Compounding Questionnaire

Updated 1/16/2025

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).

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, outsourcing facility or pharmacy.

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.

The Board defines compounding as follows:

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, for the purpose of licensure, **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:

1. 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

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labeling for administration and beyond use dating.

2. 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.

3. 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 or clinic 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.

Compounding Questionnaire

Ohio Board of Pharmacy

1. Do you perform non-sterile compounding?

○ YES ○ NO

2. If yes to question 1, indicate the non-sterile compounding type you perform (check all that apply)? See USP 795 for definitions.

☐ Simple non-sterile compounding ☐ Moderate non-sterile compounding

☐ Complex non-sterile compounding ☐ Hazardous drug non-sterile compounding

3. Do you perform sterile compounding?

○ YES ○ NO

4. If yes to question 3, indicate the sterile compounding type you perform (check all that apply)? See USP 797 for definitions.

☐ Low-Risk sterile compounding ☐ Medium-Risk sterile compounding

☐ High-Risk sterile compounding ☐ Hazardous drug sterile compounding

5. Do you purchase compounded drugs from FDA registered outsourcing facilities?

○ YES ○ NO

6. Do you order patient specific compounded drugs from pharmacies to give to patients to take home and use later?

○ YES ○ NO

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921. AND 4729. OF THE OHIO REVISED CODE THAT THE ANSWERS PROVIDED ON THIS FORM AND IN THE ONLINE APPLICATION SUBMITTED TO THE STATE BOARD OF PHARMACY ARE **TRUE, CORRECT, AND COMPLETE.**	
Signature of Applicant (digital or wet ink)	Date Signed
Print Applicant Name	
Name of Facility	TDDD License No. (if applicable)