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BILL



ANALYSIS

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Senate Bill 92 (Substitute S-5 as reported by the Committee of the Whole) *(as passed by the Senate)*
Sponsor: Senator Mike Green
Committee: Regulatory Reform

Date Completed: 4-3-13

RATIONALE

Michigan is one of six states that do not regulate pharmacy technicians. These are individuals who assist pharmacists with a variety of functions. Depending on the pharmacy, for example, a technician might compound drugs, receive verbal orders for prescriptions, assist in the dispensing process, and transfer prescriptions. Because Michigan does not require pharmacy technicians to be licensed or certified, it is possible that someone without adequate training could be hired to perform these tasks, or a store with a pharmacy could ask any other employee to fill in for an absent pharmacy technician. In order to protect patient safety, minimize the diversion of controlled substances, and allow pharmacists to focus on patient care services, it has been suggested that the State should require the licensure of pharmacy technicians.

CONTENT

The bill would amend Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to provide for the licensure of pharmacy technicians. The bill would do the following:

- Require an individual to be licensed as a pharmacy technician if he or she performed specific functions.
- Require a license applicant to pass the Certified Pharmacy Technician Examination, another nationally recognized exam approved by the Michigan Board of Pharmacy, or a Board-approved employer-based training program exam.

- Excuse certain people from the examination requirement.
- Allow the Department of Licensing and Regulatory Affairs (LARA) to issue a 210-day temporary license to a person who was preparing for the required exam.
- Allow LARA to issue a limited license to someone who was employed as a pharmacy technician on the bill's effective date and had worked at least 1,000 hours in the previous year.
- Establish a \$25 application fee and a \$30 annual license fee for a pharmacy technician license; a \$15 fee for a temporary license; and \$10 annual fee for a limited license.
- Require a pharmacy or dispensing prescriber that used the services of a pharmacy technician to ensure that certain requirements were met.
- Allow the Board of Pharmacy to require a person to meet continuing education requirements for the renewal of a pharmacy technician license.
- Add a pharmacy technician to the Board.

The bill would take effect 90 days after it was enacted.

License Requirement

Under the bill, a person who performed any of the following functions would be considered to be serving as a pharmacy technician and, except as otherwise provided in Part 177, would have to be licensed:

- Assisting in the dispensing process.
- Handling transfer of prescriptions, except controlled substances prescriptions.
- Compounding drugs.
- Preparing or mixing intravenous drugs for injection into a human or veterinary patient.
- Contacting prescribers concerning prescription drug order clarification, not including drug regimen review or clinical or therapeutic interpretation.
- Receiving verbal orders for prescription drugs, except orders for controlled substances.
- Subject to Section 16215 (which concerns the delegation of functions), performing any other functions authorized under rules promulgated under Part 177.

The bill would define "pharmacy technician" as an individual who is required to hold a health profession subfield license under Part 177 to serve as a pharmacy technician.

Licensure Criteria

The Department of Licensing and Regulatory Affairs could license an individual as a pharmacy technician if he or she met all of the following requirements:

- Submitted a complete application to LARA on a form prescribed by the Department.
- Graduated from an accredited high school or comparable school or educational institution or passed the general educational development test or other graduate equivalency exam.
- Passed and submitted proof of passage of any of the examinations listed below, except as otherwise provided.

Passage of any of following examinations would qualify an individual for licensure:

- The Certified Pharmacy Technician Examination given by the Pharmacy Technician Certification Board.
- The Certified Pharmacy Technician Examination given by the National Healthcareer Association.
- Any other nationally recognized and administered certification exam approved by the Board of Pharmacy.
- A Board-approved employer-based training program exam that covered the

subjects listed in the bill (e.g., basic drug information, quality control procedures, State and Federal laws and regulations regarding pharmacy technician duties, and drug record-keeping requirements).

In addition, an applicant for licensure would have to satisfy the requirements of Section 16174 of the Code. (That section requires an individual who is licensed or registered under Article 15 (Occupations) of the Code to be at least 18 years old; be of good moral character; have a specific education or experience in the health profession and/or training equivalent as prescribed by Article 15 or rules of a board; have a working knowledge of the English language; pay the appropriate fees; and establish that disciplinary proceedings are not pending against him or her. An applicant for initial licensure or registration also must submit his or her fingerprints to the State Police for a criminal history check.)

