Novel Naloxone Distribution Strategies

Grayken Center for Addiction at Boston Medical Center:

Training and Technical Assistance

Novel Naloxone Distribution Strategies

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Introducing Novel Nasal Naloxone Distribution Strategies

Throughout the last 20 years, spikes in deaths related to drug overdoses have significantly impacted the United States (NIDA, 2021). The high death toll has increased in the last five to ten years due to the introduction of synthetic opioids, such as fentanyl, into the illicit drug supply (Lippold et al., 2019). Illicit fentanyl's intensity and rapid onset of effects have resulted in over 130 daily deaths, a rate that is secondary to the daily summation of all opioid- overdose related deaths (HRSA, 2018). For the last several decades, escalating trends in deaths related to overdose have incentivized public health and policy to focus on a multifaceted approach that strives to address the complexities encompassing the drug overdose epidemic.

According to the Biden-Harris Administration Office of National Drug Control Policy seven priorities have been identified as necessary amidst the overdose and addiction crisis (ONDCP, 2021). Specifically, priority three of the Biden-Harris administration plan, *Enhancing Evidence-Based Harm Reduction Efforts*, identifies the need to explore funding streams for many harm reduction services and treatments, including reimbursement for naloxone (ONDCP, 2021). Naloxone, an antagonist that binds at the mu-opioid receptor, has often been referred to as the antidote to an opioid overdose: Naloxone quickly takes effect in 2-3 minutes, lasting 60-80 minutes, effectively reversing overdose symptoms to restore spontaneous respirations (McDonald et al., 2018).

For the last couple of decades, the distribution of nasal naloxone has been of vital focus to confront risks associated with opioid use disorder, especially risks affecting patients and their loved ones. Substantial evidence supports a correlation between the distribution of nasal naloxone to community members and a reduction in mortality, as naloxone facilitates a rapid response for overdose symptoms (LDI, 2019). Naloxone distribution is especially impactful among groups with elevated risks of overdose. Distribution strategies have been implemented and exemplified by methods such as secondary distribution, public safety distribution, and post-overdose "door knock" programs. In addition, naloxone has become accessible through harm reduction agencies, such as syringe service programs (Townsend et al., 2020).

Ultimately, there has been a drastic uptick in the availability and accessibility of naloxone in the community; however, public health dollars have been the primary source of funding for

naloxone availability. Considering naloxone distribution is the only component in a necessary multifactorial approach that addresses the drug overdose epidemic, there is an imperative need for the implementation of cost-effective avenues across health systems (Murrin, 2020). A recent report through Centers for Medicare & Medicaid Services (CMS) examines the utilization of nasal naloxone through pharmacy distribution. The report reveals an astounding lack of access through this cost-effective method of distribution (Murrin, 2020). Unfortunately, most community members are accessing naloxone through distribution streams vastly subsidized by public health dollars, despite the medication's prompt availability through pharmacies and insurance. The discrepancy is an urgent call to action to work collaboratively and creatively within current healthcare frameworks to reduce barriers to naloxone access. It is vital that patients can access this life-saving medication through traditional and reimbursable avenues without reducing access to the medication at a community level.

The purpose of this document is to outline potential strategies to increase patient access to nasal naloxone by serving as a guide for administrators, healthcare providers, and non-medical providers attempting to create reimbursable streams for naloxone. There are five distinct locations in which workflows have been designed to increase access to naloxone in a manner that benefits the patient and the pharmacy by preventing and reducing the need for subsidized doses of naloxone. Due to the collaborative nature of the workflows presented, the collective cooperation of pharmacy partners, hospital administrators, billing specialists, and clinical staff is critical in determining the most appropriate workflow for one's organization, along with adjustments based on local laws, institution policies, and institution procedures. All of these models provide infrastructure to enable nurses to distribute nasal naloxone directly to the patient in the treatment setting. This document outlines distribution methods that may be adapted by other organizations to allow patients and community members to receive this life-saving medication from the nurse in their treatment setting, decreasing barriers to overdose prevention.

Naloxone and Opioid Overdose Response

Recognizing an overdose and knowing how to administer naloxone are critical elements to decrease the rate of overdose-related deaths in the United States. This is especially true given the prevalence of fentanyl in the drug supply and trends indicating escalating rates of overdose-related deaths.

Mechanism of Action

- Naloxone is an opioid antagonist medication used for the reversal of opioid overdose.
- Opioid antagonists have a high affinity for the opioid receptors in the body, meaning that they can both block and displace opioids at those receptor sites.
- In an opioid overdose, the opioid receptors in the central nervous system are saturated by opioids leading to decreased respiratory rate, heart rate, risk for hypoxia/anoxia, and associated death.
- Naloxone works by displacing the opioids occupying those receptors, reversing the central nervous system suppression, and allowing the person to breathe again (SAMHSA, 2021).

Formulation and Administration

- Naloxone is available in a solution that may be administered intranasally, intravenously, subcutaneously, and intramuscularly.
- Intranasal formulations of naloxone are traditionally used in outpatient and community settings due to the ease of administration and rapid onset.
- Intranasal naloxone kits come with two actuated nasal sprays, each containing 4mg/0.1mL of naloxone, while intramuscular kits come in vials of 8mg/0.1mL of naloxone. In addition to opioid overdose reversal, potential side effects of naloxone administration are symptoms of acute opioid withdrawal, including body aches, gastrointestinal upset (diarrhea, nausea, vomiting), anxiety, agitation, rhinorrhea, and piloerection.

Recognizing and Reversing an Overdose

- Naloxone is a very safe and effective medication. Administration of naloxone for suspected opioid overdose, even without confirmation of opioid use, is recommended (Wermeling, 2015).
- Signs of overdose include (1) pale or blue skin, (2) constricted pupils, (3) loss of consciousness, (4) slow or shallow breathing, and (5) unresponsiveness to voice or sternal rub (CDC, 2020).
- After identifying a suspected overdose, individuals should assess that the scene is safe for intervention and determine if the person affected is conscious by speaking loudly and administering a hard sternal rub to the chest plate (National Harm Reduction Coalition, 2020).
- If there is no response, call emergency services and proceed with inserting the intranasal naloxone kit into the individual's nostril and pressing the plunger for administration.
- Rescue breaths can be administered every 5 seconds by responders previously in contact with the individual who has overdosed or by those with proper airway protection.
- Repeat administration of an additional dose after 2-3 minutes, alternating nostrils. Continue to provide ventilation support until the person becomes conscious or emergency services arrive. If the person responds to naloxone, turn them to their side into a recovery position and provide support (National Harm Reduction Coalition, 2020).

Overview of Current Clinical Overdose Education and Naloxone Distribution Practice

Current clinical practices for Overdose Education and nasal Naloxone Distribution (OEND) focus on providing patients, at high risk of overdose, with improved access to naloxone in both community and commercial pharmacies. Legislation has allowed for third party prescribing of naloxone, while either encouraging or mandating co-prescribing of nasal naloxone in conjunction with all opioid prescriptions for pain and opioid use disorder. Multiple studies' findings have demonstrated efficacy in increasing naloxone access and distribution through targeted clinical interventions. Targeted clinical interventions improve provider distribution of nasal naloxone to high-risk patients.

Third Party Prescribing

- Laws which permit an individual prescriber to write a prescription for someone who is not the end recipient of a specific medication.
- Allows providers to write prescriptions for family members or loved ones of an individual at-risk for fatal opioid overdose.
- Permitted in all but two states (Kansas and Minnesota) (SAFE Project, 2021).
- Includes screening of all patients about whether they know anyone at risk for fatal overdose and if they are interested in naloxone (Hughes, 2016).
- Reference **Figure 2, Appendix D** to view an example of a third-party naloxone prescription.

Co-Prescribing

- A practice that involves a prescriber writing a prescription for naloxone at the same time they write for opioid medications.
- May involve education and counseling around opioid overdose and the risks of substance use disorder for patients on chronic opioid therapy.
- Naloxone should routinely be prescribed in conjunction with medications for opioid use disorder, including those on methadone, buprenorphine, and naltrexone in the event of unexpected, recurrent substance use.
- Consideration for co-prescribing should occur for patients who receive opioid medications in combination with other CNS depressant medications, including benzodiazepines.

- Some electronic health records have “hard” stops to prevent providers from sending prescriptions for opioid medications without also sending a prescription for naloxone.
- Data has demonstrated that laws requiring or encouraging co-prescribing have increased rates of naloxone prescriptions for individuals at highest risk for opioid overdose fatalities (see **Figure 1**, **Appendix A**).

Overview of Community Overdose Education and Naloxone Distribution Practice

The introduction of standing orders for the dispensing of naloxone is a cornerstone of community-level Overdose Education and Naloxone Distribution (OEND). Improved access to nasal naloxone in non-traditional settings has been possible due to standing orders and changes in legislation regarding distribution. Different standing orders can be viewed in **Appendix B**. Examples provided in this section are of clinical and non-clinical settings in which nasal naloxone distribution exhibits increased access for patients. Unfortunately, community-based OEND practices are limited by barriers of cost to the public health department's purchase of naloxone doses.

Standing Orders

- A standing order is a system by which a healthcare provider with prescribing privileges, often a state health officer, provides a prescription that permits the distribution of a medication to a large group of people (SAFE Project, 2021). Standing orders from a state health officer may additionally grant distribution of naloxone by non-clinical staff (public safety, harm reduction, outreach workers, etc. (SAFE Project, 2021).
- Individual practice settings in which nurses are permitted to transmit naloxone to the pharmacy in collaboration with a provider must follow federal and state regulations and the organizations policies and procedures for standing orders.
- Refer to **Figure 1**, **Appendix B** to view a statewide standing order for MA and refer to **Figure 2**, **Appendix B** to view standing order for Boston Medical Center.

Programs that Dispense Naloxone Under Standing Orders

Naloxone Distribution at Needle and Syringe Programs

Needle and syringe service agencies should have naloxone on site to distribute under a standing order. The distribution is intended for individuals in the community at-risk for overdose or individuals in frequent proximity to those at-risk for overdose. Naloxone is often provided to these agencies through public health or grant funds, allowing individuals to have the medication in hand (Lambdin, 2020).

Community Outreach Programs

Community outreach programs actively seek out individuals at risk of opioid overdose to distribute naloxone. Community health workers (CHWs) or other recovery support personnel

may provide counseling and education about OEND and demonstrate naloxone administration from available stock (Wheeler et al., 2012).

Recovery Support Centers or Recovery Support Programs

Recovery coaches may engage those new to recovery or individuals in long-term recovery in overdose prevention and education. Distribution of naloxone is essential as new recoverees may have regular contact with people actively using, increasing one's chances of witnessing an overdose. People at any stage in their recovery from substance use are susceptible to returning to use. Individuals with a period of recovery who have a recurrence of opioid use are highly susceptible to accidental overdose given their loss of opioid tolerance. Therefore, it is important that overdose education and prevention be incorporated into services for people in recovery.

Other Harm Reduction Support Centers or Programs for Drug-user Health

Drug user health programs that are able to offer comprehensive services often have drop-in models to obtain naloxone from non-clinical staff. Many of these programs are supported through grants or public health funds to purchase naloxone stock for distribution (Piper et al., 2008).

