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Senate Bill 340 (as introduced 5-22-19)
Sponsor: Senator Curtis S. VanderWall
Committee: Health Policy and Human Services

Date Completed: 5-23-19

CONTENT

The bill would amend Part 117 (Pharmacy Practice and Drug Control) of the Public Health Code to do the following:

- **Require the Michigan Board of Pharmacy to grant a pharmacy license to an applicant seeking to operate a remote pharmacy if the applicant met certain requirements.**
- **Allow a parent pharmacy to continue operating a remote pharmacy if the Board later granted a license to a pharmacy within 10 miles of the remote pharmacy.**
- **Require a remote pharmacy not under the personal charge of a pharmacist to be staffed by a pharmacy technician.**
- **Require that the pharmacist in charge (PIC) of a parent pharmacy also would have to serve as the PIC of the remote pharmacy.**
- **Require the PIC of a parent pharmacy to establish and maintain a written policy and procedural manual that contained certain information related to a remote pharmacy.**
- **Exempt a remote pharmacy from certain provisions related to the use of a pharmacy technician's services.**
- **Modify certain provisions pertaining to a pharmacist's dispensing a drug to apply to a remote pharmacy.**
- **Specify that certain procedures pertaining to refilling a prescription would not apply to a parent pharmacy or a remote pharmacy under certain circumstances.**

Licensure

Under the bill, the Michigan Board of Pharmacy would have to grant a pharmacy license to an applicant seeking to operate a remote pharmacy if the applicant met all of the following:

- Submitted a completed application and paid the applicable fee under Section 16333 an application fee of \$35 and an annual license fee of \$50.
- Demonstrated to the satisfaction of the Board that the parent pharmacy and the remote pharmacy shared common ownership.
- Met any other requirements for licensure as a pharmacy as established by the Board.

Also, the parent pharmacy and remote pharmacy would have to demonstrate to the satisfaction of the Board that, at the time of the application, the location of the remote pharmacy was not within 10 miles of another pharmacy. This provision would not apply if the remote pharmacy were located at a hospital, clinic, or mental health facility. The Board could waive this requirement.

A parent pharmacy could not operate a remote pharmacy in the State unless the parent pharmacy and the remote pharmacy were each operated in the State and licensed as a pharmacy under Part 117.

"Parent pharmacy" would mean a pharmacy that operates a remote pharmacy through a telepharmacy system. "Telepharmacy system" would mean an interoperable computer system that shares continuous, real-time data and uses a continuous, real-time audio and video link to connect a pharmacist at a parent pharmacy with a remote pharmacy operated by the parent pharmacy.

If the Board granted a pharmacy license to a pharmacy that was located within 10 miles of a remote pharmacy after the remote pharmacy's license was granted or renewed, the parent pharmacy could continue to operate the remote pharmacy.

If a remote pharmacy were not under the personal charge of a pharmacist, the PIC of the parent pharmacy would have to ensure that the remote pharmacy was staffed by a pharmacy technician who, while assisting in the dispensing process, was overseen through the use of a telepharmacy system by a pharmacist who was permitted to oversee activities at a remote pharmacy. ("Pharmacy technician" would mean a pharmacy technician who held a license other than a temporary license or a limited license.)

A pharmacist who was located at a parent pharmacy could not oversee the activities at a remote pharmacy unless the pharmacist was employed by or under contract with the parent pharmacy, or was employed by or under contract with a pharmacy that had contracted with the parent pharmacy, and he or she had access to all relevant patient information that was maintained by the parent pharmacy.

The bill specifies that a prescription dispensed at a remote pharmacy, including a prescription for a controlled substance, would be considered dispensed at the remote pharmacy by the pharmacist who was overseeing the remote pharmacy.

Additionally, if a remote pharmacy were not under the personal charge of a pharmacist, a pharmacist overseeing the pharmacy would have to provide patient counseling through the telepharmacy system in a manner that complied with the Health Insurance Portability and Accountability Act (HIPAA), or regulations promulgated under that Act, before a drug or device was dispensed at the remote pharmacy.

Pharmacist in Charge

Under the Code, a pharmacy must designate a pharmacist licensed in the State as the PIC for the pharmacy. The bill specifies that for a remote pharmacy, the pharmacist designated as the PIC of the parent pharmacy also would have to serve as the PIC of the remote pharmacy.

The Code specifies that a pharmacist may be designated as the PIC for more than one pharmacy, and that he or she must work an average of eight hours a week at each pharmacy for which he or she is the PIC. Under the bill, a pharmacist could be designated as the PIC for not more than three pharmacies, including remote pharmacies. The PIC of a remote pharmacy also would not have to be physically present at the remote pharmacy to satisfy the eight-hour requirement, but could satisfy the requirement through the use of a telepharmacy system.

The Code specifies that a pharmacy open for business must be under the personal charge of a pharmacist. A pharmacist must not simultaneously have personal charge of more than one pharmacy, and the services of the pharmacy must be conducted under the control and

personal charge of the pharmacist. Under the bill, these provisions would not apply to a remote pharmacy.

Policy and Procedural Manual

Under the bill, the PIC of the parent pharmacy would have to establish and maintain a written policy and procedural manual that would have to be available to the Board for inspection upon request and would have to contain each of the following:

- A description of how the remote pharmacy would comply with federal and state laws, rules, and regulations.
- The procedure by which a pharmacist who was overseeing a remote pharmacy would oversee a pharmacy technician at the remote pharmacy who was assisting in the dispensing process, and the procedures by which the pharmacist would provide counseling to patients at the remote pharmacy.
- The procedure for reviewing the prescription drug inventory at the remote pharmacy, and the prescriptions or equivalent records approved by the Board that were on file at the remote pharmacy.
- The policy and procedure for providing adequate security to protect the confidentiality and integrity of a patient's protected health information.
- The procedure for recovering from an event that interrupted or prevented a pharmacist who was overseeing the remote pharmacy from overseeing those operations through the telepharmacy system.
- The procedure for ensuring that a pharmacist who was overseeing the remote pharmacy complied with the Michigan Automated Prescription System before a controlled substance was dispensed.
- The specific acts, tasks, and functions that a pharmacy technician could perform at the remote pharmacy.