The examination requirement would not apply to an individual who met any of the following:

- He or she was a student in a pharmacy technician program approved by the Board, while performing duties assigned in the course of training.
- He or she was applying for a temporary license under the bill.
- He or she was applying for a limited license under the bill.

Temporary Licensure

The Department could issue a temporary pharmacy technician license to an individual who was preparing for the examination required for licensure. A temporary license would expire 210 days after it was issued.

An individual requesting a temporary license would have to submit a completed application to LARA and pay the applicable fee.

An individual holding a temporary license would be subject to all of the requirements of Part 177 and the rules promulgated under it, except the examination requirement.

Limited License

The Department could issue a limited license as a pharmacy technician to an individual if all of the following were met:

- The individual was employed as a pharmacy technician by a pharmacy on the bill's effective date and had been continuously employed by that pharmacy since that date.
- The individual submitted a completed application to LARA and met the requirements of Section 16174.
- The individual provided documentation of satisfactory employment as a pharmacy technician for at least 1,000 hours during the one-year period immediately before the date of his or her application.
- The applicable fee was paid.

An individual holding a limited license could act as a pharmacy technician for the employing pharmacy only until he or she was no longer employed by that pharmacy to perform pharmacy technician functions, or he or she performed any of those functions for another pharmacy.

The term of a limited license would be the same as the term of a pharmacy technician license.

An individual holding a limited license would be subject to all of the requirements of Part 177 and the rules promulgated under it, except the examination requirement.

Continuing Education

The Board of Pharmacy could require a licensee seeking renewal of a pharmacy technician license to give the Board satisfactory evidence that, during the two years immediately before application for renewal, he or she had attended at least 20 hours of continuing education courses or programs, approved by the Board, or satisfactorily completed a proficiency examination according to rules promulgated by the Board.

Pharmacy Responsibilities

A pharmacy or dispensing prescriber that used the services of a pharmacy technician would have to ensure that all of the

following requirements, as applicable, were met:

- The pharmacy technician was licensed or otherwise authorized to serve as a pharmacy technician under Part 177.
- The pharmacy technician performed only the activities or functions that he or she was licensed or otherwise authorized to perform under Part 177 or rules promulgated under that part.
- Except as provided by rule, the pharmacy technician performed only those activities or functions under the supervision and personal charge of the pharmacist or dispensing prescriber.

An individual who was not a pharmacist, pharmacist intern, or pharmacy technician could not perform for a pharmacy any of the functions listed in the bill that would require licensure as a pharmacy technician. A pharmacist could not allow any individual employed or otherwise under the pharmacist's personal charge to violate this prohibition. A person who owned, managed, operated, or conducted a pharmacy also could not allow any individual employed or under the person's control to violate the prohibition.

Other Provisions

The Michigan Board of Pharmacy currently consists of six pharmacists and five public members. The bill would add one pharmacy technician and reduce the number of public members to four.

Part 177 defines "practice of pharmacy" and describes professional functions associated with the practice. Under the bill, practice of pharmacy would include the direct or indirect provision of professional functions and services associated with the practice.

Part 177 lists words, titles, and letters that may be used only by people authorized to use them. The bill would add the following to the list: "pharm.d", "doctor of pharmacy", "pharmacy intern", "pharmacy technician", "licensed pharmacy technician", "certified pharmacy technician", "cpht", and "dispensary".

The Code prescribes an application fee and an annual license fee of \$50 and \$25, respectively, for a clinical thermometer. The bill would delete these fees.

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

The trend in Michigan has been to discontinue occupational regulation, and not to regulate additional occupations, unless there is a real need to protect the public. Considering the serious medical consequences that could result from mistakes in drug dispensing, the regulation of pharmacy technicians is clearly important for consumer safety. Although pharmacy technician training programs appear to be abundant, and national certification is available, the requirement for training or certification varies by state. Because Michigan is one of the few states that has no state-level regulation, it is technically possible that someone could be employed as a pharmacy technician without any training. Pharmacies, stores, hospitals, nursing homes, and other locations that employ pharmacy technicians may set their own standards, and most presumably do require or provide some level of training, or require certification. Licensure by the State, however, would ensure that pharmacy technicians met uniform competency requirements, as demonstrated by passage of a national certification exam or a Board-approved employer training program exam. Licensure also would provide a mechanism for regulators to investigate complaints and take action when necessary. While the Board of Pharmacy oversees licensed pharmacists, its authority does not extend to other individuals who assist with the delivery of medication. Under the bill, the licensure of pharmacy technicians would be a subfield of pharmacy practice, and would fall under the Board's regulatory authority.

