FINAL BILL REPORT
HB 1800

C 146 L 13
Synopsis as Enacted

Brief Description: Changing regulations concerning the compounding of medications.

Sponsors: Representatives Cody, Morrell and Schmick.

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

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 state and federal regulatory requirements beyond those established for pharmacists engaged in compounding.

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:

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.

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.

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.

Votes on Final Passage:

House	97	0	
Senate	48	0	(Senate amended)
House	95	0	(House concurred)

Effective: May 7, 2013