SENATE BILL REPORT
SHB 1445

As Reported by Senate Committee On:
Health & Long Term Care, March 22, 2021

Title: An act relating to the definition of compounding for purposes of the practice of pharmacy.

Brief Description: Concerning the definition of compounding for purposes of the practice of pharmacy.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Thai, Cody, Ormsby, Pollet and Harris-Talley).

Brief History: Passed House: 3/6/21, 98-0.
Committee Activity: Health & Long Term Care: 3/19/21, 3/22/21 [DP].

Brief Summary of Bill

- Clarifies the meaning of drug compounding by a licensed pharmacist.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: Do pass.
Signed by Senators Cleveland, Chair; Frockt, Vice Chair; Muzzall, Ranking Member; Conway, Holy, Keiser, Padden, Randall, Rivers, Robinson, Van De Wege and Wilson, J.

Staff: Ricci Crinzi (786-7253)

Background: Compounding is the practice of combining two or more ingredients in the preparation of a prescription. A pharmacist may compound drug products for an individual patient based on the existence of a pharmacist-patient-prescriber relationship pursuant to a prescription or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. Both the patient and the prescriber must authorize the use of a compounded product before it can be substituted for a commercially available product. Medicinal products that are compounded for patient use or administration must meet the

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standards of the official United States Pharmacopeia as it applies to sterile and non-sterile administered products. The Federal Food, Drug, and Cosmetic Act provides that compounding does not include mixing, reconstituting, or other such acts performed in accordance with directions contained in United States Food and Drug Administration (FDA) approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling. A product's FDA approved labeling is a compilation of information about the product based on FDA's analysis of a new drug application or biologics license application submitted by the product's manufacturer.

Reconstitution is the process of a pharmacist adding a diluent to a dry ingredient to make it a liquid. Medications that need to be reconstituted include manufacturer provided directions that instruct the pharmacist how to reconstitute the medication.

Summary of Bill: The reconstitution and mixing of sterile products according to FDA approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately, or in accordance with package labeling.

The reconstitution and mixing of non-sterile products according to FDA approved labeling does not constitute compounding if prepared pursuant to a prescription.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony: PRO: This bill updates the definition of pharmaceutical compounding in Washington State. The new definition is an update to match the FDA and U.S. Pharmacopeia definition of compounding. Updating the definition will allow pharmacists to prepare compounded medications without having to do unnecessary extra work to meet current statutory compounding requirements.

Persons Testifying: PRO: Jenny Arnold, Washington State Pharmacy Association; Dawn Ipsen; Tim Lynch, Washington State Pharmacy Quality Assurance Commission; Chris Greer.

Persons Signed In To Testify But Not Testifying: No one.