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PERMANENT ADMINISTRATIVE ORDER

BP 25-2023
CHAPTER 855
BOARD OF PHARMACY

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

EFFECTIVE DATE: 10/17/2023

AGENCY APPROVED DATE: 10/13/2023

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ADOPT: 855-045-0205

REPEAL: Temporary 855-045-0205 from BP 9-2023

NOTICE FILED DATE: 08/17/2023

RULE SUMMARY: Permanently adopts a temporary rule from 5/5/2023 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