

Legislative Analysis



REGULATE COMPOUNDING PHARMACIES

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Senate Bill 704 (Substitute S-3)
Senate Bill 904 without amendment
Sponsor: Sen. Joe Hune
House Committee: Regulatory Reform
Senate Committee: Health Policy

Complete to 6-9-14

A SUMMARY OF SENATE BILLS 704 & 904 AS PASSED BY THE SENATE 5-13-14

Senate Bill 704 would amend the Public Health Code by revising regulations for *compounding pharmacies* and creating penalties for noncompliance with those regulations, including misdemeanor and felony penalties.

Senate Bill 904 would make complementary amendments to the Code of Criminal Procedure to put the felony penalties into the statutory sentencing guidelines.

The term "compounding" refers in the bills to the preparation, mixing, assembling, packaging, and labeling of drugs or devices by a pharmacist under certain specified circumstances, including upon the receipt of a prescription for a specific patient; a medical or dental order from a prescriber or agent for use in the treatment of patients; in anticipation of the receipt of a prescription or medical or dental order based on routine, regularly observed patterns; and for the purpose of or incidental to research, teaching, or chemical analysis.

The bills are tie-barred, meaning neither can take effect unless both are enacted. A more detailed summary follows.

Senate Bill 704

The bill would amend Part 161 (general provisions) and Part 177 (pharmacy practice and drug control) of the Public Health Code.

Part 161 would be amended to allow for the summary suspension of a pharmacy license if the Department of Licensing and Regulatory Affairs (LARA) receives 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 to be suspended, LARA would have to report the name and address of the suspended 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.

Part 177 would be amended so that:

- A person providing compounding services in the state would have to be licensed as a pharmacy or manufacturer, and an outsourcing facility would have to be licensed as a pharmacy.
- An applicant for a pharmacy license for a pharmacy that would provide compounding services for sterile pharmaceuticals would be required to submit verification of current accreditation through a national accrediting organization.
- A pharmacist must maintain records of compound sterile pharmaceuticals.
- A pharmacy, manufacturer, or wholesale distributor would have to designate a licensed pharmacist as the pharmacist in charge (PIC), and allow a pharmacist to be designated as such for more than one pharmacy. The bill also would establish the duties of a pharmacist in charge.
- Certain applicants for a new pharmacy, manufacturer, or wholesale distributor license would be required to undergo a criminal history check.
- A pharmacy would have to notify 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
 - An investigation by any agency into a violation of accreditation standards, within 30 days of knowledge of the investigation or complaint.
- An out-of-state applicant or licensee would be required to reimburse LARA for expenses incurred in an inspection or investigation of the applicant or licensee.
- LARA must maintain, post, and update a list of pharmacies and pharmacists authorized to compound pharmaceuticals for a prescriber, health facility, or agency on a quarterly basis.
- Criminal penalties would be established for violations of Sections 17748a and 17748b. Unless otherwise provided a violation of those sections would be a misdemeanor. (Section 17748a deals with verification of accreditation, compliance with FDA requirements, notification to LARA of complaints, maintenance of records, the prohibition on offering excess compounded pharmaceuticals to other pharmacies for resale, and compounding and manufacturing drug products at the same location. Section 17748b are general provisions on compounding nonsterile and sterile pharmaceuticals without a prescription.) The felony penalties would be as follows:

- A person that knowingly or willfully violated those sections or that falsified prescriptions in order to compound a pharmaceutical in bulk would be guilty of a felony punishable by imprisonment for up to two years and/or a fine of not more than \$1,000.
- The same violation that results in personal injury would be a felony punishable by imprisonment for not more than four years and/or a fine of not more than \$4,000.
- If the violation results in a serious impairment of a body function, it would be a felony punishable by imprisonment for not more than five years and/or a fine of not more than \$5,000.
- A violation that results in death would be a felony punishable by imprisonment for not more than 15 years and/or a fine of not more than \$20,000.

SB 704 also would do the following:

- Allow LARA to promulgate rules regarding conditions and facilities for compounding pharmaceuticals.
- 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.
- Create an application process and standards for a pharmacist or pharmacy compounding pharmaceuticals for a prescriber, health facility, or agency without a prescription.

Senate Bill 904 would amend Section 13n of the Code of Criminal Procedures (MCL 777.13n) by adding the felonies established in SB 704, as well as by making wording changes to some existing felonies listed in this section. The felonies and the respective penalty for each is listed below:

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

FISCAL IMPACT:

Senate Bill 704 would have a minor negative impact on the Department of Licensing and Regulatory Affairs due to the one-time cost of changes LARA would have to make to its licensing database to accommodate pharmacists in charge (PICs) and listing compounding pharmacies. There would be no fiscal impact on local units of government.

Costs to state and local correctional systems would be increased, based on the number of additional convictions and incarcerations. New felony convictions would result in increased costs related to state prisons, county jails, and/or state probation supervision. New misdemeanor convictions would increase costs related to county jails and/or local misdemeanor probation supervision.

The average cost of prison incarceration in a state facility is roughly \$35,600 per prisoner per year, a figure that includes various fixed administrative and operational costs. The costs of local incarceration in a county jail and local misdemeanor probation supervision vary by jurisdiction. State costs for parole and felony probation supervision average about \$3,600 per supervised offender per year. Any increase in penal fine revenues would increase funding for local libraries, which are the constitutionally-designated recipients of those revenues.

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■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.