

OHIO DEPARTMENT OF HEALTH REQUEST FOR PROPOSAL (RFP)

The Ohio Department of Health (ODH) is soliciting proposals for professional services.

1. PROJECT INFORMATION.

- 1.1. Project Title. Project Dawn (Deaths Avoided With Naloxone): Overdose Education and Naloxone Distribution Program
- 1.2. Posting Date. February 16, 2016
- 1.3. Due Date. March 4, 2016
- 1.4. Inquiry Period Start Date. February 16, 2016
- 1.5. Inquiry End Date. February 26, 2016

2. PROJECT BACKGROUND, OBJECTIVE & BUDGET.

- 2.1. Project Background. The Ohio Violence & Injury Prevention Program (VIIPP) is a comprehensive injury prevention program for the State of Ohio. One of the main goals of the VIIPP is reduce unintentional drug overdose through evidence-informed policies and programs.
- 2.2. Project Objective. To prevent drug overdose deaths through the expanded availability and use of the overdose reversal drug naloxone.
- 2.3. Project Budget. \$240,000.00. Five (5) agreements at \$24,000.00/per year.

3. MINIMUM REQUIREMENTS.

3.1. Applicant Experience Requirements.

- 3.1.1. Ability to implement an overdose education and prevention program in a community-based setting whereby all individuals, when there is reason to believe is at risk of experiencing an opioid-related overdose; or a family member, friend, or other person in a position to assist individuals who there is reason to believe is at risk of experiencing an opioid-related overdose can obtain training and a Project DAWN overdose reversal kit at no cost to the individual-;
- 3.1.2. Ability to provide one physician to serve as the program's medical director that is demonstrated in a letter of commitment from the physician;
- 3.1.3. Ability to dispense naloxone with standing orders and protocol (through an existing terminal distributor license from the Ohio Board of Pharmacy or the intent to apply for one) or through a participating local pharmacy, as demonstrated by a letter of commitment from either the proposed medical director (for on-site dispensing) or the participating pharmacy (for off-site dispensing);
- 3.1.4. Ability to identify an individual to serve as a Project Dawn coordinator to manage the program.
- 3.1.5. Ability to provide a sustainability plan of how the Overdose Education and Naloxone Distribution Program (OENDP) will be sustained beyond the period for which funding is requested including the formation of partnerships (notably hospitals and health systems), capacity to bill for services and/or leveraging of additional resources.

3.2. Candidate Experience Requirement.

- 3.2.1. Ability to demonstrate at least three (3) years of experience with providing health care and/or substance abuse treatment services.

3.3. Licenses &/or Certifications Required.

- 3.3.1. Terminal Distributors license.
- 3.3.2. Prescriber licensing.

4. SCOPE OF WORK.

- 4.1. Scope of Work. The scope of work shall include the following:

4.1.1.	Establish a Project DAWN OENDP in their community and procure all of the supplies necessary to assemble and distribute the Project DAWN kits for the period on or about March 1, 2016 through June 30, 2017. (Note: State Fiscal Year [SFY] 16 is July 1, 2015 – June 30, 2016. SFY 17 is July 1, 2016 – June 30, 2017.) A minimum of 300 individuals shall be recruited and trained by the program. The participants will receive a pre-assembled Project DAWN kit (See
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	Attachment C for a sample budget guidance and naloxone kit contents) over the course of the agreement. This number may include friends and families of at-risk opioid users. [Note: Under current Ohio law (House Bill 4) a prescription is no longer required to obtain naloxone. (See Attachment B.) (SFY 16 and SFY 17)
4.1.2.	With technical assistance from VIPP, develop and submit a program policies and procedures document signed by the ODH Medical Director that includes the following: 1) Clinical Pharmacology of Naloxone; 2) Purpose of Project DAWN; 3) Program Description; 4) Program Operative Dynamics and Procedures (which includes staff training); and 5) Data Collection and Evaluation. Sample policies and procedures attached in Appendix A, B and F (SFY 16)
4.1.3.	With technical assistance from VIPP, develop and submit the intake form, refill form, and data collection tracking sheet. Samples form in Appendix F. (SFY 16)
4.1.4.	Provide to VIPP an annual marketing plan that outlines how entity will identify and recruit individuals at risk of experiencing an opioid-related overdose; or a family member, friend, or other person in a position to assist individuals who there is reason to believe is at risk of experiencing an opioid-related overdose (See Attachment D for Project DAWN criteria of an individual at-risk of opioid overdose) to participate in their program. Plan will include outreach efforts to increase the number of law enforcement agencies who carry and administer Naloxone, specific recruitment efforts, education, and awareness strategies. (SFY 16 and SFY 17)
4.1.5.	Conduct an evaluation of the new program including the submission of a final data collection tracking sheet, sustainability plan, and overall project assessment including challenges and lessons learned by the end of the agreement period. Guidance will be provided by the VIPP (SFY 17).
4.1.6.	Participate in bi-monthly conference calls with Violence and Injury Prevention Program (VIPP) staff to discuss program implementation and agreement deliverables. (SFY 16 and SFY 17)
4.1.7.	Host one program site visit for VIPP staff. (SFY 16 or 17)

4.2. Deliverables. The deliverables shall include the following.

	Deliverables	Due Date	Compensation
	During the Agreement Period, Applicant and ODH agree to the following:		
4.2.1.	Implement a Project DAWN OENDP, as outlined in program policies and procedures at the site specified in their proposal.	March 2016 - June 30, 2017.	
4.2.2.	Provide the following: program policies and procedures, program intake form, refill form, and data collection tracking sheet. (SFY 16)	March 15, 2016	
4.2.3.	Provide data tracking sheet on July 15, 2016, October 15, 2016, January 15, 2017, March 15, 2017 and June 30, 2017 (SFY 16 and SFY 17)	As listed in deliverable.	
4.2.4.	Provide annual marketing plans. (SFY 16 and SFY 17)	FY16 due June 1, 2016 and for FY17 by October 1, 2016	
4.2.5.	Complete a program evaluation report.	June 30, 2017	
4.2.6.	Participate in bi-monthly conference calls.	Bi-monthly March 2016 - June 2017.	
4.2.7.	Host one ODH VIPP site visit. (SFY 16 or 17)	Date to be agreed upon by VIPP staff and successful bidder.	

