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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 9-2023

CHAPTER 855

BOARD OF PHARMACY

FILED

04/19/2023 8:08 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

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

EFFECTIVE DATE: 05/05/2023 THROUGH 10/31/2023

AGENCY APPROVED DATE: 04/13/2023

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NEED FOR THE RULE(S):

Temporarily 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).

JUSTIFICATION OF TEMPORARY FILING:

There are numerous and complex process changes required for compliance with the revised USP Chapters <795> and <797>. These process changes require the new rule to be effective immediately and continue to be effective until the board can permanently adopt the rule.

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>

ADOPT: 855-045-0205

RULE SUMMARY: 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. In addition, USP <800> will become enforceable on November 1, 2023. The board anticipates adopting these updated USP Chapters (<795> and <797>) by reference effective November 1, 2023. USP <800> was published on July 1, 2020 is already required in rule. Due to the numerous and complex process changes required for compliance, registrants may implement the revised USP Chapters <795> and <797> prior to that date.

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