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BILL ANALYSIS



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House Bill 4217 (Substitute H-4 as passed by the House)

Sponsor: Representative Joseph N. Bellino, Jr.

House Committee: Health Policy
Ways and Means

Senate Committee: Health Policy

Date Completed: 6-18-20

CONTENT

The bill would amend the Public Health Code to do the following:

- **Beginning January 1, 2021, require a prescriber or his or her agent to transmit a prescription, including a prescription for a controlled substance, electronically to a pharmacy of the patient's choice.**
- **Specify certain circumstances under which the requirement to transmit a prescription electronically would not apply.**
- **Allow a prescriber to apply to the Department of Licensing and Regulatory Affairs (LARA) for a waiver, and require LARA to grant the waiver, if the prescriber could not electronically transmit a prescription because of certain circumstances.**
- **Allow a practitioner to dispense a controlled substance included in Schedules 2 through 5 that was a prescription drug after receiving a prescription that was electronically transmitted.**
- **Include a violation of the electronic transmission requirements among the grounds for disciplinary action.**
- **Require a disciplinary subcommittee to assess a fine against a licensee who violated the bill's provisions.**
- **Specify that, if the Federal Centers for Medicare and Medicaid Services delayed the Medicare requirement for the electronic transmission of prescriptions for controlled substances beyond January 1, 2021, LARA could delay the implementation of the electronic transmission requirement.**

Electronic Transmission of Prescription

Under the Code, except as otherwise provided by Article 7 (Controlled Substances), Article 8 (Pharmaceutical-Grade Cannabis), and the Federal Food, Drug, and Cosmetic Act (FDCA), a prescriber or his or her agent may transmit a prescription electronically if the prescription is transmitted in compliance with the Health Insurance Portability and Accountability Act (HIPAA), or regulations promulgated under HIPAA, and the data are not altered or modified in the transmission process. The prescription must include certain information from the prescriber, including the full name of the patient, an electronic signature or other identifier from the prescriber, the time and date of the transmission, the pharmacy intended to receive the prescription, and any other information required by FDCA or State law.

The electronic equipment or system utilized in the transmission and communication of electronically transmitted prescription must provide adequate confidentiality safeguards and

be maintained to protect patient confidentiality as required under any applicable Federal and State law and to ensure against unauthorized access. The electronic transmission of a prescription must be communicated in a retrievable, recognizable form acceptable to the intended recipient.

Before dispensing a prescription that is electronically transmitted, a pharmacist must exercise professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.

Under the bill, these provisions would apply until the bill's effective date.

Additionally, under the bill, except as otherwise provided under Article 8, the FDCA, or below, beginning January 1, 2021, a prescriber or his or her agent would have to transmit electronically a prescription, including a prescription for a controlled substance, directly to a pharmacy of the patient's choice. An electronically transmitted prescription would have to comply with HIPAA as described above, and would have to include all of the information currently required for electronically transmitted prescriptions.

The electronic equipment or system utilized in the transmission and communication of electronically transmitted prescription would have to provide adequate confidentiality safeguards and be maintained to protect patient confidentiality as required under any applicable Federal and State law and to ensure against unauthorized access. The electronic transmission of a prescription could not include "dispense as written" or "d.a.w." as a default setting.

Before dispensing a prescription that was electronically transmitted, a pharmacist would have to exercise professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.

An electronically transmitted prescription that met the bill's requirements would be the original prescription.

Exceptions

The requirement to transmit a prescription electronically would not apply under any of the following circumstances:

- A veterinarian licensed under Article 15 (Pharmacy Practice and Drug Control) issued the prescription.
- The prescription was issued under a circumstance in which electronic transmission was not available due to a temporary technological or electrical failure.
- The prescriber had received a waiver from LARA, as described below.
- The prescription was orally prescribed under the Code.
- The prescriber issued a prescription to be dispensed outside of the State.
- The prescription was issued by a prescriber who was located outside of the State to be dispensed by a pharmacy located inside the State.
- The prescription was issued and dispensed in the same health care facility and the individual for whom the prescription was issued used the drug exclusively in the health care facility.
- The prescription contained content that was not supported by the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard.
- The prescription was for a drug for which the Food and Drug Administration (FDA) required the prescription to contain content that could not be transmitted electronically.

- The prescription was issued under circumstances in which the prescriber was not required to include on the prescription the name of a patient for whom the prescriber issued it.
- The prescriber issued a prescription under a research protocol.

(As used above, "health care facility" would include a hospital, a hospice, a dialysis treatment clinic, a freestanding surgical outpatient facility, a nursing home, or another long-term care facility that provided rehabilitative, restorative, or ongoing skilled nursing care to an individual who needed assistance with activities of daily living.)

