HOUSE BILL REPORT
HB 1800

As Passed Legislature

Title: An act relating to compounding of medications.

Brief Description: Changing regulations concerning the compounding of medications.

Sponsors: Representatives Cody, Morrell and Schmick.

Brief History:
Committee Activity:
Health Care & Wellness: 2/19/13, 2/22/13 [DP].
Floor Activity:
Passed House: 3/11/13, 97-0.
Senate Amended.
Passed Senate: 4/17/13, 48-0.
House Concurred.
Passed House: 4/22/13, 95-0.
Passed Legislature.

Brief Summary of Bill

- Expands the definition of "manufacture," as used in pharmacist practice, to include the distribution of certain compounded drugs to other licensed persons or commercial entities for resale or distribution.
- Establishes exceptions to the definition of "manufacture" related to certain compounded products and repackaged medications.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: Do pass. Signed by 16 members: Representatives Cody, Chair; Jinkins, Vice Chair; Schmick, Ranking Minority Member; Hope, Assistant Ranking Minority Member; Angel, Clibborn, Green, Manweller, Moeller, Morrell, Riccelli, Rodne, Ross, Short, Tharinger and Van De Wege.

Staff: Chris Blake (786-7392).

Background:

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.

Compounding is a practice in which a pharmacist prepares a prescription by combining two or more ingredients. Compounding is authorized in specific situations and in limited quantities. The compounding of an inordinate amount of drugs, relative to the practice site in anticipation of receiving prescriptions without any historical basis, is considered "manufacturing." Manufacturers must obtain a license and meet additional state and federal regulatory requirements.

The Board of Pharmacy allows pharmacists to conduct compounding in limited situations. Pharmacists may compound drugs for individual patients when there is a pharmacist/patient/prescriber relationship and the patient presents a prescription. Pharmacists may also compound drug products that are commercially available for individual patients when it is in anticipation of orders based upon routine, regularly observed prescribing patterns. In addition, pharmacists may compound drugs in very limited quantities prior to receiving a prescription based upon a history of receiving prescriptions from a certain pharmacist/patient/prescriber relationship.

Pharmacists are prohibited from offering compounded drug products to others for resale, except to a practitioner to administer to an individual patient.

Summary of Bill:

The term “manufacture” is expanded to include the distribution of a compounded drug to other licensed persons or commercial entities for resale or distribution, unless the product item has been approved by the Board of Pharmacy.

The term "manufacture" excludes (1) compounding products in anticipation of an order of a practitioner to administer to patients under their direct supervision; (2) repackaging commercially available medication in small, reasonable quantities for practitioners to use for office use; (3) distributing compounded drugs to other entities under common ownership of the facility in which the compounding takes place; or (4) delivering compounded products that are dispensed pursuant to a valid prescription to alternate delivery locations when requested by the patient, the prescriber to administer to the patient, or another pharmacy to dispense to the patient.

Compounded products or products prepared for patient administration or distribution to a practitioner for patient use must meet the nonsterile product and sterile administered product standards of the United States Pharmacopeia.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill contains an emergency clause and takes effect immediately.

Staff Summary of Public Testimony:

(In support) Recent changes have limited the ability to access medications needed on an urgent basis or in post-operative situations. The law needs to balance urgent access, safety,

and cost-consciousness. Injections of these medications are very safe and they are only used in situations that are vision-threatening. The cost of the noncompounded drugs and the preapproval process for medications create a burden for patients.

(With concerns) Compounding is an important part of the practice of pharmacy because it provides patient-specific products when prescribed by a health care provider; however, creating drugs for general distribution is considered manufacturing and requires careful safeguards to ensure quality. Washington has controls in place to protect residents from a tragedy like the recent New England Compounding Center (NECC) case. Washington's current laws draw clear lines between compounding and manufacturing; however, pharmacy compounding of medications without appropriate oversight could lead to a repeat of the NECC tragedy. The Board of Pharmacy has recently opened its rules to consider revisions to its compounding standards and whether limited compounding of nonpatient specific drugs can be done safely and under what circumstances. The Board of Pharmacy should be allowed to work within the rulemaking process to see what kinds of changes can be made to accommodate current practices. This bill has a narrow exemption that does not deal with the underlying problem. The bill creates a need to have to return for additional legislative fixes, rather than taking a comprehensive approach.

(Opposed) None.

Persons Testifying: (In support) Aaron Weingeist, Washington Academy of Eye Physicians and Surgeons.

(With concerns) Mary Selecky, Washington State Department of Health; and Dedi Hitchens, Washington State Pharmacy Association.

Persons Signed In To Testify But Not Testifying: None.