

HOUSE BILL REPORT

HB 1352

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to drug compounding.

Brief Description: Compounding drugs.

Sponsors: Representatives Thai, Harris, Slatter, Appleton, Jinkins and Ortiz-Self.

Brief History:

Committee Activity:

Health Care & Wellness: 2/6/19, 2/15/19 [DPS].

Brief Summary of Substitute Bill

- Changes requirements regarding the compounding of drugs 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 15 members: Representatives Cody, Chair; Macri, Vice Chair; Schmick, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Chambers, Davis, DeBolt, Harris, Jinkins, Maycumber, Riccelli, Robinson, Stonier, Thai and Tharinger.

Staff: Jim Morishima (786-7191).

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 non-sterile and sterile administered products.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Summary of Substitute Bill:

Compounding is limited to combining two or more active ingredients, instead of two or more ingredients. Compounding does not include mixing, reconstitution, or other acts that are performed in accordance with directions contained in approved labelling provided by the product's manufacturer and other manufacturer directions consistent with the labeling.

The Pharmacy Quality Assurance Commission may adopt rules implementing drug compounding requirements. Both medicinal products and preparations must meet the United States Pharmacopeia standards, instead of only medicinal products.

Substitute Bill Compared to Original Bill:

The substitute bill:

- allows the Pharmacy Quality Assurance Commission adopt rules implementing compounding requirements; and
- removes the requirement that the Pharmacy Quality Assurance Commission adopt rules identifying which provisions of the official United States Pharmacopeia are applicable to non-sterile and sterile products and preparations compounded for patient administration or distribution to a licensed practitioner for patient use or administration.

Appropriation: None.

Fiscal Note: Available.

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

Staff Summary of Public Testimony:

(In support) This bill will ensure safety and consistency in drug compounding and bring Washington into alignment with the rest of the country. Currently, compounding includes mixing inactive ingredients with active ingredients. This prohibits professionals like medical assistants from mixing medications with water per instructions. This puts strain on public health resources because professions are not being utilized to the top of their licenses. It also forces patients who only have access to community pharmacies to perform these tasks themselves. The United States Pharmacopeia (Pharmacopeia) should be the standard, but it is constantly being updated. The Pharmacy Quality Assurance Commission (PQAC) should have the authority to write rules based on the most recent standards. This bill will allow the PQAC to require best practices to be used and would allow rules that exceed the minimum standards of the Pharmacopeia.

(Opposed) Safety is the number one concern for workers at the PQAC. The current law on compounding was enacted in response to the New England compounding scandal. Current law requires adherence to the Pharmacopeia, but this bill allows the PQAC to deviate from those standards without oversight or review. Staff at the PQAC are not aware of any incident where a patient was unable to get the medications they need under the current law. The Legislature should retain its power to set standards, not delegate it to an appointed board. Ensuring safety is more important than convenience.

Persons Testifying: (In support) Representative Thai, prime sponsor; Jennifer Kreidler-Moss, Peninsula Community Health Services; Jeff Rochan, Washington State Pharmacy Association; and Kenneth Kenyon, Washington State Pharmacy Commission.

(Opposed) Dennis Eagle, Washington Federation of State Employees.

Persons Signed In To Testify But Not Testifying: None.