

# **WEST VIRGINIA LEGISLATURE**

## **2016 REGULAR SESSION**

**Introduced**

### **House Bill 4335**

By MR. SPEAKER (MR. ARMSTEAD) AND DELEGATE MILEY

BY REQUEST OF THE EXECUTIVE

[Introduced January 29, 2016; Referred  
to the Select Committee on Prevention and Treatment  
of Substance Abuse then Health and Human  
Resources.]

1 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 a pharmacist or pharmacy intern to dispense,  
4 pursuant to a protocol, an opioid antagonist without a prescription; requiring the Board of  
5 Pharmacy in consultation with the Bureau for Public Health to develop a protocol; requiring  
6 patient counseling; requiring educational materials; requiring documentation of distribution  
7 of opioid antagonists in the West Virginia Controlled Substances Monitoring Program  
8 database; revising existing reporting requirements; providing limited liability to pharmacist  
9 and pharmacy interns; revising reporting requirements; and reorganizing existing code  
10 language.

*Be it enacted by the Legislature of West Virginia:*

1 That §16-46-3, §16-46-5 and §16-46-6 of the Code of West Virginia, 1931, as amended,  
2 be amended and reenacted; and that said code be amended by adding thereto a new section,  
3 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.**

1 (a) All licensed health care providers in the course of their professional practice may offer  
2 to initial responders a prescription for opioid antagonists, including a standing order, to be used  
3 during the course of their professional duties as initial responders.

4 (b) All licensed health care providers in the course of their professional practice may offer  
5 to a person considered by the licensed health care provider to be at risk of experiencing an opiate-  
6 related overdose, or to a relative, friend, caregiver or person in a position to assist a person at  
7 risk of experiencing an opiate-related overdose, a prescription for an opioid antagonist.

8 (c) All licensed health care providers who prescribe an opioid antagonist under this section  
9 shall provide educational materials to any person or entity receiving such a prescription on opiate-

10 related overdose prevention and treatment programs, as well as materials on administering the  
11 prescribed opioid antagonist.

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

18 ~~(e) Any person who administers an opioid antagonist to a person whom they believe to be~~  
19 ~~suffering from an opioid-related overdose is required to seek additional medical treatment at a~~  
20 ~~medical facility for that person immediately following the administration of the opioid antagonist to~~  
21 ~~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.**

1 (a) Pursuant to the protocol developed under subsection (f) of this section, a pharmacist  
2 or pharmacy intern under the supervision of a pharmacist may dispense an opioid antagonist  
3 without a prescription.

4 (b) A pharmacist or pharmacy intern who dispenses an opioid antagonist without a  
5 prescription under this section shall provide patient counseling to the individual for whom the  
6 opioid antagonist is dispensed regarding, but not limited to, the following topics: (1) The proper  
7 administration of the opioid antagonist, (2) the importance of contacting emergency services as  
8 soon as practicable either before or after administering the opioid antagonist, and (3) the risks  
9 associated with failure to contact emergency services following administration of an opioid  
10 antagonist. The patient counseling described in this section is mandatory and the person receiving  
11 the opioid antagonist may not opt-out.

12 (c) A pharmacist shall document the dispensing of an opioid antagonist without a  
13 prescription as set forth in the protocol developed under subsection (f) of this section and the  
14 reporting requirements set forth in subsection (a), section four, article nine, chapter sixty-a of this  
15 code.

16 (d) All pharmacists or pharmacy interns who dispense an opioid antagonist under this  
17 section shall provide educational materials to any person receiving such an opioid antagonist on  
18 opiate-related overdose prevention and treatment programs, as well as materials on administering  
19 the opioid antagonist.

20 (e) This section does not affect the authority of a pharmacist or pharmacy intern to fill or  
21 refill a prescription for an opioid antagonist.

22 (f) To implement the provisions of this section, the Board of Pharmacy shall, after  
23 consulting with the Bureau for Public Health, (1) Develop a protocol under which pharmacists or  
24 pharmacy interns may dispense an opioid antagonist without a prescription; (2) specify  
25 educational materials which shall be provided to the individual receiving the opioid antagonist;  
26 and (3) develop a form, template, or the like to be used by pharmacists and pharmacy interns  
27 when dispensing the opioid antagonists without a prescription. The protocol developed by the  
28 board may be updated or revised as necessary.

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

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

6 (b) For purposes of this chapter and chapter sixty-a, any prescription written, as described  
7 in section three of this article, shall be presumed as being issued for a legitimate medical purpose

8 in the usual course of professional practice unless the presumption is rebutted by a  
9 preponderance of the evidence.

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

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

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

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

1 (a) Beginning March 1, 2016, and annually thereafter ~~thereafter~~ after that the following reports shall  
2 be compiled:

3 (1) The Office of Emergency Medical Services shall collect data regarding each  
4 administration of an opioid antagonist by an initial responder. The Office of Emergency Medical  
5 Services shall report this information to the Legislative Oversight Commission on Health and  
6 Human Resources Accountability and the West Virginia Bureau for Behavioral Health and Health  
7 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  
12 responder;

13 ~~(D) The number of individuals who received an opioid antagonist administered by an initial  
14 responder who were revived;~~

15 ~~(E) The number of individuals who received an opioid antagonist administered by an initial  
16 responder who were not revived; and~~

17 ~~(F) The cause of death of individuals who received an opioid antagonist administered by  
18 an initial responder and were not revived.~~

19 ~~(2) Each licensed health care provider shall submit data to the West Virginia Board of  
20 Pharmacy by February 1 of each calendar year, excluding any personally identifiable information,  
21 regarding the number of opioid antagonist prescriptions written in accordance with this article in  
22 the preceding calendar year. The licensed health care provider shall indicate whether the  
23 prescription was written to an individual in the following categories: An initial responder; an  
24 individual at risk of opiate-related overdose; a relative of a person at risk of experiencing an opiate-  
25 related overdose; a friend of a person at risk of experiencing an opiate-related overdose; or a  
26 caregiver or person in a position to assist a person at risk of experiencing an opiate-related  
27 overdose.~~

28 ~~(3)~~ (2) The West Virginia Board of Pharmacy shall query the West Virginia Controlled  
29 Substances Monitoring Program database to compile all data ~~described in subdivision (2) of this~~  
30 ~~section and~~ related to the dispensing of opioid antagonists and combine that data with any  
31 additional data maintained by the Board of Pharmacy related to prescriptions for and distribution  
32 of opioid antagonists. By ~~March~~ February 1 and annually thereafter, the Board of Pharmacy shall  
33 provide a report of this information, excluding any personally identifiable information, to the  
34 Legislative Oversight Commission on Health and Human Resources Accountability and the West

35 Virginia Bureau for Behavioral Health and Health Facilities.

36 (b) To implement the provisions of this article, including establishing the standards for  
37 certification and approval of opioid overdose prevention and treatment training programs and  
38 protocols regarding a refusal to transport, the Office of Emergency Medical Services may  
39 promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter  
40 twenty-nine-a of this code and shall propose rules for legislative approval in accordance with the  
41 provisions of article three, chapter twenty-nine-a of this code.

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.