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JOINT REGULATORY STATEMENT

Prescription of Naloxone to High-Risk Individuals and Third Parties who are in a Position to Assist an Individual who is Experiencing Opioid-related Overdose Updated - November 2015

*This statement provides information concerning the prescription of naloxone to individuals at high-risk of an opioid overdose **as well as the prescription of naloxone to a third party (family member, friend or other individual) that is in a position to assist an individual who is at risk of experiencing an opioid overdose.** This statement is only intended to provide an overview. Prior to prescribing naloxone, prescribers should seek detailed information regarding risk factors for opioid overdose, the use of naloxone, and the laws and rules regulating prescribers in Ohio, i.e., physicians, physician assistants and advanced practice registered nurses with a certificate to prescribe. This statement should not be construed as legal or health care advice, but as information intended to increase the awareness and knowledge of authorized prescribers, pharmacists and the public about the use of naloxone to prevent or reverse the effects of opioids. Prescribers should seek legal counsel if clarification or legal advice is needed.*

Background

Preventing Drug Overdoses

From 2000 to 2013, Ohio's death rate due to unintentional drug overdoses increased 413 percent. Due to the alarming increase in drug overdose deaths, the Governor's Cabinet Opiate Action Team, the Prescription Drug Abuse Action Group (PDAAG), Project DAWN (Deaths Avoided with Naloxone) and Ohio's professional licensing boards are working toward ways to enhance professional awareness and educate licensees on how we can all contribute to saving lives, especially when faced with meeting the formidable challenge of treating opioid abuse and addiction. This statement is intended to raise awareness about the benefits of naloxone (also known as Narcan®) for individuals at high-risk of opioid overdose and those who are in a position to assist an individual who is experiencing an opioid-related overdose (such as a first responder, friend or family member).

Naloxone is a medication used to counter the effects of opioid overdose. Specifically, naloxone is used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally. When administered during an overdose, naloxone blocks the effects of opioids on the brain to restore effective breathing. In the presence of physical dependence on opioids, naloxone will induce withdrawal symptoms. Emergency medical professionals have safely used naloxone with patients for over 40 years. Naloxone is not known to produce tolerance or cause physical or psychological dependence in patients. Contraindication for naloxone is in patients who are known to be hypersensitive to the medication.

Prescribing Considerations

Prescribing Naloxone

The intended use of naloxone is to prevent opioid overdose. Naloxone can be legally prescribed by a physician, physician assistant, or advanced practice registered nurse who is an Ohio authorized prescriber for the following individuals:

- Patients who present a high-risk for opioid overdose, after they are appropriately evaluated and determined by the prescriber to benefit from the prescription for naloxone. When prescribed, indications for and methods of administration should be explained to patients, along with any potential risks.
- A family member, friend, or other individual who is in a position to assist an individual who is apparently experiencing or at risk of experiencing an opioid-related overdose. The naloxone must be furnished to, or the prescription is issued to and in the name of, a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.
- An authorized prescriber is required by law to instruct the individual receiving the naloxone supply or prescription to summon emergency services either immediately before or immediately after administering naloxone to an individual apparently experiencing an opioid-related overdose.

Due to recent changes in Ohio law, there are no restrictions on the formulations of naloxone that can be prescribed or personally furnished. For more information on the different formulations of naloxone available, please review the Board of Pharmacy's guidance document, which can be accessed here: www.pharmacy.ohio.gov/naloxone

Personally Furnishing Naloxone to a Patient

"Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting. In Ohio, physicians, physician assistants and advanced practice registered nurses are authorized to personally furnish naloxone for administration by using a device manufactured for the intranasal administration of liquid drugs or by using an autoinjector in a manufactured dosage form. Drugs that are personally furnished by a prescriber should adhere to Ohio Administrative Code 4729-5-17 and should include the following information affixed to the medication:

- (1) The name and address of the prescriber.
- (2) The name of the patient for whom the drug is intended.
- (3) Name and strength of the dangerous drug.
- (4) Directions for use.
- (5) Date furnished.

Personally Furnishing Naloxone Pursuant to a Physician Protocol

Section 4731.941 of the Ohio Revised Code permits a physician to authorize one or more individuals to personally furnish a supply of naloxone pursuant to a protocol to either of the following:

- (1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose; or
- (2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

According to the section 4731.941 of the Ohio Revised Code, a physician established protocol for personally furnishing naloxone must include all of the following in writing:

- (1) A description of the clinical pharmacology of naloxone;
- (2) Precautions and contraindications concerning furnishing naloxone;
- (3) Any limitations the physician specifies concerning the individuals to whom naloxone may be furnished;
- (4) The naloxone dosage that may be furnished and any variation in the dosage based on circumstances specified in the protocol;
- (5) Labeling, storage, record-keeping, and administrative requirements;
- (6) Training requirements that must be met before an individual will be authorized to furnish naloxone;
- (7) Any instructions or training that the authorized individual must provide to an individual to whom naloxone is furnished.