Family and Loved One Distribution Programs

Programs founded by families and loved ones affected by a loss to overdose may engage in efforts to distribute naloxone to individuals at-risk and their family members. Third-party prescribing and standing orders may work in tandem for families to obtain and distribute naloxone. Family distribution programs may obtain naloxone in bulk from other agencies for distribution, or they may receive and distribute naloxone through third-party prescribing practices (Bagley et al., 2018).

Post-Overdose Outreach Programs

Post-Overdose Outreach Programs. These programs sometimes referred to as "Door-Knock" programs, are staffed by community outreach workers, harm reduction specialists, emergency medical services providers, public safety officers, or a combination of all. Typically 2-3 days after an overdose, specialty teams or individuals may return to an address or a site of an opioid overdose to offer individuals naloxone. In communities at-risk for repeated opioid

overdoses or for socially isolated individuals, post-overdose outreach programs may prevent a subsequent overdose (McCammon, 2018) (Formica et al, 2021).

Emergency Outreach Programs. Emergency service personnel may distribute nasal naloxone to an individual or peers at the scene of a prior opioid overdose. Some community outreach programs may contact a person who has been discharged from an emergency room post-overdose to check in and offer naloxone from a community supply (Albright & Castillo, 2018).

Novel Distribution Pathways to Improve Nasal Naloxone Access

The following novel naloxone distribution pathways have been identified and described to address both the growing need for rapid naloxone access and disparities in access due to barriers. Each of the unique pathways increases naloxone distribution directly to patients through the nurse on their treatment team covered by their insurance provider. Pathway descriptions include (1) a description of the practice location, (2) the necessary entities or team members involved in maintaining the pathway, (3) the steps of a workflow for the program currently instituted (4) and an overview of potential implementation challenges and potential solutions. The entities included in each pathway lists team members central to naloxone distribution in the example practice setting but should not limit organizations from adapting these work flows to meet their needs by integrating other team members. In addition, each distribution pathway includes an illustration to demonstrate the naloxone distribution workflow for easy reference for participating entities. Illustrations of workflow can be found among figures in **Appendix C.** Relevant practice agreements, tracking documents, example naloxone labels, and order and delivery forms described in distribution pathways are provided among figures in **Appendix D**. Depictions of patient education sheets and storage supplies referenced in workflows are provided in **Appendix E**. Lastly, a *Nasal Naloxone Protocol* is provided in **Appendix F**.

Ambulatory Distribution with Co-Located Pharmacy

Practice Location Description

The Boston Medical Center Office Based Addiction Treatment (OBAT) Program is an addiction treatment program within a primary care setting using the nurse-care manager model. In the nurse-care manager model, nurses work to the fullest scope of their license to provide patients with comprehensive addiction treatment in an outpatient, primary care setting. The model achieves efficient coordination of complex patient care through a multidisciplinary team of professionals. Most patients treated in the OBAT program receive medications for opioid use disorder, most common of which is buprenorphine. The OBAT program has adopted a harm reduction approach to addiction treatment; therefore, nurses often follow patients who have recently used a substance, who recurrently use an illicit substance while receiving treatment, or who may be new to treatment. Patients are not only at an elevated risk for overdose, but may interact with social networks in which individuals are more likely to experience an opioid overdose. Rapid access to naloxone in a clinical setting allows nurses to ensure that a patient receives the life-saving medication and develops creative strategies for storing naloxone for ready availability on their person.

Administrative Requirements

- Organization specific naloxone protocol, nursing standing orders for naloxone transmission to pharmacy in collaboration with provider.

Entities Involved

- OBAT clinic nurses, providers, hospital administration, internal pharmacy staff.

Steps of Distribution Workflow

Nurse care managers offer nasal naloxone to all patients in OBAT care: The medication is offered to all patients with a substance use disorder, not only those with an opioid use disorder. In providing all patients with naloxone, nurses acknowledge the high risk of fentanyl adulterated drug supply and understand the public health importance of preparing individuals to respond to a suspected overdose. The steps of the workflow for OBAT's distribution are as follows (also illustrated in **Figure 1, Appendix C**):

1. Given the varied experiences of people who use drugs, it is important to assess the level of knowledge patients have regarding overdose identification, response, and reversal. For

patients with ample experience, it is prudent to provide focused education and information about naloxone and availability (see **Figure 2**, **Appendix E**).

2. For patients unfamiliar with overdose response and naloxone administration, they should receive education regarding overdose identification and response, including the administration of naloxone and emergency response.
3. Nurses explain to the patient that their insurance will be billed for naloxone received in the clinic that day.
4. Nurse documents distribution of naloxone in the patient's electronic medical record and updates the patient's medication list or routes to provider for historical documentation based on the organization's policies and procedures.
5. The nurse removes two doses of nasal naloxone 4mg/0.1mL actuation nasal spray (one rescue kit) from the clinic supply and affixes a patient label to both the medication and the *Nasal Naloxone Distribution Tracking Sheet* (see **Figure 3**, **Appendix D**).
6. The nurse may work with the patient to remove the medication from the manufacturer package and identify alternative storage methods to accommodate discretion and rapid access to medication in the event of an overdose. Often, when patients carry naloxone, they may want to keep their naloxone concealed. In its original packaging, naloxone is contained in a bulky box. To respect the privacy of patients while also keeping patients safe, the following repackaging measures can be taken to make patients comfortable:
    a. The OBAT program offers patients several small nylon pouches, including a zipper and carabiner clip (see **Figure 1**, **Appendix E**).
    b. Pouches fit two doses of naloxone, gloves, and a face shield.
    c. Pouches can fit in a purse, backpack, lanyard or attach to an article of clothing or accessories with a carabiner.
7. Weekly, the charge nurse sends the *Nasal Naloxone Distribution Tracking Sheet* to the pharmacy team member responsible for billing for naloxone.
8. The registered pharmacist may contact the patient directly or reach out to clinic staff to clarify matters related to patient's insurance or demographic information.
9. Repeat the distribution process as necessary. Continue to offer naloxone to patients in living or social situations that elevate the risk of encountering or responding to an opioid overdose to ensure improved distribution.

Potential Challenges

- Storage of medication within the clinic that is secure and easily accessible to clinic staff when needed.
    - Daily inventory and inventory on the dispensation of the naloxone supply is recommended to prevent the loss or theft of the naloxone supply.
    - Regularly check medication expiration dates to ensure the supply is safe for distribution.
- Consistent communication between the pharmacy team and clinic staff, particularly in regards to patient's insurance coverage.
    - A regular check-in between pharmacy staff and OBAT staff should occur to rectify any outstanding concerns or issues.
    - In the event that a patient is uninsured or their insurance does not cover the cost of naloxone, a pre-identified process should exist for the pharmacy to recoup the cost of the medication (cost center, private fund, etc.).

Example Forms

- *Boston Medical Center's OBAT Nasal Naloxone Protocol* at **Figure 2, Appendix F** and the Nursing Script at **Figure 1**, **Appendix F**.
- *Nasal Naloxone Distribution Tracking Sheet* can be viewed at **Figure 3**, **Appendix D.**
- OBAT Clinic Nasal Naloxone Inventory Tracking document can be viewed at **Figure 4**, **Appendix D**.

Ambulatory Distribution with an Off-Site Pharmacy

Practice Location Description

The Community Health Center has an existing Office Based Addiction Treatment (OBAT) program, however the institution does not have a pharmacy within the current practice location. Thus, the patient care team relies on local commercial pharmacies for patients to access all of their medications. To improve access and distribution of nasal naloxone to at-risk patients, the Community Health Center and a commercial pharmacy collaborate on an agreement to reduce barriers to traditional patient medication access.

Administrative Requirements

- Organization specific naloxone protocol, nursing standing orders for naloxone transmission to pharmacy in collaboration with provider.

Entities Involved

- OBAT clinic staff (nurses, providers, recovery coaches, care coordinators), community pharmacy partners (pharmacists, pharmacy technicians).

Steps of Distribution Workflow

Establishing a practice agreement between the commercial pharmacy and the community health center may be beneficial to creating an efficacious workflow between the two organizations. A collaborative practice agreement may outline different strategies for naloxone distribution to the health center level by the pharmacy, including (1) providing a small stock of naloxone for the health center, (2) providing a weekly or daily delivery of naloxone to the health center, or (3) providing a same day courier service to specific practice locations.

The practice agreement between the Community Health Center and the commercial pharmacy outlined enables the Community Health Center to store a small stock of nasal naloxone from the commercial pharmacy, which is replenished weekly by a courier service, to be billed to patient insurance following distribution. The steps of the workflow for the Community Health Center's distribution with a clinic supply of naloxone are as follows (also illustrated in **Figure 2**, **Appendix C**):

1. Nurse care managers offer naloxone to all patients in OBAT care: The medication is offered to all patients with a substance use disorder, not only those with an opioid use

disorder. Offering the medication to all patients with an opioid use disorder and other substance use disorders acknowledges the high risk of fentanyl adulterated drug supply and the public health importance of responding to a suspected overdose.

2. Given the varied experiences of people who use drugs, it is important to assess the level of knowledge patients have regarding overdose identification, response, and reversal. For patients with ample experience, it is prudent to provide focused education and information about naloxone and availability (see **Figure 2**, **Appendix E**).
3. Nurses explain to the patient that their insurance will be billed for naloxone received in the clinic that day.
4. Nurse documents distribution of naloxone in the patient's electronic medical record and updates the patient's medication list or routes to provider for historical documentation based on the organization's policies and procedures.
5. The nurse removes two doses of nasal naloxone 4mg/0.1mL actuation nasal spray (one rescue kit) from the clinic supply and affixes a patient label to both the medication and the *Nasal Naloxone Distribution Tracking Sheet* (see **Figure 3**, **Appendix D**).
6. The nurse may work with the patient to remove the medication from the manufacturer package and identify alternative storage methods to accommodate discretion and rapid access to medication in the event of an overdose. Often, when patients carry naloxone, they may want to keep their naloxone concealed. In its original packaging, naloxone is contained in a bulky box. To respect the privacy of patients while also keeping patients safe, the following repackaging measures can be taken to make patients comfortable:
    a. Discuss patient hesitance or discomfort with carrying naloxone and provide patients with a reliable and easily transportable mechanism for storing naloxone to encourage keeping naloxone on their person.
    b. Offer patients several small pouches, including a zipper and an optional carabiner clip (see **Figure 1**, **Appendix E**).
    c. Accommodate patients with pouches that can fit in a purse, backpack, lanyard, or attach to an article of clothing or accessories with a carabiner.

7. Weekly, the nurse sends the *Nasal Naloxone Distribution Tracking Sheet* to the commercial pharmacy team member responsible for billing for naloxone.
8. The registered pharmacist may contact the patient directly or reach out to clinic staff to clarify matters related to patient's insurance or demographic information.
9. Repeat the distribution process as necessary. Continue to offer naloxone to patients in living or social situations that elevate the risk of encountering or responding to an opioid overdose to ensure improved distribution.

