

REQUIREMENT TO TRANSMIT PRESCRIPTIONS ELECTRONICALLY

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House Bill 4217 (H-3) as referred to second committee

Sponsor: Rep. Joseph N. Bellino, Jr.

1st Committee: Health Policy

2nd Committee: Ways and Means

Complete to 12-3-19

BRIEF SUMMARY: House Bill 4217 would amend Part 73 (Manufacture, Distribution, and Dispensing), Part 161 (General Provisions), and Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code. Largely, the bill would change the provision that currently allows a prescription to be transmitted electronically, as long as it complies with certain requirements, to require a prescriber or his or her agent to transmit the prescription electronically under those circumstances, beginning January 1, 2021. The prescription, including one for a controlled substance, would have to be transmitted directly to the patient's chosen pharmacy.

FISCAL IMPACT: House Bill 4217 would not be expected to have a significant fiscal impact on the Department of Licensing and Regulatory Affairs (LARA) or other units of state or local government. The bill would require the department to issue waivers and promulgate rules, as provided within the bill. There will likely be minor administrative costs to the department for these activities, but costs would likely be sufficiently covered by existing departmental appropriations. The bill would establish a fine of \$250 for each violation of section 17754a of the act, with a cap of \$10,000 in one calendar year (with an increase in limits to \$500 and \$20,000 in 2024). Revenues from fines would depend on the volume of violations and is currently indeterminate.

THE APPARENT PROBLEM:

In response to the recent opioid crisis, various measures have been proposed to reduce the likelihood of fraudulent prescriptions; the electronic prescribing of controlled substances, or EPCS, as an alternative to paper prescriptions, is one of those options. According to committee testimony, 97% of Michigan pharmacies already accept e-prescriptions, with the remaining 3% mostly in hospital and other non-retail environments.

The federal SUPPORT for Patients and Communities Act,¹ which was signed into law in October of 2018, mandated the use of electronic prescribing of controlled substances (EPCS) for all controlled substances under Medicaid Part D by January 1, 2021. This move toward electronic prescribing has driven an increase in legislation on that subject at the statewide level. Reportedly, at least four states² have mandates currently in effect, while

¹ Public Law 115-271, <https://www.congress.gov/bill/115th-congress/house-bill/6/text>

² Minnesota (2011), New York (2016), Maine (2017), Connecticut (2018). <https://mdtoolbox.com/eprescribe-map.aspx?AspxAutoDetectCookieSupport=1>

another 18 states³ have laws requiring e-prescribing for at least certain controlled substances scheduled to take effect between 2019 and 2023.

THE CONTENT OF THE BILL:

The bill would change the provision in the Public Health Code that currently allows a prescription to be transmitted electronically, as long as it complies with certain requirements, to require a prescriber or his or her agent to transmit the prescription electronically under those circumstances, beginning January 1, 2021.

Exceptions

However, the requirement to transmit the prescription would not apply under any of the following circumstances:

- The prescription is issued by a licensed veterinarian.
- Electronic transmission is unavailable due to a temporary technological or electrical failure.
- The prescriber has received a waiver from LARA based on an inability to electronically transmit prescriptions due to an economic hardship, technical limitation beyond his or her control, or other exceptional circumstance. (A prescriber would have to notify LARA if the inability ceased to exist. A waiver would be valid for up to one year, and would be renewable).
- The prescriber reasonably believes that electronically transmitting the prescription would make it impractical for the patient to obtain the prescription drug in a timely manner and that the delay would adversely affect the patient's medical condition.
- The prescription for a schedule 2 through 5 controlled substance is dispensed orally due to a specified emergency situation.
- The prescription would be dispensed outside of Michigan.
- The prescription would be dispensed in Michigan but the prescriber is located out of state.
- The prescription would be issued and dispensed in the same health care facility and the patient would use the prescription exclusively in that facility.
- The prescription contains content not supported by the National Council for Prescription Drug Programs' prescriber/pharmacist script standard.
- The prescription is for a drug for which the FDA requires content that cannot be transmitted electronically.
- The prescription is issued under circumstances in which the prescriber is not required to include the name of the patient on the prescription.
- The prescription is prescribed under a research protocol.
- The drug would be administered in a hospital, nursing home, hospice, dialysis treatment clinic, freestanding surgical outpatient facility, or assisted living residence.

