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BILL ANALYSIS

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Senate Bill 879 (as enacted) **PUBLIC ACT 322 of 2020**
Senate Bill 920 (as enacted) **PUBLIC ACT 324 of 2020**
Sponsor: Senator Peter MacGregor
Senate Committee: Health Policy and Human Services (discharged)
House Committee: Government Operations

Date Completed: 1-19-21

CONTENT

Senate Bill 879 amended the Insurance Code to require an insurer that delivers, issues for delivery, or renews in the State a health insurance policy that provides coverage for prescription drugs to provide coverage for emergency and early refills that meet certain requirements, until March 31, 2021.

Senate Bill 920 amended Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to do the following while a qualified order or declaration is in effect:

- **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 are met, through March 31, 2021.**
- **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 is 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 is licensed in another state to do business in Michigan.**
- **Prohibit an out-of-state pharmacy from delivering a controlled substance, unless it is a compound for a drug shortage, as determined by the FDA.**
- **Allow a pharmacy to confirm delivery of a prescription drug, excluding a controlled substance, by any reasonable means.**

The bills took effect on December 29, 2020.

Senate Bill 879

Under the Insurance Code, an insurer that delivers, issues for delivery, or renews in the State a health insurance policy that provides coverage for prescription drugs and limits those benefits to drugs included in a formulary must do the following:

-- Provide for participation of participating physicians, dentists, and pharmacists in the development of the formulary.

-- Disclose to health care providers and upon request to insureds the nature of the formulary restrictions.
-- Provide for exceptions from the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative.

Upon request for an expedited review of coverage for a nonformulary alternative based on exigent circumstances, an insurer must make a determination and notify the enrollee or the enrollee's designee and the prescribing physician, or other prescriber, as appropriate, of the determination within 24 hours after the insurer receives all information necessary to determine whether the exception should be granted. If this does not apply, an insurer must make a determination on coverage for a nonformulary alternative and notify the enrollee or the enrollee's designee and the prescribing physician, or other prescriber of the determination within 72 hours after the insurer receives all information necessary for the determination.

Under the bill, these provisions are subject to Section 3406w.

The bill creates Section 3406w to specify that, beginning on the bill's effective date, an insurer that delivers, issues for delivery, or renews in the State a health insurance policy that provides coverage for prescription drugs must do both of the following:

-- Provide coverage for an emergency refill of up to a 60-day supply of any covered maintenance prescription drug.
-- Provide coverage for an early refill of any 30-day or 60-day covered maintenance prescription drug to allow for up to a 90-day supply, without regard to whether the pharmacy is mail order or in-person.

"Emergency refill" means a refill where, in the pharmacist's professional judgment, failure to refill the prescription may interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being as provided in Section 17713 of the Public Health Code, which Section Bill 920 adds.

"Maintenance prescription drug" means a prescription drug that meets the requirements under Section 3406t(1)(b)(i) to (iii) of the Insurance Code. (Under Section 3406t(1)(b)(i) to (iii), maintenance prescription drugs must be covered by a group or individual policy, certificate, or contract that provides prescription drug coverage, must be used for management and treatment of a chronic long-term care condition and have authorized refills that remain available to the insured or enrollee, and are not Schedule 2 to 5 controlled substances (not including antiepileptic prescription drugs).

Section 3406w does not apply after March 31, 2021.

Senate Bill 920

Emergency Refill Prescription

The bill allows a pharmacist to dispense, while a qualified order or declaration is in effect and through March 31, 2021, 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 might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. All of the following apply for the purpose of this provision:

-- The pharmacist must inform the patient that the prescription was dispensed under these circumstances.

-- The pharmacist must 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 must make a reasonable effort to communicate with the prescriber regarding refilling it and make a record of the efforts made, including the reason for refilling a prescription.
-- A prescriber is not subject to criminal prosecution, civil liability, or administrative sanction as a result of a pharmacist refilling a prescription in the manner described above.

"Qualified order or declaration" means one of the following issued in response to a qualified epidemic:

-- A state of disaster or state of emergency issued under the Emergency Management Act.
-- An emergency order issued under Section 2253 of the Public Health Code.

(Under Section 2253, if the Director of the Department of Health and Human Services (DHHS) determines that control of an epidemic is necessary to protect the public health, he or she may issue certain emergency orders.)

"Qualified epidemic" means an epidemic involving a respiratory disease that can easily spread between individuals and may result in serious illness or death.

