



Non-Resident Pharmacy Compounding in Ohio

Updated 2/18/2026

This guidance applies to non-resident (i.e., out-of-state) pharmacies compounding drugs.

A separate guidance for in-state compounding pharmacies is available here:

www.pharmacy.ohio.gov/pharmcompound

Effective February 28, 2026, revisions to OAC [4729:7-1-01](#) go into effect. These revisions require compliance with the newest versions of United States Pharmacopeia (USP) 797 & USP 795 (both adopted by USP on March 1, 2023).

IMPORTANT REMINDERS:

- While the rule is effective on February 28, 2026, the Board has extended the enforcement date of the rule until **February 28, 2027**, via resolution (see Q1 of this document).
- Licensees have until February 28, 2027, to become compliant with the newest versions of USP 797 & USP 795. Per rule, the Board is permitted to provide temporary extensions (see Q3 of this document for more information).
- These USP standards are required for any compounded drug dispensed into Ohio by a non-resident pharmacy.
- Only licensees that have fully adopted the newest versions may utilize the new beyond-use dates in USP 797 & USP 795.
- A pharmacy licensed as a non-resident pharmacy that is engaged in drug compounding shall have an Ohio licensed pharmacist as the responsible person on its terminal distributor of dangerous drugs license (see Q5 of this document).

For questions regarding pharmacy compounding standards, 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: www.pharmacy.ohio.gov/contact

Ohio's Non-Resident Pharmacy Compounding Rules:

| Rule Number | Rule Title |
|------------------------------------|--|
| <u>4729:7-1-01</u> | Compounding references. (Effective 2/28/2026) |
| <u>4729:7-2-01</u> | Definitions - pharmacy compounding. |
| <u>4729:5-8-04</u> | Drugs compounded by a nonresident pharmacy. |

Ohio's USP Requirements for Non-Resident Pharmacies:

| Type of Compounding | Version of USP Enforced |
|----------------------------|--|
| Sterile | USP 797 (last major revision in 2008) – Until February 27, 2027 -OR- USP 797 (in effect on March 1, 2023) – Required February 28, 2027 |
| Non-Sterile | USP 795 (last major revision in 2014) – Until February 27, 2027 -OR – USP 797 (in effect on March 1, 2023) – Required February 28, 2027 |
| Hazardous | USP 800 (in effect on December 1, 2022) NOTE: This is applicable to all antineoplastic agents listed on Table 1 of <u>NIOSH List</u> of Hazardous Drugs. |

IMPORTANT: These USP standards are required for any compounded drug dispensed into Ohio by a non-resident pharmacy.

Q1) The compounding references rule is effective on February 28, 2026, am I required to comply with the new USP 797/795 compounding chapters on that date?

No. Per the following resolution, licensees have until **February 28, 2027**, to become fully compliant with the new versions of USP 797 and USP 795:

To allow for licensees to transition to the most current version of USP 797 and USP 795, the Ohio Board of Pharmacy hereby delays the implementation of paragraphs (B) and (C) of OAC 4729:7-1-01 until February 28, 2027. Licensees shall have until February 28, 2027, to come into full compliance with the versions of USP 797 and USP 795 set forth in OAC [4729:7-1-01](#).

Licensees that utilize beyond-use dating from the versions of USP 797 and USP 795 in OAC 4729:7-1-01 (effective Feb. 28, 2027) shall also demonstrate full compliance with those versions to be deemed in compliance with this resolution and OAC 4729:7.

IMPORTANT: Licensees are prohibited from utilizing beyond-use dates from the newest versions of USP 797/795 unless they can demonstrate full compliance with those new versions.

For an overview of the proposed changes, review the updates in the [USP-NF](#). A summary of the changes for each chapter is available from the American Society of Health-System Pharmacists (ASHP):

- [ASHP - USP 797 – Key Changes](#)
- [ASHP - USP 795 – Key Changes](#)

IMPORTANT: These USP standards are required for any compounded drug dispensed into Ohio by a non-resident pharmacy.

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

OAC [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 OAC [4729:7-1-01](#).