5. EVALUATION POINTS AND CRITERIA.5.1. Evaluation Points.

Criteria	Maximum Allowable Points
Technical Proposal	500 Points
Presentations and Interviews	0 Points
Cost Proposal	200 Points
Total	700 Points

5.2. Evaluation Criteria.

APPLICANT PROFILE		Weight
5.1.	Has the ability to implement an Overdose Education and Naloxone Distribution Program (OENDP) in a community-based setting whereby individuals at risk of experiencing an opioid-related overdose; or a family member, friend, or other person in a position to assist individuals who there is reason to believe is at risk of experiencing an opioid-related overdose can obtain training and a Project DAWN overdose reversal kit at no charge to the individual.	5
5.2.	Is able to dispense naloxone on-site (as evidenced by an existing terminal distributor license from the Ohio Board of Pharmacy or the intent to apply for one) or through a participating local pharmacy, as demonstrated by a letter of commitment from either the proposed medical director (for on-site dispensing) or the participating pharmacy (for off-site dispensing). (See Attachment B for information regarding naloxone prescribing and dispensing in Ohio).	5
5.3.	Identification of significant need for an Overdose Education and Naloxone Distribution Program in their community with an unintentional drug overdose death rate higher than the state average, significant increase in deaths from 2013 to 2014, 25 deaths in 2013 and 2014 and community has no existing community based Project Dawn program.	10

STAFFING PLAN (PERSONNEL PROFILE)		Weight
5.4.	Has at least one physician to serve as the program's medical director that is demonstrated in a letter of commitment from the physician (See Attachment A for a sample outline of the responsibilities of a Project DAWN Medical Director).	5
5.5.	Identifies and provides a job description or responsibilities for a Project Dawn Coordinator.	5
5.6.	Can demonstrate 3 years of experience with providing health care and or substance abuse treatment services.	5

WORK PLAN		Weight
5.7.	Provides a sustainability plan of how the OENDP will be sustained beyond the period for which funding is requested including the formation of	10

	partnerships (notably hospitals and health systems), capacity to bill for services and/or leveraging of additional resources.	
5.8.	Evaluation plan description.	10
5.9.	Identification of outreach plan that outlines how they will identify and recruit individuals at risk of experiencing an opioid-related overdose; or a family member, friend, or other person in a position to assist individuals who there is reason to believe is at risk of experiencing an opioid-related overdose during the funding period.	15
5.10.	Description of participant follow-up and data collection of overdose reversals.	10
5.11.	Detailed work plan including objectives, key activities, timeline, staff responsible and complete and reasonable budget.	15
5.12.	Identified community partners that offer treatment for substance abuse and establish a referral process.	5

TOTAL		100
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AWARD. Five (5) agreements at \$24,000.00/per year.

Notice: This RFP is not an award

Parties interested in submitting a formal offer must submit a written response on provision of the required services or supplies specified in this RFP.

6. REQUEST FOR PROPOSAL INSTRUCTIONS

6.1. Company Narrative. Responses to the RFP shall include a short narrative describing the following:

- 6.1.1. Applicant's profile and experience with projects of similar size and scope.
- 6.1.2. Applicant's ability to meet minimum requirements.
- 6.1.3. Applicant's capacity to provide the services required and, the ability and experience of the staff intended to work on the Project.
- 6.1.4. Applicant's plan for successful execution of the project.

6.2. Where Proposals Must Be Delivered. Proposal must be delivered to the following address:

Ohio Department of Health
Office of Procurement Services
Attention: Carol Cook
246 North High Street
Columbus, OH 43215

6.3. Proposals are a Public Record. Once proposals have been reviewed, they will be forwarded to the ODH Project Manager to begin evaluation and award process. After proposals are opened they are public records as defined in Ohio Revised Code Section 149.43 and are subject to all laws appurtenant thereto. Applicant may request that certain information, such as trade secrets or proprietary data, be designated as confidential and not considered as public records. Pricing is not considered as confidential. The decision as to whether or not such trade secrets or proprietary data shall be disclosed shall rest solely with ODH.

6.4. Applicant May Request Clarification. If Applicant discovers an inconsistency, error or omission in this RFP, the Applicant should request clarification from ODH Office of Procurement Services.

6.5. ODH Modifications to the RFP. When it is necessary to modify an RFP, ODH does so by written addendum only.

6.6. Rejected Proposals. ODH may reject any quote in whole or in part, if any of the following circumstances are true:

- 6.6.1. Proposals are not in compliance with the requirements stated in the RFP.
 - 6.6.2. The price is excessive in comparison with market conditions or with the available funds of the Agency.
 - 6.6.3. ODH determines that awarding any item is not in the best interest of the Agency.
- 6.7. Proposal Preparation. ODH assumes no responsibility for costs incurred by the Applicant prior to the award of funds resulting from this RFP.
 - 6.8. Damages Arising from RFP Specifications. Applicant may not be compensated for damages arising from inaccurate or incomplete information in the RFP, specifications or from inaccurate assumptions based upon the specifications.
 - 6.9. Unit Costs. Applicant shall not insert a unit cost of more than two (2) digits to the right of the decimal point. Digits beyond the two (2) will be dropped and not used in the evaluation of the Proposal.
 - 6.10. Responsive Applicant. An Applicant is responsive if its proposal responds to the RFP completely and contains no irregularities or deviations from the RFP that would affect the proposal or otherwise give the Applicant an unfair advantage.
 - 6.11. Responsible Applicant. ODH will determine if an applicant is responsible using the following factors:
 - 6.11.1 Experience of the applicant.
 - 6.11.2 Applicant's financial condition.
 - 6.11.3 Applicant's previous conduct and performance.
 - 6.11.4 Applicant's facilities.
 - 6.11.5 Applicant's management skills.
 - 6.11.6 Applicant's ability to execute the work properly.
 - 6.11.7 Review of Federal and State debarment lists.
 - 6.12. Estimated Usage. Unless otherwise stated, the usage indicated for each item(s) are to be considered as estimates only and should be considered as information relative to potential purchases that may be made from the award. ODH makes no representation or guarantee as to the actual amount of the items(s) to be purchased.
 - 6.13. Information Requested. ODH may request additional information to evaluate an applicant's responsiveness to the RFP or to evaluate an applicant's responsibility. If an applicant does not provide the requested information, it may adversely impact ODH evaluation of the Applicant's responsiveness or responsibility.
 - 6.14. Samples. ODH may require applicant to provide samples or examples of work, at the Applicant's expense. Samples must be clearly identified by the Applicant, the RFP number, and the item the sample represents. ODH will return samples that are not destroyed in testing, at the Applicant's expense, upon the Applicant's timely request. ODH may keep the samples of the Applicant awarded until the completion of the agreement.
 - 6.15. ODH Withdrawal of the RFP. ODH reserves the right to withdraw the RFP at any time prior to the award the agreement.
 - 6.16. Applicant Evaluation. The ODH Project Manager will evaluate the proposal(s) received and determine the proposal(s) that fulfill the project in the best interests of ODH. Each proposal will be scored and numerical technical point values will be assigned according to the criteria listed in 5.1. The scale below (0-5) will be used to rate each Proposal response to the RFP on the technical evaluation sections listed in 5.1.

