

ELECTRONIC TRANSMISSION OF PRESCRIPTIONS

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House Bill 4217 as enacted
Public Act 134 of 2020
Sponsor: Rep. Joseph N. Bellino, Jr.

Analysis available at
<http://www.legislature.mi.gov>

Senate Bill 248 as enacted
Public Act 136 of 2020
Sponsor: Sen. Ruth Johnson

Senate Bill 254 as enacted
Public Act 135 of 2020
Sponsor: Sen. Dale W. Zorn

1st House Committee: Health Policy
2nd House Committee: Ways and Means
Senate Committee: Health Policy and Human Services
Complete to 4-9-21

BRIEF SUMMARY: The bills amend the Public Health Code to change a provision that previously allowed a prescription to be transmitted electronically, as long as it complied with certain requirements, to instead require a prescriber or his or her agent to transmit a prescription electronically, beginning October 1, 2021. The prescription, including one for a controlled substance, must be transmitted directly to the patient's chosen pharmacy. Additionally, SB 248 includes technical amendments to resolve issues concerning the registration and licensure of acupuncturists.

FISCAL IMPACT: The bills would have an indeterminate fiscal impact on the Department of Licensing and Regulatory Affairs (LARA) and would not affect any other unit of state or local government. (See **Fiscal Information**, below, for a detailed discussion.)

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 (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 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 23 states² have mandates currently in effect, while another seven states³ have laws requiring e-prescribing for at least certain controlled substances scheduled to take effect between 2021 and 2023.

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); Pennsylvania (2019); Arizona, Iowa, North Carolina, Oklahoma, Rhode Island, and Virginia (2020); and Arkansas, Delaware, Florida, Indiana, Kentucky, Massachusetts, Missouri, Nevada, South Carolina, Tennessee, Texas, and Wyoming (2021).
<https://mdtoolbox.com/eprescribe-map.aspx>

³ California, Colorado, Kansas, Maryland, New Mexico, Utah, and Washington.

THE CONTENT OF THE BILLS:

House Bill 4217 amends Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to remove a provision that allowed a prescription to be transmitted electronically as long as it complied with the Health Insurance Portability and Accountability Act (HIPAA) and other confidentiality, format, and information requirements. The bill instead requires a prescriber or his or her agent to transmit a prescription electronically, directly to a pharmacy of the patient's choice, beginning October 1, 2021. The prescription must still comply with HIPAA and the other requirements. A pharmacist must exercise professional judgment regarding the accuracy, validity, and authenticity of an electronically transmitted prescription before dispensing it.

Exceptions

However, the requirement to transmit the prescription electronically does 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 from the requirement to transmit prescriptions electronically, as described below. (A waiver is valid for up to two years, and is renewable).
- The prescriber reasonably believes that electronically transmitting the prescription makes 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. (In documenting this exception as required below, the prescriber must document the specific reason for his or her belief that the delay would have an adverse effect on 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 is issued, dispensed, and used exclusively in a hospital, nursing home, hospice, dialysis treatment clinic, freestanding surgical outpatient facility, or assisted living residence.
- The prescription contains content not supported by the prescriber/pharmacist script standard of the National Council for Prescription Drug Programs.
- The prescription is for a drug for which the federal Food and Drug Administration (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.

If a prescription was not electronically transmitted because of an exception specified above, the prescriber must document the applicable exception in the patient's medical record and provide the documentation to LARA upon request. A pharmacist does not have to determine whether an exception applies before dispensing a prescription that was not transmitted electronically.

Waiver from requirement to transmit electronically

If a prescriber cannot meet the requirements to transmit prescriptions electronically while complying with HIPAA and the other confidentiality and information requirements, the prescriber may apply for a waiver from LARA. The rules established by LARA for a waiver cannot be more stringent than federal Medicare waiver rules, and LARA must grant a state waiver if a prescriber shows evidence of a federal waiver.

If the federal Centers for Medicare & Medicaid Services delays the Medicare requirement for electronic transmission of controlled substance prescriptions beyond October 1, 2021, LARA must, by rule, delay the bill's implementation date to the implementation date of the Medicare requirement.

MCL 333.17754 and proposed MCL 333.17754a

Senate Bill 254 adds violation of the provisions of HB 4217 (e.g., the new requirement to properly transmit a prescription electronically unless an exception or waiver applies) to the list of grounds for action by a health profession's disciplinary subcommittee. If LARA has a reasonable basis to believe that a violation occurred, it is not required to investigate, but may issue a letter notifying the licensee of the violation. The letter is not considered discipline.

MCL 333.16221 and 333.16221b

Senate Bill 248 allows a pharmacist to dispense, in good faith, a controlled substance included in Schedules 2 to 5 that is a prescription drug under federal law upon receiving a prescription that is electronically transmitted under HB 4217. As before, a practitioner may also in good faith dispense a controlled substance upon receipt of a prescription on a prescription form or a Schedule 3 to 5 controlled substance upon receipt of a practitioner's oral prescription.

The bill also removes the ability of a prescriber to transmit a prescription for a controlled substance by fax of a printed prescription form or electronic transmission of a printed prescription form once the provisions of HB 4217 become effective.

Violation and penalty

The bill provides that, if a health professional violates the provisions of HB 4217 (e.g., fails to properly transmit a prescription electronically unless an exception or waiver applies), a disciplinary subcommittee must impose a fine of \$250 for each violation.

Acupuncturists

2019 PA 140 amended the Public Health Code to remove provisions regarding the registration of acupuncturists and instead provide for their licensure.⁴ That amendatory act provided that its licensure provisions do not take effect until rules are promulgated to implement them, yet it also immediately removed from the law many provisions governing registration, leaving a gap in the transition from one regulatory framework to the other.

SB 248 restores, until the rules providing for licensure have been promulgated, provisions that allow for and govern the registration of acupuncturists.

MCL 333.7333 et seq.

⁴ See <https://www.legislature.mi.gov/documents/2019-2020/billanalysis/House/pdf/2019-HLA-4710-AAF6505B.pdf>

BACKGROUND:

Under Part 177, which House Bill 4217 amends, *electronically transmitted prescription* means the communication of an original prescription or refill authorization by electronic means including computer to computer, computer to fax machine, or email transmission that contains the same information as when the prescriber or his or her agent transmitted the prescription. It does not include a prescription or refill authorization transmitted by phone or fax machine.

FISCAL INFORMATION:

House Bill 4217 would not be expected to have a significant fiscal impact on LARA or other units of state or local government. The bill would require LARA to issue waivers and promulgate rules. There will likely be minor administrative costs incurred for these activities, but such costs would likely be sufficiently covered by existing departmental appropriations.

Senate Bills 248 and 254, jointly examined, would have an indeterminate fiscal impact on LARA. Senate Bill 248 would allow the imposition of a \$250 fine for violations related to the electronic transmission of prescriptions. Revenue from the fines would depend on the volume of violations and is presently indeterminate, though LARA indicated that any fine revenue would be deposited to the Health Professions Regulatory Fund. LARA would have expanded administrative responsibilities under the bills, including conducting investigations to determine whether grounds for disciplinary action exist (with respect to the contents of the bills). Existing departmental resources would likely be sufficient to absorb the costs of these activities. The bills would not affect any other unit of state or local government.

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.

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■ 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.