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ARCHIVES DIVISION

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

08/17/2023 8:53 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Incorporates additional USP <795> and USP <797> standards adopted by reference

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/27/2023 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Portland, OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 09/27/2023

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy - Virtual Meeting, 800 NE Oregon St., Suite 150, Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony virtually during this hearing, sign up on our website at

www.oregon.gov/pharmacy/pages/

rulemaking-information or email your first and last name, email address and phone number to

pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which

rule(s) you would like to comment on.

You must submit written comments before 4:30PM on September 27, 2023. Email written comments to

pharmacy.rulemaking@bop.oregon.gov.

REMOTE MEETING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 503-446-4951

CONFERENCE ID: 764448015

NEED FOR THE RULE(S)

Permits Drug Outlet pharmacies to implement USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (v. 11/01/2022) and <797> Pharmaceutical Compounding—Sterile Preparations (v. 11/01/2022) as an alternative to USP <795> (05/01/2020 v. 2014) and USP <797> (05/01/2020 v. 2008). This is currently a temporary rule that needs to be

permanently adopted prior to the temporary rule 10/31/2023 expiration date in order to facilitate timely compliance with USP standards.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (v. 11/01/2022) – Publication Announcement
<https://www.uspnf.com/notices/795-pub-announcement-20221101>

USP <797> Pharmaceutical Compounding—Sterile Preparations (v. 11/01/2022)- Publication Announcement
<https://www.uspnf.com/notices/797-pub-announcement-20221101>

OAR 855-045-0205 Temporary Rule https://www.oregon.gov/pharmacy/Documents/855-045-0205_BP_9-2023TrackedChanges.pdf

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

FISCAL AND ECONOMIC IMPACT:

None anticipated.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved with the development of proposed amendments.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

This is currently a temporary rule that needs to be permanently adopted prior to the temporary rule 10/31/2023 expiration date in order to facilitate timely compliance with USP standards.

ADOPT: 855-045-0205

RULE SUMMARY: Permanently adopts the current temporary rule that allows Drug Outlet pharmacies to implement USP <795> Pharmaceutical Compounding Non-Sterile Preparations (v. 11/01/2022) and <797> Pharmaceutical Compounding – Sterile Preparations (v. 11/01/2022).

The United States Pharmacopeia (USP) published its revised standards for USP General Chapters <795> and <797> on November 1, 2022. These new USP standards will be effective on November 1, 2023. The board anticipates future rulemaking to adopt USP <795> (v. 11/01/2022) and <797> (v. 11/01/2022) by reference and repeal USP Chapters <795> (05/01/2020 v. 2014) and USP <797> (05/01/2020 v. 2008). Due to the numerous and complex process changes required for compliance, registrants may implement the revised USP <795> (v. 11/01/2022) and <797> (v. 11/01/2022).

CHANGES TO RULE:

855-045-0205

Compliance with New Standards

As an alternative to the requirements in OAR 855-045-0200(3)(a) and (3)(b) registrants may comply with any or all standards contained in: ¶

(1) USP <795> Pharmaceutical Compounding-Non-Sterile Preparations (11/1/2022).¶

(2) USP <797> Pharmaceutical Compounding-Sterile Preparations (11/1/2022).

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155