



Pharmacy Compounding in Ohio

Updated 6/18/2021

This guidance applies to in-state pharmacies compounding drugs. A separate guidance for non-resident compounding pharmacies is available here:

www.pharmacy.ohio.gov/NRPcompound

Effective July 1, 2021, the following pharmacy compounding rules will go into effect:

| Rule Number | Type | Rule Title |
|-----------------------------|------|---|
| 4729:7-2-01 | New | Definitions - pharmacy compounding. |
| 4729:7-2-02 | New | Sterile compounding exemptions. |
| 4729:7-2-03 | New | Drugs compounded in a pharmacy. |
| 4729:7-2-04 | New | Record keeping. |
| 4729:7-2-05 | New | Drugs compounded for veterinarian office use. |

REMINDER: Prescriber compounding rules are located in [Chapter 4729:7-3](#) of the Ohio Administrative Code. A prescriber compounding inspection guide can be accessed here: www.pharmacy.ohio.gov/prescribercomp.

Important Reminders

Licensees should be aware of the following:

- The enforcement of USP 800 for hazardous drugs has been delayed until February 1, 2022 (see [FAQ #1 of this document](#)).
- The pharmacy compounding rules do not enforce newer versions of USP 797 and USP 795 that are still under review by USP. Compounding pharmacies are reminded that

the Board will continue conducting compliance inspections using the current version of USP 797 (last revised in 2008) and USP 795 (last revised in 2014) and not the revised version released in June 2019 that is currently on hold pending further review. Please be advised that any change in compounding enforcement standards will be communicated to licensees well in advance of implementation.

- New rules require the reporting of product quality issues to the Board (see [FAQ#5 of this document](#)).
- Free versions of the currently enforced USP compounding chapters can be downloaded by visiting: <https://go.usp.org/l/323321/2020-03-09/3125jw>
- These new rules replace the following current pharmacy compounding rules:

| Rule Number | Type | Rule Title |
|----------------------------|-------------|---|
| 4729-16-01 | Rescind | Definitions. |
| 4729-16-03 | Rescind | Drugs compounded in a pharmacy. |
| 4729-16-05 | Rescind | Drugs compounded in a fluid therapy pharmacy. |
| 4729-16-06 | Rescind | Recordkeeping for compounding. |
| 4729-16-07 | Rescind | Drugs compounded for human use at an in-state pharmacy for direct administration by a prescriber. |
| 4729-16-08 | Rescind | Drugs compounded by a nonresident pharmacy. |
| 4729-16-09 | Rescind | Terminal distributor licenses for compounding drugs and ordering compounded drugs. |
| 4729-16-10 | Rescind | In-state pharmacy compounding for drug shortages. |

For questions regarding pharmacy compounding standards, please review the frequently asked questions starting on the next page of 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) Rule 4729:7-2-03 requires compliance with USP 800 for hazardous drug compounding. Will the Board begin enforcing USP 800 on July 1, 2021?

No. On March 1, 2021, the State of Ohio Board of Pharmacy adopted the following resolution:

The State of Ohio hereby postpones the enforcement of USP 800 as required in rule 4729:7-2-03 and rule 4729:5-8-04 until February 1, 2022. Licensees are encouraged to adopt and comply with the provisions of USP 800 but will not be required to comply with its provisions until February 1, 2022. Instead, licensees shall comply with the hazardous drug compounding provisions in USP 797 (last revised in 2008).

Q2) How does the Board define hazardous drugs for the purpose of eventual compliance with USP 800?

Rule 4729:7-2-01 of the Administrative Code, defines a hazardous drug as follows:

"Hazardous drug" means any drug listed on the National Institute for Occupational Safety and Health's List of Antineoplastic and other Hazardous Drugs in Healthcare Settings as referenced in rule [4729:7-1-01](#) of the Administrative Code.

The NIOSH document can be accessed here: <https://www.cdc.gov/niosh/docs/2016-161/default.html>

Rule 4729:7-2-03 requires pharmacies to comply with USP 800 for the following drugs:

For all antineoplastic compounded hazardous drug preparations listed in table one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule [4729:7-1-01](#) of the Administrative Code, the pharmacy shall comply with United States pharmacopeia chapter 800.

