WEST VIRGINIA CODE CHAPTER 16 ARTICLE 46

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§16-46-1. Purpose and findings.

(a) The purpose of this article is to prevent deaths in circumstances involving individuals who have overdosed on opiates.

(b) The Legislature finds that permitting licensed health care providers to prescribe opioid antagonists to initial responders as well as individuals at risk of experiencing an overdose, their relatives, friends or caregivers may prevent accidental deaths as a result of opiate-related overdoses.

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§16-46-2. Definitions.

As used in this article:

(1) "Initial responder" means emergency medical service personnel, as defined in subdivision (g), section three, article four-c of this chapter, including, but not limited to, a member of the West Virginia State Police, a sheriff, a deputy sheriff, a municipal police officer, a volunteer or paid firefighter and any other person acting under color of law who responds to emergencies.

(2) "Licensed health care provider" means a person, partnership, corporation, professional limited liability company, health care facility or institution licensed by or certified in this state to provide health care or professional health care services. This includes, but is not limited to, medical physicians, allopathic and osteopathic physicians, pharmacists, physician assistants or osteopathic physician assistants who hold a certificate to prescribe drugs, advanced nurse practitioners who hold a certificate to prescribe drugs, hospitals, emergency service agencies and others as allowed by law to prescribed drugs.

(3) "Opiates" or "opioid drugs" means drugs that are members of the natural and synthetic opium family, including, but not limited to, heroin, morphine, codeine, methadone, oxycodone, hydrocodone, fentanyl and hydromorphone.

(4) "Opioid antagonist" means a federal Food and Drug Administration-approved drug for the treatment of an opiate-related overdose, such as naloxone hydrochloride or other substance, that, when administered, negates or neutralizes, in whole or in part, the pharmalogical effects of an opioid in the body.

(5) "Opioid overdose prevention and treatment training program" or "program" means any program operated or approved by the Office of Emergency Medical Services as set forth in rules promulgated pursuant to this article.

(6) "Overdose" means an acute condition, including, but not limited to, life-threatening physical illness, coma, mania, hysteria or death, which is the result of the consumption or use of opioid drugs.

(7) "Standing order" means a written document containing rules, policies, procedures, regulations and orders for the conduct of patient care, including the condition being treated, the action to be taken and the dosage and route of administration for the drug prescribed.

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§16-46-3. Licensed health care providers may prescribe opioid antagonists to initial responders and certain individuals; required educational materials; limited liability.

(a) The following individuals may prescribe an opioid antagonist in the manner prescribed by this subsection:

(1) A licensed health care provider acting in good faith and exercising good reasonable care may directly or by standing order prescribe an opioid antagonist to:

(A) A person at risk of experiencing an opioid-related overdose; or

(B) A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

(2) A licensed health care provider acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to any governmental or non-governmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high risk behaviors, for the purpose of distributing, through its agents, the opioid antagonist, to:

(A) A person at risk of experiencing an opioid-related overdose or

(B) A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

(b) A pharmacist may dispense an opioid antagonist to a person or organization pursuant to a prescription issued in accordance with subsection (a) of this section.

(c)(1) A governmental or non-governmental organization, including a local health department, a law enforcement agency, or organization that promotes scientifically proven ways to mitigate health risks associated with substance use disorders and other high-risk behaviors may, through its trained agents, distribute an opioid antagonist obtained pursuant to a prescription issued in accordance with this section to:

(A) A person at risk of experiencing an opioid-related overdose or

(B) A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

(2) An organization, through its trained agents, shall include with any distribution of an opioid antagonist pursuant to this subsection required education including opioid-related overdose prevention and treatment programs and instruction on how to administer the opioid antagonist.

(d) A person who receives an opioid antagonist that was prescribed pursuant to subsection

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(a) or distributed pursuant to subsection (c) may administer an opioid antagonist to another person if:

(1) The person has a good faith belief that the other person is experiencing a drug-related overdose; and

(2) The person exercises reasonable care in administering the drug to another person.