The Agency will score the responses by multiplying the score received in each category by its assigned weight and adding all categories together for the Offeror's total technical score. Representative numerical values are defined as follows:

DOES NOT MEET (0): Response does not comply substantially with requirements or is not provided.

WEAK (1): Response was poor related to meeting the objectives.

BELOW AVERAGE (2): Response indicates the objectives will not be completely met or at a level that will be below average.

MEETS (3): Response generally meets the objectives (or expectations).

ABOVE AVERAGE (4): Response indicates the objectives will be exceeded.

STRONG (5): Response significantly exceeds objectives (or expectations) in ways that provide tangible benefits or meets objectives (or expectations) and contains at least one enhancing feature that provides significant benefits.

- 6.17. Applicant Negotiation. It is at the discretion of DOH whether to permit negotiations. An applicant must not submit a proposal assuming that there will be an opportunity to negotiate any aspects of the RFP. When it has been determined that it is in the Agency's best interest to conduct negotiations, ODH may request a submission of a best and final quotation.

- 6.18. Agreement Contents. If this RPP results in an award, the agreement will consist of this RFP, along with attachments, addenda, purchase orders, change orders, and terms and conditions. ODH reserves the right to award multiple agreements under this RFP.
- 6.19. Agreement Award. ODH plans to award the Agreement based on the proposal that is in the best interests of the Agency.
- 6.20. Agreement Start Date. If the Applicant is unable or unwilling to commence work, ODH reserves the right to cancel the award and resume the evaluation process with the next most advantageous proposal.
- 6.21. Non-Collusion Certification. The Applicant certifies that he/she is (sole owner, partner, president, secretary, etc.) of the party making the forgoing proposal, that such proposal is genuine and not collusive or sham; that Applicant has not colluded, conspired or agreed, directly or indirectly, with any applicant or person, to submit a sham proposal; or colluded or conspired to have another not participate; and has not in any manner, directly or indirectly, sought by agreement or collusion, or communication or conference, with any person to fix the proposal price or any other applicant, or to fix any overhead, profit or cost element of the proposal price, or of that of any other applicant, to secure any advantage against any applicant or any person or persons interested in the proposed award and that all statements contained in the proposal are true; and further, that the applicant has not, directly or indirectly, submitted this proposal, or the contents thereof, or divulged any related information or data to any association or to any member or agent of any association.
- 6.22. Scope of Work and Specifications. ODH is authorized to prepare scope of work and specifications to obtain supplies and services. The purpose of the scope or work or deliverables is to describe the supplies or services to be purchased and will serve as a basis for comparison of quote responses.



Policies and Procedures

Name of Location

Guidelines for the Project DAWN: Community-Based Overdose Education and Naloxone Distribution Program

Purpose: The purpose of this document is to outline the policies and procedures for the **Name of Entity** to conduct Project DAWN: Deaths Avoided With Naloxone, a community-based Overdose Education and Naloxone Distribution Program. Staff of the Project DAWN program, under the supervision of the Medical Director, will register and train Opioid Overdose Responders to administer nasal naloxone (Narcan©) to individuals experiencing an opioid overdose. Naloxone is an opioid antagonist, which is used to reverse the effects of an opioid overdose. It is a non-controlled substance.

Definitions:

Project DAWN Overdose Education and Naloxone Distribution Program: Project DAWN provides overdose prevention education and take-home overdose reversal kits containing naloxone to individuals who complete an established training and who are at-risk for opioid overdose according to established program criteria.

Project DAWN: A program conducted by the **Name of Entity** which provides overdose prevention and response education within the community to at-risk populations and trains Opioid Overdose Responders in accordance with established program policies.

Project DAWN Project Manager: The individual employed by the **Name of Entity** who has overall responsibility for administering the Overdose Education and Naloxone Distribution Program with clinical oversight from the Medical Director.

Project DAWN Overdose Prevention Educator: A person trained by the Project DAWN Project Manager, under the supervision of the Medical Director, to conduct Opioid Overdose Responder trainings.

Opioid Overdose Responder: A person who successfully completed an Opioid Overdose Prevention Training within the past two years, providing that the training was presented by an approved Project DAWN Overdose Prevention Educator.

Attachment A – Sample Policies and Procedures (Includes Medical Director Responsibilities)

Opioid Overdose Prevention Training: A standard curriculum that teaches an Opioid Overdose Responder overdose prevention techniques and basic first aid response to an opioid overdose event including the importance of implementing first aid, using naloxone and summoning EMS.

Medical Director: A physician licensed by the State of Ohio and who holds a valid DEA license and who is assigned responsibility by the Name of Entity to:

- 1) Provide medical oversight in general, including clinical oversight to the Project DAWN program;
- 2) Approve the established curriculum and the distribution policies regarding the naloxone administered through the Project DAWN Program;
- 3) Serve as an educational resource and advocate for Naloxone use among other healthcare professionals.

Authorized Prescriber: Any healthcare provider who possesses prescriptive authority under an accredited licensing Board in the state of Ohio as specified in the Ohio Revised Code, such as a Physician, an Advanced Practice Nurse, or a Physician's Assistant.

Opioid Antagonist: An FDA approved drug that negates or neutralizes, in whole or in part, the pharmacological effects of an opioid in the body. The opioid antagonist permitted under these guidelines is limited to intranasal naloxone.

Opioid Overdose Prevention Training: A training curriculum approved by the Medical Director, which instructs an Opioid Overdose Responder on prevention and reversal of opioid overdoses, including the importance of contacting emergency medical services, providing rescue breathing, and administering intranasal naloxone.

Responsibilities of Medical Director

1. The Medical Director shall oversee the clinical aspects of Project DAWN.
2. The Medical Director will approve the policies and procedures of Project DAWN, including the training curriculum.
3. The Medical Director will advise the program relative to any medical questions that may arise.
4. The Medical Director may or may not provide direct clinical care.
5. The intranasal naloxone may be purchased by the Name of Entity under a Board of Pharmacy terminal distributor license or special ordered to a nearby pharmacy.
6. *The Medical Director shall be responsible for establishing a protocol that authorizes one or more other individuals from Project DAWN or other agency staff to furnish naloxone pursuant to the protocol to a person at risk of an opioid-related overdose or to another person in a position to assist that person. Required components of such a protocol are listed in guidance from the Ohio Board of Pharmacy at: <http://pharmacy.ohio.gov/naloxone>. Click on the link "Guidance Document - Personally Furnishing Naloxone Pursuant to a Protocol".*
7. The Medical Director will be available to the Project DAWN staff for consultation on Project DAWN operations related to providing naloxone.
8. The Medical Director will ensure proper storage of naloxone if personally furnished on-site and that the program is compliant with all state and federal rules on the dispensing of prescription medication.

