

ALLOW REMOTE PHARMACIES

Phone: (517) 373-8080
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Senate Bill 340 (H-3) as reported from House committee

Sponsor: Sen. Curtis S. VanderWall

1st House Committee: Health Policy

2nd House Committee: Ways and Means

Senate Committee: Health Policy and Human Services

Complete to 12-6-19

Analysis available at
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(Enacted as Public Act 4 of 2020)

BRIEF SUMMARY: Senate Bill 340 would amend Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to allow remote pharmacies under certain specified circumstances, overseen either personally by a pharmacist or remotely using a telepharmacy system. The bill would require that a remote pharmacy and the parent pharmacy overseeing it both be located in Michigan and licensed as a pharmacy under Part 177 of the code.

FISCAL IMPACT: Senate Bill 340 would have an indeterminate net fiscal impact on the Department of Licensing and Regulatory Affairs (LARA). LARA would assume increased administrative responsibility for licensure of remote pharmacies. It is unclear whether licensing activities under this bill would require additional departmental staff or resources. The bill would stipulate that remote pharmacies would be required to pay licensure fees under MCL 333.16333, presumably the same fee that regular pharmacies pay, which is an application processing fee of \$35 and an annual license fee of \$50.

THE APPARENT PROBLEM:

Currently, people in rural areas who need to pick up medication often have to travel long distances to do so. With the rise of technology in medicine, making telemedicine and video conferencing possible, some have suggested allowing remote pharmacies, which would allow pharmacy technicians to dispense medications locally under the supervision of pharmacists. Twenty-three states currently allow remote pharmacies, including states bordering Michigan such as Indiana, Illinois, and Wisconsin. Legislation has been proposed to allow remote pharmacies in Michigan.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to allow *remote pharmacies* under certain specified circumstances, overseen either personally by a pharmacist or remotely using a *telepharmacy system*.

Telepharmacy system would be defined by the bill as an interoperable computer system meeting both of the following requirements:

- 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.

- Uses a camera that is of sufficient quality and resolution to allow a pharmacist at a parent pharmacy who is reviewing a prescription to visually identify the markings on tablets and capsules at the remote pharmacy.

Application requirements and waiver

LARA would have to grant a pharmacy license to a remote pharmacy if it submitted an application and paid the applicable fee, showed LARA that the parent pharmacy and proposed remote pharmacy shared common ownership, demonstrated that the remote pharmacy would not be within 10 miles of another pharmacy (except under certain circumstances), and met any other licensure requirements set by LARA in consultation with the Board of Pharmacy. A remote pharmacy applicant could apply to the board for a waiver of the 10-mile requirement, which the board could grant only if the applicant showed that the area had limited access to pharmacy services and that compelling circumstances justified the waiver.

Oversight at remote pharmacies

A remote pharmacy not under the personal charge of a pharmacist would have to be staffed by a **qualified pharmacy technician** overseen through a **surveillance system** and a telepharmacy system by a qualified pharmacist while assisting in the dispensing process. A pharmacist employed and located at the parent pharmacy could oversee the activities at a remote pharmacy only if the pharmacist had access to all relevant patient information maintained by the parent pharmacy. A prescription dispensed in this way would be considered dispensed at the remote pharmacy by the pharmacist at the parent pharmacy.

A **qualified pharmacy technician** would have to hold a pharmacy technician license other than a temporary license or limited license, have accumulated at least 1,000 hours working in a pharmacy after being granted a qualifying license, and hold national certification as a pharmacy technician from a board-approved organization.

Surveillance system would mean a real-time, continuous audio and visual camera system that connects a pharmacist at a parent pharmacy with a remote pharmacy for the purposes of providing oversight and security surveillance.

Currently under the code, a pharmacist can be designated the pharmacist in charge (PIC) of only one pharmacy. The bill would allow the pharmacist to serve as PIC for up to three pharmacies, including remote pharmacies. (However, not more than two of the pharmacies could be remote pharmacies.) The PIC at a parent pharmacy would be the PIC at the remote pharmacy. A manufacturer would have to designate a pharmacist as PIC for the manufacturer or, if the manufacturer did not hold a license as a pharmacy, the manufacturer would designate an employee with the appropriate education or experience to assume responsibility for compliance with licensing requirements as facility manager for the manufacturer.

The bill also states that, in the case of remote pharmacies, the PIC need not be physically present, but could satisfy the supervision requirements through the telepharmacy system.

