

Legislative Analysis



MEASURES TO ADDRESS OPIOID ABUSE

Phone: (517) 373-8080
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Senate Bill 270 (H-2) as reported from House committee
Sponsor: Sen. Steven Bieda

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

Senate Bill 273 (S-1) as reported from House committee
Sponsor: Sen. Rick Jones

Senate Bill 274 (S-2) as reported from House committee
Sponsor: Sen. Marty Knollenberg

House Committee: Health Policy
Senate Committee: Health Policy
Complete to 10-18-17

(Enacted as Public Acts 247, 250, and 251 of 2017)

BRIEF SUMMARY:

Senate Bills 270, 273, and 274 would amend the Public Health Code to include certain measures intended to combat opioid abuse. SB 270 would require a bona fide prescriber-patient relationship before a licensed prescriber could prescribe a schedule 2 to 5 controlled substance, with certain exceptions. SB 273 would require provision of substance use disorder services information when treating a patient for an opioid-related overdose. SB 274 would limit the supply of an opioid a prescriber could prescribe to a patient being treated for acute pain. Senate Bills 273 and 274 would take effect 90 days after enactment.

FISCAL IMPACT:

Senate Bill 270 would likely result in minor cost increases for the Department of Licensing and Regulatory Affairs (LARA). There would not be significant costs to other units of state or local government.

The bill would create several new responsibilities for LARA, specifically for the Bureau of Community and Health Systems (BCHS). LARA would be required to promulgate rules in conjunction with several state boards that regulate the medical professions. The BCHS would be responsible for investigating instances where a bona fide relationship does not exist between a patient and a prescriber. Section 16226 of the bill would allow LARA to assess fees on prescribers who violate the new provisions, which would allow the department to mitigate some of its costs.

Senate Bill 273 would likely result in a minor cost increase for the Department of Licensing and Regulatory Affairs, specifically for the Bureau of Community and Health Systems (BCHS). The BCHS may experience increased costs for additional investigatory functions and for enforcement actions. The bill would not have any fiscal impact for other units of state or local government.

Senate Bill 274 would not have any significant fiscal impacts on any units of state or local government.

THE APPARENT PROBLEM:

The bills are part of a larger push by the legislature to combat the ongoing opioid epidemic in Michigan and nationwide. According to the Centers for Disease Control and Prevention, 91 Americans die each day from an opioid overdose.¹

In response, concerned parties have considered solutions ranging from improved education about the risk and responsible use of prescription opioids; additional reporting requirements for physicians and other prescribers; and increased availability of opioid antagonists, which could prevent deaths from overdoses. Michigan's October 2015 Prescription Drug & Opioid Abuse Task Force report² included a series of findings and recommendations, some of which have been introduced in the bills described in this analysis and HBs 4403-4408 (described below, in **Background**), as well as Senate Bills 47,³ 166, 167, and 360.⁴

Senate Bill 270 is intended to address one of those findings: that the absence of a bona-fide physician-patient relationship often results in the over-prescribing of controlled substances. Recommendation #7 in the Treatment section of the report “recommends requiring a bona-fide physician-patient relationship as defined in Michigan law prior to prescribing controlled substances.” (pg. 21 of the report)

THE CONTENT OF THE BILLS:

Senate Bill 270: Bona Fide Prescriber-Patient Relationship Required

Senate Bill 270 would amend the Public Health Code to provide that, beginning March 31, 2018, a licensed provider may not prescribe a controlled substance listed in schedules 2 to 5 unless the prescriber is in a bona fide prescriber-patient relationship with the patient being prescribed the controlled substance. Instances in which a bona fide relationship are not required may be defined by the Department of Licensing and Regulatory Affairs (LARA), in consultation with certain interested parties (described below) within a year of the date this bill takes effect. Additionally, with certain exceptions, the prescriber must provide follow-up care or refer the patient to a licensed prescriber for follow-up care. Finally, the bill would prescribe disciplinary sanctions for violation of the relationship requirement.