Attachment A – Sample Policies and Procedures (Includes Medical Director Responsibilities)

Program Requirements/ Staffing

Project DAWN Project Manager - The Project DAWN program must have a designated Project Manager. The manager shall be responsible for overseeing all elements of the program and ensuring compliance with program requirements including, but not limited to:

- Ensure that Project DAWN Overdose Prevention Educators are trained using the approved curriculum and routinely evaluated for effectiveness and adherence to program guidelines;
- Securely maintain all required records and submit required reports to the Ohio Department of Health;
- Establish policies concerning safe storage of nasal intranasal and appropriate documentation and reporting;
- Establish and maintain relationships with area services providers and stakeholders who may be appropriate to receive and conduct Overdose Prevention Training, who may have access to segments of the target population, and/or, who may collaborate with the project in other ways; and
- Training of Project DAWN Overdose Prevention Educators. All Overdose Prevention Educators who will be training and/or registering Overdose Responders must attend the approved training program with the Project DAWN Project Manager.

At a minimum the training curriculum shall address:

- Risk factors for opioid overdose
- Prevention strategies
- Signs of an overdose
- Calling 911
- Rescue breathing
- Administering intranasal naloxone
- Completion of proper documentation
- Proper storage of naloxone
- Post-overdose care
- Refill procedure

Quality Assurance: All Project DAWN Overdose Prevention Educators will attend a mandatory training conducted by the Project Manager, with oversight from the Medical Director. The training will cover the above mentioned topics in-depth.

The Project DAWN Project Manager will supervise all Overdose Prevention Educators providing overdose prevention education when they begin working and provide quarterly quality control checks. The Project Manager will review all documentation completed by the Overdose Prevention Educators monthly, including the Registration and Refill forms to ensure accuracy. Any clinical issues related to the dispensing of naloxone and any adverse events reported by participants will be referred immediately to the Medical Director.

Training of the Opioid Overdose Responders:

1. A *Project DAWN Registration Form* will be completed with each Opioid Overdose Responder as part of the training session. The Project DAWN Overdose Prevention Educator will conduct a

Attachment A – Sample Policies and Procedures (Includes Medical Director Responsibilities)

brief overdose risk assessment as part of the registration process and will ensure that all paperwork is completed accurately.

2. Project DAWN Overdose Prevention Educators shall be responsible for training Opioid Overdose Responders using the Project DAWN training curriculum. The training will consist of those elements listed in the Training Curriculum section, and will include live demonstrations from the participants to assess their understanding and ability to respond in an overdose situation. The Overdose Kit will contain an instructional DVD that will serve to reinforce these training steps. Opioid Overdose Responders will be encouraged to share the instructional DVD with family and friends so that they may be better able to assist them in an overdose situation.
3. Trainings may be conducted in a variety of settings. The trainings may be in small groups, conducted one-on-one or in community settings. The duration of the training shall depend on the number of responders in the class and their familiarity with drug administration and overdose.
4. Opioid Overdose Responders who complete the training shall be issued a naloxone kit to take with them that contains the items listed in the “Distribution of Naloxone Kits” section below.

Distribution of Naloxone Kits: The contents of the overdose reversal kits shall be distributed by the Opioid Overdose Prevention Educators in accordance with procedures approved by the Medical Director. The Project DAWN staff are responsible for putting the contents of each kit together. Each kit shall include:

1. Two prefilled Syringes - Naloxone 2mg/2 ml vial – (two vials per kit)
2. Two mucosal atomization devices
3. An instructional DVD and Project DAWN booklet which contains step-by-step instructions for naloxone intranasal administration and emergency response techniques
4. A mouth-to-mouth resuscitation barrier device
5. An identification card

Naloxone refills shall be made available to anyone who has previously completed the training and is a registered Overdose Responder. The Overdose Prevention Educator shall complete the required reporting form and record the reason for the refill, i.e. loss, theft, expiration, or use for an overdose reversal.

Data Collection and Record Keeping: A *Project DAWN Registration Form* shall be completed with each trained OD Responder. Copies of the forms shall be securely stored at the program site and will comply with all state and federal regulations pertaining to the proper storage of medical records. A *Project DAWN Refill Form* shall be completed for each report of the use of the naloxone or request for a refill.

Safe Storage of Naloxone Supplies and Program Records: The Project DAWN Project Manager shall ensure that all naloxone kits are securely stored in a locked cabinet at the program site and consistent with the manufacture’s guidelines. A system will be developed to remind the Project Manager when a participant’s naloxone is due to expire-and efforts will be made to contact the participant in the month preceding the expiration date.

Attachment A – Sample Policies and Procedures (Includes Medical Director Responsibilities)

Reviewed: _____ Date: _____

SAMPLE

Attachment B - Prescribing/Personally Furnishing Naloxone in Ohio



State Medical Board of Ohio
30 E. Broad St., 3rd Floor
Columbus, OH 43215-6127
614-466-3934



Ohio State Board of Pharmacy
77 S. High Street, Room 1702
Columbus, OH 43215-6126
614-466-4143



Ohio Board of Nursing
17 S. High Street
Columbus, OH 43215-7410
614-466-3947

JOINT REGULATORY STATEMENT **Prescription of Naloxone to High-Risk Individuals** *April 2013*

This statement provides information concerning the prescription of Naloxone to individuals at high-risk of 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 1999 to 2010, Ohio's death rate due to unintentional drug overdoses increased 372 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 regarding additional ways we can all contribute to saving lives, especially when faced with meeting the formidable challenge of treating opiate abuse and addiction. This statement is intended to raise awareness about the benefits of naloxone (Narcan™) for individuals at high-risk of opioid overdose.

Naloxone is a medication primarily used to prevent or reverse the effects of opioids, including respiratory depression, sedation and hypotension. 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. A contraindication for naloxone use is in patients who are known to be hypersensitive to the medication.

Prescribing Considerations

Prescribing Naloxone

Naloxone can be legally prescribed by a physician, physician assistant, or advanced practice registered nurse who is an Ohio authorized prescriber for patients who present a high-risk for opioid overdose, after the patient is evaluated by the prescriber who determines the patient would benefit from the prescription for naloxone. When prescribed, indications for and methods of administration should be explained to patients, along with any potential risks.

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, only physicians are authorized to personally furnish naloxone. Physician assistants and advanced practice registered nurses are not authorized to personally furnish naloxone.

Providing Naloxone to a Third-Party

Authorized prescribers may not prescribe or personally furnish naloxone to an individual for the purpose of encouraging the individual to distribute or administer the medication to others.

Risk Factors, Education, and Naloxone Prescription Programs

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. 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 opioid 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
- Enrollment 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 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.

