangerous drugs (TDDD), verify using Ohio's online licensing registry that the license is active and in good standing; or
- b. If the prescriber is not currently licensed as a TDDD:
 - The wholesale distributor, manufacturer, third-party logistics provider or any similar entity licensed by the Board shall provide the prescriber the requirements in Ohio law ([ORC 4729.51](#)) of when a prescriber must hold a terminal distributor of dangerous drugs (TDDD) and instructions on where to access the Board's guidance document on prescriber licensure requirements. This may be a summary statement with a link to the requirements. The guidance for prescriber licensure that can be accessed here: www.pharmacy.ohio.gov/prescriberTDDD.
 - Require the prescriber who claims an exemption to the terminal distributor of dangerous drug licensing requirement to attest, **at least annually**, that the prescriber's facility meet the licensing exemptions ([ORC 4729.541](#)).
 - Ensure that all attestations are maintained for a period of 3-years in accordance with the recordkeeping requirements of Chapter 4729-9 of the Ohio Administrative Code.

Option 2b listed above is only applicable to the verification of licensure prior to the sale of samples/complimentary supplies of non-controlled dangerous drugs to a licensed prescriber. NOTE: If a complimentary supply is being shipped to a pharmacy at the request of a prescriber, verification of licensure prior to sale/shipment is required.

A wholesale distributor, virtual wholesaler, third-party logistics provider, manufacturer, outsourcing facility or repackager licensed by the Board shall verify a prescriber's licensure as a category III terminal distributor of dangerous drugs prior to any sale of any controlled substance dangerous drug sample in accordance with the applicable provisions of the Ohio Revised Code and Ohio Administrative Code.

PLEASE NOTE: It is the expectation of the Board that a virtual wholesaler, third-party logistics provider, manufacturer, outsourcing facility or repackager licensed by the Board must do one of the following prior to sale or transfer of a non-controlled sample drug:

1. Obtain and verify a valid TDDD number of the prescriber practice; or
2. Obtain an attestation (after notification of Ohio's licensing requirements) that the prescriber is exempt from licensure.

Failure to obtain and verify a TDDD number or an attestation the prescriber practice is exempt, prohibits the entity from conducting the sale or distribution of dangerous drugs in Ohio.

Q2) How does the Board define a sample and a complimentary supply?

The Board has adopted the following definitions, which are in the process of being incorporated into rule 4729-9-13 of the Administrative Code:

"Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

"Complimentary supply" also known as "starter packs," "initial dose packs," "starter stocks," "replacement programs," or any other similar supply means a drug or pharmaceutical preparation that is distributed without charge by licensed wholesale distributors or manufacturers to pharmacies licensed as terminal distributors or prescribers to assist patients in the initiation of drug therapy. A complimentary supply shall not contain the markings or labeling of a sample drug.

Q3) Where can I access the Board's guidance document on prescriber licensure requirements?

The guidance document is currently located on the Board's Terminal Distributor of Dangerous Drugs Licenses page (<http://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>) under the "General Information" header. The document is entitled: [Terminal Distributor Licensing of Prescriber Practices](#).

The Board has also created a short link to the document:
www.pharmacy.ohio.gov/PrescriberTDDD

Q4) Does this process also apply to drug sales representatives?

Yes.

Q5) Does this process apply to third party logistics providers (3PL) shipping drug samples or complimentary supplies on behalf of a wholesaler or manufacturer?

If the 3PL can produce documentation that the wholesaler or manufacturer has complied with this process, then the 3PL does not have to conduct a separate verification process.

Q6) What type of licensure type is required to possess non-controlled dangerous drugs?

To possess non-controlled dangerous drugs a prescriber must possess either a category II or category III license as a Terminal Distributor of Dangerous Drugs, unless the prescriber meets an [exception](#).

For limited licenses, the seller must confirm that the Terminal Distributor's drug list permits the possession of the sample or complimentary supply. To view a licensee's drug list, please visit: <http://www.pharmacy.ohio.gov/Licensing/PublicDocuments.aspx>

NOTE: All prescribers requesting controlled substance drug samples or complimentary supplies MUST have a category III license as a Terminal Distributor of Dangerous Drugs.

Q7) What type of licensure status types are considered valid?

While Ohio's e-licensing system includes several license status types, the following are those utilized by the Board that indicate valid licensure:

- Active
- Active – Paid in Review
- Active in Renewal
- Active in Renewal – PAID

For any other questions regarding valid licensure status, please contact the Board's Licensing Department by calling 614-466-4143.

Q8) What if a prescriber's address is different from what is listed on the Board's licensing page?

Terminal Distributor licenses are location-based so the address should match the ordering prescriber's address. The only instance where the address may not be an exact match is if the prescriber is practicing at a hospital. In this instance, the Board typically issues a campus license.

"Campus", as used to describe a type of terminal distributor of dangerous drugs license issued pursuant to division (E) of section [4729.51](#) of the Revised Code, means an establishment or place consisting of multiple buildings where dangerous drugs are stored that are located on a contiguous plot of land. All such buildings and stocks of dangerous drugs shall be under common ownership and control.

Q9) How often are licenses updated in the Board's e-licensing system?

Once a license is activated by Board staff, it is automatically updated in near real-time in the e-licensing system.

Q10) Is there a list of current licenses I can download?

Yes. A list of active licensees in a Microsoft Excel spreadsheet can be accessed by visiting: www.pharmacy.ohio.gov/list

This list is typically updated daily (except for weekends and holidays).

A wholesale or terminal distributor of dangerous drugs may utilize this licensing information to verify licensure status prior to sale or purchase. The spreadsheet must be accessed on a weekly basis to ensure the most up-to-date licensure status.