The bill defines a ***bona fide prescriber-patient relationship*** as a treatment or counseling relationship between a prescriber and a patient in which both of the following are present:

- The prescriber has reviewed the patient's relevant medical or clinical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant medical evaluation of the patient conducted in person or via telehealth.

¹ <https://www.cdc.gov/drugoverdose/epidemic/index.html>

² http://www.michigan.gov/documents/snyder/Prescription_Drug_and_Opioid_Task_Force_Report_504140_7.pdf

³ [http://www.legislature.mi.gov/\(S\(p4lkalqd15zt3b3gugjrjrxo\)\)/mileg.aspx?page=getObject&objectName=2017-SB-0047](http://www.legislature.mi.gov/(S(p4lkalqd15zt3b3gugjrjrxo))/mileg.aspx?page=getObject&objectName=2017-SB-0047)

⁴ <http://www.legislature.mi.gov/documents/2017-2018/billanalysis/House/pdf/2017-HLA-0360-CC6B1241.pdf>

- The prescriber has created and maintained records of the patient's condition in accordance with medically accepted standards.

(A *prescriber* is defined in Section 17708 of the Code as a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed physician's assistant, a licensed optometrist certified under Part 174 to administer and prescribe therapeutic pharmaceutical agents, an advanced practice registered nurse as that term is defined in Section 17201 who meets the requirements of Section 17211a, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.)

Exceptions to a bona fide prescriber-patient relationship

Within one year of the date this bill takes effect, LARA, in consultation with certain interested parties, may promulgate rules describing the circumstances under which a bona fide prescriber-patient relationship is not required for purposes of prescribing a schedule 2 to 5 controlled substance, as otherwise required in this bill. The interested parties would include: the Michigan Board of Medicine, the Michigan Board of Osteopathic Medicine and Surgery, the Michigan Board of Dentistry, the Michigan Board of Podiatric Medicine and Surgery, the Michigan Board of Optometry, the Michigan Task Force on Physician's Assistants, and the Michigan Board of Nursing.

In instances in which the parties determine a bona fide prescriber-patient relationship is not required, the parties may prescribe an alternative requirement which must be met in order to prescribe a schedule 2 to 5 controlled substance.

Follow-up care

Under the bill, if a licensed prescriber prescribes a controlled substance under the new rule, the prescriber must provide follow-up care to monitor the efficacy of the controlled substance as a treatment of the patient's medical condition. If unable to provide follow-up care, the prescriber must refer the patient for follow up care to the patient's primary care provider or, if the patient does not have a primary care provider, to another licensed prescriber who is geographically accessible to the patient.

Violation of the bona fide prescriber-patient relationship

Additionally, the bill would add violation of the new requirement for a bona fide prescriber-patient relationship when prescribing certain controlled substances to the list of grounds for disciplinary subcommittee action. When one of these grounds is alleged, LARA must investigate the allegation, and may hold hearings, administer oaths, and order the taking of relevant testimony in the course of its investigation. After its investigation, LARA must provide a copy of the administrative complaint to the appropriate subcommittee. If the subcommittee finds that one or more of the grounds exist, it must proceed with the sanctions detailed in Section 16226 of the Code.

Under the bill, if the requirement is violated, a prescriber would be subject to probation, limitation, denial, fine, suspension, revocation, or permanent revocation.

MCL 333.7303a, 333.16221, and 333.16226, and proposed 333.16204e

Senate Bill 273: Provision of Substance Use Disorder Services Information

Senate Bill 273 would amend the Public Health Code to require a licensee or registrant who treats a patient for an opioid-related overdose to provide information to the patient on substance use disorder services.

Substance use disorder services as used in the bill includes both of the following, as defined in Section 100d of the Mental Health Code (MCL 330.1100d):

Substance use disorder prevention services: services that are intended to reduce the consequences of substance use disorders in communities by preventing or delaying the onset of substance abuse and that are intended to reduce the progression of substance use disorders in individuals. Substance use disorder prevention is an ordered set of steps that promotes individual, family, and community health; prevents mental and behavioral disorders; supports resilience and recovery; and reinforces treatment principles to prevent relapse.