The Community Health Center, without the ability to ensure clinic supply of naloxone, may (1) send the naloxone prescription to the patient's preferred pharmacy to be picked up by the patient and/or (2) collaborate with a pharmacy to provide delivery of naloxone ordered for a specific patient to be distributed at the next visit. Meaning, that rather than having a clinic supply of naloxone that could be distributed to any patient and billed to insurance following, this site would send a prescription to the pharmacy to be billed to insurance and delivered to the site for distribution to that specific patient. The Community Health Center may choose to both send a prescription for patient pick-up and arrange for future delivery of naloxone to ensure immediate access to naloxone at upcoming appointments. The steps of the workflow outlined below is for the Community Health Center's distribution without a clinic supply of naloxone are as follows (also illustrated in **Figure 2**, **Appendix C**):

1. Nurse care managers offer naloxone to all patients in OBAT care: The medication is offered to all patients with a substance use disorder, not only those with an opioid use disorder. Offering the medication to all patients with an opioid use disorder and other substance use disorders acknowledges the high risk of a fentanyl adulterated drug supply and the public health importance of responding to a suspected overdose.
2. Given the varied experiences of people who use drugs, it is important to assess the level of knowledge patients have regarding overdose identification, response, and reversal. For patients with ample experience, it is prudent to provide focused education and information about naloxone and availability (see **Figure 2**, **Appendix E**).
3. Nurses explain to the patient that nasal naloxone 4mg/0.1mL actuation nasal spray will be sent to the pharmacy for same-day pick up.

4. Nurse explains that a prescription for naloxone 4mg/0.1 mL actuation nasal spray can also be sent to a community pharmacy for delivery to the health center for distribution to the patient at future visits. This discussion should be completed during the first nursing encounter to ensure patients can receive same day naloxone in clinic at future appointments.
    a. Patient's who agree to naloxone delivery will complete the *Prescription Delivery Authorization Form* **(**see **Figure 5**, **Appendix D**).
5. Nurse documents patient preference for delivery of naloxone to the community health center in the patient's electronic medical record and ensures nasal naloxone was transmitted to community pharmacy or routes to provider for transmission following the organization's policies and procedures.
6. During subsequent encounters in which naloxone is distributed directly to the patient, the nurse may educate the patient on how to remove the medication from the manufacturer package and identify alternative storage methods to accommodate discretion and rapid access to medication in the event of an overdose following receipt of naloxone pharmacy or in clinic.
    a. Discuss patient hesitance or discomfort with carrying naloxone and provide patients with a reliable and easily transportable mechanism for storing naloxone to encourage keeping naloxone on their person.
    b. Offer patients several small pouches, including a zipper and an optional carabiner clip (see **Figure 1**, **Appendix E**).
    c. Accommodate patients with pouches that can fit in a purse, backpack, lanyard, or attach to an article of clothing or accessories with carabiner.
7. The nurse completing the visit ensures naloxone was sent to collaborating community pharmacy with ample refills. For example, dispense 4 nasal naloxone 4mg/0.1mL actuation nasal spray with 99 refills.
8. Nurse documents distribution of naloxone in the patient's electronic medical record and ensures naloxone is on the patient's medication list or routes to provider for historical documentation based on the organization's policies and procedures.
9. Weekly, the nurse or clinic staff reviews new and current patients to ensure those who have agreed to have naloxone delivered to the health center have active prescriptions

with the community pharmacy. Upon receipt of delivery, naloxone should be logged and stored per organization protocols and noted in upcoming patient appointment to remind team to distribute to the patient. See *Nasal Naloxone Distribution Tracking Sheet* (see **Figure 3**, **Appendix D**).

10. The community pharmacist may contact the patient directly or reach out to clinic staff to clarify matters related to patient's insurance or demographic information.
11. Repeat the distribution process as necessary. Continue to offer naloxone to patients in living or social situations that elevate the risk of encountering or responding to an opioid overdose to ensure improved distribution.

Potential Challenges

- The primary challenge in establishing an alternative pathway for naloxone distribution with an off-site commercial pharmacy is identifying a potential collaborative partner.
    - Start by meeting with commercial pharmacies that are known to serve patients from the OBAT clinic and have been good partners in the past.
    - Communicate requests for collaboration before meeting with the pharmacy to allow internal discussion of workflow and request permission from their corporate office.
    - Smaller community pharmacies may be more willing to partner with your agency if they have been serving OBAT patients for an extended period of time.
    - Have alternative strategies for naloxone distribution (storage at the clinic vs. delivery to the clinic) to provide the commercial entity with options that may better suit their needs.
- Storage of medication within the clinic that is secure and easily accessible to clinic staff when needed.
    - Daily inventory and inventory on the dispensation of the naloxone supply is recommended to prevent the loss or theft of the naloxone supply.
    - Regularly check medication expiration dates to ensure the supply is safe for distribution.
- Consistent communication between the pharmacy team and clinic staff, particularly in regards to patient's insurance coverage.

- A regular check-in between pharmacy staff and OBAT staff should occur to rectify any outstanding concerns or issues.
- In the event that a patient is uninsured or their insurance does not cover the cost of naloxone, a pre-identified process should exist for the pharmacy to recoup the cost of the medication (cost center, private fund, etc.).

Example Forms

The *Nasal Naloxone Distribution Tracking Sheet* can be viewed at **Figure 3**, **Appendix D.** The *Prescription Delivery Authorization Form* can be viewed at see **Figure 5**, **Appendix D**.

Opioid Treatment Program with an Off-Site Pharmacy

Practice Location Description

The Spectrum Opioid Treatment Program (OTP), located at Lincoln St. in Worcester, is an opioid treatment program that provides daily dosing of medications for opioid use disorder with clinician observation. Most patients utilize the practice for daily methadone dosing to treat opioid use disorders. Patients who receive methadone treatment may be engaged in social networks with individuals who are also at elevated risk of an opioid overdose due to recurrent illicit opioid use or at risk in the early stages of recovery. Daily visits with OTP staff make the collaboration with local commercial pharmacies a viable option for direct naloxone distribution for patients that may be involved with others or at elevated risk themself for opioid overdose.

Administrative Requirements

- Organization specific naloxone protocol, nursing standing orders for naloxone transmission to pharmacy in collaboration with provider.

Entities Involved

- OTP team (nurses, providers, administrative team, clinical staff), community pharmacy partners (pharmacists, pharmacy technicians).

Steps of Distribution Workflow

Spectrum Opioid Treatment Program's workflow involves multiple entities and does not result in same-day access to naloxone. However, the nature of the OTP setting requiring patients receive daily methadone doses under observation facilitates a one-to-two-hour delivery time for any patient requesting naloxone. The steps of the workflow for Spectrum OTP's distribution at are as follows (also illustrated in **Figure 3**, **Appendix C**):

1. A patient receiving services at the OTP must first tell their provider (nurse or clinician) that they are interested in obtaining naloxone.
2. The patient will complete the *Prescription Delivery Authorization Form* **(**see **Figure 5**, **Appendix D**) and the *Naloxone Intake Form* (see **Figure 6, Appendix D**).
3. OTP staff faxes the *Naloxone Intake Form* and the *Prescription Delivery Authorization Form* to the partner commercial pharmacy.
4. The pharmacy reviews the order form and contacts the patient directly by phone with any questions regarding the patient's insurance information and request.

5. The pharmacy fills the nasal naloxone and has it delivered to the OTP staff.
6. OTP staff provides the patient with the ordered doses of naloxone and reviews overdose prevention and response counseling.
7. The patient is provided with a printed-out education pamphlet regarding use of naloxone and overdose response strategies (see **Figure 2**, **Appendix E**).
8. Nurse documents distribution of naloxone in the patient's electronic medical record and updates the patient's medication list or routes to provider for historical documentation based on the organization's policies and procedures.
9. Repeat the order form process as necessary. Continue to offer naloxone to patients in living or social situations that elevate the risk of encountering or responding to an opioid overdose to ensure improved distribution.

Potential Challenges

- The primary challenge in establishing an alternative pathway for naloxone distribution with an offsite commercial pharmacy is identifying a potential collaborative partner.
    - Start by meeting with commercial pharmacies that are known to serve patients from the OBAT clinic and have been good partners in the past.
    - Communicate requests for collaboration before meeting with the pharmacy to allow internal discussion of workflow and request permission from their corporate office.
    - Smaller community pharmacies may be more willing to partner with your agency if they have been serving OBAT patients for an extended period of time.
    - Have alternative strategies for naloxone distribution (storage at the clinic vs. delivery to the clinic) to provide the commercial entity with options that may better suit their needs.
    - Distribution delays in a system that relies on regular medication delivery to the site can be problematic, particularly for locations that may be affected by inclement weather.
    - Be proactive in placing requests for nasal naloxone. Consider upon entry into the OTP and then with regular intervals.
    - Consider ordering naloxone for patients and allowing patients to store excess naloxone on-site in a medication locker or patient medication box.

Example Forms

The *Prescription Delivery Authorization Form* and the *Naloxone Intake Form* can be viewed at **Figure 5**, **Appendix D** and **Figure 6**, **Appendix D**, in respective order.

Inpatient to Outpatient Disposition Distribution

Practice Location Description

The D-Unit at Boston Medical Center is a 12-bed inpatient unit located within Boston Medical Center's Emergency Department. The location and structure of the unit require that patients assigned to the D-Unit (D-POD) are cognitively intact, ambulatory, and requiring of a short inpatient medical stay. Many of the patients admitted to this unit receive care from Family Medicine, General Medicine, Hospitalist Service, and Infectious Disease. In addition, the Addiction Consult Service is frequently called for patients admitted to the D-POD with substance use disorders. Patients experiencing a substance use disorder may require management of their withdrawal symptoms, or they may request the initiation of medication for their addiction. The D-unit experiences high and frequent patient turnover, as patients are often diagnosed and treated quickly and efficiently. The D-POD is exclusively staffed by Medical-Surgical Float Pool Nurses.

Administrative Requirements

Organization specific naloxone protocol.

Entities Involved

Medical-Surgical Float Pool nurses, care managers, inpatient medical teams, consulting services, social work.

Steps of Distribution Workflow

A standing order for nasal naloxone is required to authorize nurses to dispense naloxone rescue kits to (1) a person at risk of experiencing an opioid-related overdose or (2)a family member, friend, or another person in a position to assist a person at risk of experiencing an opioid-related overdose (see **Figure 2**, **Appendix B**). The steps of the workflow for the D-POD's inpatient to outpatient disposition distribution at are as follows (also illustrated in **Figure 4, Appendix C**):

1. Nurses provide a brief risk assessment and offer naloxone to all patients admitted to the D-POD identified as having high risk for an opioid overdose or likely to witness an overdose. Discussion and promotion of naloxone should be provided to any patient who has identified a concern for themselves, a family member, friend, colleague, or acquaintance who may be at risk for an opioid overdose.

