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BILL ANALYSIS

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Senate Bill 704 (as introduced 12-3-13)
Senate Bill 904 (as introduced 4-23-14)
Sponsor: Senator Joe Hune
Committee: Health Policy

Date Completed: 4-24-14

CONTENT

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

- **Require an applicant for a pharmacy license for a pharmacy that would provide compounding services 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.**
- **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), and establish the duties of a PIC.**
- **Require certain applicants for new pharmacies, manufacturers, or wholesale distributors to undergo a criminal history check.**
- **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 the Department of Licensing and Regulatory Affairs received a notice of imminent risk to public health or safety from the United States Food and Drug Administration (FDA) or the Centers for Disease Control and Prevention (CDC).

Senate Bill 904 would amend the Code of Criminal Procedure to include in the sentencing guidelines the offenses proposed by Senate Bill 704.

Senate Bill 904 is tie-barred to Senate Bill 704.

Senate Bill 704

Regulation of Compounding Pharmacies

Under proposed Section 17748a, an applicant for a new pharmacy license for a pharmacy that would provide compounding services would have to submit verification of current accreditation through an approved national accrediting organization or verify that the pharmacy was in the accreditation process. The Department of Licensing and Regulatory Affairs could not issue a license to the pharmacy if it were not accredited, unless the applicant demonstrated compliance with USP standards.

(The bill would define "compounding" as "the preparation, mixing, assembling, packaging, and labeling of a drug or device by a pharmacist" upon the receipt of a prescription for a specific patient or a prescriber's medical order for treatment of patients within the course of the prescriber's practice, or in anticipation of receiving a prescription or medical order based on routine, regularly observed prescription or medical order practices, or for research, teaching, or chemical analysis purposes. Compounding would not include the compounding of a drug product that is essentially a copy of a commercially available product, or the mixing, reconstitution, or similar act performed according to directions on the label provided by the manufacturer of a commercially available product. "USP standards" would mean "the pharmacopeial standards for drug substances, dosage forms, and compounded preparations based on designated levels of risk as published in the official compendium".)

Within one year after the bill's effective date, a pharmacy that was licensed on that date and provided compounding services would have to be accredited by a national accrediting organization approved by the Michigan Board of Pharmacy or be in compliance with USP standards in a manner determined by the Board. A pharmacy that provided compounding services would have to submit with its license renewal application verification of accreditation or compliance with USP standards.

A pharmacy would have to notify LARA of a complaint regarding compounding activities filed in another state for a violation of that state's pharmacy laws, a Federal investigation regarding violations of Federal law, or an investigation by any agency into violations of accrediting standards within 30 days of knowledge of the complaint or investigation.

Section 17748a also would require a pharmacist to maintain a record of compound sterile pharmaceuticals in the same manner and for the same retention period as prescribed for other prescription records. The record would have to include the following information: a) the name, strength, quantity, and dosage form of the compounded pharmaceutical, b) the formula to compound that included mixing instructions, all ingredients and their quantities, and any other necessary information to prepare the compounded pharmaceutical, c) the prescription number or assigned internal identification number, d) the preparation date, e) the manufacturer and lot number of each ingredient, f) the expiration or beyond-use date, g) the name of the person who prepared the pharmaceutical, and h) the name of the pharmacist who approved the compounded pharmaceutical.

A pharmacist would be prohibited from offering excess compounded pharmaceuticals to other pharmacies for sale, and a compounding pharmacy would be prohibited from distributing samples of compounded pharmaceuticals to a health professional, but would be permitted to advertise or promote the fact that it offered compounding services. A pharmacist could compound a nonsterile or sterile pharmaceutical not commercially available if there were a health professional-patient relationship and a valid prescription, or in anticipation of the receipt of a prescription based on routine, regularly observed prescription practices. A person also would be banned from compounding and manufacturing drug products or allowing the compounding and manufacturing of drug products at the same location.

In consultation with the Board, LARA could promulgate rules regarding conditions, good compounding practices, and facilities for the compounding of sterile and nonsterile pharmaceuticals.

