Senate Fiscal Agency
P.O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986

Senate Bill 248 (Substitute S-4 as reported)
Senate Bill 254 (Substitute S-2 as reported)
Sponsor: Senator Ruth Johnson (S.B. 248)
Senator Dale W. Zorn (S.B. 254)
Committee: Health Policy and Human Services

Date Completed: 7-11-19

RATIONALE

Electronic prescribing, or e-prescribing, is the use of a technological system by prescribers to write and transmit a patient's prescription to a participating pharmacy. If a physician uses e-prescribing, the process often replaces the use of written or faxed prescriptions. Some believe that the use of e-prescribing, instead of written or faxed prescriptions, creates a healthier and more accurate prescription process by improving patient's compliance and adherence to certain medications, improving oversight of interactions between concurrently prescribed drugs, and deterring tampered and fraudulent prescriptions.

Evidently, e-prescribing has grown significantly in past years, and as of 2018, the Federal government signed legislation requiring all Medicare Part D controlled substance prescriptions to be sent through e-prescribing by January 1, 2021. Moreover, e-prescription practices are becoming more widely accepted. At least 23 states across the United States now require e-prescribing with certain exemptions. The current national average for prescriptions processed through e-prescribing is 24%; the average in states like Maine and New York, which have required the use of e-prescribing in recent years, are 55% and 76%, respectively. Accordingly, it has been suggested that the Legislature require physicians to use the e-prescribing process for all prescriptions, including scheduled drugs, to increase the use of the process and achieve the associated benefits.

CONTENT

Senate Bill 248 (S-4) 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 due to certain circumstances.**
-- **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.**
-- **Require a disciplinary subcommittee to assess a fine against a licensee who violated the bill's provisions.**

Senate Bill 254 (S-2) would amend the Public Health Code to do the following:

-- 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.

The bills are tie-barred. Each bill would take effect 90 days after its enactment.

Senate Bill 248 (S-4)

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, 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, 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.

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 was issued for an individual who was the patient of a hospices and the individual used the drug exclusively while under the care of the hospice.
-- 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.
-- The prescription was issued by a prescriber who was providing care to a patient who was the subject of the prescription on a voluntary, unpaid basis or which neither the patient nor a third party would be charged or billed.

(As used above, "health care facility" would include a hospital, dialysis treatment clinic, a freestanding surgical outpatient facility, a skilled nursing facility, 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, including a prescription under Section 5110, 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 (Section 5110 governs expedited partner therapy, which essentially allows a patient to receive a prescription without an examination under certain circumstances related to certain sexually transmitted infections.)

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 a 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 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.

Sanction for Violation; 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. 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 bill would prescribe a fine for a licensee who violated the bill's provisions.

The fine for a violation would be $250; however, the aggregate fine that a disciplinary subcommittee could impose for multiple violations could not exceed $5,000 in one calendar year.

Rules

Under the bill, LARA, in consultation with the Board of Pharmacy, would have to promulgate rules to implement the contents of the bill by July 1, 2020.

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.

Senate Bill 254 (S-2)

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 could dispense a controlled substance in Schedule 2, 3, 4, or 5 after receiving an electronically transmitted prescription as proposed in Senate Bill 248 (S-4).

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 were a violation of the proposed requirement to transmit a prescription electronically.

MCL 333.16226 & 333.17754 (S.B. 248)
333.7333 & 333.16221 (S.B. 254)

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

According to the National Institute on Drug Abuse, opioid abuse and addiction is a serious national crisis related to public health and social and economic welfare. More than 130 people die every day in the United States from opioid overdoses. In Michigan, a 2015 report from the Prescription Drug and Opioid Abuse Task Force indicated that the number of drug overdose deaths in the State had more than tripled since 1999, and that, in 2015, the State ranked 15th in the nation for drug overdose deaths.

Electronic prescribing could help fight the opioid crisis in the State by deterring "doctor shopping", a strategy employed by people to acquire narcotic prescriptions from several doctors, by facilitating prescriptions through a central location. Requiring e-prescriptions also could prevent prescription fraud and forgery by reducing the risk of alterations to a prescription during transmission from prescriber to pharmacy. As a preventative measure, e-prescribing could lead to less illicit drug diversion, which, according to testimony before the Senate Committee on Health Policy and Human Services, is a method employed by 3.0 % to 9.0 % of opioid abusers. Electronic prescribing could contribute greatly as the State continues to combat the opioid crisis.

