

REVISE PHARMACY TECHNICIAN LICENSURE & COMPOUNDING PHARMACY ACCREDITATION

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Senate Bill 468 (reported from House committee)

Sponsor: Sen. Mike Green

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 133 of 2015)

BRIEF SUMMARY: The bill would 1) make an exception to the requirement that a pharmacy tech have graduated from high school; 2) increase from 210 days to one-year the duration of a temporary license; 3) allow a pharmacy technician employed at a multi-site pharmacy to work at any of the pharmacy's in-state locations; and 4) delay for one-year (from September 30, 2015, to September 30, 2016) the deadline for a licensed compounding pharmacy to be accredited by a national accrediting organization.

FISCAL IMPACT: Senate Bill 468, as reported from committee, would likely have a neutral or nominal fiscal impact on the Department of Licensing and Regulatory Affairs (LARA) dependent on: (1) how many individuals who did not earn a high school diploma or pass the GED apply for licensure and (2) how many individuals employed as pharmacy technicians as of October 1, 2015, and applying for a limited license perform their duties at multiple pharmacy locations owned by a single employer. The number of such applicants is currently unknown as the licensure requirements do not become effective until October 1, 2015, but is more than likely not substantial.

According to LARA, approximately 16,213 total applications for pharmacy technician licensure were submitted as of September 9, 2015, with 300 to 400 more anticipated before the end of the fiscal year.

THE APPARENT PROBLEM:

Last year, the Michigan legislature enacted Public Act 280 of 2014 to provide a way that legal action could be taken against a compounding pharmacy, and to require that compounding pharmacies be accredited through a national accrediting organization approved by the Michigan Board of Pharmacy. The regulatory framework was created because tainted drugs led to a nationwide outbreak of meningitis that resulted in 64 documented deaths, including 19 in Michigan.

In addition, the legislature enacted Public Act 285 of 2014 to license pharmacy technicians, because Michigan was then one of only six states that failed to require licensure or certification. The new law set minimum educational requirements—a high school degree or GED equivalent—with the expectation that pharmacy assistants having more schooling would better protect patient safety and minimize the diversion of controlled substances.

Legislation has now been introduced to revise these requirements—both to 1) delay for one year the requirement that compounding pharmacies be accredited, and 2) to provide exceptions to the requirement that pharmacy technicians have a high school education.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to do the following concerning pharmacy technician licensure and practice:

- Make an exception to the requirement that a license applicant have graduated from high school or passed a GED test, if the person were a student in a pharmacy training program or were applying for a temporary license or a limited license.
- Increase from 210 days to one year the duration of a temporary license (issued to a person who is preparing for an examination required for licensure).
- Allow a person employed as a pharmacy technician for an employer with multiple pharmacy locations to work as a limited license pharmacy technician at any of those locations in the state.

[A limited license may be issued to an individual who was working as a pharmacy technician on December 22, 2014, (the date the licensure requirement took effect). An individual who holds a limited license may act as a pharmacy technician only for the pharmacy that he or she worked for on that date.]

In addition, the bill would delay for one year (from September 30, 2015, to September 30, 2016) the deadline for a licensed pharmacy that provides compounding services for sterile pharmaceuticals to be accredited by a national accrediting organization approved by the Michigan Board of Pharmacy, be verified by the Board as being in the accreditation process, or be in compliance with USP (U.S. Pharmacopeial Convention) standards in a manner determined by the Board.

HOUSE COMMITTEE ACTION:

The House Policy Committee reported out the Senate-passed version of Senate Bill 468 without amendments.

ARGUMENTS:

For:

Proponents of the bill argue that without this change in the law, 800 pharmacy technicians will lose their jobs on October 1, 2015, because they have been working without having earned a high school diploma or having passed a GED exam.

Against:

Unwisely, this bill delays for one-year the requirement that a compounding pharmacy be accredited by a national accreditation organization. Within the last several years, there

have been 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 of the pharmacies that engage in the practice. Timely national accreditation remains an important requirement of Michigan's regulatory efforts, and it should not be delayed.

Against:

Pharmacy technicians need a high school education, and specialized training that should be monitored through regulatory oversight. Originally, the credentialing of pharmacy technicians was recommended by the Controlled Substances Advisory Commission, which was established by statute in 1988 to monitor controlled substance abuse and diversion, and to recommend ways to mitigate drug abuse.

The Commission first included a recommendation to credential pharmacy technicians in its 2006-2007 report, basing its recommendation upon a study of *controlled substance loss reports*. Reportedly, pharmacy technicians accounted for about 75 percent of the thefts of hydrocodone and oxycodone (two popular and addictive painkillers) between 2002 and 2005.

The problem of employee theft continues to exist. According to U.S. Drug Enforcement Agency reports for 2007 to 2011, compared with armed robbery and break-ins, employee theft accounted for a significantly greater portion of drug theft at chain pharmacies.

POSITIONS:

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

The Michigan Health & Hospital Association supports the bill. (9-22-15)

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

The Department of Licensing & Regulatory Affairs supports the bill. (9-22-15)

The National Association of Chain Drug Stores supports the bill. (9-22-15)

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

Rite Aid 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.