# Washington State House of Representatives Office of Program Research

## BILL ANALYSIS

## **Health Care & Wellness Committee**

## HB 1445

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

**Sponsors:** Representatives Thai, Cody, Ormsby, Pollet and Harris-Talley.

#### **Brief Summary of Bill**

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

**Hearing Date:** 2/8/21

**Staff:** Corey Patton (786-7388).

#### **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. 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.

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### **Summary of Bill:**

Compounding by a licensed pharmacist does not include reconstitution and mixing according to United States Food and Drug Administration-approved packaging.

Appropriation: None.

Fiscal Note: Requested on February 3, 2021.

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