2. Patients receive education regarding overdose identification and response, including naloxone administration (see **Figure 2**, **Appendix E**).
3. Nurses explain to the patient that their insurance will be billed for the receipt of naloxone.
4. Nurses document nasal naloxone 4mg/0.1 mL actuation nasal spray in the patient's historical medication list in the electronic medical records (EMR).
5. The nurse removes two doses of nasal naloxone 4mg/0.1mL actuation nasal spray (one rescue kit) from the clinic supply and affixes a patient label to both the medication and the *Nasal Naloxone Distribution Tracking Sheet*.
6. The nurse may work with the patient to remove the medication from the manufacturer package and identify alternative storage methods to accommodate discretion and rapid access to medication in the event of an overdose. Often, when patients carry naloxone, they may want to keep their naloxone concealed, and in its original packaging, naloxone is contained in a bulky box. To respect the privacy of patients while also keeping patients safe, the following repackaging measures can be taken to make patients comfortable:
    a. Discuss patient hesitance or discomfort with carrying naloxone and provide patients with a reliable and easily transportable mechanism for storing naloxone to encourage keeping naloxone on their person.
    b. Offer patients several small pouches, including a zipper and an optional carbainer clip (see **Figure 1**, **Appendix E**).
    c. Accommodate patients with pouches that can fit in a purse, backpack, lanyard, or attach to an article of clothing or accessories with carabiner.
7. Daily, the charge nurse will send the *Nasal Naloxone Distribution Tracking Sheets* to a designated member of the pharmacy team responsible for appropriate billing for naloxone. This communication can be done using an image captured on a work phone that is sent to the pharmacy contact. This communication will also provide information necessary for maintaining an adequate supply of naloxone for the unit.
8. The registered pharmacist may contact the patient directly or reach out to clinic staff to clarify matters related to patient's insurance or demographic information.
9. Repeat the distribution process as necessary. Continue to offer naloxone to patients in living or social situations that elevate the risk of encountering or responding to an opioid overdose to ensure improved distribution.

Potential Challenges

- Storage of medication within the unit that is secure and easily accessible to clinic staff when needed.
    - Daily inventory and inventory on the dispensation of the naloxone supply is recommended to prevent loss or theft.
    - Regularly check medication expiration dates to ensure the supply is safe for distribution.
- Consistent communication between the pharmacy team and clinic staff, particularly in regards to patient's insurance coverage.
    - A regular check-in between pharmacy staff and OBAT staff should occur to rectify any outstanding concerns or issues.
    - In the event that a patient is uninsured or their insurance does not cover the cost of naloxone, a pre-identified process should exist for the pharmacy to recoup the cost of the medication (cost center, private fund, etc.).
- Education and comfort of inpatient nursing staff regarding the identification and distribution of the medication is another important component of this distribution process.
    - Training for inpatient nursing staff to be able to autonomously identify patients at elevated risk for opioid overdose.
    - Training for inpatient nursing staff on how to provide naloxone administration, education and opioid overdose response.
    - Education to nursing staff about 3rd party prescribing of nasal naloxone to individuals who may be in contact with others at elevated risk for opioid overdose.
    - Consider a pilot program with one unit of smaller staff in the hospital before larger scale roll out to other units to identify problems in the workflow.
    - Consider having a unit champion who can be used for informal education and troubleshooting with other nurse colleagues to promote this distribution pathway.

Example Forms

For additional details, please view *Boston Medical Center's Nasal Naloxone Protocol* at **Figure 2**, **Appendix F** and the Nursing Script at **Figure 1, Appendix F**.

Emergency Department Distribution

Practice Location Description

The Massachusetts General Hospital (MGH) and Boston Medical Center (BMC) are busy urban emergency departments (ED) located in the city of Boston. Patients in the emergency department range from acute or crisis level of care to ambulatory care needs. Patients may be seen for overdose or post-overdose care, and patients may vary in readiness to address their substance use. An addiction team, consisting of advanced practice nurses and recovery coaches, offer specialized addiction care in the emergency department, in addition to other emergency services.

Administrative Requirements

Emergency room/organization specific naloxone protocol.

Entities involved

- Emergency department team (nurses, providers, clinicians, and recovery coaches), internal outpatient/emergency department pharmacists and staff.

Steps of Distribution Workflow

The steps for the workflow of Emergency Department distribution are as follows (also illustrated in **Figure 5**, **Appendix C**):

1. Patients who arrive to the emergency department are assessed as needing nasal naloxone; they present at elevated risk for overdose or request it.
2. Given the varied experiences of people who use drugs it is important to assess the level of knowledge patients have regarding overdose identification, response, and reversal. For patients with ample experience, it is prudent to provide focused education and information about naloxone and availability (see **Figure 2**, **Appendix E**).
3. The addiction team or the primary provider caring for the patient in the emergency room setting can place an order for nasal naloxone 4mg/0.1 mL actuation nasal spray through the discharge medication set in the electronic medical record (EMR).
4. Emergency room pharmacy staff receive and process the order for nasal naloxone 4mg/0.1 mL actuation nasal spray through the patient's insurance as an outpatient medication to be dispensed to the patient upon discharge from the emergency department setting.

5. The emergency room pharmacist delivers the nasal naloxone rescue kit to the patient's bedside with the appropriately affixed label and scan code (see **Figure 1, Appendix D**).
6. The emergency room pharmacist (or provider or nurse) provides the patient with education regarding the use of the nasal naloxone kit and overdose prevention. Inform the patient that the scan code on the manufacturer packaging contains links to overdose prevention education.
7. In the event of downtime, a paper prescription may be printed and brought to an outpatient pharmacy for medication pickup or for drop off by pharmacy staff to the patient in the emergency department.

Potential Challenges

- Staffing challenges in the emergency department setting may limit the amount of time nursing or other clinical staff have to pick up medications from the pharmacy.
    - Consider utilization of other members of the healthcare team: pharmacists, nursing assistants, recovery coaches, patient transport staff, and mental health workers to facilitate delivery of the medication bedside.
- Educating the emergency nursing staff regarding the identification and distribution of the medication is an important component of this distribution process.
    - Train emergency room nursing staff to be able to autonomously identify patients at elevated risk for opioid overdose.
    - Train inpatient nursing staff on how to provide naloxone administration education and opioid overdose response.
    - Educate the nursing staff about 3rd party prescribing of nasal naloxone to individuals who may be in contact with others at elevated risk for opioid overdose.
    - Consider having a unit champion who can be used for informal education and troubleshooting with other nurse colleagues to promote this distribution pathway.

Example Forms

- Example of *Emergency Department Protocol* see **Figure 5**, **Appendix C**.

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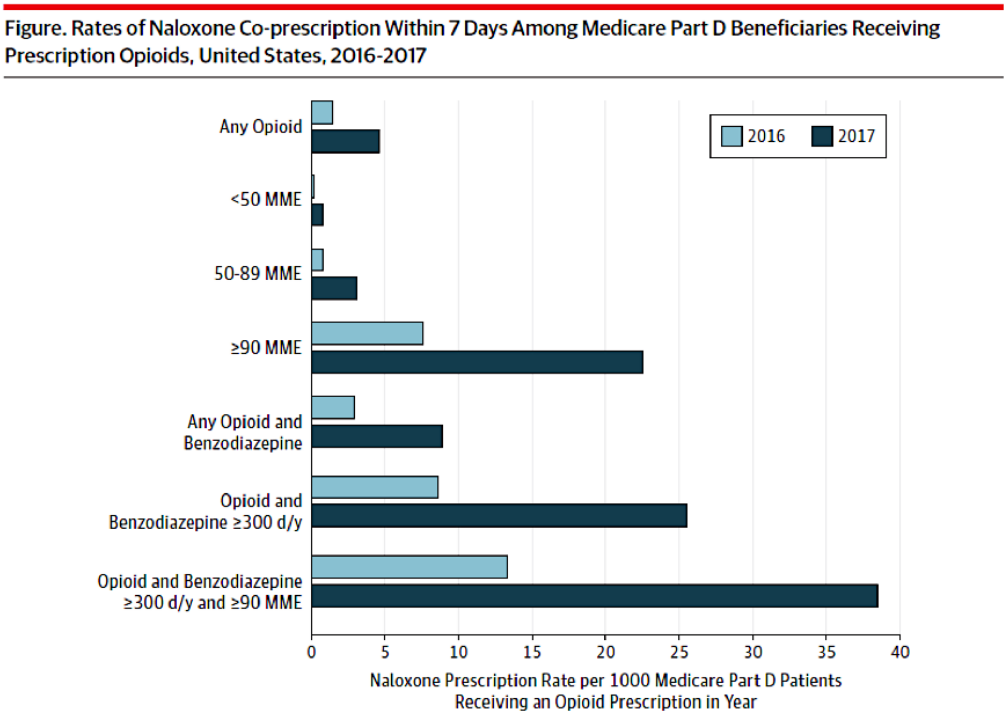
Appendix A

Figure 1 *Rates of Naloxone Co-prescription Within 7 Days Among Medicare Part D Beneficiaries Receiving Prescription Opioids, United States, 2016-2017*



Note. The data indicates an increase in co-prescribing of naloxone with opioids prescribed for chronic pain within a year. Trends of an increase in co-prescribing practices with naloxone among Medicare D patients are confirmed by researches from the National Institutes of Health, the Centers for Disease Control and Prevention, and the Office of Assistant Secretary of Health (NIDA, 2019). From *Naloxone Co-prescribing to Patients Receiving Prescription Opioids in the Medicare Part D Program, United States, 2016-2017,* by Jones et al., 2019, *JAMA,* 322(5), p. 463.

Appendix B

Figure 1 *Statewide Standing Order for Dispensing Naloxone Rescue Kits*

Standing Order for Dispensing Naloxone Rescue Kits

This standing order is issued pursuant to M.G.L. c. 94C, § 19B, as amended by section 32 of chapter 208 of the acts of 2018, *An Act for Prevention and Access to Appropriate Care and Treatment of Addiction,* which expands access to naloxone through a statewide standing order, rather than requiring each pharmacy to secure and file one individually. This standing order authorizes licensed pharmacists to dispense naloxone rescue kits to a person at risk of experiencing an opioid-related overdose, family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

Chapter 208 protects the physician signing the statewide order, and all practitioners prescribing or dispensing naloxone from criminal or civil liability or any professional disciplinary action. (M.G.L. c. 94C, § 19B(f)) In addition to the immunity established under M.G.L. c. 94C, § 34A, chapter 208 also provides criminal and civil immunity for anyone, acting in good faith, who administers an opioid antagonist to an individual appearing to experience an opioid-related overdose. (M.G.L. c. 94C, § 19B(g))

For intranasal administration:

- **Naloxone 4mg/0.1mL nasal spray**
  Dispense 2 doses.
  Directions for use: Administer a single spray of naloxone in one nostril. Repeat after 3 minutes if no or minimal response.

OR

- **Naloxone 2mg/2mL single-dose Luer-Jet prefilled syringe**
  Dispense 2 doses.
  Include one luer-lock mucosal atomization device (MAD 300) per dose dispensed.
  Directions for use: Spray 1 mL in each nostril. Repeat after 3 minutes if no or minimal response.

For intramuscular injection:

- **Naloxone 0.4mg/mL in 1mL single dose vials**
  Dispense 2 doses.
  Include one 3cc, 25 gauge, 1" syringe per dose dispensed.
  Directions for use: Inject 1 mL IM in shoulder or thigh. Repeat after 3 minutes if no or minimal response.

OR

- **Naloxone 2mg/0.4mL auto-injector**
  Dispense 2 doses.
- Directions for use: Follow audio instructions from device. Place on thigh and inject 0.4 mL. Repeat after 3 minutes if no or minimal response.

October 4, 2018

Physician's Signature **Date**

Alexander Y. Walley, MD, MSc **MA 221133**

Physician's Name and MA License No. (print legibly)

Figure 2 *Boston Medical Center's Standing Order for Dispensing Naloxone Rescue Kits to Individuals at Risk of Experiencing or Witnessing Opioid-Related Overdose*

Massachusetts Department of Public Health
Naloxone
Boston Medical Center Outpatient Pharmacy

Requirements:

- A copy of the standing order must be maintained on file and readily retrievable at each participating pharmacy site
- Standing order must be filed with the Board of Registration in Pharmacy (Board) via email: **naloxonestandingorders@Massmail.State.MA.US**.