Compounding Pharmaceuticals for a Prescriber, Facility, or Agency

Under proposed Section 17748b, a pharmacist or pharmacy would be prohibited from compounding nonsterile or sterile pharmaceuticals for a prescriber, health facility, or agency licensed under Article 17 to administer to the prescriber's, facility's, or agency's patients without a prescription. (Article 17 governs facilities and agencies.) The Department could

authorize this activity for limited quantities, however, upon application by a pharmacist or compounding pharmacy. Authorization could not be granted if the pharmacist or pharmacy were under investigation, in the process of being disciplined, or in disciplinary status.

The form of the application would be prescribed by the Department, and would have to include all of the following information: a) the name and license number of the pharmacist or pharmacy requesting authorization to compound, b) the name of the specific prescriber, health facility, or agency requesting compounded pharmaceuticals and an affidavit from the prescriber or designated agent of the facility or agency attesting to the need and that the compounded pharmaceuticals were only for patients located in Michigan or immediately adjacent states, c) the pharmaceuticals to be compounded and the reason for compounding, d) the anticipated quantities of pharmaceuticals to be compounded each month and the frequency of the need to compound, and e) the conditions of operation including practices consistent with USP standards and requirements for third-party testing.

A pharmacist or compounding pharmacy authorized to compound nonsterile or sterile pharmaceuticals for a prescriber, facility, or agency would have to maintain accurate and complete monthly records of requests from and pharmaceuticals compounded for each prescriber, facility, or agency, and provide the records to LARA as specified in rules or upon request. If a pharmacy or pharmacist became aware of an adverse event associated with a compounded pharmaceutical, the pharmacy or pharmacist would have to report the event to the Department within 10 days after becoming aware of the event.

The authorization would last for one year, and would be subject to renewal by LARA. The Department could inspect the facility where the compounding occurred without prior notice to the pharmacist or the pharmacy. The Department could immediately revoke the authorization if there were a confirmed deviation or violation of the compounding process, or if an adverse event associated with a compounded pharmaceutical were detected. If the health, safety, and welfare of the public were not in immediate danger, LARA would have to provide 30 days' notice of the revocation.

A prescriber, facility, or agency that obtained compounded pharmaceuticals under Section 17748b could not redistribute or sell the compounded pharmaceuticals to a patient, prescriber, facility, or agency.

The Department would be required to post and maintain a list of pharmacies and pharmacists authorized to compound pharmaceuticals on its website.

Compounding Commercially Available Pharmaceuticals

The bill would prohibit a pharmacist from compounding a commercially available pharmaceutical unless, in the judgment of the prescriber, the commercially available pharmaceutical were modified to produce a significant difference between the compounded pharmaceutical for the patient and the commercially available pharmaceutical, and the commercially available pharmaceutical were not available in normal distribution channels in a timely matter to meet the patient's needs. A pharmacist who compounded a commercially available pharmaceutical would have to maintain documentation of the reason for compounding.

Summary Suspensions

The Public Health Code allows, and in some cases, requires, the Department to summarily suspend a license or registration if the public health, safety, or welfare requires immediate action. The bill would allow LARA to summarily suspend a pharmacy license if the Department received a notice from the FDA or CDC that there was an imminent risk to the public health, safety, or welfare, and emergency action in accordance with the

Administrative Procedures Act was appropriate. A summary suspension under these circumstances would remain in effect for the duration of the emergency situation. The Department would not be required to conduct an investigation or consult with the Board of Pharmacy to take emergency action.

If a pharmacy's 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 administering Federal health care programs, and the appropriate professional association.

Licensure of Pharmacies

The Code requires a pharmacy, drug manufacturer, or wholesale distributor doing business in Michigan to obtain a license. The license is renewable every two years.

A pharmacy, manufacturer, or wholesale distributor also must designate an individual to serve as the licensee for the entity. The designated individual has the responsibility of ensuring the entity's complies with Part 177.