(e) A person and organization acting in good faith under the provisions of this section are immune from civil or criminal liability.

(f) A person and organization may possess an opioid antagonist, regardless of whether the person or organization holds a prescription for the opioid antagonist.

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§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 antagonist. The patient counseling described in this section is mandatory and the person receiving 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.

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§16-46-4. Possession and administration of an opioid antagonist by initial responders; limited liability.

(a) Local and state governmental agencies that employ initial responders must provide opioid antagonist rescue kits to their initial responders, require initial responders to successfully complete the training required by §16-46-6(b) of this code, and require the initial responders to carry the opioid antagonist rescue kits in accordance with agency procedures so as to optimize the initial responders' capacity to timely assist in the prevention of opioid overdoses: Provided, That a local or state governmental agency has designated sufficient funding or supplies of opioid antagonist rescue kits.

(b) In the absence of gross negligence or willful misconduct, nothing in this section shall be construed to impose civil or criminal liability on a local or state governmental agency or an initial responder acting in good faith in the administration or provision of an opioid antagonist in cases where an individual appears to be experiencing an opioid overdose.

(c) As used in this section, an "opioid antagonist rescue kit" means a kit containing:

(1) Two doses of an opioid antagonist in either a generic form or in a form approved by the United States Federal Food and Drug Administration; and

(2) Overdose education materials that conform to Office of Emergency Medical Services or federal Substance Abuse and Mental Health Services Administration guidelines for opioid overdose education that explain the signs and causes of an opioid overdose and instruct when and how to administer in accordance with medical best practices:

(A) Life-saving rescue techniques; and

(B) An opioid antagonist.

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§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.

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

(a) Beginning March 1, 2016, and annually 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, Joint Committee on Health and the West Virginia Bureau for Behavioral Health and Health Facilities. The data collected and reported shall include:

(A) The number of training programs operating in an Office of Emergency Medical Services-designated training center;

(B) The number of individuals who received training to administer an opioid antagonist;

(C) The number of individuals who received an opioid antagonist administered by an initial responder;

(2) The distribution of an opioid antagonist by a governmental or non-governmental entity, granting institution, medical provider, or pharmacy whose software cannot automatically report to the West Virginia Controlled Substance Monitoring Program database must report to the West Virginia Office of Drug Control Policy on a monthly basis. Report must be generated and submitted by the 10th day of each month for the opioid antagonists dispensed or distributed in the previous month. The following information must be reported:

(A) The name and address of the entity dispensing or distributing the opioid antagonist;

(B) The name and national drug code for each formulation of opioid antagonist dispensed or distributed;

(C) The total quantity of each formulation of opioid antagonist dispensed or distributed.

(3) The West Virginia Board of Pharmacy shall query the West Virginia Controlled Substances Monitoring Program database to compile all data related to the dispensing of opioid antagonists and combine that data with any additional data maintained by the Board of Pharmacy related to prescriptions for and distribution of opioid antagonists. The aggregate data shall be reported to the West Virginia Office of Drug Control Policy by the 10th day of each month. By February 1 and annually thereafter, the West Virginia Office of Drug Control Policy shall provide a report of this information, excluding any personally identifiable information, to the Legislative Oversight Commission on Health and Human Resources Accountability, Joint Committee on Health 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

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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.

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§16-46-7. Statewide standing orders for opioid antagonist.

(a) The state health officer may prescribe on a statewide basis an opioid antagonist by one or more standing orders to eligible recipients.

(b) A standing order must specify, at a minimum:

(1) The opioid antagonist formulations and means of administration that are approved for dispensing;

(2) The eligible recipients to whom the opioid antagonist may be dispensed;

(3) Any training that is required for an eligible recipient to whom the opioid antagonist is dispensed;

(4) The circumstances under which an eligible recipient may distribute or administer the opioid antagonist; and

(5) The timeline for renewing and updating the standing order.

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