Gov. Whitmer Issues Executive Order Relaxing Rules on Pharmacists and Out-of-State Wholesale Distributors Amid Coronavirus Pandemic

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On March 10, 2020, Michigan identified its first case of coronavirus ("COVID-19"), prompting Gov. Whitmer to declare a state of emergency. Since then, the Governor issued a series of executive orders to contain the public health and economic effects of COVID-19. On March 25, 2020, Gov. Whitmer signed Executive Order 2020-25 (the "Order"), which eases restrictions on pharmacists and out-of-state wholesale distributors during the COVID-19 pandemic.[1] The Order sets forth a number of emergency procedures to enhance operational capacity, flexibility, and efficiency of pharmacies and distributors. In turn, the Order protects consumer-patients during a time of crisis by regulating the insurance industry.

The Order takes effect immediately and ends on April 22, 2020, but may be renewed as needed.[2] Below is an overview of the Order and its effects on the pharmaceutical, wholesale supplier, and insurance industries.

COVID-19 Treatment by Pharmacists

To effectively and efficiently treat COVID-19 patients, Gov. Whitmer implemented the following rules for pharmacists:

- Pharmacists may temporarily operate a pharmacy in an area that is not designated on the pharmacy license. However, pharmacists cannot prepare sterile drug products beyond low-risk preparations, as defined by USP standards, in these temporary facilities.
- Pharmacists may dispense and/or administer drugs as needed to treat COVID-19 patients. However, the pharmacist must adhere to protocol established by the Centers for Disease Control and Prevention, National Institute of Health, or as determined by the appropriate Chief Medical Executive of the Department of Health and Human Services.

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- In the event of medication shortages, pharmacists may substitute a therapeutic medication for an equivalent without the authorization of the prescriber. The pharmacist must inform the patient and the prescriber of any substitutions within a reasonable time.
- To increase the number of pharmacists servicing patients during the pandemic, preceptors (practitioner-teachers) may supervise student pharmacists remotely. Doing so will also fulfill the student pharmacist's eligibility for licensure and avoid delaying graduation from pharmacy school.

Emergency Prescription Refills

In response to the public need for increased access to therapeutic medication, Gov. Whitmer ordered the following:

- All pharmacists located in Michigan may dispense emergency refills (up to a 60-day supply) of non-controlled, maintenance medication for patients in the state. The pharmacists may use their professional judgment to determine if a failure to refill the prescription will interrupt the patient's ongoing care and have adverse effects on the patient's well-being.
- The pharmacist must inform the prescriber <u>in writing</u> of any emergency prescriptions dispensed under the Order within a reasonable time. The pharmacist must also inform the patient that the medication is prescribed under the Order.
- Prior to refilling a prescription, the pharmacist must make reasonable efforts to communicate with the prescriber about the prescription refill. The pharmacist must make a record of its efforts in informing the prescriber of the refill, as well as record the basis for doing so.
- A prescriber must not incur any criminal or civil liability, or licensing disciplinary action, as the result of the pharmacist refilling the prescription.

Remote Supervision of Pharmacy Technicians and Staff

To ease the burden on pharmacists during the COVID-19 crisis, the Order provides as follows:

- Pharmacists may supervise pharmacy technicians and staff remotely. Supervision must be conducted through real-time technologies with video to allow the pharmacist to see the markings on tablets/capsules.
- While remotely supervising technicians, the pharmacist must have access to all relevant patient information.
- Remote supervision does NOT apply to sterile and non-sterile compounding. A pharmacy technician may not perform sterile or non-sterile compounding without a pharmacist on the premises.

Out-of-State Pharmacies Are Temporarily Licensed in Michigan



In an effort to combat potential medication shortages, the Order provides as follows:

- Pharmacies holding a license, certificate, or another permit in good standing in another state are deemed licensed in the State of Michigan. The following restrictions apply:
 - The out-of-state pharmacies must not deliver controlled substances into the state;
 - The out-of-state pharmacies must abide by all applicable Michigan regulations; and
 - The out-of-state pharmacies must hold a current accreditation from a national organization approved by the Michigan Board of Pharmacy before providing sterile compounding services to patients in Michigan.

Out-of-State Wholesale Distributors are Temporarily Licensed in Michigan

Again, in an effort to combat potential shortages of medication and medical supplies, the Order provides as follows:

- Wholesale distributors holding a license, certificate, or another permit in good standing in another state are deemed licensed to do business in the State of Michigan. The following restrictions apply:
 - The out-of-state wholesale distributor must not deliver controlled substances into the state; and
 - The out-of-state wholesale distributor must abide by all applicable Michigan regulations.

<u>Insurance Coverage for Emergency Prescriptions</u>

The Executive Order also addresses coverage for emergency prescriptions by insurers, which includes disability insurance policies:

- Insurers must cover any emergency refills of covered prescription drugs dispensed by a pharmacist under the Order.
- Health maintenance organizations or disability insurance policies with prescription coverage must cover any emergency refills of covered prescriptions dispensed by a pharmacist under the Order.
- Insurers and health maintenance organizations must also allow for early refills of all 30-day or 60-day covered prescription maintenance medications to allow for up to a 90-day supply regardless of whether the pharmacy is mail-in or order-in-person.
- Insurers and health maintenance organizations may still apply policy or contract provisions governing out-of-network benefits and cost-sharing.

The Order is one of many directives from the Governor's Office to combat the potentially devastating impacts of COVID-19. During a time where medical resources are stretched thin, pharmacists are given leeway to efficiently treat patients affected by the virus while maintaining the health of their usual patients. The Order also protects consumer-patients from running out of medication, while simultaneously mandating coverage for emergency prescriptions. While the Order does relax the rules of administration, pharmacists, wholesale distributors, and insurance carriers should be mindful



of the additional obligations imposed, as set forth above.

The full text of the Order may be found here.

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[1] Office of the Governor, Executive Order No. 2020–25, "Temporary Enhancements to Operational Capacity, Flexibility, and Efficiency of Pharmacies," Dated March 25, 2020.

[2] The Order expires on April 22, 2020 at 11:59 p.m., but may be renewed as needed. A willful violation of the Order is a misdemeanor.

