SENATE BILL REPORT
HB 1800

As Reported by Senate Committee On:
Health Care, March 28, 2013

Title: An act relating to compounding of medications.

Brief Description: Concerning the compounding of medications for physician offices or ambulatory surgical centers or facilities to be used by a physician for ophthalmic purposes for nonspecific patients.

Sponsors: Representatives Cody, Morrell and Schmick.

Brief History: Passed House: 3/11/13, 97-0.
Committee Activity: Health Care: 3/27/13, 3/28/13 [DPA].

SENATE COMMITTEE ON HEALTH CARE

Majority Report: Do pass as amended.
Signed by Senators Becker, Chair; Dammeier, Vice Chair; Keiser, Ranking Member; Bailey, Cleveland, Ericksen, Parlette and Schlicher.

Staff: Mich'l Needham (786-7442)

Background: 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.

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.

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 (Recommended Amendments): The definition of the term manufacturing for the compounding of medications for physician offices and ambulatory surgical facilities to be used by a physician for ophthalmic purposes for nonspecific patients is removed.

The exceptions to manufacturing include the following:

- compounding of products in anticipation of an order of a practitioner to administer to patients under their direct supervision;
- repackaging of commercially available medication in small, reasonable quantities for practitioners to use for office use;
- distribution of compounded drugs to other entities under common ownership of the facility in which the compounding takes place;
- delivery of 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; or
- distribution of a compounded drug to other licensed persons or commercial entities for resale or distribution, without specific product item approval by the Board of Pharmacy.

Compounded products or products prepared for patient administration or distribution to a practitioner for patient use must meet the oral product and parenteral product standards of the United States pharmacopeia.

EFFECT OF CHANGES MADE BY HEALTH CARE COMMITTEE (Recommended Amendments): Eliminates the exception to the term manufacturing for the compounding of medications for physician offices and ambulatory surgical facilities to be used by a physician for ophthalmic purposes for nonspecific patients.

Adds exceptions to term manufacturing for the: (1) compounding of products in anticipation of an order of a practitioner to administer to patients under their direct supervision; (2) repackaging of commercially available medication in small, reasonable quantities for practitioners to use for office use; (3) distribution of compounded drugs to other entities under common ownership of the facility in which the compounding takes place; (4) delivery of 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; or (5) distribution of a compounded drug to other licensed persons or commercial entities for resale or distribution, without specific product item approval by the Board of Pharmacy.

Compounded products or products prepared for patient administration or distribution to a practitioner for patient use must meet the oral product and parenteral product standards of the United States pharmacopeia.

Appropriation: None.

Fiscal Note: Available.

Committee/Commission/Task Force Created: No.

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

Staff Summary of Public Testimony on House Bill: PRO: As you know there was a problem with a compounding pharmacy in New England and our Board of Pharmacy looked at the issues and began some enforcement. The change caused a problem specifically for optometrists and eye care providers. But we worked on an amendment that addresses the issue more broadly than this version, and we worked out the changes with the pharmacy association and eye providers. We lost access to compounded medications for our patients with the Board's action. Many of the patients have conditions that can be blinding and it is critical to maintain their vision with timely treatment. It becomes an issue of timing and cost – the compounded drugs can be available quickly and easily, and they cost significantly less per dose. For example the eye drops I was providing were $40 per dose as opposed to $2,000 per dose. The current bill has a narrow focus while the proposed amendment addresses the broader issues with compounding and access to products. We support taking a broader view.

OTHER: When the compounding incident happened with the New England pharmacy, our Board of Pharmacy took action to protect patients and ensure that there are clear standards on compounding and manufacturing. There needs to be clear lines between the manufacture and the compounding. The amendment that is prepared has more detailed safety mechanisms, with better patient protections so we could support the bill with the proposed amendment.

Persons Testifying: PRO: Representative Cody, prime sponsor; Dr. Aaron Weingeist, WA Academy of Eye Physicians and Surgeons; Dedi Hitchins, WA State Pharmacy Assn.

OTHER: Kristi Weeks, WA State Dept. of Health.