Also, the electronic transmission requirement would not apply if the prescription were issued by a prescriber who reasonably believed 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 his or her medical condition.

If a prescription for a controlled substance were not electronically transmitted under certain specified exceptions, the prescriber would have to document the applicable exception at the time the prescriber issued the prescription. If the prescription were not electronically transmitted because the prescriber reasonably believed 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 his or her medical condition, the prescriber also would have to document the specific reason for not electronically transmitting the prescription. The prescriber would have to provide the documentation required to LARA upon request.

A pharmacist who received a prescription that was not transmitted electronically to the pharmacy could dispense the prescription without determining whether an exception described above applied.

Waiver

If a prescriber could not meet the electronic transmission requirements, the prescriber could apply to LARA for a waiver. The Department would have to grant a waiver to a prescriber if it determined that the prescriber could not meet the transmission requirements due to an economic hardship, technological limitation that was not reasonably within the control of the prescriber, such as insufficient internet connectivity or the use of a health record technology certified by the Federal Centers for Medicare and Medicaid services that did not allow for the electronic transmission of a prescription for a controlled substance, or another exceptional circumstance. A waiver would be valid for a period of up to one year and would be renewable.

Dispensing a Controlled Substance

Under the Code, a practitioner, in good faith, may dispense a controlled substance included in Schedule 2 after receiving a prescription from a practitioner licensed under the Code. A practitioner, in good faith, also may dispense a controlled substance included in Schedule 3, 4, or 5 that is a prescription drug as determined by the FDCA, or Section 17708 of the Code, after receiving a prescription on a prescription form, or a practitioners' oral prescription. Under the bill, a practitioner also could dispense a controlled substance in Schedule 2, 3, 4, or 5 after receiving an electronically transmitted prescription.

The Code prohibits a prescribing practitioner from using a prescription form for a purpose other than prescribing. A prescribing practitioner may not postdate a prescription form that contains a prescription for a controlled substance.

A prescriber may transmit a prescription by facsimile of a printed prescription form and by electronic transmission of a printed prescription form, if not prohibited by Federal law. Under the bill, this provision would apply until the bill's effective date.

Disciplinary Action; Sanctions for Violation

Section 16221 requires LARA to investigate allegations that grounds exist for disciplinary action against a licensee or registrant, and authorizes LARA to investigate activities related to the practice of a health profession licensee, registrant, or applicant for licensure or registration. After its investigation, LARA must provide a copy of the administrative complaint to the appropriate disciplinary subcommittee. After finding the existence of one or more of the grounds for disciplinary subcommittee action as described under the Code, a disciplinary subcommittee must impose one or more sanctions as prescribed by the Code.

The listed grounds relate to one or more general categories, including a violation of a general duty consisting of negligence or failure to exercise due care, a personal disqualification (such as incompetence, lack of moral character, or substance use disorder), a prohibited act, an unethical business practice, or unprofessional conduct, or specific violations of the Public Health Code or other acts.

Under Section 16226, after finding the existence of one or more of the grounds for disciplinary action, a disciplinary subcommittee must impose one or more sanctions for each violation.

Under the bill, the disciplinary subcommittee would have to proceed under Section 16226 if it found that there was a violation of the proposed requirement to transmit a prescription electronically. The bill would prescribe a \$250 fine for a licensee who violated the bill's provisions.

Under Section 16621b, if LARA has a reasonable basis to believe that a licensee has failed to register or to obtain and review a MAPS report, LARA is not required to investigate and may issue a letter notifying the licensee of the violation. A letter is not considered discipline. Under the bill, these provisions also would apply to a licensee who violated provisions pertaining to electronic transmission of a prescription.

Rules

Under the bill, LARA, in consultation with the Board of Pharmacy, would have to promulgate rules to implement the bill's provisions.

In addition, if the Federal Centers for Medicare and Medicaid Services delayed the Medicare requirement for the electronic transmission of prescriptions for controlled substances beyond January 1, 2021, then LARA could, by rule, delay the implementation date of the bill's proposed changes to a date that did not extend past the date established by the Federal Centers for Medicare and Medicaid Services for the Medicare requirement.

MCL 333.7333 et al.

Legislative Analyst: Stephen Jackson

FISCAL IMPACT

The bill would have a minor fiscal impact on the Department of Licensing and Regulatory Affairs and no fiscal impact on local units of government. The bill would establish a \$250 fine for violations of the electronic prescription transmission requirement. The revenue collected from this fine would depend on the number of violations. The cost of promulgating rules and

monitoring compliance with the new requirements likely would be absorbed by existing appropriations.

Fiscal Analyst: Elizabeth Raczkowski

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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.