

Notice on the Enforcement of USP Compounding Chapters for Pharmacies

Updated 9/26/2019

This notice only applies to pharmacies. A separate update for prescriber compounders will be released next week.

The State of Ohio Board of Pharmacy is aware of <u>USP's recent announcement</u> that was released on September 23, 2019, pertaining to the effective dates of revised USP Chapters <795>, <797>, and <825>. The Board has received multiple inquiries as to how this announcement will affect the Board's enforcement of USP <800> when it becomes effective December 1, 2019.

Please be advised that the Board will **NOT** begin enforcing <USP 800> on December 1, 2019.

Rather, the Board will be discussing the effective date of updated compounding rules that require adherence to USP <800> for all drugs listed in table one on the <u>National Institute for Occupational Safety and Health's List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings</u> at its November meeting. More information will be provided following the meeting.

Be advised that when the Board files its updated rules requiring compliance with USP <800>, it will provide, at a minimum, a six-month implementation window and additional guidance. Please note, this does not prohibit or restrict a pharmacy from coming into compliance with USP <800> prior to the effective date of the Board's updated compounding rules.

As a reminder, the updated compounding rules finished the rulemaking process in September. This means that the rule text will not be modified further unless otherwise approved by the Board.

Please be aware, these rules do not yet have an effective date. To review the text of the updated rules, click on the rule numbers below:

Rule Number	Rule Title
4729:7-1-01	Compounding references.
4729:7-2-01	Definitions - pharmacy compounding.
4729:7-2-02	Sterile compounding exemptions.
4729:7-2-03	Drugs compounded in a pharmacy.
4729:7-2-04	Record keeping.
4729:7-2-05	Drugs compounded for veterinarian office use.
4729:5-8-04	Drugs compounded by a nonresident pharmacy.

IMPORTANT: These rules only apply to pharmacies engaged in drug compounding and do not have an effective date.

If you need any additional information regarding drug compounding, the most expedient way to have your questions answered will be to email the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