Drug Dispensing & Substitution

A pharmacist may operate temporarily a pharmacy in a location that is not designated on a pharmacy license. However, the pharmacy may not prepare a sterile drug product beyond a low-risk preparation, as defined by USP standards, for immediate inpatient administration. (The US Pharmacopeia establishes reference standards for drug substances, food ingredients, degradation, among other things.)

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

A pharmacy may confirm the delivery of a prescription drug, excluded a controlled substance, to a patient by any reasonable means, including a telephone call, a text message, or e-mail.

The provisions described above apply while a qualified order or declaration is in effect.

Remote Oversight

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

A pharmacist may oversee a pharmacy technician and other pharmacy staff remotely through the use of a real-time, continuous audiovisual system that is capable of allowing the pharmacist to visually identify the markings on tablets and capsules. The pharmacist must

have access to all relevant patient information to accomplish remote oversight and must be available at all times during the oversight to provide real-time patient consultation. A pharmacy technician may not perform sterile or nonsterile compounding without a pharmacist on premises.

The provisions described above apply while a qualified order or declaration is in effect.

Out-of-State Business

An out-of-State pharmacy that is in good standing is considered licensed to do business in the State. An out-of-State pharmacy may not deliver a controlled substance into the State, except notwithstanding Article 7 (Controlled Substances) or any rule promulgated under Article 7, an out-of-State pharmacy may deliver a controlled substance that is a compound for a drug shortage, as determined by the FDA. An out-of-State pharmacy must comply with Part 177 and the rules promulgated under it, except that an out-of-State pharmacy does 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 must hold a current accreditation from a national organization approved by the Michigan Board of Pharmacy.

"Out-of-state pharmacy" means 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 is licensed in another state is 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 holds a license in good standing in another state may distribute temporarily a controlled substance in the State to a hospital or to a manufacturer or wholesale distributor that is licensed under Part 177.

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

The provision described above apply while a qualified order or declaration is in effect.

MCL 500.3406o et al. (S.B. 879)
Proposed MCL 333.17713 (S.B. 920)

BACKGROUND

Coronavirus disease 2019, COVID-19, is a respiratory illness caused by a virus that can spread from person to person. Generally, coronaviruses cause mild, cold-like symptoms; however, severe diseases, such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) also are examples of diseases caused by other forms of coronavirus. Reported symptoms of COVID-19 have ranged from mild (if any) cold-like symptoms in the majority of individuals, to severe illness or death.

The virus that causes COVID-19 was identified as the cause of an outbreak detected in Wuhan City, China, in November 2019. In late January 2020, the first case of COVID-19 in the United States was confirmed. The Michigan DHHS identified the first two positive cases of COVID-19 in Michigan on March 10, 2020. As of January 14, 2021, the DHHS has reported 531,004 confirmed cases and 13,672 deaths attributable to COVID-19.

Throughout the course of the COVID-19 pandemic, Governor Whitmer issued several executive orders under authority granted under the Emergency Management Act (EMA) and the Emergency Powers of the Governor Act (EPGA). These executive orders included orders allowing pharmacists to dispense emergency refills of prescriptions for up to 60 days' worth of supply and requiring insurers to cover early refills for up to 90 days' worth of supply during the ongoing pandemic.

On October 2, 2020, the Michigan Supreme Court issued its ruling on legal challenges to the Governor's authority to issue emergency executive orders under the EMA and EPGA.[1] The Court ruled that the EMA authorized the Governor to issue emergency executive orders only within 30 days of the original declaration of emergency under EO 2020-4, and for additional days authorized by a concurrent resolution adopted by the Legislature. In addition, the Court held that the Governor did not have the authority to exercise emergency powers under PA 302 because that Act delegated legislative power to the executive branch in violation of the Michigan Constitution. This means that any orders in effect on April 30, 2020, were invalidated on May 1, 2020, and any subsequent orders issued after April 30 were invalid and unenforceable upon issuance.

Legislative Analyst: Stephen Jackson

FISCAL IMPACT

Senate Bill 879

The bill requires health insurers to allow early and emergency refills of prescriptions until March 31, 2021. Because, in some cases, the early and emergency refills may last longer than some of the original scripts (60 or 90 days), there may be marginal indeterminate savings from lower dispensing fee costs.

Senate Bill 920

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

Fiscal Analyst: Steve Angelotti
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[1] *In re* Certified Question from the US District Court, Western District of Michigan (*Midwest Institute of Health, PLLC v. Governor*), Docket No. 161492.

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