Pharmacy Technician

Under the Code, a pharmacy or dispensing prescriber that uses the services of a pharmacy technician must 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.
- The pharmacy technician performs only the activities or functions that he or she is licensed or otherwise authorized to perform.

In addition, a pharmacy or dispensing prescriber that uses the services of a pharmacy technician must ensure that the pharmacy technician only performs the activities or functions described above that he or she is licensed or otherwise authorized to perform under the supervision and personal charge of the pharmacist or dispensing prescriber. Under the bill, this provision would not apply to a remote pharmacy.

Drug Dispensing

The Code prohibits a pharmacist from dispensing a drug requiring a prescription under the federal act or State law except under authority of an original prescription or an equivalent record of an original prescription. Under the bill, a pharmacist who was overseeing a remote pharmacy could dispense a drug pursuant to an original prescription received at a remote pharmacy if he or she received, reviewed, and verified an exact digital image of the prescription received at the remote pharmacy before the drug was dispensed.

The Code also specifies that a pharmacist may dispense a prescription written and signed; in the manner prescribed only if the pharmacist in the exercise of his or her professional judgement determines all of the following:

- Except as otherwise authorized if the prescriber is a physician or dentist, that the prescription was issued pursuant to an existing physician-patient or dentist-patient relationship.
- That the prescription is authentic.
- That the prescribed drug is appropriate and necessary for the treatment of an acute, chronic, or recurrent condition.

Under the bill, this provision would be subject to the provision allowing a pharmacist to dispense a drug pursuant to an original prescription received at a remote pharmacy.

In addition, the Code specifies that a pharmacist may not dispense a drug or device under a prescription transmitted by facsimile or created by an electronic format and printed out for use by the patient unless the prescriber manually signed the document. This provision currently does not apply to a prescription transmitted by a computer to a facsimile machine if that prescription complies with Section 17754. Under the bill, the provision also would not apply to a prescription that was received by a remote pharmacy and made available for review and verification in the manner required above to a pharmacist who was overseeing a remote pharmacy.

(Section 17754 requires an electronically transmitted prescription to comply with HIPAA and to include certain, unaltered information.)

Under the bill, a pharmacist who was overseeing a remote pharmacy would have to review a prescription as required by State and Federal law, rules, and regulations before the drug or device that was the subject of the prescription was dispensed. The pharmacist also would have to ensure that the pharmacist's and the pharmacy technician's initials or other means of identifying the pharmacist and the pharmacy technician involved in the dispensing process were recorded on the prescription and that the specific acts, tasks, or functions performed by the pharmacist or pharmacy technician during the dispensing process were recorded in the pharmacy management system.

Under the Code, after consultation with and agreement from the prescriber, a pharmacist may add or change a patient's address, a dosage form, a drug strength, a drug quantity, a direction for use, or an issue date with regard to a prescription. A pharmacist must note the details of the consultation and agreement and must maintain that documentation with the prescription. The bill specifies that if the drug was dispensed at a remote pharmacy, the pharmacist would have to note the details of the consultation and agreement on the exact digital image of the prescription.

Prescription Refill

Under the Code, a licensee or dispensing prescriber must preserve a prescription or equivalent record of the prescription for not less than five years. A pharmacist may refill a copy of a prescription from another pharmacy if the original prescription has remaining authorized refills, and the copy is issued according to the following procedures:

- The pharmacist issuing a written or oral copy of a prescription must cancel the original prescription and record the cancellation.

- The written or oral copy issued must be a duplicate of the original prescription except that it also must include the prescription number, the name of the pharmacy issuing the copy, the date issued, and the number of authorized refills remaining available to the patient.
- The pharmacist receiving a written or oral copy of the prescription must exercise reasonable diligence to determine whether it is a valid copy, and having done so may treat the copy as an original prescription.
- Except as issued under Part 117, all other copies furnished must be used for information purposes only and clearly marked "for information or reference purposes only".

The Code specifies that the above procedures do not apply to pharmacies that share a real-time, on line database or other equivalent means of communication, or to pharmacies that transfer prescriptions pursuant to a written contract for centralized prescription processing services as provided under Section 17753. (Section 17753 allows a pharmacy to perform centralized prescription processing services, or to outsource those services, if the pharmacies have the same owners or have written a contract outlining the provided services, responsibilities, and accountabilities of each party, and meet other requirements.)

Under the bill, those procedures also would not apply to a parent pharmacy if it received a copy of a prescription from a remote pharmacy that it operated, or to a remote pharmacy if it received a copy of a prescription from a parent pharmacy. "Equivalent record of the prescription approved by the board" or "equivalent record" would include an exact digital image of the prescription.

MCL 333.17707 et al.

Legislative Analyst: Tyler VanHuyse

FISCAL IMPACT

The bill likely would have a minor indeterminate fiscal impact on the Department of Licensing and Regulatory Affairs and no impact on local government. The bill would allow applicants to apply for and obtain a pharmacy license for the operation of a remote pharmacy. The revenue generated likely would cover the administrative and operational costs for those activities.

Fiscal Analyst: Elizabeth Raczkowski

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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.