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BILL ANALYSIS

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Senate Bill 254 (as introduced 4-9-19)
Sponsor: Senator Dale W. Zorn
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, 2021, require a prescription for a controlled substance that was an opioid or benzodiazepine to be transmitted electronically to a pharmacy in a manner that complied with the Code.**
- **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 transmit electronically a prescription due to certain circumstances.**
- **Specify certain circumstances under which the requirement to transmit a prescription electronically would not apply.**
- **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.**

Electronic Transmission of Prescription

Currently, the Code allows a prescriber to 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. If, with a patient's consent, a prescription is electronically transmitted, it must be transmitted directly to a pharmacy of the patient's choice by the prescriber or the prescriber's authorized agent, and the data must not be altered, modified, or extracted in the transmission process. Under the bill, these provisions would be subject to Section 7333c.

Under the bill, except as otherwise provided, beginning January 1, 2021, a prescription for a controlled substance that was an opioid or a benzodiazepine would have to be transmitted electronically to a pharmacy in a manner that complied with Section 17754 of the Code. An electronically transmitted prescription would have to include information described in Section 17754 and would have to be transmitted directly to a pharmacy of the patient's choice by the prescriber or the prescriber's authorized agent.

(Section 17754 of the Code requires the electronic transmission of a prescription to comply with Article 7 (Controlled Substances) and Article 8 (Pharmaceutical-Grade Cannabis) of the Code, and the Federal Food, Drug, and Cosmetics Act. The electronic transmission also must comply with the Health Insurance Portability and Accountability Act (HIPAA), or regulations promulgated under HIPAA, and the data of the prescription may not be altered or modified in the transmission process. The electronic transmission 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 HIPAA or State law).

"Electronically transmitted prescription" would mean that term as defined in Section 17703 of the Code: the communication of an original prescription or refill authorization by electronic means including computer to computer, computer to facsimile machine, or electronic mail transmission that contains the same information it contained when the prescriber or his or her agent transmitted the prescription. The term would not include a prescription or refill authorization transmitted by telephone or facsimile machine.

Waiver

If a prescriber could not meet the requirements proposed above, he or she could apply to LARA for a waiver. The Department would have to grant the prescriber a waiver if it determined that the prescriber could not meet the requirements due to an economic hardship, a technological limitation that was not reasonably within the control of the prescriber, or another exceptional circumstance. 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 would be valid for a period not to exceed one year and would be renewable.

Exceptions

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

-- A veterinarian issued the prescription.
-- The prescription were issued under a circumstance in which electronic transmission were not available due to a temporary technological or electrical failure.
-- A prescriber who had received a waiver issued the prescription.
-- 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 drug in a timely manner and that the delay would adversely affect the patient's medical condition.
-- The prescription was orally prescribed under the Code.
-- A 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 who was prescribing under a research protocol.
-- The prescription was for a drug that was administered to the individual for whom it was prescribed in a hospital, nursing home, hospice, dialysis treatment clinic, freestanding surgical outpatient facility, or assisted living residence.

-- "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.

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

Grounds for Disciplinary Action

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 7333c.

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 7333c, the bill would require a disciplinary subcommittee to impose a fine of $250; 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 administrative activities. Existing 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 maximum 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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