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 Prescription Programs

Naloxone Prescription Programs (NPPs), which provide overdose training and take-home doses of intranasal naloxone to high-risk patients, 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 NPPs resulting in 10,171 overdose reversals using naloxone. In addition to providing naloxone for administration in cases when medical help is not immediately available, NPPs 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 NPPs, such as Project DAWN, and the use of the prescription of naloxone for persons at high-risk of an opioid drug overdose. For additional information please refer to <http://www.healthyohioprogram.org/vipp/drug/ProjectDAWN.aspx>.



Guidance Document – Personally Furnishing Naloxone **Pursuant to a Protocol**

Updated 7-20-2015

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.

For questions regarding these changes, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

More information about these recent law changes can also be accessed here:
<https://www.legislature.ohio.gov/legislation/legislation-documents?id=GA131-HB-4>

Q1) What are the requirements for the protocol?

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.

Q2) Is there a sample protocol available?

Currently a sample protocol does not exist. However, the Board has created a sample protocol for dispensing pharmacies that may be helpful, as it has some overlapping requirements. This sample protocol can be accessed here: www.pharmacy.ohio.gov/naloxone.



Please note: The pharmacy protocol does differ in its requirements from what is listed in Q1.

Q3) What type of naloxone can be personally furnished pursuant to the physician approved protocol?

The law has also been changed to allow any formulation of naloxone to be personally furnished via a protocol (or directly by a prescriber). The type of naloxone that may be dispensed may include all of the following formulations:

Intramuscular naloxone:

- Naloxone 0.4 mg/ml single dose vial, 2 vials
- NDC No. 00409-1215-01
- SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat ×1.

- Syringe 3 ml 25G ×1 inch No. 2
- SIG: Use as directed for naloxone administration

Intranasal naloxone:

- Naloxone 2 mg/2 ml prefilled syringe, 2 syringes
- NDC No. 76329-3369-01
- SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat ×1.

- Two mucosal atomization devices ([MAD300](#))
- SIG: Use as directed for naloxone administration

Auto-injector (intramuscular naloxone):

- Naloxone 0.4 mg/0.4 ml
- NDC No. 60842-030-01
- No. 1 twin pack
- SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat ×1.

Please note: The type of naloxone that may be personally furnished is subject to the formulations approved within the physician protocol. If new formulations are developed, they may be added to the protocol.

Q4) Where do I obtain the naloxone and the required delivery devices?

The single-dose vial, prefilled syringe, auto-injector and IM syringes are available from Ohio licensed wholesale distributors. The atomizers ([MAD300](#)) for nasal administration are available from medical supply vendors and, in some cases, can be purchased directly from a wholesaler.

Q5) Does the Board of Pharmacy have specific requirements for personally furnishing prescription drugs such as naloxone?

Unless specifically exempted by law, all sites that possess prescription drugs (such as naloxone) are required to be licensed as terminal distributors of dangerous drugs. Such licensure requires any drug that is personally furnished to meet all of the following requirements:

- Labeling: <http://codes.ohio.gov/oac/4729-5-17> **(The naloxone must be personally furnished in the name of the person who requests it.)**
- Storage/Security Requirements: <http://codes.ohio.gov/oac/4729-9-11>
- Recordkeeping: <http://codes.ohio.gov/oac/4729-9-22>

These requirements (labeling for example) will be delegated in the protocol to an authorized individual to perform on behalf of the physician. However, the physician should provide an appropriate level of oversight to ensure that the authorized individuals are complying with the requirements in the protocol.

Board staff is available to answer any questions you may have regarding these requirements and our inspectors can assist should you need on-site assistance.

To see if your location is licensed as a terminal distributor, please visit:
<https://license.ohio.gov/lookup/default.asp?division=96>

The following entities are exempt from obtaining a terminal distributor of dangerous drugs:

- **Law enforcement (for naloxone only):** A guidance document for law enforcement is available by visiting: www.pharmacy.ohio.gov/naloxone
- **Certain prescriber practices:** For more information, please visit: www.pharmacy.ohio.gov/prescribertddd

Q6) My organization is already licensed as a terminal distributor of dangerous drugs, do I need to do anything else to begin ordering naloxone?

If your organization has an unlimited TDDD category II or III license with the State of Ohio Board of Pharmacy, you can order, store and personally furnish naloxone to third parties (family, friends, etc.) and individuals who are at-risk for an opioid overdose.

For those organizations that have a limited TDDD category II or III license with the Board, you will need to update your drug list and protocols to reflect the addition of naloxone. To update these documents please use the following link: <http://pharmacy.ohio.gov/TDDD/DrugList.aspx>

IMPORTANT: BOTH your Drug List and Protocols must be signed by the medical director and notarized.

IMPORTANT: When uploading new documents, the old documents are OVERWRITTEN. Be sure to upload the ENTIRE Drug List and Protocols, NOT just the changes.

We ask that you allow for a 7-10 day approval period for these documents.

Q7) Is there written information available to assist with the training of patients?

Yes. The Board has developed a brochure that covers many of the typical training requirements for providing naloxone to laypersons. The brochure is available electronically by visiting: www.pharmacy.ohio.gov/naloxone

Additional training materials can also be accessed here:

Ohio Department of Health - Project DAWN (Deaths Avoided with Naloxone):
<http://www.healthy.ohio.gov/vipp/drug/ProjectDAWN.aspx>

Prescribe to Prevent: <http://prescribetoprevent.org/>

Q8) The law allows me to personally furnish naloxone to “a person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose”. How do I go about making this determination?

Many individuals work in environments where they may assist an individual experiencing an overdose including, but not limited, to the following:

- Colleges (residence life staff) and schools (school nurses, administrators, teachers, etc.)
- Substance abuse treatment programs (residential and nonresidential)
- Halfway houses
- Homeless shelters
- Home healthcare agencies

Please note: The authorizing physician should indicate in their protocol the individuals that meet this requirement or should be directly consulted if there are any questions. The naloxone must be personally furnished in the name of the person who requests it. Therefore, it must also be billed in the name of that person (if billing insurance).

Q9) What type of prescribers are able to authorize the protocol?

Ohio licensed physicians must authorize the protocol. The law does not limit the number of protocols a physician may authorize therefore a physician may authorize a protocol for a number of locations (or individuals). However, a physician should provide an appropriate level of oversight to ensure that the authorized individuals are complying with the requirements in the protocol. *Please note: Oversight does not mean the physician has to be physically present when naloxone is personally furnished.*

Q10) Are there any protections for physicians and individuals authorized to personally furnish naloxone on behalf of the physician pursuant to a protocol?

Yes. A physician and a person authorized by the physician to personally furnish naloxone, acting in good faith, are not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Q11) When does the protocol expire?

