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BILL ANALYSIS

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Senate Bill 248 (as introduced 3-21-19)
Sponsor: Senator Ruth Johnson
Committee: Health Policy and Human Services

Date Completed: 6-6-19

CONTENT

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

- **Beginning January 1, 2020, 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 due to certain circumstances.**
- **Allow a practitioner to dispense a controlled substance in Schedule 2, 3, 4, or 5 after receiving of a prescription that was electronically transmitted.**
- **Include a violation of the electronic prescription transmission requirement among the grounds for disciplinary action.**
- **Require a disciplinary subcommittee to assess a fine against a licensee who violated the bill's provisions.**

The bill would take effect 90 days after its enactment.

Electronic Transmission of Prescription

The Code currently allows a prescriber to transmit a prescription by facsimile of a printed prescription form, if not prohibited by Federal law. If, with the patient's consent, a prescription is transmitted electronically, it must be transmitted directly to a pharmacy of the patient's choice and the data must not be altered, modified, or extracted in the transmission process. The bill would delete this provision.

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, 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.

Under the bill, except as otherwise provided under Article 8, the FDCA, or below, beginning January 1, 2020, 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.

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 transition 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 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.
-- 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 the prescription.
-- The prescription was issued by a prescriber under a research protocol.
-- The prescription was for a drug that was administered to the individual for whom the drug was prescribed in a hospital, nursing home, hospice, dialysis treatment clinic, freestanding surgical outpatient facility, or assisted living residence.

(As used above, "health care facility" would include a hospital, hospice, 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.)

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, due to an economic hardship, a technological limitation that was not reasonably within the control of the prescriber, or another exceptional circumstance, could not transmit a prescription electronically and maintain adequate confidentiality safeguards as required under any applicable Federal and State law.

A prescriber who was granted a waiver would have to notify LARA in writing if he or she subsequently could meet the requirements. A waiver that was granted under this provision would be valid for a period not to exceed one year and would be renewable.

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

Prescription Dispensing; Controlled Substance

The Code specifies that, except as otherwise provided, 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 could dispense a controlled substance in Schedule 2, 3, 4, or 5 after receiving an electronically transmitted prescription as described above.

Grounds for Disciplinary Action; Submission of Prescription Electronically

Section 16221 of the Public Health Code 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.

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 the bill, the disciplinary subcommittee would have to proceed under Section 16226 if it found that there was a violation of Section 17754 (the requirement to transmit a prescription electronically).

Sanction for Violation

If a disciplinary subcommittee finds that one or more of the grounds for disciplinary action in Section 16221 exist, it must impose one or more of the sanctions described in Section 16226. The sanctions vary depending on the nature of the grounds for disciplinary action. For a conviction of a violation of Section 17754, the bill would require a disciplinary subcommittee to impose a fine of $250 for each violation; however, the aggregate fine that could be imposed on a licensee or registrant for multiple violations could not exceed $5,000 in one calendar year.

MCL 333.7333 et al.

Legislative Analyst: Tyler VanHuyse

FISCAL IMPACT

The bill would have an indeterminate fiscal impact on State government and no fiscal impact on local government. The Department of Licensing and Regulatory Affairs could incur some costs associated with rule promulgation administrative activities. Current appropriations likely would be sufficient to fund these costs. A disciplinary subcommittee could impose a fine of $250 per violation, but aggregate fines imposed on a licensee or registrant would be limited to a total of $5,000 per calendar year. Fine revenue would be deposited into the Health Profession Regulatory Fund.

Fiscal Analyst: Elizabeth Raczkowski

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