The bill, instead, would require a pharmacy to designate a pharmacist licensed in Michigan as the pharmacist in charge for the pharmacy. A manufacturer or distributor would have to designate a pharmacist licensed in Michigan or another state as the PIC. The PIC would be responsible for ensuring compliance with Part 177 and rules promulgated under it, and would have to do all of the following:

-- Be responsible for purchasing, storing, compounding, repackaging, dispensing, and distributing all drugs and devices.
-- Establish policies and procedures for employees for the procurement, storage, compounding, and dispensing of drugs and communication of information to patients in relation to drug therapy.
-- Supervise employees and provide oversight of the pharmacy if it were also licensed as a manufacturer.
-- Establish and supervise the method and manner for the storage and safekeeping of drugs.
-- Establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs.
-- Notify the Board immediately upon the knowledge that the PIC's services had been or would be terminated.
-- Establish policies and procedures for individuals within the pharmacy who would be delegated tasks by the PIC.

A pharmacy, manufacturer, or wholesale distributor would have to report to the Department a change in ownership, management, location, or designated PIC within 30 days of the change.

An applicant for a new pharmacy, manufacturer, or wholesale distributor license who was not a health professional licensed or authorized to engage in a health profession or who was a health professional but was licensed or authorized to engage in a health profession prior to October 1, 2008, would have to submit fingerprints in the same manner as required under Section 16174 for a criminal history check. (Section 16174 requires an applicant for a license to forward his or her fingerprints to the Department of State Police for a criminal history check with a request that the fingerprints be forwarded to the Federal Bureau of Investigation for a national criminal history check.) The Department, the Board, and the Department of State Police also would have to comply with Section 16174. This requirement for a criminal history check would not apply if a check that met the requirements of Section

16174 had been obtained for the applicant within the two years before the date of the application. To qualify for this exception, the applicant would have to submit proof of the previous criminal history check with the application for a new license. If LARA or the Board determined that the criminal history check did not meet the requirements of Section 16174, or had not been obtained within the prescribed timeframe, the applicant would have to undergo a new criminal history check.

Criminal Penalties

The bill would authorize the Attorney General or a local prosecutor to advance and prosecute the criminal charges described below.

A person who violated proposed Section 17748a or 17748b would be guilty of a misdemeanor. If a person knowingly or willfully violated either section, or if a person falsified prescriptions in order to compound a pharmaceutical in bulk, the person would be guilty of a felony punishable by up to two years in prison or a maximum fine of $1,000, or both.

If a person knowingly or willfully violated Section 17748a or 17748b, or if a person falsified prescriptions in order to compound a pharmaceutical in bulk, and the violation resulted in personal injury, the person would be guilty of a felony punishable by up to four years in prison or a fine of up to $4,000, or both. If the violation resulted in the serious impairment of a body function, the person would by guilty of a felony punishable by up to five years in prison or a fine of up to $5,000, or both. If the violation resulted in death, the person would be guilty of a felony punishable by up to 15 years in prison or a maximum fine of $20,000, or both.

"Serious impairment of a body function" would be defined as that term is defined in Section 58c of the Michigan Vehicle Code. ("Serious impairment of a body function" includes but is not limited to, one or more of the following: a) loss of a limb or loss of use of a limb, b) loss of a foot, hand, finger, or thumb or loss of use of a foot, hand, finger, or thumb, c) Loss of an eye or ear or loss of use of an eye or ear, d) loss or substantial impairment of a bodily function, e) serious visible disfigurement, f) a comatose state that lasts for more than 3 days, g) measurable brain or mental impairment, h) a skull fracture or other serious bone fracture, i) subdural hemorrhage or subdural hematoma, j) loss of an organ.)

Senate Bill 904

The bill would include the felonies proposed by Senate Bill 704 in the sentencing guidelines as follows:

-- Compounding pharmacy violation would be a Class G crime against a person with a statutory maximum of two years.
-- Compounding pharmacy violation resulting in personal injury would be a Class F crime 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 crime against a person with a statutory maximum of five years.
-- Compounding pharmacy violation resulting in death would be a Class C crime 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

The bills would have no fiscal impact on the Department of Licensing and Regulatory Affairs.

The bills 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.

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