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Senate Bill 195 (as passed by the Senate)  
Sponsor: Senator Joe Hune  
Committee: Health Policy

Date Completed: 4-10-15

### **RATIONALE**

Within the last several years, there have been several instances in which drugs distributed by compounding pharmacies were found to be tainted. In at least one case, tainted drugs led to a nationwide outbreak of meningitis that resulted in 64 documented deaths, including 19 in Michigan. In response, Public Act 280 of 2014 amended the Public Health Code to provide for stricter regulation of the practice of compounding and the pharmacies that engage in the practice. The Code requires a pharmacy, manufacturer, or wholesale distributor of pharmaceuticals to be licensed in Michigan. Public Act 280 specifies that a person who provides compounding services must obtain a pharmacy or manufacturer's license, and an outsourcing facility must obtain a pharmacy license. Additionally, Public Act 280 extended to applicants for new pharmacy, manufacturer, and wholesale distributor licenses a requirement applicable to licensed health professionals to submit fingerprints and undergo a background check. In practice, however, it appears that the scope of this requirement is much broader than was anticipated. For example, if the license applicant is a corporation, the background check requirement applies to individuals who have no physical contact with the drugs, such as shareholders and board members. Some people believe that this requirement presents an unnecessary barrier to the issuance of some pharmacy licenses and should be eliminated for the time being.

### **CONTENT**

**The bill would amend Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to eliminate a requirement that an applicant for a pharmacy, manufacturer, or wholesale distributor license provide his or her fingerprints for a criminal history check.**

The Code requires a pharmacy, manufacturer, or wholesale distributor, regardless of location, to be licensed under Part 177 in order to do business in Michigan. A person that provides compounding services must be licensed as a pharmacy or manufacturer and, if a pharmacy, also must be authorized to provide compounding services under the Code, in order to do business in Michigan. An outsourcing facility also must be licensed as a pharmacy in order to do business in this State.

An applicant for a new pharmacy, manufacturer, or wholesale distributor license who is not a health professional licensed or otherwise authorized to engage in a health profession, or who is a health professional but was licensed or otherwise authorized to engage in his or her profession before October 1, 2008, must submit fingerprints in the same manner as required in Section 16174 (described below, under **BACKGROUND**) for the purpose of a criminal history check. This requirement does not apply if a criminal history check that meets the Code's requirements was obtained for the applicant within two years before the date of the application, as determined by the Department of Licensing and Regulatory Affairs or the Board of Pharmacy.

The bill would delete these fingerprint and criminal history check provisions.

(Part 177 defines "manufacturer" as a person that prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or

otherwise changes the container or the labeling of such a drug or device, and that supplies, distributes, sells, offers for sale, barter, or otherwise disposes of such a drug or device, to another person for resale, compounding, or dispensing.

"Wholesale distributor" means a person, other than a manufacturer, who supplies, distributes, sells, offers for sale, barter, or otherwise disposes of, to other people for resale, compounding, or dispensing, a prescription drug or device that the distributor has not prepared, produced, derived, propagated, compounded, processed, packaged, or repackaged, or otherwise changed the container or the labeling of the drug or device.

"Outsourcing facility" means that term as it is defined in 21 USC 353b, i.e., a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility, and complies with all requirements prescribed in that section.

"Compounding" means the preparation, mixing, assembling, packaging, and labeling of a drug or device by a pharmacist under any of the following circumstances:

- Upon receiving a prescription for a specific patient.
- Upon receiving a medical or dental order from a prescriber or agent for use in the treatment of patients within the course of the prescriber's professional practice.
- In anticipation of receiving a prescription or medical or dental order based on routine, regularly observed prescription or medical or dental order patterns.
- For the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.

"Applicant" means a person applying for a pharmacy, manufacturer's, or wholesale distributor's license. The term includes the following:

- An individual, if the person applying is an individual.
- All partners, including limited partners, if the person applying is a partnership.
- All stockholders, officers, and members of the board of directors, if the person applying is a privately held corporation.)

MCL 333.17748

## **BACKGROUND**

Under Section 16174 of the Public Health Code, an applicant for licensure or registration to engage in a health profession must submit his or her fingerprints to the Michigan Department of State Police (MSP) to have a criminal history check conducted, and request the MSP to forward his or her fingerprints to the Federal Bureau of Investigation (FBI) to determine the existence of any national criminal history pertaining to the applicant. The MSP must give the Department of Licensing and Regulatory Affairs (LARA) a written report of the check if it contains any criminal history record information, and must forward the results of the FBI determination to LARA within 30 days after the request is made. The Department of Licensing and Regulatory Affairs must notify the applicable board and the applicant of the type of crime disclosed in the FBI determination without disclosing the details of the crime. The MSP may charge a reasonable fee to cover the cost of conducting the criminal history check.

## **ARGUMENTS**

*(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)*

### **Supporting Argument**

Public Act 280 of 2014 aimed to provide a mechanism for any necessary legal action against a compounding pharmacy that sells products in Michigan but does not have a physical presence in the State. At that time, the true scope of the criminal history check requirement was not recognized. In the case of a corporate license applicant, all shareholders, officers, and board

members must be fingerprinted and submit to a background check. With regard to proposed pharmacy branches owned by corporate chains, this requirement is impractical and serves no purpose in addressing the concerns that prompted the enactment of Public Act 280. The requirement is an inadvertent and needless impediment to the issuance of these pharmacy licenses. A more narrowly focused vetting process should be crafted, and the existing background check requirement should be eliminated so that pending license applications are not delayed in the meantime.

### **Opposing Argument**

Although it is apparent that in some cases the fingerprint and background check requirement is impractical and should be revised, it would be unwise to eliminate it completely at this time. Due to the seriousness of the public health situation that prompted its enactment, the requirement should remain in place until policymakers can formulate an alternative that both permits new pharmacies to open and protects patient safety.

Furthermore, while the requirement was enacted in response to unsanitary conditions at a particular facility, reportedly it also has been useful in combatting fraud in government-sponsored insurance programs, as well as private health plans. Some years ago, the Public Health Code required a licensed pharmacy to be at least partially owned by a licensed pharmacist. That requirement, however, was eliminated in the 1980s, enabling virtually anyone to secure a license to operate a pharmacy. Unscrupulous actors have taken advantage of this statutory change to set up false pharmacy locations and bill insurers for bogus prescriptions. The background check requirement is a tool for stopping those with a record of egregious behavior from continuing to cheat the system. It is not necessary to eliminate this requirement in order to address its resulting administrative snags; instead, the State simply could provide that it does not apply to a corporate applicant's stockholders, officers, and board members.

Legislative Analyst: Julie Cassidy

### **FISCAL IMPACT**

The bill would have a neutral fiscal impact on the Department of Licensing and Regulatory Affairs and no fiscal impact on local units of government. Fingerprinting and background checks are performed through the Department of State Police and the cost of those services is passed on to the applicant. Since the services are essentially cost-neutral to both LARA and the State Police, removing this requirement would have no appreciable fiscal impact on either Department.

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.