

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
FOR A STANDING ORDER FOR DISPENSING OPIOID ANTAGONISTS
EMERGENCY RULES

CERTIFICATE OF NEED FOR EXTENSION OF EMERGENCY RULES

Pursuant to Section 48(1) of 1969 PA 306, as amended, MCL 24.248(1), I hereby certify that it is necessary to extend the effectiveness of the Standing Order for Dispensing Opioid Antagonists Rules, which were filed with the Secretary of State on May 27, 2017, for an additional 6 months, therefore, "Standing Order for Dispensing Opioid Antagonists" Rules shall remain effective until May 27, 2018.



Rick Snyder, Governor

11/21/2017

Date

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING

EMERGENCY RULES

FOR A STANDING ORDER FOR DISPENSING OPIOID ANTAGONISTS

Filed with the Secretary of State on

These rules take effect upon filing with the Secretary of State
and shall remain in effect for 6 months

(By the authority conferred on the Department of Licensing and Regulatory Affairs by section 17744e, of 1978 PA 368, being MCL 333.17744e and on the Department of Health and Human Services by sections 2221, 2226, and 2233, of 1978 PA 368, being MCL 333.2221, 333.2226 and 333.2233)

FINDING OF EMERGENCY

These rules are promulgated by the Department of Licensing and Regulatory Affairs (LARA) to establish emergency rules for the implementation of provisions from 2016 PA 383 (Act), effective March 28, 2017, which allows the Office of the Chief Medical Executive to issue a standing order that does not identify particular patients at the time it is issued for the purpose of a pharmacist dispensing opioid antagonists. The Act requires LARA, in consultation with the Michigan Department of Health and Human Services and local health departments, to promulgate rules regarding dispensing, training, and referral to implement the Act.

Michigan has been experiencing a persistently growing opioid abuse problem over the last several years. Opioids, in the form of powerful painkillers that are highly addictive, have led to rising numbers of opioid dependence among Michigan's citizens. Moreover, prescribed opioids have led to an uncontrollable increase in the use of highly addictive and dangerous illegal substances, especially heroin. According to the 2015 statistics from Center for Disease Control, Michigan saw its third consecutive year of record drug overdose deaths. In 2015, 1,981 people died from drug overdoses, up 13.5% from 2014. Furthermore, over the last 17 years, deaths from drug overdoses in Michigan quadrupled, compounded by the fact that the state was ranked 10th in the nation in per capita prescribing rates of opioid pain relievers in 2012.

The Act allows for the dispensing of opioid antagonists, such as Naloxone, to family members, acquaintances, and health professionals capable of assisting individuals in the throes of opioid addiction. Opioids antagonists are drugs used to bind to the opioid receptors in the body, resulting in the blocking of the body's opiate receptors, preventing the body from having an adverse response to drugs such as heroin and other opiates. Prior to the statute becoming law, drug abusers themselves could obtain opioid antagonists to self-administer in the event of an overdose. However, for a variety of reasons, it is unrealistic to believe that an individual in the midst of an accidental opioid overdose would have the faculties to recognize the onset of an overdose and take appropriate action.

May 24, 2017

Most importantly, permanent administrative rules cannot be promulgated quickly enough to stem the loss of life which is increasing on a daily basis. Time is of the essence, and 2016 PA 383 presents an opportunity to rapidly place life-saving opioid antagonists within the hands of those most readily able to stop and reverse opioid overdoses, and immediately save lives.

LARA, in consultation with the Department of Health and Human Services and local health departments, finds an urgency exists to prevent continued death and to preserve the public health, safety, and welfare from the opioid overdose epidemic which requires the promulgation of emergency rules without following the notice and participation procedures required by sections 41, 42, and 48 of 1969 PA 306, as amended, being MCL 24.241, MCL 24.242, and MCL 24.248 of the Michigan Compiled Laws.

Rule 1. Definitions.

As used in these rules:

- (1) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.
- (2) "Department" means the Michigan Department of Health and Human Services.
- (3) "Eligible individuals" means individuals within the State of Michigan, who are seeking opioid antagonists.
- (4) "Standing order" means a standing order issued by the Office of the Chief Medical Executive pursuant to section 17744e of the Code, being MCL 333.17744e.

Rule 2. Dispensing opioid antagonists; standing order; requirements.

- (1) Upon issuance of the standing order, a pharmacy shall register with the department prior to dispensing opioid antagonists under the standing order.
- (2) A pharmacy dispensing an opioid antagonist pursuant to the standing order, shall submit the following information, without individual identifiers, to the department on a quarterly basis, in a manner established by the department:
 - (a) The total number of doses of opioid antagonist dispensed under the standing order.
 - (b) The total number of doses of opioid antagonists dispensed under any type of prescription, including the standing order.
 - (c) The number of each type of formulation dispensed.

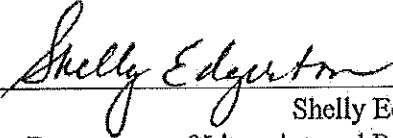
Rule 3. Training for the administration of opioid antagonists; requirements.

- (1) Pharmacists who dispense opioid antagonists pursuant to the standing order shall obtain training in the proper use and administration of opioid antagonists and in opioid overdose response. The training programs can be obtained on-line, in person, or in writing.
- (2) Pharmacists who dispense opioid antagonists pursuant to the standing order shall provide educational material, approved by the Office of the Chief Medical Executive, on the administration of opioid antagonists to eligible individuals.

Rule 4. Referral to resource information.

- (1) Pharmacists who dispense opioid antagonists pursuant to the standing order shall provide the eligible individual with resource information regarding referral for treatment services.

MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS



Shelly Edgerton, Director
Department of Licensing and Regulatory Affairs

Pursuant to Section 48(1) of 1969 PA 306, as amended, being MCL 24.248(1), I hereby concur in the finding of the Department of Licensing and Regulatory Affairs that the circumstances creating an emergency have occurred and the promulgation of the above rules is required for the preservation of the public health, safety, and welfare.



Rick Snyder, Governor

5/24/17
Date