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Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding

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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).

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. **All potential applicants are encouraged to apply as soon as possible to ensure their license application is processed prior to the statutory deadline.**

NOTE: This requirement applies to all locations and includes previously exempted prescriber practices (dentist, solo-practitioners, etc.) if they possess compounded drugs or engage in drug compounding.

For questions regarding this licensing requirement, please review the following frequently asked questions. 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) How does the Board define compounding?

In rule 4729-16-01 (effective 4.1.2017), compounding is defined as, "…the preparation, mixing, assembling, packaging, and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance."

However, compounding **DOES NOT** include the following, pursuant to rule 4729-16-04 (effective 4.1.2017), as it relates to **NON-HAZARDOUS DRUGS ONLY** when administered to an individual patient:

- The preparation of a drug device designated as such and approved by the United States Food and Drug Administration strictly in accordance with the manufacturer's labeling for administration and beyond use dating.

- The reconstitution or dilution of a conventionally manufactured nonsterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration and beyond use dating. NOTE: Any other reconstitution or dilution of a conventionally manufactured nonsterile product is considered compounding and shall be performed in accordance with United States Pharmacopeia Chapter, USP 39-NF 34, or any official supplement thereto.

- The reconstitution or dilution of a conventionally manufactured sterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration and beyond use dating. NOTE: Any other reconstitution or dilution of a conventionally manufactured sterile product is considered compounding and shall be performed in accordance with rule 4729-16-04 or 4729-16-13 of the Ohio Administrative Code.

If a prescriber office is engaged in any of the three activities previously described, the office is not required to obtain licensure as a terminal distributor of dangerous drugs.

NOTE: If any activities involve the compounding, combining, admixing, mixing, diluting, or reconstituting of hazardous drugs, then the prescriber practice is required to obtain a terminal distributor license pursuant to rule 4729-16-11 of the Administrative Code.

Q2) I compound drugs in my office, what rules am I required to follow?

In addition to security and recordkeeping requirements in Chapters 4729-5 and 4729-9 of the Ohio Administrative Code, prescribers engaged in compounding are required to comply with the following Board of Pharmacy regulations:

OAC 4729-16-04: This rule provides the requirements for prescribers that prepare non-hazardous compounded drug products. This rule does not apply to prescribers preparing hazardous compounded drug products (OAC 4729-16-11) or non-hazardous compounded drug products for immediate-use (OAC 4729-16-13).

OAC 4729-16-11: This rule provides the requirements for prescribers that prepare and handle hazardous compounded drug products. More information on this rule can be accessed by visiting: www.pharmacy.ohio.gov/hazardous

OAC 4729-16-13: This rule provides the requirements for prescribers that prepare immediate-use non-hazardous compounded drug products. Immediate-use drug products must meet all the following criteria:

(1) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous drug products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(2) Personnel shall adhere to appropriate aseptic technique, including all of the following:

(a) Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure; and

(b) Compounding personnel shall don powder free gloves prior to engaging in compounding activities.

(3) If not immediately administered, the finished drug product is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug products, and direct contact of outside surfaces.

(4) Notwithstanding paragraph (B)(1) of rule 4729-9-01, the beyond-use date for an immediate use compounded drug product is no later than six hours following preparation of the drug.

(5) If administration has not begun within the beyond-use dating described in paragraph (B)(4) of rule 4729-16-13, the drug shall be promptly, properly, and safely discarded.

(6) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the compounded drug product shall bear a label listing the exact beyond-use date.

(7) Immediate-use compounded drug products are for administration only and shall not be personally furnished by a prescriber.

(8) For immediate-use compounded drug products administered via injection, a new sterile needle shall be used to administer the compounded drug product to the patient.

Preparations that are medium-risk level and high-risk level compounded drug products as defined in United States Pharmacopeia Chapter <797> , USP 39 - NF

34, or any official supplement thereto (5/1/2016) shall not be prepared as immediate use.

Preparations that cannot meet any of the requirements listed in rule 4729-16-13 must comply with the requirements in rule 4729-16-04.

Q3) How does the Board define a hazardous drug?

The Board uses the definition of hazardous drugs that is found in USP 800. USP 800 defines hazardous drugs as any drug identified by at least one of the following criteria:

- Carcinogenicity, teratogenicity, or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low dose in humans or animals
- Genotoxicity or new drugs that mimic existing HDs in structure or toxicity

The National Institute for Occupational Safety and Health maintains a list of hazardous drugs used in healthcare settings. The list can be accessed here: https://www.cdc.gov/niosh/docs/2016-161/.

For more information on hazardous drug compounding by prescribers, visit: www.pharmacy.ohio.gov/hazardous

Q4) How do I know if I am ordering compounded drugs to my office?

Compounded drugs are those medications that are not commercially available in the strength, concentration, or form needed for a prescriber office or specific patient. The medications are provided by a pharmacy (usually a specialty or compounding pharmacy) or an FDA registered outsourcing facility.

Please note: The terminal distributor licensure requirement applies if the prescriber is ordering patient-specific compounded drugs to their location to be picked up by the patient in accordance with rule 4729-5-10 of the Ohio Administrative Code.

A list of Ohio licensed outsourcing facilities can be accessed here: www.pharmacy.ohio.gov/outsourcing

Q5) What if I already have a license?

If you currently possess a terminal distributor license, then you are already compliant with the requirements of the law.

Application Information

- To obtain a license as a terminal distributor of dangerous drugs, please visit the Pharmacy Board's licensing page: http://www.pharmacy.ohio.gov/Licensing/TDDD.aspx
- Scroll down to the APPLICATIONS header and select "Facility or Practitioner Application"
- On question 5 of the application, be sure to select "Category II" or "Category III" license.
    a. Category II licenses are for non-controlled drugs;
    b. Category III licenses are for the possession of both non-controlled and controlled substance medications.
- For more information regarding the legal questions (8 & 9), there is a guidance document included at the end of the application. This guidance document can also be accessed here: www.pharmacy.ohio.gov/legal
- If you are engaged in the practice of compounding, make sure to complete the prescriber compounding survey in the application.
- Applications must be signed using a wet-ink signature and original copies must be submitted to the Board with the correct payment. The Board will not process incomplete or scanned copies of applications.
- If you were previously exempted from licensure based on your business type, you are eligible for a reduced fee of $60.00. Please review and sign the fee attestation form included in the application.

Responsible Person on an Application

Every terminal distributor license is required to have a responsible person at all times. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of dangerous drugs (i.e. prescription drugs). For a prescriber office or clinic, the responsible person must be any of the following: MD, DO, APRN, RPH, DDS, DVM or DPM.

Pursuant to rule 4729-5-11 of the Administrative Code:

Unless otherwise approved by the Board, no responsible person for locations licensed as a terminal distributor of dangerous drugs shall:

(a) Have ever been denied a license by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(b) Have been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(c) Have been convicted of any of the following: (i) a felony; (ii) a misdemeanor related to, or committed in, the person's professional practice; (iii) an act of moral turpitude; or (iv) a crime of moral turpitude as defined in section 4776.10 of the Revised Code.