IMPORTANT: There are different requirements for pharmacies that prepare non-antineoplastic compounded hazardous drug preparations listed in table one and other hazardous drugs. See paragraph (D) of rule 4729:7-2-03 of the Administrative Code.

Q3) When will the Board begin enforcing newer versions of USP 797 and 795?

The rules do not enforce newer versions of USP 797 and USP 795 that are still under review by USP. Compounding pharmacies are reminded that the Board will continue conducting

compliance inspections using the current version of USP 797 (last revised in 2008) and USP 795 (last revised in 2014) and not the revised version released in June 2019 that is currently on hold pending further review. Please be advised that any change in compounding enforcement standards will be communicated to licensees well in advance of implementation.

Q4) Are there any exemptions to current compounding requirements in the new rules?

The following table provides a general overview of some of the exemptions* to Ohio’s compounding requirements that were included as part of the new rule package:

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| <p>Flavoring Agents</p> | <p>The addition of a flavoring agent to a conventionally manufactured drug product** is not considered compounding [OAC 4729:7-2-01 (D)(4)].</p> |
| <p>Preparation of Non-Hazardous, Conventionally Manufactured Non-Sterile Products</p> <ul style="list-style-type: none"> ▪ antibiotic oral suspension ▪ topical cream kits | <p>The preparation of non-hazardous, conventionally manufactured non-sterile products** in accordance with the directions contained in the approved labeling provided by the product's manufacturer is not considered compounding.</p> <p>However, a pharmacist is still required to perform the final check of the product prior to distribution to the patient. "Final check" means the final verification check for accuracy and conformity to the formula of the compounded preparation or product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product. [OAC 4729:7-2-01 (D)(1)].</p> |
| <p>Preparation of Non-Hazardous, Conventionally Manufactured Sterile Products (under certain conditions)</p> <p>Examples:</p> <ul style="list-style-type: none"> ▪ Reconstitution of powdered drug in vial for administration ▪ Dilution of drug for immediate | <p>Preparation of non-hazardous, conventionally manufactured sterile products** in accordance with the directions contained in approved labeling provided by the product's manufacturer is not subject to the requirements of the pharmacy compounding rules if all the following apply:</p> |

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| <p>administration</p> | <p>(1) Administration of the drug product must begin within one hour of beginning the preparation (e.g., within one hour of initial entry into or puncture of a single-dose container).</p> <p>(2) Aseptic technique must be followed. Procedures must be in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other products or compounded sterile preparations.</p> <p>(3) A pharmacist or prescriber performs the final check of the product and documents that it was conducted using positive identification.</p> <p>(4) Any unused starting ingredient that is not labeled as a multiple dose container must be discarded after preparation is complete.</p> <p>(5) Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible) and date and time prepared or beyond-use date. [OAC 4729:7-2-02 (A)]</p> <p>IMPORTANT: Any non-hazardous, conventionally manufactured sterile products that are not prepared as stated above are subject to the pharmacy compounding requirements.</p> |
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** As these are exemptions, they are not subject to the requirements of the compounding rules. However, licensees are still required to maintain these drugs in accordance with the applicable Board of Pharmacy rules for non-compounded drugs.*

*** "Product" means a drug in a commercially manufactured pharmaceutical dosage form that*

has been evaluated for safety and efficacy by the United States Food and Drug Administration. Products are accompanied by full prescribing information, which is commonly known as the United States Food and Drug Administration-approved manufacturer's labeling or product package insert [OAC 4729:7-2-01 (O)].

Q5) Are there any other new requirements to the new pharmacy compounding rules?

Yes, pharmacies engaged in drug compounding are now required to report the following:

- **Reporting Product Quality Issues:** A pharmacy licensed as a terminal distributor shall report to the Board of Pharmacy within seventy-two hours upon discovery, using the [product quality reporting form](#), any product quality issue attributed to a compounded drug dispensed by the pharmacy.

For the purposes of reporting, a product quality issue means any of the following:

- (1) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;
- (2) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or
- (3) Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond use date.

NOTE: A product quality issue does not include an isolated allergic reaction to a substance included in a compounded drug preparation.

IMPORTANT: This form is only required to be submitted for a quality issue related to a compounded drug dispensed by an Ohio pharmacy regardless of whether the compounded drug is sold.

A direct link to the Pharmacy Compounding Product Quality Reporting Form can be accessed here: www.pharmacy.ohio.gov/CompoundReport