Legislative Analysis



STANDING ORDER FOR OPIOID ANTAGONIST

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House Bill 5326 as enacted Public Act 383 of 2016

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

Sponsor: Rep. Anthony G. Forlini House Committee: Health Policy Senate Committee: Health Policy

Complete to 2-5-18

BRIEF SUMMARY: House Bill 5326 amends the Public Health Code to allow the state's chief medical executive to issue a standing order that does not identify a particular patient for the purpose of allowing a pharmacist to dispense an opioid antagonist. The standing order would also allow a pharmacist to act upon that order and dispense an opioid antagonist to be used to treat a person for a drug overdose. The bill also makes other amendments to the Code.

FISCAL IMPACT: House Bill 5326 has minor one-time fiscal implications for the Department of Health and Human Services (DHHS) to collaborate with the Department of Licensing and Regulatory Affairs (LARA) on the promulgation of rules. The bill would not likely have a significant fiscal impact on LARA. It would require LARA to promulgate rules (in consultation with the DHHS and local health departments) regarding dispensing, training, and referral to implement a standing order issued by the chief medical executive for the dispensing of opioid antagonists. The cost of rules promulgation is not likely to be significant. The bill would not have a significant fiscal impact on local units of government.

THE APPARENT PROBLEM:

The Partnership for Michigan's Health has testified that "our communities face a crisis that affects people across the demographic spectrum. Opioid overdoses are taking the lives of mothers, fathers, and children at alarming rates." (As they note, "Opioids include heroin and prescription pain pills like morphine, codeine, oxycodone, methadone and Vicodin.")¹

As part of continuing efforts by the DHHS to address opioid and heroin use in the state, the Michigan Prescription Drug and Opioid Abuse Task Force appointed by Governor Snyder released its report of findings and recommendations for action in October of 2015. The introduction of the bill stems from this report, specifically its finding that "Naloxone is a safe and life-saving drug that should be more accessible."

Between 1999 and 2014, according to the report, accidental drug deaths quadrupled in Michigan, with opioids the leading cause. Administering naloxone hydrochloride after an opioid overdose incident requires only basic training, but is often the difference between life and death. This bill expands its availability.

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¹ http://house.michigan.gov/sessiondocs/2015-2016/testimony/Committee335-4-26-2016.pdf

² http://www.michigan.gov/documents/snyder/Presciption Drug and Opioid Task Force Report 504140 7.pdf

THE CONTENT OF THE BILL:

House Bill 5326 amends the Public Health Code to allow the state's chief medical executive to issue a standing order that does not identify a particular patient for the purpose of allowing a pharmacist to dispense an opioid antagonist. It would also allow a pharmacist to act upon that order and dispense an opioid antagonist to be used to treat a person for a drug overdose.

Standing order for opioid antagonist

Section 17744b of the Code allows a prescriber to issue a prescription for, and a pharmacist to dispense an opioid antagonist to, any of the following:

- An individual patient at risk of experiencing an opioid-related overdose.
- A family member, friend, or other individual in a position to assist the patient.
- A person who acts at the direction of the prescriber or dispensing prescriber, stores the
 opioid antagonist in compliance with applicable rules, dispenses or administers the opioid
 antagonist under a valid prescription, and performs these functions without charge or
 compensation.

The bill adds Section 17744e to Part 177 of the Code (Pharmacy Practice and Drug Control) to expand the parameters for prescription and dispensation to include a standing order by the state's chief medical executive for the purpose of a pharmacist's dispensing opioid antagonists to individuals suffering from drug overdoses.

The chief medical executive who issues the standing order and the pharmacist who dispenses the opioid antagonist <u>are not liable</u> in a civil action for damages resulting from the dispensing of the opioid antagonist or the administration of or failure to administer the opioid antagonist.

Additionally, the bill requires LARA, in consultation with the DHHS, to promulgate rules regarding dispensing, training, and referral to implement this section.

Chief medical executive: Section 2202 of the Code provides that if the director of the DHHS appointed by the governor is not a physician, the director must appoint a physician to serve as chief medical executive and to be responsible to the director for the medical content of policy and programs.

Opioid antagonist: Section 1106 of the Code defines this as naloxone hydrochloride or any other similarly acting and equally safe drug approved by the federal Food and Drug Administration for the treatment of a drug overdose.

Other Public Health Code amendments

The bill amends Section 7321, which prescribes inventory requirements for manufacturers, distributors, prescribers, and dispensers of controlled substances, to require that the inventory be retained and available for inspection by DHHS for two years, rather than being submitted annually to the Michigan Board of Pharmacy. The bill also removes a \$25,000 civil fine for failing to conduct the inventory or submit it to the Board.

The bill also amends Section 7333a to continue the applicability of two provisions that had either recently expired or were set to expire soon. The first allows the director of DHHS to share data from the state's controlled substances electronic monitoring system with health care

payment or benefit providers, notwithstanding any patient-practitioner privilege. The second allows the DHHS to request information from health care payment or benefit providers regarding their access to and use of the electronic monitoring system in the previous calendar year.

In the same section, the bill removes two provisions relating to the Controlled Substances Advisory Commission, which was abolished by Executive Order 2016-15. The first required the Controlled Substances Advisory Commission to report every year on the implementation of the electronic monitoring system. The second listed the Controlled Substances Advisory Commission among entities that must consult with the DHHS on paper prescription forms that minimize the potential for forgery.

Finally, the bill amends Section 18813 to provide that statutory continuing education requirements for veterinarians and veterinary technicians take effect January 1, 2020.

MCL 333.7109 et seq. and proposed MCL 333.17744e

BACKGROUND INFORMATION:

The Highlights of the 2015 American Heart Association Guidelines Update for CPR and ECC³ added the following language to address specific actions recommended in case of an opioid overdose:

For patients with known or suspected opioid addiction who are unresponsive with no normal breathing but a pulse, it is reasonable for appropriately trained lay rescuers and BLS [Basic Life Support] providers, in addition to providing standard BLS care, to administer intramuscular (IM) or intranasal (IN) naloxone. Opioid overdose response education with or without naloxone distribution to persons at risk for opioid overdose in any setting may be considered.

Reportedly, more than half of the 50 states have naloxone standing order programs, through which a doctor <u>may</u> issue a standing order under the doctor's license. In 2015, Pennsylvania and Maryland initiated <u>statewide</u> standing orders for naloxone.⁴

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[■] 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.

³ https://eccguidelines.heart.org/wp-content/uploads/2015/10/2015-AHA-Guidelines-Highlights-English.pdf

⁴See https://www.governor.pa.gov/naloxone-standing-order/ and

 $[\]frac{http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/Documents/Standing\%20Order\%202015/ORP\%20Statewide\%20Naloxone\%20Standing\%20Order\%20Pharmacy\%20Guidance\%20FINAL.pdf}{}$