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Senate Bill 195 (as introduced 3-10-15)  
Sponsor: Senator Joe Hune  
Committee: Health Policy

Date Completed: 3-24-15

### **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

ected 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.)

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.

Legislative Analyst: Julie Cassidy

### **FISCAL IMPACT**

The bill would have a neutral fiscal impact on the Department of Licensing and Regulatory Affairs (LARA) and no fiscal impact on local units of government. As discussed above, the bill would remove the requirement that an applicant for a new pharmacy, manufacturer of pharmaceuticals, or wholesale distributor of pharmaceuticals who is not otherwise a licensed health professional submit to fingerprinting and a criminal background check. Fingerprinting and background checks are performed through the Department of State Police and the cost of those services is passed through 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.