



March 2026 – Rules & Resolutions

Resolutions:

Delay of Enforcement of USP 797/795

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.

For Filing with JCARR:

4729:7-1-01 – Compounding references

As used in this division and in agency 4729 of the Administrative Code:

(A) "The national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings" means publication number 2025-103 (December 2024).

(B) "United States Pharmacopeia Chapter <795>" or "USP <795>" means United States Pharmacopeia Chapter <795> (November 1, 2023).

(C) "United States Pharmacopeia Chapter <797>" or "USP <797>" means United States Pharmacopeia Chapter <797> (**November 1, 2023 February 1, 2026**).

(D) "United States Pharmacopeia Chapter <800>" or "USP <800>" means United States Pharmacopeia Chapter <800> (December 1, 2022).

(E) The board may grant an existing licensee a temporary extension to the requirements to comply with the standards listed in paragraphs (B) and (C) of this rule if the licensee can demonstrate all of 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.

Rationale: USP recently added a cross reference in USP 797 to USP 1085 (effective February 1, 2026).

12.3 Bacterial Endotoxins Testing

endotoxin limit calculated as described in (85) based on the largest recommended dose and weight (or average weight for more than a single animal) of the target animal species unless a different limit is scientifically supported. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs. See also [Guidelines for Bacterial Endotoxins Testing \(1085\)](#) (CN 1-Feb-2026)

4729:4-1-05 – Individual licensee or registrant probation

(A) Probation will be reviewed by members of the board's probation committee and board staff. When a licensee or registrant is placed on probation, the board shall require, at a minimum, the following probationary and limiting terms, unless otherwise determined by the board or its probation committee:

...

(13) Continuing compliance with the terms of the monitoring contract entered into with the treatment provider and **or** approved monitoring provider, provided, that where terms of the monitoring contract conflict with the terms of the settlement agreement or board order, the terms of the settlement agreement or board order shall control.

For Filing with CSI & JCARR:

4729:9-1-01.1 – Mitragynine-Related Compounds (NEW)

The following are classified as schedule I controlled substances:

(A) Mitragynine-related compounds, whether synthetic or naturally occurring substances contained in the plant, or in the resinous extractives of mitragyna speciosa (also known as kratom) and/or synthetic substances, derivatives, prodrugs, isomers, esters, ethers, salts and salts of isomers, esters and ethers with similar chemical structure.

Mitragynine-related compounds include, but are not limited to, the following: 7-hydroxymitragynine; mitragynine pseudoindoxyl; dihydro-7-hydroxy mitragynine; and 7-acetoxymitragynine. Mitragynine-related compounds do not include any of the following:

(1) Any dangerous drug that is the subject of an application approved by the United States food and drug administration under subsections 505(c) or (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c) or (j)) (December 12, 2025) for marketing as a dangerous drug;

(2) Any compound used in food consistent with either:

(a) A food additive regulation published in the United States code of federal regulations; or

(b) A “no questions response” issued by the United States food and drug administration in response to a generally recognized as safe notice.

(3) Any drug approved by the United States food and drug administration to that may be lawfully sold over the counter without a prescription in accordance with section 505G of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h) (December 12, 2025).

(4) Mitragynine, **except for kratom** in vegetation form, including natural kratom leaf and ground natural kratom leaf, **and** in accordance with Chapter 3715. of the Revised Code.