



Senate Fiscal Agency
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BILL ANALYSIS



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Senate Bill 704 (Substitute S-3 as reported by the Committee of the Whole)
Senate Bill 904 (as reported without amendment)
Sponsor: Senator Joe Hune
Committee: Health Policy

CONTENT

Senate Bill 704 (S-3) would amend Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to do the following:

- Require a person providing compounding services in this State to be licensed as a pharmacy or manufacturer, and require an outsourcing facility to be licensed as a pharmacy.
- Require an applicant for a pharmacy license for a pharmacy that would provide compounding services for sterile pharmaceuticals, to submit verification of current accreditation through a national accrediting organization.
- Create an application process and standards for a pharmacist or pharmacy compounding pharmaceuticals for a prescriber, health facility, or agency without a prescription.
- Require a pharmacist to maintain records of compound sterile pharmaceuticals.
- Require a pharmacy, manufacturer, or wholesale distributor to designate a licensed pharmacist as the pharmacist in charge (PIC), allow a pharmacist to be designated as PIC for more than one pharmacy, and establish the duties of a PIC.
- Require certain applicants for a new pharmacy, manufacturer, or wholesale distributor license to undergo a criminal history check.
- Prohibit a pharmacist from compounding commercially available pharmaceuticals unless the commercially available pharmaceutical was modified to produce a significant difference and was not available in normal distribution channels to meet the patient's needs in a timely manner.
- Require a pharmacy to notify the Department of Licensing and Regulatory Affairs (LARA) of a complaint regarding compounding activities filed by another state for violation of that state's pharmacy laws, an investigation by Federal authorities regarding a violation of Federal law, or an investigation by any agency into a violation of accreditation standards, within 30 days of knowledge of the investigation or complaint.
- Require an out-of-State applicant or licensee to reimburse LARA for expenses incurred in an inspection or investigation of the applicant or licensee.
- Require LARA to maintain, post, and update on a quarterly basis, a list of pharmacies and pharmacists authorized to compound pharmaceuticals for a prescriber, health facility, or agency.
- Allow the LARA to promulgate rules regarding conditions and facilities for compounding pharmaceuticals.
- Prescribe criminal penalties for violations of some of the above provisions.

The bill also would amend Part 161 (General Provisions) of the Code to provide for the summary suspension of a pharmacy license if LARA received a notice of imminent risk to public health or safety from the United States Food and Drug Administration or the Centers for Disease Control and Prevention. If a license were summarily suspended, LARA would have to report the name and address of the suspended pharmacy license to the Department

of Community Health, the Department of Insurance and Financial Services, the State and Federal agencies responsible for fiscal administration of Federal health care programs, and the appropriate professional association.

Senate Bill 904 would amend the Code of Criminal Procedure to include the felonies proposed by Senate Bill 704 (S-3) in the sentencing guidelines as follows:

- Compounding pharmacy violation would be a Class G felony against a person with a statutory maximum of two years.
- Compounding pharmacy violation resulting in personal injury would be a Class F felony against a person with a statutory maximum of four years.
- Compounding pharmacy violation resulting in serious impairment of a body function would be a Class E felony against a person with a statutory maximum of five years.
- Compounding pharmacy violation resulting in death would be a Class C felony against a person with a statutory maximum of 15 years.

MCL 333.16233 et al. (S.B. 704)
777.13n (S.B. 904)

Legislative Analyst: Jeff Mann

FISCAL IMPACT

Senate Bill 704 (S-3) would have a minor, but likely negative fiscal impact on the Department of Licensing and Regulatory Affairs, and no fiscal impact on local units of government. The bill would likely have little fiscal impact on LARA in terms of ongoing operations, but it would require LARA to make changes to its pharmacist/pharmacy licensing database to accommodate pharmacists in charge and listing compounding pharmacies. These changes would result in one-time costs that would be borne by existing resources.

Senate Bills 704 (S-3) and 904 would create new misdemeanor and felony penalties. The sentences for felony convictions would cost the State approximately \$35,000 per prisoner per year. The penalties associated misdemeanor convictions would have a financial cost to local jails and court systems to administer the sentences. If any associated fine revenue were collected from convictions under the new penalties, the revenue would be directed to local public libraries.

Date Completed: 5-7-14

Fiscal Analyst: Josh Sefton
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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.