Substance use disorder treatment and rehabilitation services: providing identifiable recovery-oriented services including early intervention and crisis intervention counseling services for individuals who are current or former individuals with substance use disorder; referral services for individuals with substance use disorder, their families, and the general public; and planned treatment services, including chemotherapy, counseling, or rehabilitation for individuals physiologically or psychologically dependent upon or abusing alcohol or drugs.

Proposed MCL 333.16282

Senate Bill 274: Limiting Prescriptions for Controlled Substances

Senate Bill 274 would amend the Public Health Code to allow a pharmacist to fill partially in increments a prescription for a Schedule 2⁵ controlled substance in certain situations. It would also limit the supply of an opioid a prescriber could prescribe to a patient being treated for acute pain, beginning July 1, 2018.

Specifically, the bill would state that a pharmacist may partially fill in increments a prescription for a Schedule 2 controlled substance in any of the following three instances:

- The pharmacist is unable to supply the full quantity of the controlled substance prescribed or the patient requests a smaller quantity of the controlled substance than

⁵ Controlled substances are classified based on the risk of abuse or harm. Schedule 1 drugs include heroin, LSD, and Ecstasy, and have no currently accepted medical use. Schedule 2 drugs have the highest potential for abuse of the medically-acceptable drugs and include Dilaudid, OxyContin, and fentanyl.

was prescribed. A prescription that was partially filled under this section must not be filled more than 30 days after the prescription was issued.

- The prescription was filled upon the oral prescription of a practitioner. The pharmacist who fills this prescription must record the quantity dispensed and maintain that documentation. A prescription partially filled under this section must not be filled more than 72 hours after the first partial filling.
- The prescription is for a terminally ill patient whose terminal illness is documented by the pharmacist as required by the Michigan Board of Pharmacy or its designated or established authority. A prescription partially filled under this section must not be filled more than 60 days after the prescription was issued.

Currently under the Code, a prescription may only be filled partially under the third instance—in the case of a terminally ill patient.

The bill would also create a new section of the Code which would provide that a prescriber treating a patient for acute pain may not prescribe more than a seven-day supply of an opioid within a seven-day period.

Acute pain as used in that section would mean pain that is the normal, physiological response to a noxious chemical or a thermal or mechanical stimulus and is typically associated with invasive procedures, trauma, and disease and usually lasts for a limited amount of time.

MCL 333.7333 and proposed 333.7333b

HOUSE COMMITTEE ACTION:

The House Health Policy committee reported out the Senate-passed versions of Senate Bills 273 and 274. The committee adopted an H-2 substitute to SB 270, which incorporated changes made to sections 16221 and 16226 of the Code by recently enacted public acts, and struck the enacting language that the bill would take effect 90 days after enactment.

BACKGROUND INFORMATION:

Earlier in the 2016-2017 session, the House Health Policy committee reported House Bills 4403-4408, which would do all of the following:

- Specifically provide that an individual may receive medically necessary treatment for opioid use. (HB 4403)
- Define and allow for the licensure of pain management facilities by the Department of Licensing and Regulatory Affairs (LARA). (HB 4404)
- Allow a pharmacist to refuse to fill a prescription for a schedule 2-5 controlled substance, if the pharmacist has a reasonable and good-faith belief that it was not written in good faith or would not be filled for a medical purpose. (HB 4405)

- Require the Prescription Drug and Opioid Abuse Commission to develop recommendations on teaching about opioid abuse in schools. (HB 4406)
- Require the Michigan Department of Education (MDE) to make available a model program of instruction based on those recommendations to school districts and public school academies (PSAs); and to ensure that the model program, at least, is included in the state's Model Core Curriculum content standards and the health education component of the Merit Curriculum graduation requirements. (HB 4407)
- Require a prescriber to discuss certain issues and obtain a signed parental consent form before issuing the first prescription to a minor in a single course of treatment for a controlled substance containing an opioid. The bill would also amend two existing sections to make failure to comply with these requirements a violation punishable by probation, limitation, denial, fine, suspension, revocation, or permanent revocation of the prescriber's license. (HB 4408)

SB 4408 was reported from the Senate Health Policy committee on October 11, 2017, and is under consideration by the Committee of the Whole. SB 4404 is currently under consideration by the full House. The other bills in that packaged have been referred to the Senate Health Policy committee.