Supporting Argument
Medication adherence generally involves factors like filling prescriptions, properly taking medications, and refilling prescriptions as needed. Poor medication adherence can disrupt disease management and treatment, which could lead to further health complications. Some studies suggest that poor medical adherence also leads to direct health care costs between $100.0 billion and $300.0 billion annually in the United States. According to the Centers for Disease Control and Prevention (CDC), medication adherence is a public health priority with the potential to drastically reduce negative health and economic outcomes associated with diseases.

Poor medication adherence results from many factors: a patient may forget to take his medication or may actively refuse due to economic constraints; providers may disincentive patients from adhering to a prescribed medication by failing to engage a patient in the treatment decision; or, the complexity of the healthcare system could confuse a patient and the patient or prescriber could fail to deliver a prescription to a pharmacy. These factors, among others, drive poor medication adherence, which results in poor economic and health outcomes.

Among other strategies, studies suggest that e-prescribing increases medical adherence. According to the CDC, the use of e-prescribing increased first-fill medication adherence by 10% when compared to paper prescriptions. Electronic prescribing also can inform patients automatically when a new prescription becomes available or should be ordered, which could improve continued adherence beyond the initially filled prescription. Similarly, e-prescribing could allow prescribers to check on a patient's medical adherence. This monitoring could inform physicians about patient safety, and could allow physicians to create better solutions for patients who fail to adhere to their medication for certain reasons. The e-prescribing bill's requirements would have positive effects on patients' health and would alleviate the economic burden of poor medical adherence on the healthcare system.

Supporting Argument
Numerous studies suggest that prescription errors are a major issue in the healthcare industry. Prescription errors could include an incorrectly dispensed drug, an incorrect dosage, or an incorrect frequency or duration of treatment. These errors often result from illegible handwriting, shorthand abbreviations, or miscalculation within the prescription process. Prescription errors detract from the efficacy and timeliness of treatment for a patient, and in severe cases, can be fatal.

Among other things, the use of the computerized systems of e-prescribing is a preventative measure that studies have found to decrease the prevalence of prescription errors. For example, one study on the effects of e-prescribing in relation to prescription errors purports that, over the course of one year and more than 3,500 prescriptions, physicians using e-prescribing technologies decreased prescription errors from 42.5 per 100 prescriptions to 6.6 per 100 prescriptions. Electronic prescribing could increase the success of treatments and save lives by ensuring that prescribers accurately can relay information to pharmacists.

Opposing Argument
While e-prescribing presents a range of benefits, requiring prescribers to adopt the practice could be unreasonably burdensome. Some barriers to the adoption of e-prescribing include cost, technology demands, and properly trained staff. According to testimony before the Senate Committee on Health Policy and Human Services, it is not unusual for practices to pay $500 or more a month for e-prescribing functions. This cost, in addition to the cost of technology upgrades and additional staff training, could become burdensome for smaller practices. The technological challenges that some physicians encounter also could inhibit the adoption of e-prescribing; rural practices often suffer from inconsistent and expensive broadband connectivity, which would be necessary for the adoption of e-prescribing. These challenges could deter many practices in Michigan from adopting e-prescribing, which could result in a fine under the bill.

To ensure that the benefits of e-prescribing are realized, the Legislature should consider ways to correct vendor behaviors that keep adoption rates of e-prescribing relatively low. One debilitating vendor behavior related to adoption of e-prescribing is the tendency to block information sharing across electronic health record interfaces; this occurs when developers and vendors do not make different interfaces compatible, and the practice generates additional, inhibitive fees. Instead of mandating e-prescribing by a certain date, the Legislature should regulate vendors to increase the affordability and organic adoption of e-prescribing.

Legislative Analyst: Tyler VanHuyse

FISCAL IMPACT

Senate Bill 248 (S-2) and Senate Bill 254 (S-4) 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

SAS\A1920\s248a