Boston Medical Center's Standing Order for Dispensing Naloxone Rescue Kits to Individuals at Risk of Experiencing or Witnessing an Opioid-Related Overdose

Naloxone Overview

- **Patient indications for Naloxone Distribution**

Naloxone is indicated for the reversal of respiratory depression or unresponsiveness caused by an opioid overdose. It may be delivered intranasally with the use of a mucosal atomizer device or intramuscularly with use of a needle.

Take-home naloxone rescue kits can be dispensed by a pharmacist without a prescription under this standing order to patients at risk of an opioid overdose or witnessing an opioid overdose.

Some indications for dispensing naloxone are:

1. Previous opioid intoxication or overdose
2. History of nonmedical opioid use
3. Treatment with methadone or buprenorphine for an opioid use disorder
4. Higher-dose (>50 mg morphine equivalent/day) opioid prescription
5. Receiving any opioid prescription for pain plus:
    a. Rotated from one opioid to another because of possible incomplete cross-tolerance
    b. Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection, other respiratory illness
    c. Renal dysfunction, hepatic disease, cardiac illness, HIV/AIDs
    d. Known or suspected concurrent alcohol use
    e. Concurrent benzodiazepine or other sedative prescription
    f. Concurrent antidepressant prescription
6. Patients who may have difficulty accessing emergency medical services (distance, remoteness)
7. Voluntary request from patient or caregiver

- **Side Effects:**

Naloxone can neither be *abused* nor cause *overdose*. Hypersensitivity (rash, worsening difficulty breathing, anxiety) is very rare. *Too much naloxone* can cause withdrawal symptoms such as:

- Anxiety, runny nose and eyes, chills, muscle discomfort, disorientation,

combativeness, nausea/vomiting, diarrhea

Take-home Naloxone Order

1. This standing order authorizes Registered Pharmacists at Boston Medical Center Outpatient Pharmacies to maintain supplies of naloxone rescue kits for the purpose of dispensing to a person at risk of experiencing an opioid-related overdose or a family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

2. This standing order authorizes Registered Pharmacist(s) at Boston Medical Center Outpatient Pharmacies to dispense naloxone rescue kits to a person at risk of experiencing an opioid-related overdose or a family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

3. The Pharmacist Manager of Record must file a copy of the signed standing order with the Massachusetts Board of Registration in Pharmacy and must maintain a copy of this signed standing order and the "*Naloxone Pamphlet*" on file and readily retrievable at each pharmacy location.

4. The pharmacy that assembles naloxone rescue kits will label kits as "naloxone rescue kit" and note the expiration date based on the expiration date of the included naloxone hydrochloride unit.

5. The Registered Pharmacist dispensing naloxone rescue kits must be familiar with the "*Naloxone Pamphlet*" and the use of naloxone rescue kits.
   - Available: www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html

6. The Registered Pharmacist dispensing naloxone rescue kits must document successful completion of 1 hour of training approved by the standing order prescriber (Dr. Walley) on overdose prevention and naloxone rescue kits.

   a. Online training that qualifies is available here: opioidprescribing.com

7. The Boston Medical Center Outpatient Pharmacies will maintain a record of the number of naloxone rescue kits dispensed from each location under the standing order and the names of the people receiving the kits. On a monthly basis, the Boston Medical Center Outpatient Pharmacies will report to the standing order prescriber (Dr. Walley) the date, location, formulation (IN or IM) and payment method (eg insurance covered or self-pay) of each naloxone rescue kit. The report will also include the date, location, formulation, and payment method for each naloxone rescue kit dispensed via traditional prescription.

NASAL NALOXONE RESCUE KITS contain the following at a minimum:

- *Single Step Nasal Naloxone*
- NARCAN Nasal Spray, a ready-to-use, needle-free device, delivers a 4 mg dose of naloxone in a single 0.1 ml nasal spray. (NDC 69547-353-02) OR

- NARCAN Nasal Spray, a ready-to-use, needle-free device, delivers a 2 mg dose of naloxone in a single 0.1 ml nasal spray. (NDC 69547-212-04)
- Patient information pamphlet with overdose prevention information and step by step instructions for overdose response and naloxone administration.
- www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html

  Or
- *Multi-step Nasal Naloxone*
- Two 2 mL Luer-Jet luer-lock syringes prefilled with naloxone (concentration 1mg/mL) (NDC 76329-3369-1)
- Two mucosal atomization devices – Teleflex MAD 300
- Patient information pamphlet with overdose prevention information and step by step instructions for overdose response and naloxone administration.
    - www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html

MUSCLE NALOXONE RESCUE KITS contain the following at a minimum:

- Naloxone HCL 0.4mg/mL
    - One 10mL multidose fliptop vial (NDC 0409-1219-01) or
    - Two 1 mL vials (NDC 00409-1215-01)
- Two intramuscular syringes, 25 gauge 3cc 1" long
- Patient information pamphlet with overdose prevention information and step by step instructions for overdose response and naloxone administration.
    - www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html

NALOXONE AUTO-INJECTOR KIT

- The pre-packaged kits (NDC 60842-0030-01 for the 0.4mg dose– [to be discontinued]: NDC 60842-051-01 for the 2mg dose) include 2 auto-injectors with audio instructions and 1 training device
- Instructions: For opioid overdose, use as directed by printed and audio instructions on auto-injector device.

ON-SITE ADMINISTRATION

This standing order authorizes Boston Medical Center pharmacists, who are:

1. Trained and certified in cardiopulmonary rescucitation and
2. Trained and certified to administer influenza vaccine,

to possess and administer naloxone to a person who is experiencing an opioid overdose.

2. Naloxone administration
    a. **Multi-Step Nasal naloxone:** Administer nasal naloxone to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:
        1. Ensure that 911 has been called.
        2. Spray one dose (01.ml[4mg]) into one nostril
        3. Repeat spray in the other nostril if there is no response after 3 minutes.

4. Remain with the person until he or she is under care of a medical professional, like a physician, nurse or emergency medical technician.

Do not administer naloxone to a person with known hypersensitivity to naloxone.

b. **Single-Step Nasal naloxone**: Administer nasal naloxone to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:
   1. Ensure that 911 has been called.
   2. Pop off two yellow caps from the delivery syringe and one cap from the naloxone vial.
   3. Screw the naloxone vial gently into the delivery syringe.
   4. Screw the mucosal atomizer device onto the top of the syringe.
   5. Spray half (1ml) of the naloxone in one nostril and the other half (1ml) in the other nostril.
   6. Repeat spray (1ml in each nostril) if there is no response after 3 minutes.
   7. Remain with the person until he or she is under care of a medical professional, like a physician, nurse or emergency medical technician.

Do not administer naloxone to a person with known hypersensitivity to naloxone.

c. **Intramuscular naloxone**: Administer intramuscular naloxone to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:
   1. Ensure that 911 has been called.
   2. Uncap the naloxone vial and uncap the muscle needle-syringe
   3. Insert the muscle needle through the rubber membrane on the naloxone vial, turn the vial upside down and draw up 1 cc of naloxone liquid and withdraw the needle.
   4. Insert the needle into the upper arm or thigh of the victim and push on the plunger to inject the naloxone.
   5. Repeat the injection if there is no response after 3 minutes.
   6. Remain with the person until he or she is under care of a medical professional, like a physician, nurse or emergency medical technician.

   Do not administer naloxone to a person with known hypersensitivity to naloxone.

d. **Auto-injector naloxone**: Administer auto-injector naloxone to a person suspected of an opioid overdose with respiratory depression or unresponsiveness as follows:
   1. Ensure that 911 has been called.
   2. Pull **auto**-injector from outer case
   3. Pull off red safety guard
   4. Place the black end of the auto-injector against the outer thigh, through clothing, if needed and press firmly and hold in place for 5 seconds.
   5. Repeat if there is no response after 3 minutes.
   6. Remain with the person until he or she is under care of a medical professional, like a physician, nurse or emergency medical technician.

   Do not administer naloxone to a person with known hypersensitivity to naloxone.

MA #221133	5/19/2018
Physician's Signature and License No.	**Date**
Alexander Y. Walley	**5/18/2019**
Physician's Name (print)	**Order Expiration Date***

Appendix C

Figure 1 *Naloxone Distribution Workflow: Ambulatory Distribution with Co-Located Pharmacy*

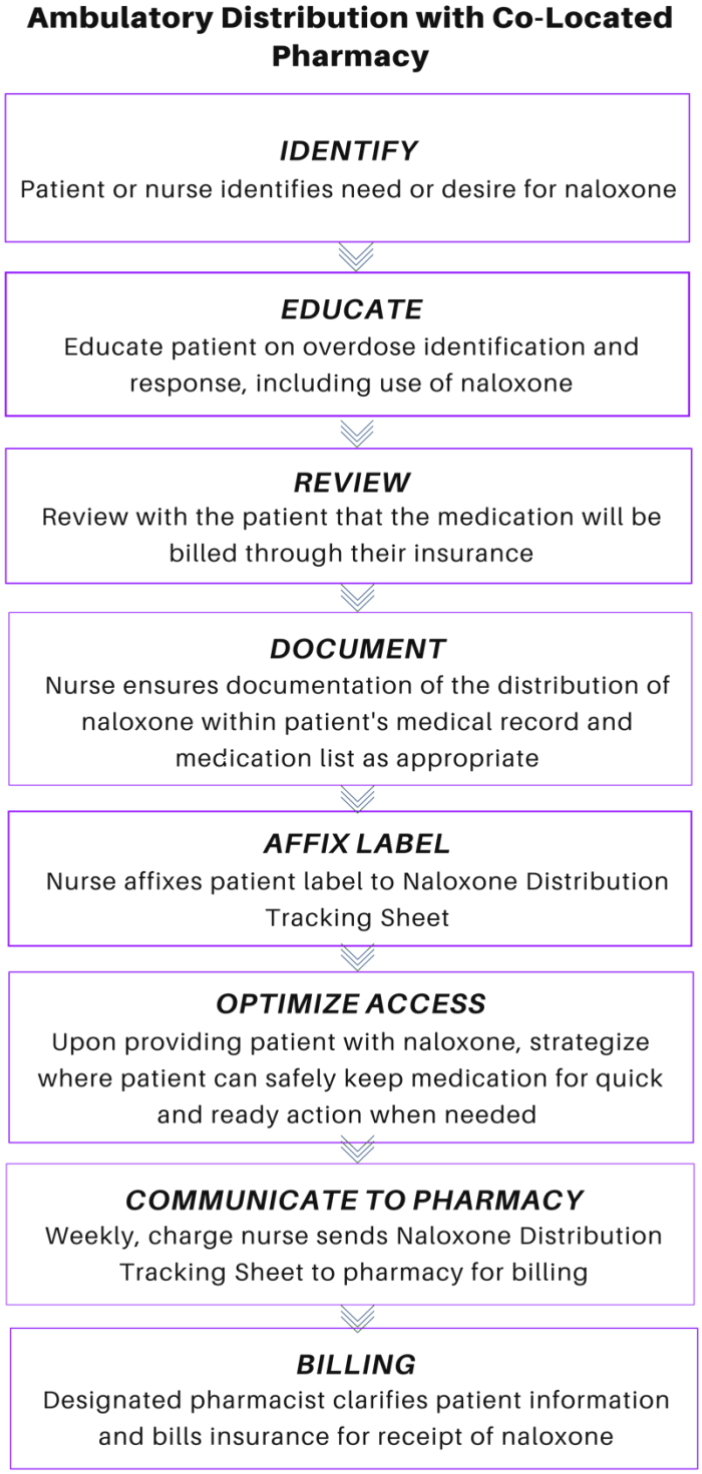


Figure 2 *Naloxone Distribution Workflow: Ambulatory Distribution with an Off-Site Pharmacy*

