



Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS



Telephone: (517) 373-5383
Fax: (517) 373-1986

Senate Bill 195 (as enacted)
Sponsor: Senator Joe Hune
Senate Committee: Health Policy
House Committee: Health Policy

PUBLIC ACT 169 of 2015

Date Completed: 1-11-17

RATIONALE

In recent years, there were 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. Under the 2014 amendments, a person who provides compounding services must obtain a pharmacy or manufacturer's license, and an outsourcing facility must obtain a pharmacy license. Additionally, the amendments required applicants for new pharmacy, manufacturer, and wholesale distributor licenses to submit fingerprints and undergo a background check, as already required for health professionals seeking a license. In practice, however, it became apparent that the scope of the new requirement was much broader than had been anticipated. If the license applicant was a corporation, for example, the background check requirement applied to individuals who had no physical contact with the drugs, such as board members. Some people believed that this requirement presented an unnecessary barrier to the issuance of some pharmacy licenses and should be narrowed.

CONTENT

The bill amended Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to modify the requirement that an applicant for a pharmacy, manufacturer, or wholesale distributor license provide his or her fingerprints for a criminal history check, by applying the requirement to specified individuals.

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.

Previously, an applicant for a new pharmacy, manufacturer, or wholesale distributor license who was not a health professional licensed or otherwise authorized to engage in a health profession, or who was a health professional but was licensed or otherwise authorized to engage in his or her profession before October 1, 2008, was required submit fingerprints in the same manner as required in Section 16174 of the Code for the purpose of a criminal history check. (As described below, that section requires the fingerprinting of applicants for a license or registration to practice a health care profession, beginning October 1, 2008.)

The bill, instead, requires fingerprints for the following individuals to be submitted with an application for a new pharmacy, manufacturer, or wholesale distributor license in the same manner as required in Section 16174 for the purpose of a criminal history check:

- An individual 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, if the application is from the individual.
- All partners and any individual who will manage the day-to-day operations of the new pharmacy, manufacturer, or wholesale distributor, if the application is from a partnership.
- Any individual who will manage the day-to-day operations of the new pharmacy, manufacturer, or wholesale distributor, if the application is from a privately held corporation that in the aggregate owns fewer than 75 pharmacies, manufacturers, or wholesale distributors on the date the corporation submits its license application.

The Michigan Board of Pharmacy, Department of Licensing and Regulatory Affairs (LARA), and Department of State Police must conduct the criminal check on the individuals listed above in the same manner as described in Section 16174.

The fingerprinting requirement does not apply if a criminal history check that meets the requirements of Section 16174 has been obtained for the individuals within the two years preceding the date of the application for a new pharmacy, manufacturer, or wholesale distributor license. To qualify for this exception, an applicant must submit proof of the previous criminal history check for each individual listed above, as applicable, with the application. If LARA or the Board of Pharmacy determines that a criminal history check for an individual does not meet the requirements of Section 16174 or was not obtained within the prescribed time period, fingerprints must be submitted for that individual.

(These provisions are similar to what the Code previously provided.)

The bill took effect on December 3, 2015.

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 to determine the existence of any national criminal history pertaining to the applicant. The MSP must give the Department of Licensing and Regulatory Affairs 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 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.

These provisions were enacted in 2006 and originally were to apply beginning on May 1, 2006. That date subsequently was changed to October 1, 2008.

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 established a regulatory structure for compounding pharmacies in order to prevent incidents resulting from unsafe and improper practices. The legislation further 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. The criminal history check requirement was enacted as part of these efforts. At that time, the true scope of the requirement was not recognized. In the case of a corporate license applicant, the fingerprinting and background check requirement applied to all officers, board members, and even shareholders. With regard to

pharmacy branches owned by corporate chains, the requirement was impractical and did not address the concerns that prompted the enactment of Public Act 280. The overly broad requirement was a needless impediment to the issuance of these pharmacy licenses.

To remedy this, the bill established a narrower vetting process that focuses on the appropriate individuals.

Legislative Analyst: Suzanne Lowe

FISCAL IMPACT

The bill has 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 in certain case has no appreciable fiscal impact on either Department.

Fiscal Analyst: Josh Sefton