If the prescription was not electronically transmitted because of certain specified exceptions, the prescriber would have to document the applicable exception in the patient's

³ Arizona, Arkansas, California, Colorado, Indiana, Iowa, Kansas, Kentucky, Massachusetts, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Virginia, Washington, Wyoming.

medical record. If it was not electronically transmitted because of technology failure or because the prescriber believed it to be impractical, the prescriber would have to document the specific reason in the patient's medical record.

Beginning on January 1, 2021, a practitioner could only dispense a prescription for a schedule 2 to 5 controlled substance upon receipt of a prescription form if he or she believed in good faith that it was issued under a qualifying exception to the electronic transmission requirement and that the prescriber had documented the reason.

Additionally, the bill would add violation of the new requirement to transmit a prescription electronically unless an exception applied to the list of grounds for disciplinary subcommittee action. When one of these grounds was alleged, LARA would have to investigate the allegation, and could hold hearings, administer oaths, and order the taking of relevant testimony in the course of its investigation. After its investigation, LARA would have to provide a copy of the administrative complaint to the appropriate subcommittee. If the subcommittee found that one or more of the grounds existed, it would have to proceed with the sanctions detailed in section 16226 of the Public Health Code.

Under the bill, until December 31, 2023, if the requirement were violated, the disciplinary subcommittee could impose a fine of \$250 for each violation, but the aggregate fine for multiple violations could not exceed \$10,000 in a calendar year. Beginning January 1, 2024, the fine would be raised to \$500 with a yearly maximum of \$20,000.

The bill would require LARA, in consultation with the Michigan Board of Pharmacy, to promulgate rules to implement these requirements.

If the federal Centers for Medicare & Medicaid Services delayed the Medicare requirement for electronic transmission of controlled substance prescriptions beyond January 1, 2021, LARA would have to, by rule, delay the implementation date to the implementation date of the Medicare requirement.

MCL 333.7333 et al.

ARGUMENTS:

For:

Supporters advanced e-prescribing as a safer, more efficient, more convenient way of transmitting prescriptions. Additionally, without the requirement that patients receive, retain, and deliver a paper copy of the prescription, proponents argue that patient adherence would be higher, with fewer abandoned prescriptions. E-prescriptions would also eliminate the difficulty of reading medical terms in indecipherable handwriting, which, in turn, would drive down health care costs.

Against:

Opponents supported the goal of aligning state and federal requirements, but expressed reservations about the cost for universal adoption of electronic health records. The internet

is not as widely available in rural areas, they argued, and mandatory e-prescribing may present a hardship. Additionally, they noted that there is not complete adoption of two-factor authentication, or two-step verification, which they cited as a key safeguard. In two-factor authentication, the prescriber must input one set of identifying features (such as email and password) and is then prompted to input another on another device (for instance, via a one-time-use password sent to the prescriber's cell phone). This step is intended to prevent fraud.

POSITIONS:

Representatives of the following entities testified in support of the bill:

Michigan Retailers Association (6-6-19)
National Association of Chain Drug Stores (6-6-19)

The following entities indicated support for the bill:

CVS Health (6-6-19)
Michigan Association of Health Plans (6-6-19)
Michigan Council of Nurse Practitioners (6-6-19)
Walgreens (6-6-19)
Michigan Pharmacists Association (6-6-19)
Blue Cross Blue Shield of Michigan (6-6-19)

Representatives of Michigan State Medical Society testified in opposition to the bill as written. (6-6-19)

The following entities indicated opposition to the bill:

Michigan Academy of Family Physicians (6-6-19)
Michigan Psychiatric Society (6-6-19)

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.