# **WEST VIRGINIA LEGISLATURE**

## 2016 REGULAR SESSION

### Introduced

## **Senate Bill 431**

By Senators Cole (Mr. President) And Kessler

(BY REQUEST OF THE EXECUTIVE)

[Introduced January 29, 2016;

Referred to the Committee on Health

and Human Resources.]

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A BILL to amend and reenact §16-46-3, §16-46-5 and §16-46-6 of the Code of West Virginia, 2 1931, as amended; and to amend said code by adding thereto a new section, designated 3 §16-46-3a, all relating to authorizing pharmacist or pharmacy intern to dispense, pursuant to a protocol, an opioid antagonist without a prescription; requiring Board of Pharmacy, in 5 consultation with Bureau for Public Health, to develop a protocol; requiring patient counseling; requiring educational materials; requiring documentation of distribution of 6 7 opioid antagonists in West Virginia Controlled Substances Monitoring Program database; 8 revising existing reporting requirements; providing limited liability to pharmacist and pharmacy interns; revising reporting requirements; and reorganizing existing code 10 language.

Be it enacted by the Legislature of West Virginia:

That §16-46-3, §16-46-5 and §16-46-6 of the Code of West Virginia, 1931, as amended, be amended and reenacted; and that said code be amended by adding thereto a new section, designated §16-46-3a, all to read as follows:

#### ARTICLE 46. ACCESS TO OPIOID ANTAGONISTS ACT.

- §16-46-3. Licensed health care providers may prescribe opioid antagonists to initial responders and certain individuals; required educational materials; limited liability.
- (a) All licensed health care providers in the course of their professional practice may offer to initial responders a prescription for opioid antagonists, including a standing order, to be used during the course of their professional duties as initial responders.
- (b) All licensed health care providers in the course of their professional practice may offer to a person considered by the licensed health care provider to be at risk of experiencing an opiaterelated overdose, or to a relative, friend, caregiver or person in a position to assist a person at risk of experiencing an opiate-related overdose, a prescription for an opioid antagonist.

(c) All licensed health care providers who prescribe an opioid antagonist under this section
shall provide educational materials to any person or entity receiving such a prescription on opiate-
related overdose prevention and treatment programs, as well as materials on administering the
prescribed opioid antagonist.

(d) Any person who possesses an opioid antagonist and administers it to a person whom they believe to be suffering from an opioid-related overdose and who is acting in good faith is not, as a result of his or her actions or omissions, subject to criminal prosecution arising from the possession of an opioid antagonist or subject to any civil liability with respect to the administration of or failure to administer the opioid antagonist unless the act or failure to act was the result of gross negligence or willful misconduct.

(e) Any person who administers an opioid antagonist to a person whom they believe to be suffering from an opioid-related overdose is required to seek additional medical treatment at a medical facility for that person immediately following the administration of the opioid antagonist to avoid further complications as a result of suspected opioid-related overdose.

# §16-46-3a. Pharmacist or pharmacy intern may dispense, pursuant to a protocol, opioid antagonists without a prescription; patient counseling required; required educational materials.

- (a) Pursuant to the protocol developed under subsection (f) of this section, a pharmacist or pharmacy intern under the supervision of a pharmacist may dispense an opioid antagonist without a prescription.
- (b) A pharmacist or pharmacy intern who dispenses an opioid antagonist without a prescription under this section shall provide patient counseling to the individual for whom the opioid antagonist is dispensed regarding, but not limited to, the following topics: (1) The proper administration of the opioid antagonist; (2) the importance of contacting emergency services as soon as practicable either before or after administering the opioid antagonist; and (3) the risks associated with failure to contact emergency services following administration of an opioid

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10	antagonist. The patient counseling described in this section is mandatory and the person receiving
11	the opioid antagonist may not opt out.

- (c) A pharmacist shall document the dispensing of an opioid antagonist without a prescription as set forth in the protocol developed under subsection (f) of this section and the reporting requirements set forth in subsection (a), section four, article nine, chapter sixty-a of this code.
- (d) All pharmacists or pharmacy interns who dispense an opioid antagonist under this section shall provide educational materials to any person receiving such an opioid antagonist on opiate-related overdose prevention and treatment programs, as well as materials on administering the opioid antagonist.
- (e) This section does not affect the authority of a pharmacist or pharmacy intern to fill or refill a prescription for an opioid antagonist.
- (f) To implement the provisions of this section, the Board of Pharmacy shall, after consulting with the Bureau for Public Health: (1) Develop a protocol under which pharmacists or pharmacy interns may dispense an opioid antagonist without a prescription; (2) specify educational materials which shall be provided to the individual receiving the opioid antagonist; and (3) develop a form, template or the like to be used by pharmacists and pharmacy interns when dispensing the opioid antagonists without a prescription. The protocol developed by the board may be updated or revised as necessary.