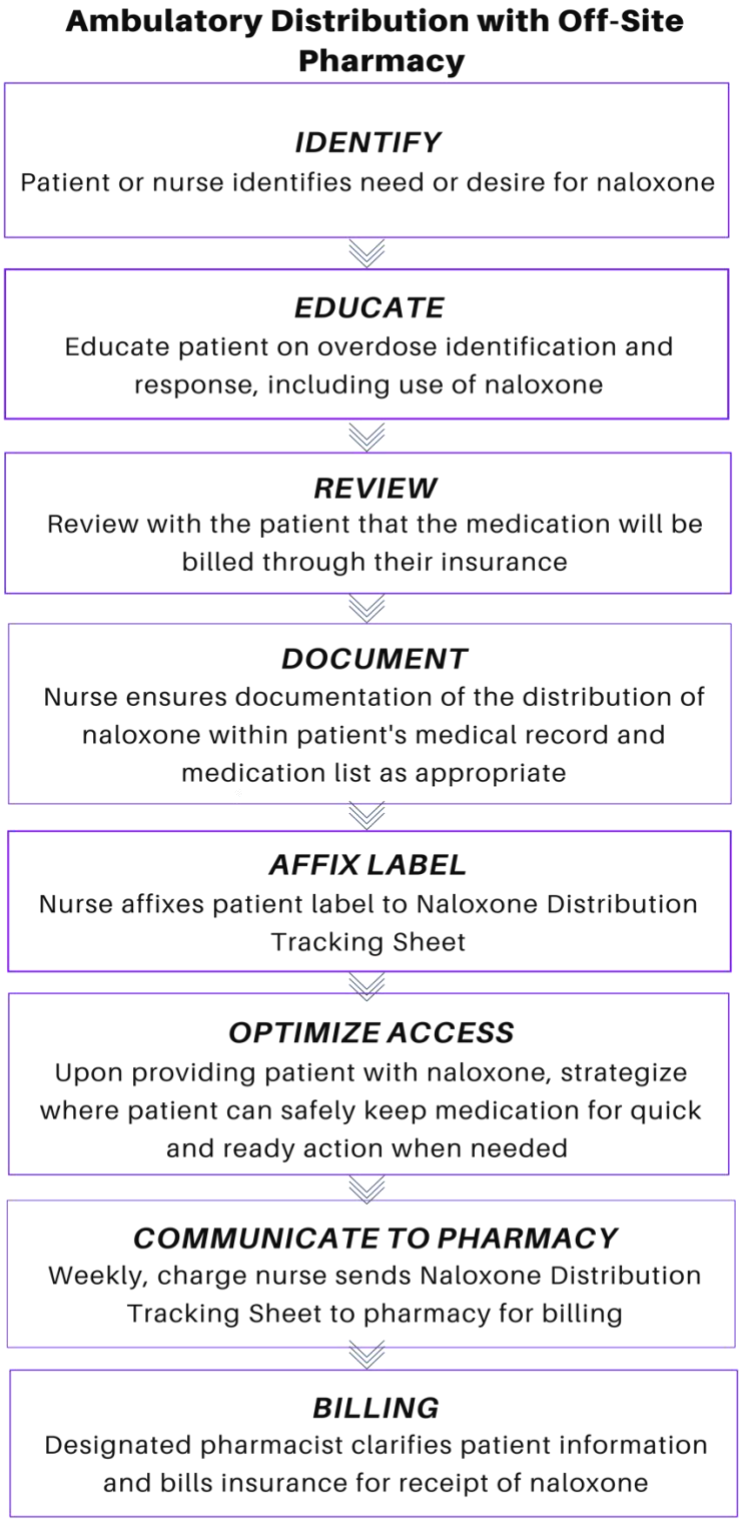


Figure 3 *Naloxone Distribution Workflow: Opioid Treatment Program with Off-Site Pharmacy*

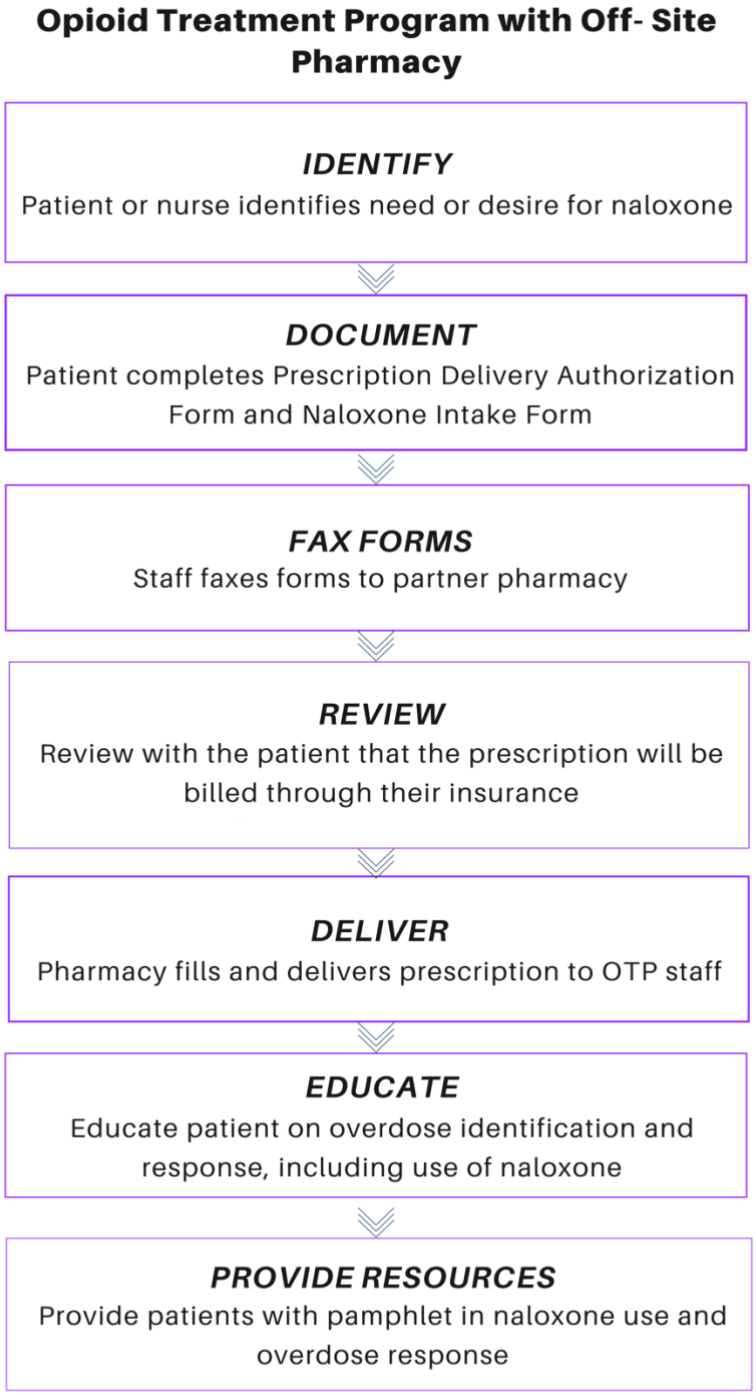


Figure 4 *Naloxone Distribution Workflow: Inpatient to Outpatient Disposition Distribution*

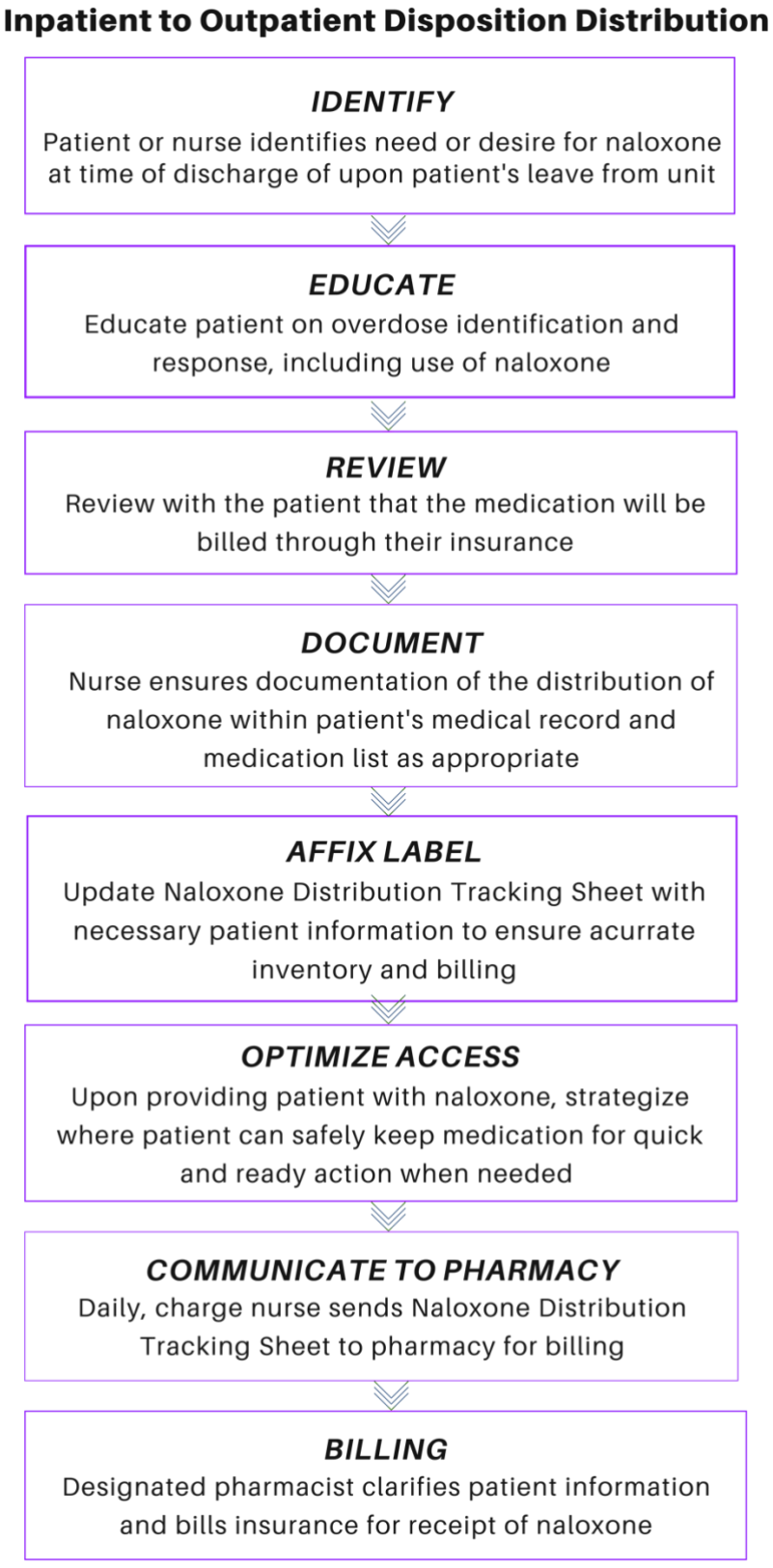
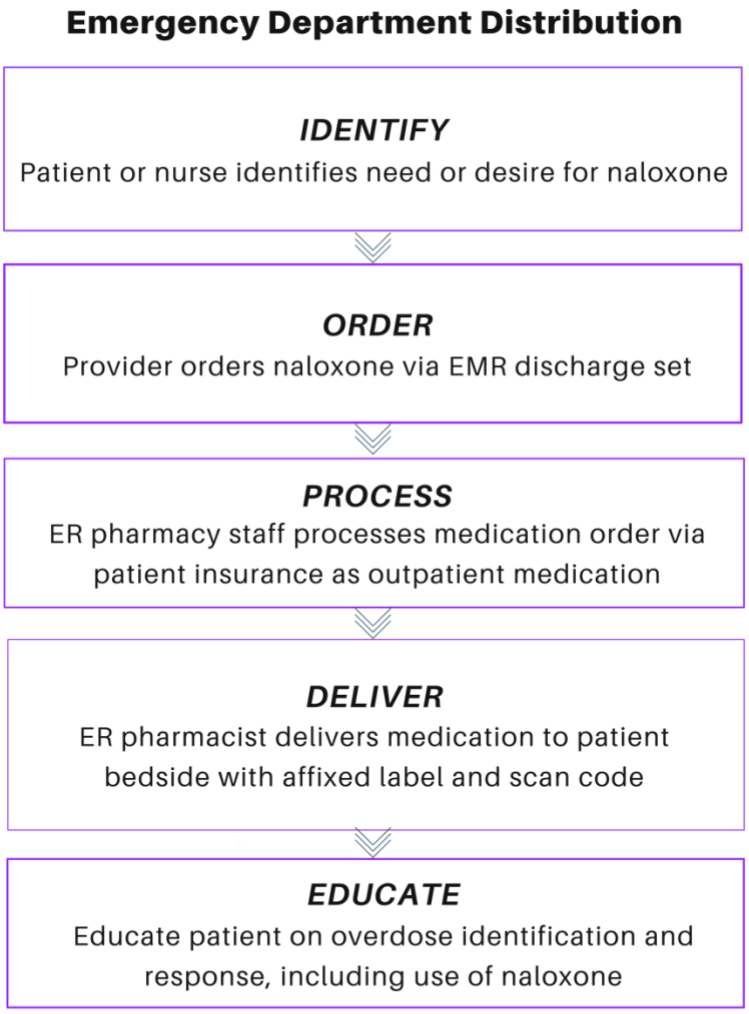


