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BILL ANALYSIS



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Senate Bill 92 (as enacted)
Sponsor: Senator Mike Green
Senate Committee: Regulatory Reform
House Committee: Health Policy

PUBLIC ACT 285 of 2014

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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. If pharmacy technicians are not required 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 was suggested that the State should require the licensure of pharmacy technicians.

CONTENT

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

- **Requires an individual to be licensed as a pharmacy technician if he or she performs specific functions.**
- **Requires 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.**
- **Excuses certain people from the examination requirement.**
- **Allows the Department of Licensing and Regulatory Affairs (LARA) to issue a 210-day temporary license to a person who is preparing for the required exam.**
- **Allows LARA to issue a limited license to someone employed as a pharmacy technician on the bill's effective date who worked as a pharmacy technician at least 1,000 hours in the previous two years.**
- **Requires a pharmacy or dispensing prescriber that uses the services of a pharmacy technician to ensure that certain requirements are met.**
- **Allows the Board of Pharmacy to require a person to meet continuing education requirements for the renewal of a pharmacy technician license.**
- **Adds a pharmacy technician to the Board, and removes one public member.**

The bill also amends Part 161 (General Provisions) to 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.

The bill will take effect on December 22, 2014.

License Requirement

Under the bill, a person who performs any of the following functions will be considered to be serving as a pharmacy technician and, except as otherwise provided in Part 177, will 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 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 by LARA in consultation with the Board.

The bill defines "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 bill permits the Department of Licensing and Regulatory Affairs to license an individual as a pharmacy technician if he or she meets all of the following requirements:

- Submits 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.
- Passes and submits proof of passage of any of the examinations listed below, except as otherwise provided.

Passage of any of following examinations will 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 covers 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 must 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 does not apply to an individual who meets any of the following:

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

Temporary Licensure

The bill allows LARA to issue a temporary pharmacy technician license to an individual who is preparing for the examination required for licensure. A temporary license will expire 210 days after it is issued.

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

An individual holding a temporary license will be subject to all of the requirements of Part 177 and the rules promulgated by LARA in consultation with the Board, except the examination requirement.

Limited License

The bill permits LARA to issue a limited license as a pharmacy technician to an individual if all of the following are met:

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

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

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

An individual holding a limited license will be subject to all of the requirements of Part 177 and the rules promulgated by LARA in consultation with the Board, except the examination requirement.

The authority to issue a limited license is in addition to the requirement of Section 16182. (That section allows a board to grant a limited license to an individual if the board determines that the limitation is consistent with the ability of the individual to practice the health profession in a safe and competent manner, is necessary to protect the health and safety of patients or clients, or is appropriate to promote the efficient and effective delivery of health care services.)

Continuing Education

The Board of Pharmacy may require a licensee seeking renewal of a pharmacy technician license to give the Department satisfactory evidence that, during the two years immediately before application for renewal, he or she 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 LARA in consultation with the Board.

Currently, the Board may require a licensee seeking renewal of a pharmacist's license to give the Board satisfactory evidence that, during the two years immediately before application for renewal, he or she attended at least 30 hours of continuing education courses or programs, approved by the Board, or satisfactorily completed a proficiency exam according to rules promulgated by the Board. Under the bill, a licensee must provide this evidence to LARA, rather than the Board. The bill also refers to rules promulgated by LARA in consultation with the Board, rather than rules promulgated by the Board.

Pharmacy Responsibilities

The bill requires a pharmacy or dispensing prescriber that uses the services of a pharmacy technician to ensure that all of the following requirements, as applicable, are met:

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

An individual who is not a pharmacist, pharmacist intern, or pharmacy technician may not perform for a pharmacy any of the functions listed in the bill that require licensure as a pharmacy technician. A pharmacist may not allow any individual employed or otherwise under the pharmacist's personal charge to violate this prohibition. A person who owns, manages, operates, or conducts a pharmacy also may 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 adds one pharmacy technician and reduces the number of public members to four.

Part 177 defines "practice of pharmacy" and describes professional functions associated with the practice. The bill specifies that practice of pharmacy includes 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 adds 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 deletes those fees.

MCL 333.16333 et al.

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. Without state-level regulation, it is technically possible for someone to 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, will ensure that pharmacy technicians meet uniform competency requirements, as demonstrated by passage of a national certification exam or a Board-approved employer training program exam. Licensure also will 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 will be a subfield of pharmacy practice, and will fall under the Board's regulatory authority.

In addition, the bill will 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 prohibits anyone other than a pharmacist, pharmacist intern, or pharmacy technician from performing the functions that will require a pharmacy technician license, and prohibits a pharmacist from allowing anyone under his or her charge to violate this prohibition. Also, a person who owns, operates, or manages a pharmacy may not allow an employee to violate the prohibition.

Supporting Argument

The credentialing of pharmacy technicians was 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 is required, a pharmacy technician who loses his or her license due to drug diversion cannot 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 will 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 approximately three dozen federally qualified health center organizations, which operate more than 200 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 are licensed by the State, they will be able to 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 will have an indeterminate fiscal impact on the Department of Licensing and Regulatory Affairs. It establishes a professional licensing milieu for pharmacy technicians, and sets 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 become licensed through the State program under the bill, LARA will collect approximately \$200,000 in application fees initially, and \$240,000 annually in license fees. It is likely that the actual amount collected will 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 establishes fees for temporary pharmacy technician licenses and limited pharmacy technician licenses of \$15 and \$10, respectively. It is unknown how much revenue will be raised by those fees, but it will generally track the number of new pharmacy technicians entering the profession each year.

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

The Department's costs to implement the new licensure program are unknown at this time. To the extent that the revenue collected under the bill exceeds those costs, the bill may 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.