For more information on personally furnishing naloxone pursuant to a physician-established protocol, please review the Board of Pharmacy's guidance document, which can be accessed here: www.pharmacy.ohio.gov/naloxone

Dispensing of Naloxone by Pharmacists and Pharmacy Interns without a Prescription

Section 4729.44 of the Ohio Revised Code and rule [4729-5-39 of the Ohio Administrative Code](#) authorizes a pharmacist or pharmacy intern under the direct supervision of a pharmacist to dispense naloxone without a prescription to the following in accordance with a physician-approved protocol:

- (1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- (2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose; or

(3) A peace officer as defined in section 2921.51 of the Revised Code.

Section 3707.56 of the Ohio Revised Code permits a local board of health, through a physician serving as the board's health commissioner or medical director, to authorize the protocol for pharmacists and pharmacy interns working in that board of health's jurisdiction.

For more information on personally furnishing naloxone pursuant to a physician-established protocol, please review the Board of Pharmacy's guidance document, which can be accessed here: www.pharmacy.ohio.gov/naloxone

Risk Factors, Patient Education, and Naloxone Distribution Programs (NDPs)

Risk factors for Opioid Overdose

Patients with the risk factors below may be in danger of an opioid overdose. These risk factors may be indicators for prescribing or personally furnishing naloxone directly to the patient or to a third party that is in a position to assist an individual who meets these risk factors. The factors include, but are not limited to:

- Recent medical care for opioid poisoning/intoxication/overdose
- Participant in a medical regime designed to provide Medication-Assistance Treatment for opiate addiction
- Suspected or confirmed history of heroin or nonmedical opioid use
- High-dose opioid prescription (≥ 80 mg/day morphine equivalence)
- Any Methadone prescription for opioid naive patient
- Recent release from jail or prison with a history of opioid abuse
- Recent release from mandatory abstinence program or drug detoxification program
- Enrolled in Methadone or buprenorphine detoxification or maintenance program (for either addiction or pain management)
- Any opioid prescription and known or suspected:
 - Smoking, COPD, emphysema, asthma, sleep apnea, or other respiratory system disease
 - Renal or hepatic disease
 - Alcohol use
 - Concurrent benzodiazepine use or any concurrent sedating medication use
 - Concurrent antidepressant prescription
 - Remoteness from or difficulty accessing medical care
- Voluntary patient request for naloxone, or any other factor that makes the patient at high-risk for opioid overdose.

Patient Education

Individuals receiving naloxone should be advised of the following:

- Overdose prevention techniques
- Recognizing signs and symptoms of overdose
- Calling 911
- Airway and breathing assessment/Rescue breathing/Recovery position

- Naloxone storage, carrying, and administration in an emergency situation
- Reporting of overdose and refill procedures
- Post-overdose follow-up care

Naloxone Distribution Programs

Naloxone Distribution Programs (NDPs), which provide overdose training and take-home doses of intranasal naloxone to high-risk patients, friends and family members, can be effective at saving lives. According to a recent report by the Centers for Disease Control and Prevention, since 1996, 53,032 individuals have been trained by NDPs resulting in 10,171 overdose reversals using naloxone. In addition to providing naloxone for administration in cases when medical help is not immediately available, NDPs provide training in recognizing the signs and symptoms of an overdose, instruction on how to perform rescue breathing and the importance of calling 911.

Summary

Due to the alarming increase in drug overdose deaths, state agencies, private entities, and Ohio's professional licensing boards are working toward ways to enhance professional awareness and education regarding the prescription and use of naloxone. This statement is an overview intended to raise awareness about the benefits of naloxone for individuals at high-risk of opioid overdose. We encourage licensees to learn more about participation in NDPs, such as Project DAWN, and the use of the prescription of naloxone to reduce Ohio's opioid overdose epidemic. For additional information on NDPs please refer to <http://www.healthy.ohio.gov/vipp/drug/ProjectDAWN.aspx>.

Approved:

Medical Board – August 2015

Nursing Board – September 2015

Pharmacy Board – November 2015