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Senate Bill 340 (Substitute S-1 as reported)
Sponsor: Senator Curtis S. VanderWall
Committee: Health Policy and Human Services

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RATIONALE

Pharmacists serve an important role in the health care environment. These licensed medical professionals oversee medication management, adherence, and safety. Pharmacists also have regular interactions with patients who return to a pharmacy to refill a prescription or follow-up with concerns. In many instances, a pharmacist at a pharmacy has more consultation with a patient than the patient's primary care physician.

According to testimony before the Senate Committee on Health Policy and Human Services, pharmacies are on the decline in Michigan; recent data on pharmacy licenses in the State show a decrease of 369 licensed pharmacies from 2016 to 2019. Many contend that the decline is a result of a low volume of patients that may not provide enough revenue for a pharmacy to remain open and retain pharmacists onsite. The decline in pharmacies, especially those in often underserved, rural areas, leads to patients traveling farther distances to access a medical professional. This could deter patients from seeking advice from a pharmacist, or adhering to their medication.

In response to these concerns, many states across the country reportedly have implemented remote pharmacy licenses. These licenses allow a pharmacist at a central pharmacy to use telecommunications technology to oversee a pharmacy technician at a remote pharmacy. It has been suggested that the introduction of remote pharmacies in Michigan through a licensure program could increase access to pharmacy services.

CONTENT

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

- **Prohibit a parent pharmacy from operating a remote pharmacy unless each was located in Michigan and licensed as a pharmacy.**
- **Require the Department of Licensing and Regulatory Affairs (LARA) to grant a pharmacy license to an applicant seeking to operate a remote pharmacy if the applicant met certain requirements, including demonstrating that the proposed remote pharmacy would not be within 10 miles of another pharmacy.**
- **Authorize the Department to waive the 10-mile requirement if the applicant provided evidence that the proposed remote pharmacy would be located in an area where there was limited access to pharmacy services.**
- **Require a remote pharmacy not under the personal charge of a pharmacist to be staffed by a qualified pharmacy technician.**
- **Require the pharmacist in charge (PIC) of a parent pharmacy 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 qualified pharmacy technician's services.**
- **Require the PIC to display in a conspicuous location at the remote pharmacy a notice that provided certain information about the remote and parent pharmacy.**
- **Prohibit a remote pharmacy from dispensing more than 225 prescriptions per day.**
- **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, LARA 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 LARA that the parent pharmacy and the remote pharmacy shared common ownership.
- Met any other requirements for licensure as a pharmacy as established by LARA in consultation with the Board.

Also, the parent pharmacy and remote pharmacy would have to demonstrate to the satisfaction of LARA 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 Department could waive this requirement if the applicant provided satisfactory evidence to LARA that the proposed remote pharmacy would be located in an area where there was limited access to pharmacy services and that a compelling circumstance justified waiving the requirement. If a pharmacy license were granted to a pharmacy that was located within 10 miles of a remote pharmacy after the remote pharmacy was granted or renewed a license, the remote pharmacy could continue to operate.

In considering whether to grant a waiver as described above, LARA would have to consider the following, based on the evidence submitted by the applicant:

- Whether the pharmacy that was located within 10 miles from the proposed remote pharmacy was open for business for limited or fewer hours than the remote pharmacy.
- Whether services would be provided at the proposed remote pharmacy that would not be available from the pharmacy that was located within 10 miles from the remote pharmacy.
- Whether access to the pharmacy that was located 10 miles from the proposed remote pharmacy was limited and whether the remote pharmacy would improve patient access to pharmacy services.
- Whether there were transportation barriers to receiving services from the pharmacy that was located within 10 miles from the proposed pharmacy.
- Whether the pharmacy that was located within 10 miles from the proposed remote pharmacy was closing.

A parent pharmacy could not operate a remote pharmacy in the State unless the parent pharmacy and the remote pharmacy each were 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 real-time data and uses a real-time audio and video link to connect a pharmacist at a parent pharmacy with a remote pharmacy operated by the parent pharmacy, and uses a camera that is of sufficient quality resolution to allow a pharmacist at a parent pharmacy who is reviewing a prescription to visually identify the marking on tablets and capsules at the remote pharmacy.

Oversight of 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 qualified pharmacy technician who, while assisting in the dispensing process, would be overseen through the use of a telepharmacy system by a pharmacist who was permitted to oversee activities at a remote pharmacy. ("Qualified pharmacy technician" would mean a pharmacy technician who had at least 1,000 hours of experience working in a pharmacy and who held a license other than a temporary license or a limited license.)

A pharmacist who was located at a parent pharmacy could only oversee the activities at a remote pharmacy if he or she were employed by or under contract with the parent pharmacy or a pharmacy that had contracted with the parent pharmacy, and if 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. A remote pharmacy also could not dispense more than 225 prescriptions per day.

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 & 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 LARA for inspection upon request. The manual 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 qualified pharmacy technician at the 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 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; including a requirement that the remote pharmacy be closed to the public during a time period in which any component of the telepharmacy system was malfunctioning, unless a pharmacist was present.
- 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.
- A requirement that a PIC complete a monthly, in-person inspection of the remote pharmacy.

In addition, the PIC of the parent pharmacy would have to include the specific acts, tasks, and functions that a qualified pharmacy technician could perform at the remote pharmacy. A qualified pharmacy technician could not do any of the following at the remote pharmacy:

- Receive oral orders for prescription drugs.
- Provide consultation regarding a prescription or regarding medical information contained in a patient medication record or patient chart.
- Perform compounding of sterile or nonsterile drugs, except for the reconstitution of an orally administered prescription drug.

Under the bill, the PIC of the parent pharmacy would have to display at the remote pharmacy in a conspicuous location, visible to the public, a notice that provided all of the following information: a) that the pharmacy services were being provided at a remote pharmacy, b) that if patient counseling was provided, it could be provided by a pharmacist using audio and video communication, and c) the address of the parent 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 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 Food, Drug, and Cosmetic 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 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 does not apply to a prescription transmitted by a computer to a facsimile machine if it 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 qualified pharmacy technician's initials or other means of identifying the pharmacist and the qualified 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. When submitting a claim or otherwise seeking reimbursement for a public or private third-party payer for a drug or device that was dispensed under the bill, the pharmacist would have to identify the remote pharmacy as the pharmacy from which the drug device was dispensed.

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, online 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.

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

Remote pharmacies have many medical and economic benefits. According to a study from North Dakota State University, the North Dakota Telepharmacy Project, which uses a centrally located pharmacist to supervise a pharmacy technician at a remote pharmacy site, has produced promising results. The study purports that approximately 80,000 rural citizens have reacquired or retained access to integral pharmacy services. The study also suggests that the Project has added \$26.5 million in economic development and 80 to 100 jobs to rural economies, specifically.

The Project, which is significantly similar to the contents of the bill, could have similar effects on rural communities that currently do not have access to pharmacies. For example, Mason County has experienced a significant reduction in pharmacies located within the county. According to testimony before the Senate Committee on Health Policy and Human Services, Mason County has lost all independently owned pharmacies, and the only pharmacies in there are located in central cities, such as Ludington and Baldwin. This trend has placed a significant burden on rural residents of the County. Allowing remote pharmacies in the State could reintroduce pharmacists to more rural areas, which could contribute to the public health and economic productivity of those areas.

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.