Policy and procedure manual

Under the bill, the pharmacist in charge of the parent pharmacy would have to establish and maintain a written policy and procedure manual made available to LARA upon request and containing each of the following:

- A description of how the remote pharmacy will comply with federal and state laws, rules, and regulations.
- The procedure by which the pharmacist at the parent pharmacy oversees a qualified pharmacy technician at the remote pharmacy who is assisting in the dispensing process and the procedure by which the pharmacist provides counseling to patients at the remote pharmacy.
- The procedure for reviewing the prescription drug inventory at the remote pharmacy and prescriptions or equivalent records approved by the board that are 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 interrupts the pharmacist at the parent pharmacy from overseeing the operations of the remote pharmacy through the surveillance system. The procedure would require that the remote pharmacy be closed to the public whenever the surveillance system or telepharmacy system was malfunctioning, unless a pharmacist was present at the remote pharmacy.
- The procedure for ensuring that the pharmacist at the parent pharmacy complies with the Michigan Automated Prescription System (MAPS) for monitoring schedule 2, 3, 4, and 5 controlled substances before dispensing them.
- The specific acts, tasks, and functions that a qualified pharmacy technician may perform at the remote pharmacy. However, a qualified pharmacy technician could not receive oral orders for prescription drugs, provide consultation regarding a prescription or regarding medical information contained in a patient medication record or patient chart, or perform compounding of sterile or nonsterile drugs, except for the reconstitution of prepackaged prescription drugs.
- A requirement that the pharmacist at the parent pharmacy complete a monthly, in-person inspection of the remote pharmacy that includes inventory reconciliation for controlled substances and reviewing video recordings as necessary.
- A policy that requires the pharmacist at the parent pharmacy to retain audio and video recordings from the surveillance system for at least 45 calendar days.

Public notice

The pharmacist at the parent pharmacy would have to display a conspicuous notice at the remote pharmacy stating that the pharmacy services are being offered remotely, that patient counseling could be provided using audio and video communication, and the address of the parent pharmacy.

Dispensation of prescriptions at remote pharmacies

The pharmacist at the parent pharmacy would have to review a prescription as required by state and federal law, rules, and regulations before dispensing it. Additionally, the pharmacist would have to ensure that the identity of the person dispensing the prescription and all other functions required to be completed by the pharmacist or qualified pharmacy

technician were recorded. Also, when seeking reimbursement, the pharmacist would have to identify the remote pharmacy as the point of dispensation.

If the parent pharmacy's pharmacist was not present at the parent pharmacy, the remote pharmacy would have to be closed for business unless another pharmacist was present at the remote pharmacy.

A remote pharmacy could not dispense more than an average of 150 prescriptions in a day during a 90-day period.

The pharmacist at the parent pharmacy could dispense drugs after viewing a digital image of the prescription, rather than the original prescription itself, before the drug is dispensed at the remote pharmacy.

Also, the code currently requires pharmacies refilling a prescription that was originally filled by another pharmacy to comply with specific rules. The bill would treat the parent pharmacy and remote pharmacy as a single entity for the purposes of those requirements.

Required counseling

If a remote pharmacy was not under the personal charge of a pharmacist, any required patient counseling that must take place before a drug or device is dispensed would have to be provided by the pharmacist at the parent pharmacy through the telepharmacy system and in compliance with federal law.

The bill would take effect 90 days after its enactment.

MCL 333.17707 et seq.

HOUSE COMMITTEE ACTION:

The House Committee on Ways and Means reported an H-3 substitute that would do the following:

- Require additional training for pharmacy technicians (1,000 hours working in a pharmacy after being granted a temporary or limited license).
- Further limit the number of prescriptions that could be dispensed. As passed by the Senate, the bill would have allowed a remote pharmacy to dispense up to 225 prescriptions per day; the H-2 substitute would limit the pharmacy to an average of 150 prescriptions in a day during a 90-day period.
- Provide that the bill would take effect 90 days after being enacted.

BRIEF DISCUSSION:

Proponents advanced the bills as a way of expanding access to pharmacy services. Especially in rural and underserved areas, lack of nearby pharmacies acts as a barrier to care. Supporters also argued that remote pharmacies have been in place since 2002 and

currently operate in 23 states, and there have been no issues or cases of drug diversion thus far.

Opposition to the bill was mainly centered on a concern that it lacked necessary safeguards. Some expressed concerns that the initial training required for pharmacy technicians was insufficient; in response, the initial flat 1,000 hour requirement was raised to 1,000 after being granted a qualifying license. Also in response to concerns, the initial requirement of a continuous video recording was replaced with a requirement that a surveillance system providing real-time, continuous audio and visual monitoring be put in place.

POSITIONS:

A representative of Cardinal Health testified in support of the bill. (10-24-19)

The following entities indicated support for the bill:

- Michigan Pharmacists Association (12-4-19)
- Michigan Council of Nurse Practitioners (10-24-19)
- Michigan Primary Care Association (10-24-19)
- Michigan Association of Health Plans (10-24-19)
- Michigan Retailers Association (10-24-19)
- Michigan Health and Hospital Association (10-24-19)
- Henry Ford Health System (10-24-19)

Hometown Pharmacy indicated support for the bill with amendments. (10-24-19)

A representative of the Oakland County Pharmacists Association testified in opposition to the bill. (10-24-19)

Legislative Analyst: Jenny McInerney
Fiscal Analyst: Marcus Coffin

■ 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.