The law does not stipulate when the protocol expires. However, the authorizing physician may include an expiration date if they so choose.

Q12) Can I bill a patient’s insurance for the naloxone?

Medicaid, Medicare, and many private insurance companies may cover the cost of naloxone. To assist with billing, the law permits a pharmacist to document the dispensing of naloxone by the pharmacist or a pharmacy intern on a prescription form. The form may be assigned a number for record-keeping purposes.

According to the Ohio Department of Medicaid, all plans, except Buckeye Health Plan, pay for all formulations of naloxone (intranasal, intramuscular and auto-injector) when dispensed to a plan member. Buckeye Health Plan will cover the intranasal formulation as part of their pharmacy benefit.

Please be advised that the auto-injector for all plans requires prior authorization.

Please note: The naloxone must be dispensed in the name of the person who is requesting it at the pharmacy. Therefore, it must also be billed in the name of that person (if billing insurance).

Q13) Can I bill a patient's insurance for the atomizer needed for intranasal use?

It may be difficult securing reimbursement for the atomizer needed for intranasal use. Currently, the atomizer lacks a National Drug Code or UPN, which are universal product identifiers typically used in insurance billing systems.

Q14) Is there a limit to the amount of naloxone that can be dispensed pursuant to a protocol?

The authorized individual personally furnishing the naloxone should refer back to their protocol to determine if there are any established limits. If no such limitations exist, they should consult with the authorizing physician to determine if additional doses may be supplied.

Q15) Are there any substance abuse resources available to patients and their families?

For anyone seeking substance abuse treatment, please refer them to the Ohio Department of Mental Health and Addiction Services' treatment referral line at 1.877.275.6364.



Dispensing of Naloxone by Pharmacists and Pharmacy Interns without a Prescription

Updated 7-22-2015

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 questions regarding these changes, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.

More information about these recent law changes can also be accessed here: <https://www.legislature.ohio.gov/legislation/legislation-documents?id=GA131-HB-4>

Q1) What are the requirements for an approved protocol in rule 4729-5-39?

According to the rule, a physician approved protocol for dispensing naloxone without a prescription must include all of the following:

- (1) A description of the clinical pharmacology of naloxone.
- (2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol.
- (3) Precautions and contraindications concerning dispensing naloxone.
- (4) Assessment and follow-up actions by the pharmacist or pharmacy intern.
- (5) Naloxone products authorized to be dispensed, including: name of product, dose, route of administration, required delivery device and directions for use.
- (6) Any patient instructions in addition to the counseling requirements in the rule.



Full text of the rule is available at the end of this document and can also be accessed here: www.pharmacy.ohio.gov/naloxone

Q2) Is there a sample protocol available?

Yes. The Board has developed a sample protocol that can be used by physicians and pharmacies as their official protocol. The sample protocol can be accessed here: www.pharmacy.ohio.gov/naloxone

Q3) What type of naloxone can be dispensed pursuant to a physician approved protocol?

The type of naloxone that may be dispensed includes all of the following formulations:

Intramuscular naloxone:

- Naloxone 0.4 mg/ml single dose vial, 2 vials
- NDC No. 00409-1215-01
- SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat ×1.

- Syringe 3 ml 25G ×1 inch No. 2
- SIG: Use as directed for naloxone administration

Intranasal naloxone:

- Naloxone 2 mg/2 ml prefilled syringe, 2 syringes
- NDC No. 76329-3369-01
- SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat ×1.

- Two mucosal atomization devices ([MAD300](#))
- SIG: Use as directed for naloxone administration

Auto-injector (intramuscular naloxone):

- Naloxone 0.4 mg/0.4 ml
- NDC No. 60842-030-01
- No. 1 twin pack
- SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat ×1.

Please note: The type of naloxone that may be dispensed is subject to the formulations specified in the physician protocol. If new formulations are developed, they may be added to the protocol.

Q4) Where do I obtain the naloxone and the required delivery devices?

The single-dose vial, prefilled syringe, auto-injector and IM syringes are available from wholesale distributors with a valid Ohio license. The atomizers ([MAD300](#)) for nasal administration are available from medical supply vendors and, in some cases, can be purchased directly from the pharmacy wholesaler, or obtained from point persons within the pharmacy corporation.

Q5) Can I bill a patient's insurance for the naloxone?

Medicaid, Medicare, and many private insurance companies may cover the cost of naloxone. To assist with billing, the law permits a pharmacist to document the dispensing of naloxone by the pharmacist or a pharmacy intern on a prescription form. The form may be assigned a number for record-keeping purposes.

According to the Ohio Department of Medicaid, all plans, except Buckeye Health Plan, pay for all formulations of naloxone (intranasal, intramuscular and auto-injector) when dispensed to a plan member. Buckeye Health Plan will cover the intranasal formulation as part of their pharmacy benefit.

Please be advised that the auto-injector for all plans requires prior authorization.

Please note: The naloxone must be dispensed in the name of the person who is requesting it at the pharmacy. Therefore, it must also be billed in the name of that person (if billing insurance).

Q6) Can I bill a patient's insurance for the atomizer needed for intranasal use?

It may be difficult securing reimbursement for the atomizer needed for intranasal use. Currently, the atomizer lacks a National Drug Code or UPN, which are universal product identifiers typically used in insurance billing systems. Most likely, the pharmacy will have to charge the patient the cost of the atomizer if not covered by insurance.

Q7) Why do I need to submit notification to the Board if my pharmacy initiates a protocol to dispense naloxone without a prescription?

Rule 4729-5-39 of the Ohio Administrative Code requires a pharmacy to submit notification to the Board within 30 days of establishing an approved protocol. The Board will use this documentation to create a list on its web site of all pharmacies that offer naloxone pursuant to a physician protocol in an effort to facilitate access to the medication. Please be advised, that a pharmacy that discontinues their protocol will also be required to notify the Board. The Naloxone Notification Form can be accessed here: www.pharmacy.ohio.gov/naloxone

NOTE: If you are a chain pharmacy that is planning to offer this service in a particular region or state-wide, please submit a signed notification on company letterhead that includes a spreadsheet of all participating pharmacies to: contact@pharmacy.ohio.gov.

Q8) How do I submit this required documentation?

Step 1: The pharmacy's responsible person completes the notification form, which can be accessed here: www.pharmacy.ohio.gov/naloxone

Step 2: Go to the general document submission page:
<http://www.pharmacy.ohio.gov/TDDD/GeneralDocumentUpload.aspx>

Step 3: When at the page, enter the following information:

- The pharmacy's TDDD license number.
- Select "Naloxone Notification Form" from the drop down menu.

- Indicate whether you are dispensing naloxone pursuant to OAC 4729-5-39 or you are no longer dispensing naloxone in accordance with the rule.
- Upload the form (.PDF only).