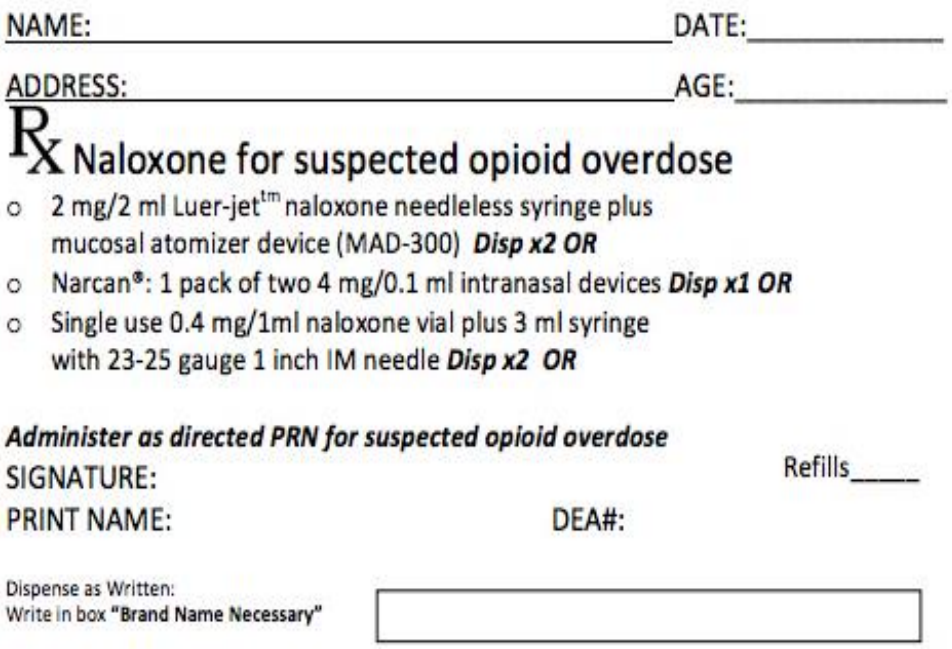
Figure 5 *Naloxone Distribution Workflow: Emergency Department Distribution*



Appendix D

Figure 1 *Example Label for Naloxone in Clinic*

Figure 2 *Example of Third-Party Prescription of Naloxone*



NAME: _____ DATE: _____

ADDRESS: _____ AGE: _____

℞ Naloxone for suspected opioid overdose

- 2 mg/2 ml Luer-jet™ naloxone needleless syringe plus mucosal atomizer device (MAD-300) ***Disp x2 OR***
- Narcan®: 1 pack of two 4 mg/0.1 ml intranasal devices ***Disp x1 OR***
- Single use 0.4 mg/1ml naloxone vial plus 3 ml syringe with 23-25 gauge 1 inch IM needle ***Disp x2 OR***

Administer as directed PRN for suspected opioid overdose

SIGNATURE: Refills_____

PRINT NAME: DEA#:

Dispense as Written:
Write in box **"Brand Name Necessary"**

Figure 3 *Nasal Naloxone Distribution Tracking Sheet*

Nasal Naloxone Distribution Tracking Sheet

Patient Label	# Doses Provided	Patient Label	# Doses Provided

Figure 4 *OBAT Clinic Nasal Naloxone Inventory Tracking*

OBAT Clinic Nasal Naloxone Inventory Tracking

Date	# Naloxone Distributed	# Remaining	Expiration date reviewed?	RN Signature #1	RN Signature #2

Figure 5 *Prescription Delivery Authorization Form*

Prescription Delivery Authorization Form

I, _____, certify that I am the ultimate end user of
Patient name & Date of Birth

the delivered medication orders and require my patient care representative to receive medications on my behalf in order to facilitate my medical treatment, because I:

- ☐ Lack a safe location for delivery
- ☐ Lack the ability to keep the medication at the appropriate temperature
- ☐ Need assistance with administration
- ☐ Other: _____

I authorize _____ to act
Name of Medical office, staff, and address

as my patient care representative for the limited purpose of receiving prescription fills and refills of my medications on my behalf.

This authorization will not expire unless terminated in writing by patient or patient care representative.

_____ _____
Patient Signature Date

_____ _____
Office Staff Signature Date

Figure 6 *Naloxone Intake Form*

NALOXONE INTAKE FORM

Community, A Walgreens Pharmacy
398 Belmont Street, Suite A
Worcester, MA: Phone: 508-713-0149 **Fax: 508-713-6005**

PATIENT INFORMATION	
Patient Name	
Address	
City, State, Zip	
Phone	
Date of Birth	Male Female
Allergies	
Social Security (Medicare Only)	

FACILITY INFORMATION	
Facility Name	
Address	
City, State, Zip	
Phone	Fax
Office Contact	
Notes:	

INSURANCE INFORMATION

MassHealth ID_____ **OR** Bin#_____PCN: _____ Group#: _____ ID: _____

CREDIT OR DEBIT CARD FOR CO-PAY (If patient does NOT have Medicaid)

Card #_____ Expiration Date _____/_____ Zip Code: _____

ADDITIONAL INFORMATION

Language: ☐ English ☐ Spanish

Delivery Address: ☐ Patient Address (must provide phone number) ☐ Facility (must sign AUTH form) ☐ Patient Pick-up

Needs by Date: _____

NALOXONE RESCUE KITS (select one option below)

- **PROVIDED WITH EVERY PRESCRIPTION**: Patient information pamphlet with overdose prevention information and step by step instructions for overdose responses and naloxone administration.

☐ **Please dispense the product that is covered by my insurance**

☐ **NARCAN NASAL SPRAY**
- NARCAN Nasal Spray, a ready-to-use, needle-free device, delivers a 4 mg dose of naloxone in a single 0.1 ml nasal spray. (NDC 69547-353-02) OR NARCAN Nasal Spray, a ready-to-use, needle-free device, delivers a 2 mg dose of naloxone in a single 0.1 ml nasal spray. (NDC 69547-212-04)
- NARCAN Nasal Spray requires no assembly or priming prior to use.

☐ **EVZIO AUTO-INJECTOR**
- The kit comes as a twin pack with 2 auto-injectors if a second dose is needed. (NDC 60842-0030-01)

☐ **NASAL NALOXONE RESCUE KIT**
- Two 2 mL Luer-Jet luer-lock syringes prefilled with naloxone (concentration l mg/mL) (NDC 76329-3369-01)
- Two mucosal atomization devices- Teleflex MAD 300

☐ **MUSCLE NALOXONE RESCUE KITS** contain the following at a minimum:
- Naloxone HCL 0.4mg/mL
  - One 10mL multidose fliptop vial (NDC 0409-1219-01) or Two 1 mL vials (NDC 00409-1215-01) 2 (two) intramuscular syringes, 25 gauge 3cc 1" long

PATIENT CONSENT

I am requesting a NALOXONE rescue kit. This request is to allow me to carry overdose prevention mediation so that in an emergency I can assist individuals I know to use opioids. I understand that I have the right to use the Pharmacy of my choice and authorize COMMUNITY, A WALGREENS PHARMACY to fill my prescription and to bill my insurance for this prescription. I am willing to sign for the receipt of my prescription and pay any copayment as required.

_____ _____
Patient Signature Date

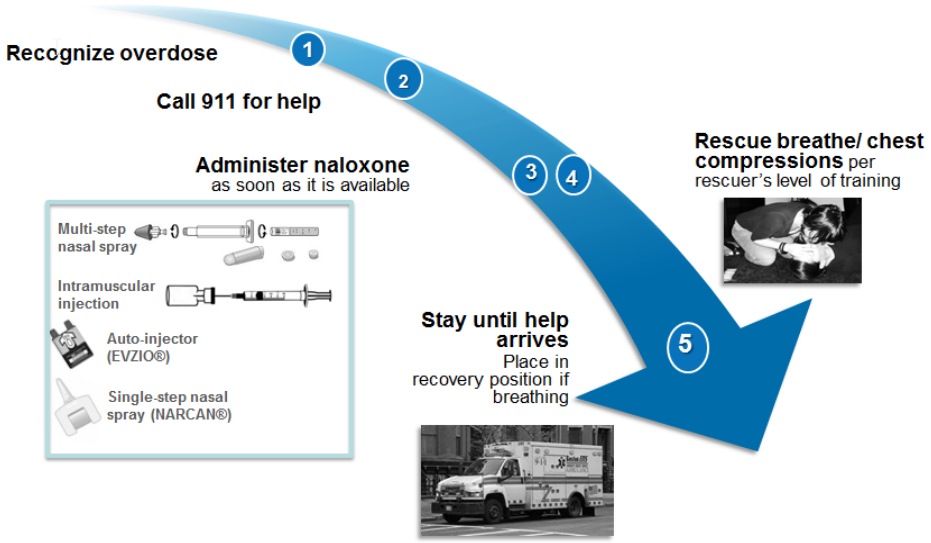
Appendix E

Figure 1 *Patient Naloxone Storage Supplies*

Note. The Boston Medical Center's OBAT program provides patients with a neoprene pouch with a zipper and carabiner to optimize patient storage and ready access to naloxone.