ARGUMENTS:

For:

Proponents believe that SB 274, which allows pharmacists to fill a prescription partially for a Schedule 2 controlled substance, would present patients and pharmacists with important flexibility. Often, patients stop taking a prescription for pain medication when the pain becomes manageable or because of adverse effects from the medication. For some patients, this means that they only take a few doses, with the remaining pills sitting in a medicine cabinet, vulnerable to abuse by family or friends. According to a recent review of six studies,⁶ between 67% and 92% of patients reported unused opioids after surgical procedures. None of those studies reported more than 9% of patients planning to follow U.S. Food and Drug Administration-recommended disposal methods for the pills.

Supporters argue that patients could request a smaller amount of Schedule 2 controlled substance if they do not want the full prescription, thereby reducing the risk of pills being improperly disposed of, lost, stolen, sold, or given to others.

Against:

Several physician groups oppose SB 274, as they believe it is unnecessary. They argue that those in the medical profession and pharmacists are already moving to limit the number of pills prescribed for acute pain. For example, CVS Pharmacy recently announced that it will limit opioid prescriptions to seven days for certain conditions starting February 1, 2018. Reportedly, other health insurance companies are beginning to implement similar limits; the largest health insurer in southeastern Pennsylvania, Independence Blue Cross, began limiting low-dose opioid prescriptions in July to a maximum of five days.⁷

⁶ "Unused Opioids Reported by Two Thirds of Surgery Patients, <https://www.medscape.com/viewarticle/883732>

⁷ <http://www.phillyvoice.com/independence-blue-cross-placing-new-limit-on-opioid-drug-prescriptions/>

If the legislature does proceed with SB 274, they suggested that the language more closely resemble that in a set of rules adopted in Ohio in August 2017. These rules, enacted by the Ohio State Medical Board, Board of Pharmacy, Dental Board, and Board of Nursing, also set a seven-day limit (five days for minors), but allow a provider to deviate from the limit if they provide a specific reason in the patient's medical record. Opponents of SB 274 believe that this is a crucial recognition of the importance of medical discretion.

POSITIONS:

A representative of Families against Narcotics testified in support of Senate Bills 270 and 273. (9-27-17)

The following organizations indicated support for all three bills:

- Department of Licensing and Regulatory Affairs (9-27-17)
- Office of the Lieutenant Governor (9-27-17)
- Michigan Association of Treatment Court Professionals (9-27-17)

The following organizations indicated support for SB 270:

- Michigan Association of Health Plans (9-20-17)
- Michigan Health and Hospital Association (9-20-17)
- Michigan Pharmacists Association (9-20-17)
- Blue Cross Blue Shield of Michigan (9-20-17)

The following organizations indicated support for SB 273:

- Office of the Attorney General (10-4-17)
- Blue Cross Blue Shield of Michigan (9-20-17)

The following organizations indicated support for SB 274:

- Michigan Association of Health Plans (9-27-17)
- Michigan Pharmacists Association (9-27-17)
- McKesson Corporation (10-4-17)

The National Association of Chain Drug Stores and the Michigan Retailers Association support SB 274 in concept. (9-27-17)

Michigan State Medical Society is neutral on the bill. (9-27-17)

The Michigan Osteopathic Association opposes SB 274 as written. (9-27-17)

The Michigan Health and Hospital Association opposes SB 274. (9-27-17)

The Michigan Academy of Family Physicians opposes SB 274 as written. (10-4-17)

Legislative Analyst: Jenny McInerney
Fiscal Analyst: Marcus Coffin

■ 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.