Step 4: Once all the information is entered and the Click the submit button.

This process is also used for notifying the Board that your pharmacy has discontinued the protocol.

NOTE: If you are a chain pharmacy that is planning to offer this service in a particular region or state-wide, please submit a signed notification on company letterhead that includes a spreadsheet of all participating pharmacies to: contact@pharmacy.ohio.gov.

Q9) What are the counseling requirements for a pharmacist or pharmacy intern prior to dispensing naloxone pursuant to a protocol?

In addition to requirements specified in the protocol, OAC 4729-5-39 requires a pharmacist or pharmacy intern to provide written and verbal counseling on the following topics:

- (1) Instructing the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone;
- (2) Risk factors of opioid overdose;
- (3) Strategies to prevent opioid overdose;
- (4) Signs of opioid overdose;
- (5) Steps in responding to an overdose;
- (6) Information on naloxone;
- (7) Procedures for administering naloxone; and
- (8) Proper storage and expiration of naloxone product dispensed.

All patient counseling shall be documented in accordance with rule [4729-5-27 of the Ohio Administrative Code](#).

Q10) Is there written information available to assist pharmacists and pharmacy interns with meeting the counseling requirements?

Yes. The Board has developed a brochure that covers all of the required counseling listed in OAC 4729-5-39. The Board has a printed supply of these brochures that can be requested by a pharmacy free-of-charge by sending a request with all of the following information to contact@pharmacy.ohio.gov:

- Name of Requestor
- Pharmacy Name
- Mailing Address
- Phone Number
- Quantity Requested (there is a 250 pamphlet limit but additional requests can be made if the pharmacy is running low)

Please allow 7-10 days for delivery from the date of the request.

The pamphlet is also available electronically by visiting: www.pharmacy.ohio.gov/naloxone

Q11) The law allows me to dispense naloxone to “a person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose”. How do I go about making this determination?

Many individuals work in environments where they may assist an individual experiencing an overdose including, but not limited, to the following:

- Colleges (residence life staff) and schools (school nurses, administrators, teachers, etc.)
- Substance abuse treatment programs (residential and nonresidential)
- Halfway houses
- Homeless shelters
- Home healthcare agencies

The pharmacist or pharmacy intern should use their professional judgement to determine if the person meets the requirement of the law.

Please note: The naloxone must be dispensed in the name of the person who is requesting it at the pharmacy. Therefore, it must also be billed in the name of that person (if billing insurance).

Q12) What type of prescribers are able to authorize the protocol?

Ohio licensed physicians must authorize the protocol. The law does not limit the number of protocols a physician may authorize therefore a physician may authorize a protocol for a number of pharmacy locations.

The law also 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.

Q13) Are there any protections for pharmacists, physicians and boards of health in the law?

Yes. A pharmacist, physician or board of health, acting in good faith, is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Q14) When does the protocol expire?

Pursuant to rule 4729-5-39 of the Ohio Administrative Code, the protocol must be renewed annually. A pharmacy may discontinue a protocol at any time as long as proper notice is provided to the Board within 30 days (see Q7).

Q15) Is there a limit to the amount of naloxone that can be dispensed pursuant to a protocol?

The pharmacist or pharmacy intern should refer back to their protocol to determine if there are any established limits. If no such limitations exist, they should exercise their professional judgement to determine if additional doses may be supplied.

Q16) Are there recordkeeping and other requirements for pharmacists and pharmacy interns dispensing naloxone pursuant to a protocol?

All laws and regulations regarding the dispensing of drugs by a pharmacy would apply to naloxone dispensed pursuant to a protocol.

Q17) Are there any substance abuse resources available to patients and their families?

For anyone seeking substance abuse treatment, please refer them to the Ohio Department of Mental Health and Addiction Services' treatment referral line at 1.877.275.6364.

Q18) Are there any training resources available for pharmacists that dispense naloxone?

Yes. A no-cost ACPE approved pharmacist continuing education course is available from Prescribe to Prevent and Boston University. It can be accessed here:

http://www.opioidprescribing.com/naloxone_module_1-landing

4729-5-39 Dispensing of Naloxone

(A) A pharmacist or pharmacy intern under the direct supervision of a pharmacist may dispense naloxone without a prescription to either of the following in accordance with an approved protocol specified in paragraph (B) of this rule:

- (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.

(B) To be considered an approved protocol pursuant to section 4729.44 of the Revised Code, the physician-established protocol for the dispensing of naloxone by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

- (1) A description of the clinical pharmacology of naloxone.
- (2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol.
- (3) Precautions and contraindications concerning dispensing naloxone.
- (4) Assessment and follow-up actions by the pharmacist or pharmacy intern.
- (5) Naloxone products authorized to be dispensed, including all of the following information:
 - (a) Name of product;
 - (b) Dose;
 - (c) Route of administration and required delivery device; and
 - (d) Directions for use.
- (6) Any patient instructions in addition to the counseling specified in paragraphs (C) and (D) of this rule.

(C) A pharmacist or pharmacy intern under the direct supervision of a pharmacist who dispenses naloxone pursuant to this rule shall instruct the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone.

(D) A pharmacist or pharmacy intern under the direct supervision of a pharmacist shall personally provide the service of verbal counseling and written educational materials to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed, including, but not limited to, all of the following:

- (1) Risk factors of opioid overdose;
- (2) Strategies to prevent opioid overdose;
- (3) Signs of opioid overdose;
- (4) Steps in responding to an overdose;
- (5) Information on naloxone;
- (6) Procedures for administering naloxone; and
- (7) Proper storage and expiration of naloxone product dispensed.

(E) The pharmacy's responsible person shall ensure that all pharmacists and pharmacy interns that dispense naloxone pursuant to this rule are appropriately trained on the use of naloxone and can meet the counseling requirements listed in paragraphs (C) and (D) of this rule.

(F) A pharmacist may document the dispensing of naloxone by the pharmacist or a pharmacy intern supervised by the pharmacist on a prescription form. The form may be assigned a number for record-keeping purposes.

(G) All physician-established protocols shall be signed and dated by the physician prior to implementation and maintained by the pharmacy's responsible person. The protocol shall be made readily available to the dispensing pharmacist or pharmacy intern under the direct supervision of a pharmacist. The pharmacy's responsible person shall renew the protocol annually with the physician.

(H) Any pharmacy that dispenses naloxone pursuant to this rule, shall notify the board, in a manner prescribed by the board, within 30 days of establishing an approved protocol. A pharmacy that no longer dispenses naloxone pursuant to this rule shall notify the board, in a manner prescribed by the board, within 30 days of discontinuation.