## §16-46-5. Licensed health care providers limited liability related to opioid antagonist prescriptions.

(a) A licensed health care provider who is permitted by law to prescribe drugs, including opioid antagonists, may, if acting in good faith, prescribe and subsequently dispense or distribute an opioid antagonist without being subject to civil liability or criminal prosecution unless prescribing the opioid antagonist was the result of the licensed health care providers gross negligence or willful misconduct.

(b) For purposes of this chapter and chapter sixty-a of this code, any prescription written,
as described in section three of this article, shall be presumed as being issued for a legitimate
medical purpose in the usual course of professional practice unless the presumption is rebutted
by a preponderance of the evidence.

(c) Any person who possesses an opioid antagonist and administers it to a person whom they believe to be suffering from an opioid-related overdose and who is acting in good faith is not, as a result of his or her actions or omissions, subject to criminal prosecution arising from the possession of an opioid antagonist or subject to any civil liability with respect to the administration of or failure to administer the opioid antagonist unless the act or failure to act was the result of gross negligence or willful misconduct.

(d) Any person who administers an opioid antagonist to a person whom they believe to be suffering from an opioid-related overdose is required to seek additional medical treatment at a medical facility for that person immediately following the administration of the opioid antagonist to avoid further complications as a result of suspected opioid-related overdose.

(e) Any pharmacist or pharmacy intern who dispenses or refuses to dispense an opioid antagonist under the provisions of this article who is acting in good faith and subject to the requirements of section three-a of this article is not, as a result of his or her actions or omissions, subject to civil liability or criminal prosecution unless dispensing the opioid antagonist was the result of the pharmacist or pharmacy interns gross negligence or willful misconduct.

#### §16-46-6. Data collection and reporting requirements; training.

- (a) Beginning March 1, 2016, and annually thereafter after that the following reports shall be compiled:
- (1) The Office of Emergency Medical Services shall collect data regarding each administration of an opioid antagonist by an initial responder. The Office of Emergency Medical Services shall report this information to the Legislative Oversight Commission on Health and Human Resources Accountability and the West Virginia Bureau for Behavioral Health and Health Facilities. The data collected and reported shall include:

8	(A) The number of training programs operating in an Office of Emergency Medical
9	Services-designated training center;
10	(B) The number of individuals who received training to administer an opioid antagonist;
11	(C) The number of individuals who received an opioid antagonist administered by an initial

- responder;
- (D) The number of individuals who received an opioid antagonist administered by an initial responder who were revived;
- (E) The number of individuals who received an opioid antagonist administered by an initial responder who were not revived; and
- (F) The cause of death of individuals who received an opioid antagonist administered by an initial responder and were not revived.
- (2) Each licensed health care provider shall submit data to the West Virginia Board of Pharmacy by February 1 of each calendar year, excluding any personally identifiable information, regarding the number of opioid antagonist prescriptions written in accordance with this article in the preceding calendar year. The licensed health care provider shall indicate whether the prescription was written to an individual in the following categories: An initial responder; an individual at risk of opiate-related overdose; a relative of a person at risk of experiencing an opiate-related overdose; or a caregiver or person in a position to assist a person at risk of experiencing an opiate-related overdose.
- (3) (2) The West Virginia Board of Pharmacy shall <u>query the West Virginia Controlled</u>

  <u>Substances Monitoring Program database to</u> compile all data <u>described in subdivision (2) of this</u>

  <u>section and related to the dispensing of opioid antagonists and combine that data with</u> any

  additional data maintained by the Board of Pharmacy related to prescriptions <u>for and distribution</u>

  of opioid antagonists. By <u>March February</u> 1 and annually thereafter, the Board of Pharmacy shall

  provide a report of this information, excluding any personally identifiable information, to the

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- Legislative Oversight Commission on Health and Human Resources Accountability and the West Virginia Bureau for Behavioral Health and Health Facilities.
- (b) To implement the provisions of this article, including establishing the standards for certification and approval of opioid overdose prevention and treatment training programs and protocols regarding a refusal to transport, the Office of Emergency Medical Services may promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code and shall propose rules for legislative approval in accordance with the provisions of said article.

NOTE: The purpose of this bill is to authorize pharmacists and pharmacy interns to dispense opioid antagonists without a prescription pursuant to a protocol and rule developed by the Board of Pharmacy.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.