



COMPOUNDING IN OHIO

Updated 2-02-2017

Sterile Compounding – USP 797

Ohio Administrative Code Rule [4729-16-03](#) requires pharmacies to adhere to U.S. Pharmacopeia (USP) Chapter 797 for preparing sterile compounded drugs. To assist pharmacies in complying with this requirement, the State of Ohio Board of Pharmacy has developed a sterile compounding inspection guide that can be accessed here:

www.pharmacy.ohio.gov/797inspection. *Note: While there are some exceptions for prescribers, the Board considers reconstitution by pharmacies to be compounding.*

Non-sterile Compounding – USP 795

Ohio Administrative Code Rule [4729-16-03](#) requires pharmacies to adhere to U.S. Pharmacopeia (USP) Chapter 795 for preparing non-sterile compounded drugs. *Note: While there are some exceptions for prescribers, the Board considers reconstitution by pharmacies to be compounding.*

Federal Law

- The State of Ohio Board of Pharmacy recognizes and enforces Federal law that compounding is performed by a pharmacist in a pharmacy and pursuant to a patient specific prescription. In addition, a pharmacy is not permitted to compound FDA approved drugs that are commercially available. Refer to [Section 503A of the Federal Food, Drug, and Cosmetic Act](#).
- On July 9, 2012, President Obama signed into law the FDA Safety and Innovation Act which, in part, grants permission for hospitals and health systems to repack and share drugs, not controlled substances, in short supply during an FDA published shortage plus 60 days after the drug is taken off the list. PLEASE NOTE: This only applies to drugs utilized within the same health system.
- The Drug Quality and Security Act, signed into law on November 27, 2013, created a new classification of compounder known as an "outsourcing facility." These facilities are permitted to provide non-patient specific compounded sterile drug products that must meet current good manufacturing practice (CGMP) requirements. A list of Ohio

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licensed outsourcing facilities can be accessed here: www.pharmacy.ohio.gov/outsourcing

Ohio Administrative Code

Drugs Compounded by a Pharmacy:

- Effective May 1, 2015, all pharmacy compounding rules were consolidated in [Chapter 4729-16](#) of the Ohio Administrative Code (OAC). This new chapter includes the following rules:
 - [4729-16-01](#): Provides the definitions for the chapter.
 - [4729-16-02](#): Requires FDA registered outsourcing facilities to be licensed in Ohio. A list of Ohio licensed outsourcing facilities can be accessed here: www.pharmacy.ohio.gov/outsourcing
 - [4729-16-03](#): Provides the requirements for the compounding of drugs in a pharmacy, including adherence to USP 797 and 795.
 - [4729-16-05](#): Provides the requirements for drugs compounded in a fluid therapy pharmacy.
 - [4729-16-06](#): Provides the recordkeeping requirements for compounded drugs.
 - [4729-16-07](#): Authorizes the compounding of human drugs at an in-state pharmacy for direct administration by a prescriber. This rule restricts this practice to in-state pharmacies only.
 - The in-state pharmacy may only provide a 72-hour supply of a non-patient specific compounded drug that is not commercially available to a prescriber for the following situations:
 - (a) To treat an emergency situation;
 - (b) For an unanticipated procedure for which a time delay would negatively affect a patient outcome;
 - (c) For diagnostic purposes.
- [4729-16-08](#): Provides the requirements for drugs compounded by non-resident (out-of-state) pharmacies. Including the following provisions:
 1. Requires all non-resident compounding pharmacies to submit documentation that the facility is in compliance with paragraphs (A) and (B) of rule [4729-16-03](#) of the Ohio Administrative Code, which requires compliance with USP 797

(for sterile products) and 795 (for non-sterile products). Upon application or renewal, the pharmacy shall submit one of the following:

- a. The most recent inspection report conducted by a regulatory or licensing agency in the pharmacy's resident jurisdiction that is less than two years old;
- b. The most recent inspection report that is less than two years old provided by the [National Association of Boards of Pharmacy's Verified Pharmacy Program](#);
- c. The most recent inspection report that is less than two years old that demonstrates compliance with paragraphs (A) and (B) of this rule conducted by accreditation commission for health care inspection services (a.k.a. ACHC inspection services or AIS); or
- d. Proof of a current pharmacy compounding accreditation board (PCAB) accreditation provided by the accreditation commission for health care (ACHC).

The board may grant a one-year, one-time extension to nonresident pharmacies in the event an inspection report is not available at the time of application or renewal and documentation is presented verifying intent to comply with this rule.

2. In addition, **non-resident compounding pharmacies are NOT permitted to provide a limited supply of non-patient specific compounded drugs for direct administration by a prescriber**, unless that facility is also licensed as an outsourcing facility pursuant to rule 4729-16-02 or provides veterinary compounded drugs pursuant to rule 4729-16-12.
 - [4729-16-09](#): Reflects changes to Ohio law that requires prescriber practices that were previously exempted from licensure to obtain a terminal distributor of dangerous drugs license to possess, have custody or control of, and distribute dangerous drugs that are compounded or used for the purpose of compounding.
 - [4729-16-10](#): Authorizes in-state pharmacies to compound drugs in the event of a drug shortage. This requires an entity to submit notification to the Board. More information can be accessed here: www.pharmacy.ohio.gov/shortage.
 - [4729-16-12](#): Authorizes pharmacies to compound drugs for in-office stock for use by a veterinarian. *Note: This rule permits a veterinarian to dispense a limited supply of in-office compounded drug stock.*

Board Resolution: Compounding Auxiliary Label

The Board has been asked whether the labeling requirements requiring the phrase "compounded drug product" can be satisfied through the use of an auxiliary label. As adjusting existing pharmacy dispensing systems to accommodate for this requirement may cause undue burden on pharmacies, the Board hereby indicates that the use of an auxiliary label to indicate the drug is a compounded product meets the requirements listed in rules 4729-16-03 and 4729-5-16.

Adopted:
7/11/2016

Rule 4729-5-16: Labeling

NOTE: Rule 4729-5-16 was recently amended to specify that the inclusion of the statement "Compounded Drug Product" or other similar statement is not required on non-sterile compounded drugs that are reconstituted in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

Note: While there are some exceptions for prescribers, the Board considers reconstitution by pharmacies to be compounding.

Drugs Compounded by a Prescriber:

[Section 4729.541 of the Ohio Revised Code](#) requires all prescriber practices to obtain a terminal distributor of dangerous drugs if the practice possesses or distributes dangerous drugs that are compounded or used for compounding. If engaged in drug compounding, the Board has adopted the following regulations for prescribers:

- [4729-16-04](#) (Effective 4.1.2017): Provides the requirements for non-hazardous drugs compounded by a prescriber. For more information on this rule, please visit: www.pharmacy.ohio.gov/prescribercompound
- [4729-16-11](#): Provides the requirements for hazardous drugs compounded by a prescriber. For more information on this rule, please visit: www.pharmacy.ohio.gov/hazardous
- [4729-16-13](#) (Effective 4.1.2017): Provides the requirements for prescribers that prepare immediate-use non-hazardous compounded drug products. For more information on this rule, please visit: www.pharmacy.ohio.gov/prescribercompound