Effective 7.16.2015

Appendix C – Sample Budget Guidance and Kit Contents

Item	Cost Estimates
Luer-Jet™ Prefilled Syringe - Naloxone 2mg/2 ml vial - \$12.78 /vial (2 vials per kit- \$25.56/kit) - \$17.90 / vial (2 vials per kit - \$35.80/kit) \$– NDC NUMBER 76329-3369-1** (http://www.amphastar.com/images/Naloxone.pdf)	\$25.56 - \$35.80
LMA MAD Nasal™, Nasal Atomizers (2 per kit) (http://www.lmana.com/pwpcontrol.php?pwpID=6359)	\$6.50 (\$3.25 each)
DVDs (with cases)***	\$1.25
Bag – Teal, Nylon CHECK WALLET 7"W X 5.5"H – (http://www.otco.com/security-bags/zipper-bags/zipper-check-wallet-bags.htm)	\$1.19
Quick Reference Guide ****	\$0.38
Laerdal® Face Shield – (http://www.laerdal.com/us/doc/115/Laerdal-Face-Shield)	\$1.64
Brochures ****	\$0.25
<p><i>**Low figure based on bulk hospital purchase and direct dispensing by a physician. Costs could increase if dispensed by a pharmacy and the medication is not purchased using a preferred contract. Bidders should work with local pharmacies or wholesale distributors (if dispensing on-site) to determine the price of naloxone in their budget.</i></p> <p><i>***Master copy of customized Project DAWN DVD Provided by ODH. Program will be responsible for the cost of duplication and cases provided.</i></p> <p><i>****All printed materials will be designed by ODH. Program will be responsible for the cost of printing materials.</i></p>	

Other budget items to consider:

- Other Printing Costs (Forms, Policy Manuals, Etc.)
- Office Supplies
- Salary & Fringe (including in-kind support)
- CPR Manikin
- Fees for licensing (i.e. Terminal Distributor License if dispensing on-site).

Please note: These figures represent estimates only. Please consult suppliers to determine costs.

Attachment D – Project DAWN Criteria of An Individual at-risk of Opioid Overdose

Overdose Education and Naloxone Distribution Programs, such as Project DAWN, target a wide-range of high-risk individuals. These individuals vary from chronic pain patients who may misuse or abuse medications to non-medical users of prescription opioids and heroin users. Additional indications include: those who are opioid naïve or have abstained from using opioids (recently released from jail or treatment facility), individuals with certain health conditions (renal dysfunction, COPD, HIV/AIDS) and those who are concurrently using other central nervous system depressants (benzodiazepine, alcohol, anti-depressants). Table 1 provides a complete list of the populations targeted by Project DAWN.

Table 1. Potential indications for prescription Naloxone and risk factor for poisoningⁱ

Potential Indication/Patient Population	Documentable Risk Factor for Poisoning
1 Emergency medical care for opioid poisoning	Increased risk for subsequent unintentional poisoning and self-harm
2 Suspected illicit or nonmedical opioid user	Risk for multiple drug use; continued (multiple) drug use; reduced opioid tolerance among inpatients
3 High-dose opioid prescription (>80 mg morphine equivalence/day)	Patient incorrectly administers opioid resulting in higher risk of toxic levels
4 Any methadone prescription to opioid naïve patient	Low threshold for overdose; inexperience with long-acting opioids
5 Any opioid use and smoking/COPD/emphysema or other respiratory illness or obstruction	Increased risk of respiratory depression due to comorbidities
6 Any opioid use and renal dysfunction or hepatic disease	Prolonged and/or increased serum concentrations of opioid due to decreased metabolism and/or excretion
7 Any opioid use and HIV/AIDS	HIV seropositivity is associated with an increased risk of overdose mortality
8 Any opioid use and known or suspected concurrent alcohol use	Additive effect of multiple central nervous system depressants
9 Any opioid use and concurrent benzodiazepine use or any concurrent sedating medication use	Additive effect of multiple central nervous system depressants
10 Any opioid use and concurrent SSRI or TCA anti-depressant use	Increased toxicological risk for opioid poisoning; higher risk for substance use and self-harm
11 Released prisoners	Relapse to/initiation of nonmedical opioid use; reduced opioid tolerance; risk for multiple substance use
12 Release from opioid detoxification or mandatory abstinence program	Relapse to nonmedical opioid use; reduced opioid tolerance; risk for multiple substance use
13 Voluntary request	Perceived risk for opioid exposure
14 Patients entering methadone maintenance treatment programs (for addiction or pain)	Increased risk for poisoning in first month; risk for multiple substance use

ⁱ Project Lazarus, NC Medical Board Position Statement, <http://www.projectlazarus.org/policymakers-media/nc-medical-board-policy-statement>;

Attachment E – Work Plan Template & Instructions

Project DAWN

Population-based Objective and Work Plan: Overdose Education and Naloxone Distribution Program (OENDP)

Goal: Establish a fully functioning and sustainable Project DAWN Overdose Education and Naloxone Distribution Program.

Objectives: State the “big steps” a program will take to attain its goal. They can be used to determine a program’s status at any given point in time, and they can be measured during the funding period. Objectives should be **S.M.A.R.T.**, that is,

- **Specific** (identify who, what, and where),
- **Measurable** (identify how many by when),
- **Achievable** (can be attained),
- **Realistic** (can be attained given time and resources available),
- **Timeframed** (identify when).

Remember: They should not include more than one expectation. Work plan should include several objectives to meet program goal (eg. Objective 1, 2, 3...).

Activities	Evaluation Benchmark	Team Members Responsible
What a program does or its specific tasks to meet its objectives and ultimately fulfill its goal. There should be multiple activities for each objective.	Describe the method for ensuring that each activity has been completed, e.g. survey data, items secured, number of providers trained, focus group results, etc. The method should be well thought out and specific.	Identify the person or agency responsible for completing the activities.

Attachment E – Work Plan Template & Instructions

EXAMPLE

Project DAWN

Population-based Objective and Work Plan: Overdose Education and Naloxone Distribution Program (OENDP)

Goal: Establish a fully functioning and sustainable Project DAWN Overdose Education and Naloxone Distribution Program.

Objective #1: By November 15, 2013, OENDP coordinator and staff will assemble 150 Project DAWN overdose reversal kits.		
Activities	Evaluation Benchmark	Team Members Responsible
Work with ODH to finalize education materials, brochure and training DVD.	Receipt of master files for DVD, brochure and educational materials from ODH.	Project DAWN Project Manager & Medical Director
Work with local printer to print education materials and duplicate DVDs.	Printed materials and DVDs delivered.	Project DAWN Project Manager
Establish account with LMA and place order for 300 MAD Nasal Atomizers	Nasal Atomizers Delivered	Project DAWN Project Manager & Medical Director
Order bags and face shields.	Bags and face shields delivered.	Project DAWN Project Manager