HOUSE BILL REPORT
SHB 1445

As Passed House:
March 6, 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:
Committee Activity:
Health Care & Wellness: 2/8/21, 2/11/21 [DPS].
Floor Activity:
Passed House: 3/6/21, 98-0.

Brief Summary of Substitute Bill

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

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 14 members: Representatives Cody, Chair; Bateman, Vice Chair; Schmick, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Bronoske, Davis, Harris, Macri, Riccelli, Rude, Simmons, Stonier, Tharinger and Ybarra.

Staff: Corey Patton (786-7388).

Background:

Compounding is the practice of combining two or more ingredients in the preparation of a

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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 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 that are 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 (also known as "professional labeling," "package insert," "direction circular," or "package circular") is a compilation of information about the product based on the FDA's analysis of a new drug application or biologics license application submitted by the product's manufacturer.

Summary of Substitute Bill:

Compounding of sterile or non-sterile products does not include reconstitution and mixing according to United States Food and Drug Administration–approved labeling if prepared pursuant to a prescription and, in the case of sterile products, administered immediately or in accordance with package labeling.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) The current definition of "compounding" includes too many simple processes, such as adding water to an antibiotic or adding saline to a COVID-19 vaccine. Neither the United States Food and Drug Administration (FDA) nor the official United States Pharmacopeia (USP) consider those processes to constitute compounding. This bill provides a definition of "compounding" that better distinguishes between compounding and mundane pharmaceutical processes. A more precise definition of "compounding" will bring Washington into alignment with FDA and USP guidelines, eliminate burdensome administrative barriers, and facilitate patient safety and access to medication.

(Opposed) None.

Persons Testifying: Representative Thai, prime sponsor; Jenny Arnold; Christopher Greer,

St. Luke's Rehabilitation Institute; Dawn Ipsen, Kusler's Compounding Pharmacy and Clark's Compounding Pharmacy; and Kenneth Kenyon, Washington State Pharmacy Quality Assurance Commission.

Persons Signed In To Testify But Not Testifying: None.