



Telephone: (517) 373-5383

Fax: (517) 373-1986

Senate Bill 920 (as introduced 5-13-20) Sponsor: Senator Peter MacGregor

Committee: Health Policy and Human Services

Date Completed: 5-13-20

CONTENT

The bill would amend Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to do the following:

- -- Allow a pharmacist to dispense an emergency refill of up to a 60-day supply of a prescription drug other than a controlled substance for a State resident if certain circumstances and requirements were met.
- -- Allow a pharmacist to operate temporarily a pharmacy in a location not designated on a pharmacy license.
- -- Allow a pharmacist to dispense and administer a drug as needed to treat an individual with COVID-19 pursuant to protocols described in the bill.
- -- Allow a pharmacist to substitute a therapeutically equivalent drug for a drug that was the subject of a critical shortage.
- -- Allow a pharmacist to oversee a pharmacy technician and other pharmacy staff remotely.
- -- Allow an out-of-State pharmacy, manufacturer, or wholesale distributor that was licensed in another state to do business in Michigan.

The bill's provisions would be repealed effective June 1, 2020.

Under the bill, notwithstanding any provision of Article 15 (Occupations) to the contrary, beginning on the effective date of the bill, all the provisions below would apply.

Emergency Refill Prescription

The bill would allow a pharmacist to dispense an emergency refill of up to a 60-day supply of a prescription drug other than a controlled substance for a resident of the State if, in the pharmacist's professional judgment, a failure to refill the prescription could interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. All of the following would apply for the purpose of this provision:

- -- The pharmacist would have to inform the patient that the prescription was dispensed under these circumstances.
- -- The pharmacist would have to inform the prescriber, in writing and within a reasonable period of time, of any refills that the pharmacist dispensed in this manner.
- -- Before refilling the prescription, the pharmacist would have to make a reasonable effort to communicate with the prescriber regarding refilling it and would have to make a record of the efforts made, including the reason for refilling a prescription.

Page 1 of 3 sb920/1920

-- A prescriber would not be subject to criminal prosecution, civil liability, or administrative sanction as a result of a pharmacist refilling a prescription in the manner described above.

Drug Dispensing & Substitution

A pharmacist could temporarily operate a pharmacy in a location that was not designated on a pharmacy license. However, the pharmacy could not prepare sterile drug products beyond low-risk preparations, as defined by USP standards, for immediate inpatient administration. (U.S. Pharmacopeia establishes reference standards for drug substances, food ingredients, degradation, among other things.)

A pharmacist could dispense and administer a drug as needed to treat an individual with COVID-19 pursuant to protocols established by the Federal Centers for Disease Control and Prevention or the National Institute of Health, or as determined by the chief medical executive in the office of chief medical executive created within the Department of Health and Human Service or the chief medical executive's designee.

A pharmacist could substitute a therapeutically equivalent drug for a drug that was the subject of a critical shortage. A pharmacist substituting a drug for this reason would have to inform the patient of the substitution and notify the prescriber of the substitution within a reasonable period of time. A prescriber would not be subject to criminal prosecution, civil liability, or administrative sanction as a result of a pharmacist's substitution.

Remote Oversight

The bill would allow a preceptor to supervise a student pharmacist remotely to fulfill eligibility requirements for licensure and to avoid a delay in graduation.

A pharmacist could oversee a pharmacy technician and other pharmacy staff remotely through the use of a real-time, continuous audiovisual system that was capable of allowing the pharmacist to visually identify the markings on tablets and capsules. The pharmacist would have to have access to all relevant patient information to accomplish remote oversight and would have to be available at all times during the oversight to provide real-time patient consultation. A pharmacy technician could not perform sterile or nonsterile compounding without a pharmacist on premises.

Out-of-State Business

An out-of-State pharmacy that was in good standing would be considered licensed to do business in the State. An out-of-State pharmacy could not deliver controlled substances into the State and would have to comply with Part 177 and the rules promulgated under it, except that an out-of-State pharmacy would not have to designate a pharmacist in charge for the out-of-state pharmacy. To provide sterile compounding service to a patient in the State, an out-of-state pharmacy would have to hold a current accreditation from a national organization approved by the Michigan Board of Pharmacy.

("Out-of-state pharmacy" would mean a facility or part of a facility that is located outside of the State and that is licensed in another state to dispense prescription drugs or prepare prescription drugs for delivery or distribution.)

In addition, a manufacturer or wholesale distributor that was licensed in another state would be considered licensed to do business in the State. Notwithstanding Article 7 (Controlled Substances) or any rule promulgated under Article 7, a manufacturer or wholesale distributor that held a license in good standing in another state could distribute temporarily a controlled

Page 2 of 3 sb920/1920

substance in the State to a hospital or to a manufacturer or wholesale distributor that was licensed under Part 177.

An out-of-State license would not be considered in good standing for purposes of the bill if it had been suspended or revoked or was the subject of pending disciplinary action in another state. If an out-of-State license described above contained restrictions or conditions, those restrictions or conditions would apply in the State for the purpose of the bill.

Proposed MCL 333.17713 Legislative Analyst: Tyler VanHuyse

FISCAL IMPACT

The bill likely would not have a significant fiscal impact on the Department of Licensing and Regulatory Affairs. It would have no fiscal impact on local units of government.

Fiscal Analyst: Elizabeth Raczkowski

SAS\S1920\s920sa

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.