In addition, the bill would prevent situations in which virtually anyone can be hired as a pharmacy technician, or a store may ask any other employee to fill in for an absent technician. The bill specifically would prohibit anyone other than a pharmacist, pharmacist intern, or pharmacy technician from performing the functions that would require a pharmacy technician license, and would prohibit a pharmacist from allowing anyone under his or her charge from

violating this prohibition. Also, a person who owned, operated, or managed a pharmacy could not allow an employee to violate the prohibition.

Supporting Argument

The credentialing of pharmacy technicians has been recommended by the Controlled Substances Advisory Commission, which was established by statute in 1988 to monitor indicators of controlled substance abuse and diversion, and recommend actions to address identified problems. The Commission first included this recommendation in its 2006/2007 report, based on a study of controlled substance loss reports. Evidently, from 2002 through 2005, pharmacy technicians accounted for about 75% of the thefts of hydrocodone and oxycodone (two popular and addictive painkillers). 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. If licensure were required, a pharmacy technician who lost his or her license due to drug diversion could not simply repeat the behavior at another pharmacy.

Supporting Argument

Pharmacy technicians work as part of a team. Using them to assist with drug dispensing and preparation enables pharmacists to focus on other areas, such as counseling patients, performing medication management, providing disease management programs, and conferring with other health care professionals. By requiring pharmacy technicians to be certified, the bill would assure pharmacists of their assistants' competence, and allow the pharmacists to deliver other patient care services.

Supporting Argument

The Michigan Primary Care Association consists of 35 federally qualified health center organizations, which operate 220 community health center sites throughout Michigan. Each site is in a medically underserved area or serves a medically underserved population. Since many of the clinics operate in remote areas or other locations where patients have little access to transportation, efforts are made to make pharmacists available on site. Recruiting

and retaining pharmacists for these clinics can be a challenge, however. The Association therefore sought approval from the Michigan Department of Community Health and the Board of Pharmacy for the use of remote dispensing devices in several locations. These devices are controlled by an off-site pharmacist who releases the proper prescription and dosage from the machine. A licensed individual still must be present at the clinic to check the accuracy and physically provide the medication to the patient. Using nurses or physician's assistants for this purpose, however, is too expensive and prevents them from providing skilled care to their patients. Pharmacy technicians, on the other hand, have the skill set appropriate for this role. If they were licensed by the State, they could staff the remote dispensing machines and allow the health centers to use nurses and physician's assistants more efficiently.

Legislative Analyst: Suzanne Lowe

FISCAL IMPACT

The bill would have an indeterminate fiscal impact on the Department of Licensing and Regulatory Affairs. It would establish a professional licensing milieu for pharmacy technicians, and establish fees for application processing and annual license renewal of \$25 and \$30, respectively. It is unknown precisely how many pharmacy technicians are employed in Michigan currently, but according to the Pharmacy Technician Certification Board (PCTB), approximately 8,000 pharmacy technicians are currently certified through the PCTB's optional certification program. If all of these pharmacy technicians became licensed through the State program under the bill, LARA would collect approximately \$200,000 in application fees initially, and \$240,000 annually in license fees. It is likely that the actual amount collected would be higher, however, as the PCTB figures include just those who are certified under its optional program; the actual number of practicing pharmacy technicians is likely higher.

The bill also would establish fees for temporary pharmacy technician licenses and limited pharmacy technician licenses of \$15 and \$10, respectively. It is unknown how much revenue would be raised by those fees, but it would generally track the

number of new pharmacy technicians entering the profession each year.

In addition, the bill would remove application processing fees and annual license fees of \$50 and \$25, respectively, for the certification of clinical thermometers. It is unknown how much revenue would be lost by removing these fees, but since the fees are collected based on the number of different models of thermometers sold in the State, it is not likely to be a large amount of revenue.

The Department's costs to implement the proposed licensure program are unknown at this time. To the extent that the revenue collected under the bill exceeded those costs, the bill could have a positive fiscal impact on LARA. The opposite is also true, so the fiscal impact is indeterminate.

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.