

Legislative Analysis



PHARMACY LICENSES: REVISE CRIMINAL HISTORY CHECK REQUIREMENT

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Senate Bill 195 (H-1) as reported from committee
Sponsor: Sen. Joe Hune
House Committee: Health Policy
Senate Committee: Health Policy
Complete to 9-24-15

Analysis available at
<http://www.legislature.mi.gov>

(Enacted as Public Act 169 of 2015)

BRIEF SUMMARY: The bill would require that applicants for pharmacy licenses submit their fingerprints to the Michigan State Police for a criminal history check, unless their fingerprints had already been taken within the past two-years.

FISCAL IMPACT: Senate Bill 195 (H-1) would not have a significant fiscal impact on the state or local units of government since the cost of fingerprinting applicants for licensure is supported by a fee paid by applicants pursuant to statute. The current fee charged by the Michigan State Police (MSP) is \$30 and the MSP's costs for processing the fingerprints and completing a criminal record check are approximately \$29.64.

THE APPARENT PROBLEM:

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, the Michigan legislature enacted Public Act 280 of 2014 (amending 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 that an outsourcing facility must obtain a pharmacy license. Further, Public Act 280 requires that applicants for new pharmacy licenses, manufacturer licenses, and wholesale distributor licenses submit their fingerprints to the Michigan State Police, and undergo a criminal history background check.

Legislation had been introduced to waive the fingerprint requirements in its entirety. However, that legislation has now been modified to require the submission of fingerprints for a background check only if fingerprints had not been submitted within the past two years.

THE CONTENT OF THE BILL:

Senate Bill 195 (H-1) would amend Part 177 of the Public Health Code, which deals with "Pharmacy Practice and Drug Control," to revise the requirement that an applicant for a pharmacy license, manufacturer license, or wholesale distribution license provide fingerprints for a criminal history check. The bill would take effect 30 days after being enacted into law.

A more detailed description of the bill follows.

Senate Bill 195 (H-1) specifies that a criminal history check that meets the requirements of Section 16174 would not be required if one had been obtained within two years preceding the application for a new pharmacy license, a manufacturer license, or a wholesale distributor license. To qualify for the exception, an applicant would be required to submit proof of the previous criminal history check with the application. If the department or board determined that a criminal history check did not meet the requirements, or was not obtained within the time-period prescribed, then fingerprints would have to be submitted.

Further, Senate Bill 195 (H-1) specifies that fingerprints for the following individuals must be submitted with an application for a new pharmacy license, manufacturer license, or wholesale distributor license, in the same manner as required by the code for a criminal history check:

- Fingerprints would be required if the application is from an individual who is not a health professional licensed or authorized to engage in a health profession, and also from an individual who is a health professional but licensed before October 1, 2008.
- Fingerprints would be required for all partners and any individual who manages the day-to-day operations of a new pharmacy, manufacturer, or wholesale distributor when the application is from a partnership.
- Fingerprints would be required for any individual who manages the day-to-day operations of a new pharmacy, manufacturer, or wholesale distributor, when the application is from a privately held corporation.

Finally, Senate Bill 195 (H-1) requires that the board, department, and Department of State Police conduct the criminal history check in the same manner as described in Section 16174.

Now under the law, the Public Health Code defines "applicant" to include an individual, if the person applying is an individual; all partners, including limited partners, if the person applying is a partnership; and all stockholders, officers, and members of the board of directors, if the person applying is a privately held corporation.

Further, the Public Health Code currently requires a pharmacy, manufacturer, or wholesale distributor, regardless of location, to be licensed under Part 177 in order to do business in Michigan. And, a person who provides compounding services must be licensed as a pharmacy or a manufacturer and, if licensed as a pharmacy, also must be authorized to provide compounding services under the code, in order to do business in Michigan. Finally,

an outsourcing facility also must be licensed as a pharmacy in order to do business in this state.

The law now requires a criminal history check (using fingerprints) for any 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, and also for an applicant who *is a health professional* licensed before October 1 of 2008.

HOUSE COMMITTEE ACTION:

The House Health Policy Committee reported from committee an H-1 substitute version of Senate Bill 195. The Senate-passed version of the bill would have eliminated fingerprinting and criminal background checks for virtually all those seeking to license pharmacies.

In contrast, Senate Bill 195 (H-1) requires pharmacy applicants to submit their fingerprints unless a criminal history background check had been completed within two-years of the licensure application.

BACKGROUND INFORMATION:

Criminal History Background Checks

Under Section 16174 of the Public Health Code, an applicant for licensure or registration to engage in a health profession must submit fingerprints to the Michigan Department of State Police (MSP) to have a criminal history check conducted, and then request the MSP to forward the fingerprints to the Federal Bureau of Investigation (FBI) to determine the existence of any national criminal history pertaining to the applicant.

The MSP must then 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. LARA must notify the applicable professional licensing board, and the applicant, about 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.

Definitions: Pharmacy Practice and Drug Control – Michigan Public Health Code

Senate Bill 195 (H-1) does not alter any of the following definitions found in Part 177 of the Public Health Code. As noted earlier, in sections 17748, 17748a, and 17768, the code defines "applicant" to mean a person applying for a pharmacy, manufacturer's, or wholesale distributor's license. The term includes only one or more of the following: an individual, if the person applying is an individual; all partners, including limited partners, if the person applying is a partnership; and all stockholders, officers, and members of the board of directors, if the person applying is a privately held corporation.

"Manufacturer" is defined to mean 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 federal law (at 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; and, for the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.

ARGUMENTS:

For:

It would be unwise for the legislature to completely eliminate criminal history background checks for those seeking to license pharmacies. Due to the seriousness of the public health situation that prompted imposition of the background checks—the deaths caused by drugs assembled in compounding pharmacies—the safety requirement should remain in place.

Senate Bill 195 (H-1) offers a compromise. Instead of eliminating the requirement for fingerprinting and a background check as the Senate proposed, the House version of the bill retains the requirement, but applies it only if an applicant has not been fingerprinted in over two years.

For:

When the Public Health Code was written, it required that licensed pharmacists own pharmacies—a policy of accountability abandoned in the 1980s. Now, virtually anyone can secure a license to operate a pharmacy. And, unscrupulous actors have taken advantage of this statutory change to set up false pharmacy locations, and then 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 used to combat fraud in government-sponsored insurance programs, as well as private health plans.

Against:

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 lacks a physical presence in the state.

Last year when the new law was enacted, the true scope of the criminal history check requirement was not recognized. For example, in the case of a corporate license applicant, all shareholders, officers, and board members must be fingerprinted and submit to a background check, despite the fact they have no physical contact with the drugs their pharmaceutical corporations sell. Most especially with regard to pharmacy branches owned by corporate chains, this requirement is impractical and, arguably it serves no purpose in addressing the concerns that prompted the enactment of Public Act 280.

The criminal background check requirement is an inadvertent and needless impediment to the issuance of these pharmacy licenses. A more narrowly focused vetting process should be crafted, and, in the meantime, the existing background check requirement should be eliminated so that pending license applications are not delayed.

POSITIONS:

The Michigan Retailers Association supports the bill. (9-22-15)

Meijer supports the bill. (9-22-15)

The Office of the Attorney General supports the bill. (9-22-15)

The Michigan Pharmacists Association supports the bill. (9-22-15)

The Michigan Association of Health Plans supports the bill. (9-22-15)

MichBio supports the bill. (9-22-15)

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