The NIOSH list can be accessed here: <https://www.cdc.gov/niosh/docs/2025-103/default.html>

OAC [4729:5-8-04](#) 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 OAC [4729:7-1-01](#), 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 (E) of rule [4729:5-8-04](#) of the Administrative Code.

Q3) Will the Board grant extensions to the February 28, 2027 enforcement deadline for USP 797/795?

OAC [4729:7-1-01](#) grants the Board the ability to provide individual licensees with a temporary extension to the February 28, 2027 enforcement deadline. To qualify for an extension, a licensee must be able to demonstrate the following:

- (1) The licensee was compliant with the standards in effect immediately prior to the effective date of this rule;
- (2) Significant hardship in meeting the standards; and
- (3) Sufficient progress towards compliance with the standards.

Extension requests will be given on a very limited basis and should be submitted to contact@pharmacy.ohio.gov by the terminal distributor's responsible person. **Such requests will not be considered or reviewed until August 1, 2026.**

Q4) Are there any exemptions to the Board’s current compounding requirements?

The following table provides a general overview of some of the exemptions* to Ohio’s compounding requirements:

| Exemption | Additional Information |
|---|---|
| <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> <p>Examples:</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 | <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> <ol style="list-style-type: none"> (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). (2) Aseptic technique must be followed. Procedures must be in place to minimize the potential for contact with |

| | |
|--|---|
| <ul style="list-style-type: none"> ▪ dilution of drug for immediate administration | <p>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 Board's 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) Is a non-resident pharmacy required to have an Ohio-licensed pharmacist as its Responsible Person?

Yes. A pharmacy licensed as a non-resident pharmacy that is engaged in drug compounding shall have an Ohio licensed pharmacist as its responsible person.

IMPORTANT: If a non-resident pharmacy engages in drug compounding but does not ship compounded drugs into Ohio, they are not required to have a responsible person who is an Ohio-licensed pharmacist.

For more information on designating a responsible person, visit:

www.pharmacy.ohio.gov/ChangeRP

For more information on pharmacist licensure by reciprocity, visit:

www.pharmacy.ohio.gov/Reciprocity.

Q6) Are there any reporting requirements for pharmacies engaged in drug compounding?

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

1) Reporting Product Quality Issues: A non-resident 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 a non-resident pharmacy to an Ohio patient.*

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

2) Warning Letters, Injunctions, or Decrees Issued by the U.S. Food and Drug

Administration: A non-resident pharmacy licensed as a terminal distributor shall report to the Board of Pharmacy, within seventy-two hours upon issuance or receipt, of any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States Food and Drug Administration. This information should be sent via email to: compliance@pharmacy.ohio.gov.

Q7) Are there any requirements for non-resident compounding pharmacies prior to initial licensure or for license renewal?

Yes. If a non-resident pharmacy is applying for an initial nonresident terminal distributor of dangerous drugs license, renewal, or the pharmacy's license has lapsed, the pharmacy must provide any of the following, in a manner determined by the board, as part of the initial or renewal application:

- (1) The most recent inspection report that is less than two years old that demonstrates applicable compliance with OAC [4729:5-8-04](#) conducted by an agent of the regulatory or licensing agency in the pharmacy's resident jurisdiction or an agent of a regulatory or licensing agency from another licensing jurisdiction.
- (2) The most recent inspection report that is less than two years old that demonstrates applicable compliance with OAC [4729:5-8-04](#) by the National Association of Boards of Pharmacy's [Verified Pharmacy Program](#).

(3) The most recent inspection report that is less than two years old that demonstrates applicable compliance with OAC [4729:5-8-04](#) conducted by [Accreditation Commission for Health Care Inspection Services](#) (a.k.a. ACHC Inspection Services or AIS).

(4) Proof of a current Pharmacy Compounding Accreditation Board (PCAB) accreditation provided by the [Accreditation Commission for Health Care Inspection Services](#) (ACHC).

(5) Proof of a current medication compounding certification from [The Joint Commission](#).

(6) Proof of a current pharmacy compounding certification from [The Compliance Team](#). **[Added by Resolution on 9/12/22]**