

FINAL BILL REPORT

SHB 1445

C 78 L 21
Synopsis as Enacted

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).

House Committee on Health Care & Wellness
Senate Committee on Health & Long Term Care

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 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 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:

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

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pursuant to a prescription and, in the case of sterile products, administered immediately or in accordance with package labeling.

Votes on Final Passage:

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| House | 98 | 0 |
| Senate | 49 | 0 |

Effective: July 25, 2021