Figure 2 *Patient Education Sheet on Overdose Identification and Response including Naloxone Use*

How to Respond to an Overdose



1. RECOGNIZING AN OVERDOSE

It is important to be able to distinguish an overdose from the symptoms of being high on opioids.

Really High	Opioid Overdose
☐ Nodding ☐ Will respond to stimulation like yelling, sternal rub, pinching, etc.	☐ Not responsive to stimulation (verbal and physical)
☐ Drowsy, but breathing -8 or more times per minute	☐ Deep snoring or gurgling (death rattle) ☐ Very infrequent or no breathing
☐ Speech is slow/slurred ☐ Pinpoint pupils	☐ Unable to talk, whether awake or not ☐ Pinpoint pupils
☐ Muscles become relaxed ☐ Sleepy looking ☐ Normal skin tone	☐ Slow heart beat/pulse ☐ Blue/gray lips and fingertips ☐ Pale, clammy skin
⇩	⇩
Stimulate and observe!	Overdose rescue!

Street Methods Now Have Better Alternatives

Many strategies have been used over the years to rescue people from an opioid overdose. While there are better alternatives today, applaud folks' ability to figure out how to keep people alive. Individuals who use drugs are creative, resilient, and care about keeping their friends and family alive. Street knowledge about how to treat an overdose often works but there is a safer and more timely method.

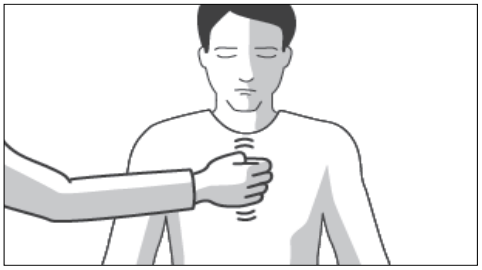
Mostly, the reason why street methods have worked is due to **stimulation**.

DO NOT…

- Leave the person alone
- Put them in a bath
- Induce vomiting
- Put ice down their pants
- Slap, kick, punch, burn, or cause harm
- Inject them with anything other than naloxone (saltwater, cocaine, milk)

These methods of stimulation take more time and can add more risk. There is a better alternative form of *stimulation*: **THE STERNAL RUB**

Stimulation: Sternal Rub



- If a person is not responding and you suspect an overdose, try to wake them up
- Call name and shake the person. If this doesn't work, rub your knuckles into the sternum (the breastbone in middle of chest)
  - You can also rub your knuckles on their upper lip
  - Tell them you are going to administer naloxone and continue to explain out-loud the steps you are taking in the response

2. CALLING 9-1-1

If a person does not respond to stimulation, **call 9-1-1!**

- Call 9-1-1 whether person responds to naloxone or not
- Person overdosing may have other medical issues
- Person can overdose again once naloxone wears off

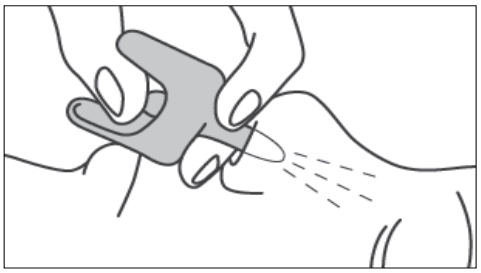
Good Samaritan Law

The Massachusetts Good Samaritan Law encourages friends, family, and/or bystanders to assist people having an overdose and to seek emergency medical assistance. The law provides limited immunity to overdose victims and bystanders that call 9-1-1.

The law protects victims and those who call 9-1-1 for help from charge, prosecution, and conviction for possession or use of controlled substances. The Law, Chapter 94C, Section 34A: "Immunity from prosecution under Secs. 34 or 35 for persons seeking medical assistance for self or other experiencing a drug-related overdose" can be found on the Massachusetts Legislature General Laws website.

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C/Section34A

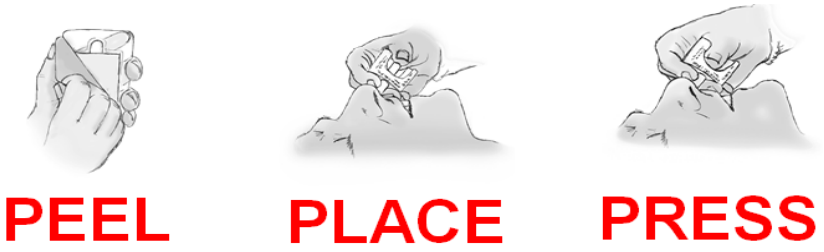
3. ADMINISTER NALOXONE



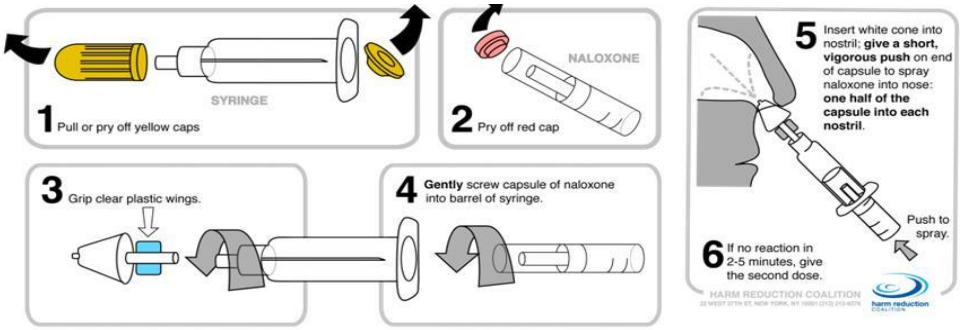
As soon as naloxone is available, the opioid overdose responder should administer the first dose. The second dose should be administered 3 minutes after the first if the person remains unresponsive with impaired breathing. While waiting for the naloxone to work, the responder should rescue breath (see Step 4) and continue to stimulate the person. Typically, one or two doses of naloxone is sufficient to successfully reverse the effects of the opioid overdose. In some overdose situations, more than two doses may be necessary.

How to Administer Single Step Naloxone

- **PEEL** back the package to remove the device. Hold the device with your thumb on the bottom of the plunger and two fingers on the nozzle.
- **PLACE** and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the person's nose.
- **PRESS** the plunger firmly to release the dose into the person's nose.



How to Administer Multi-Step Naloxone



Intramuscular Naloxone

Many successful overdose prevention programs worldwide use intramuscular naloxone and have found that needle stick injury with intramuscular naloxone is rare. A limited number of MDPH OEND program sites offer IM naloxone to program participants. In MA, IM naloxone uses the naloxone from the above-mentioned multi-step naloxone and affixes a luer-lock safety needle to the dose.

Some key points about intramuscular naloxone include:

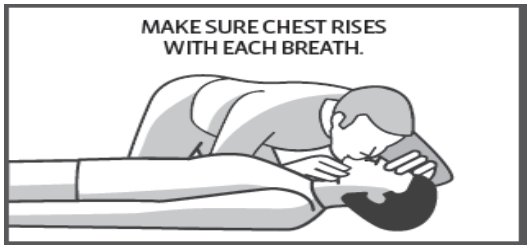
- IM allows for titration of the naloxone dose
- More potent than multi-step nasal naloxone
- More potent than traditional IM (2mg/2ml vs. 0.4mg/1ml)

Figure: Inject into the muscle

How to administer intramuscular naloxone:

- Pop off the orange top vial
- Draw up 1cc of naloxone into the syringe 1cc=1mL=100u
- Intramuscular injection sites include the thigh, shoulder, or upper/outer quadrant of the butt
- Insert the needle straight in to make sure to hit the muscle
- Withdraw before injecting to ensure the needle is not in a blood vessel

4. RESCUE BREATHING



- Make sure there is nothing in the mouth
- Tilt head back, lift chin, pinch nose
- Give a breath every 5 seconds
- If the opioid overdose responder is trained in CPR, they should proceed as per the rescuer's level of training

Equipment to Assist Rescue Breathing

- CPR masks/mouth barriers/Ambu bags can protect the rescuer. They are one-time-only use equipment.
  - Discard after each use and replace
- Practice using these devices is worthwhile
- Proper Use:
  - If using CPR mask, place mask over the nose and mouth and apply pressure to make a tight seal. Breathe into mask and watch chest rise.
  - If using mouth barrier, place barrier over mouth, apply pressure to make a tight seal and pinch nose. Breathe into barrier and watch chest rise.
- If an Ambu bag is attached to the CPR mask, squeeze the bag to force air through the mask and watch chest rise. If stomach expands, readjust mask or barrier to create a tight seal, and attempt again.

5. STAY UNTIL HELP ARRIVES

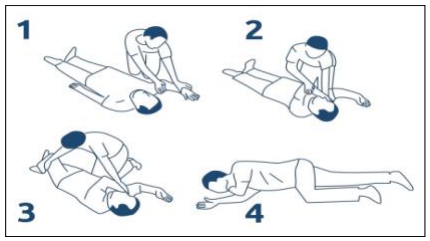
If you must leave the scene of an overdose for whatever reason, ensure that the person who overdosed is in the recovery position and easily accessible by first responders.

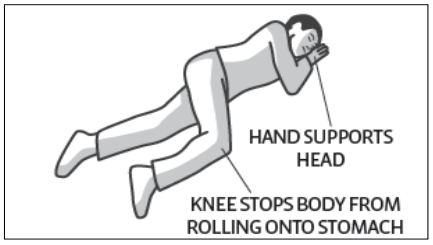
If the person is breathing well, put them on their side as per the illustration.

If they are not breathing well, continue rescue breathing.

Monitor and Support: It is important to monitor and support the person who just overdosed because:

- Naloxone lasts 30-90 minutes…
  - But the duration of the opioid effect can last 4 hours or longer, especially with longer acting opioids like methadone.
- The person who overdosed will need to understand that they should not use again until the naloxone wears off to reduce the risk of re-overdose.
- The likelihood of overdosing again depends on several things including:
  - How much of the opioid was used in the first place and the duration of action of the drug(s) taken
  - The health of the person who overdosed
  - If the person uses again
- The opioid overdose responder should encourage that person to seek additional medical attention from the hospital.





Appendix F

Figure 1 *Example Nurse Script*

We like to offer nasal naloxone to all of the patients because of the ongoing opioid epidemic and the heightened risk that you may witness or experience an opioid overdose, even if you aren't using illicit opioids. Would you like a prescription for nasal naloxone today?

The nasal naloxone we will provide you with today will be billed through the BMC pharmacy downstairs and will be on your medication list in the EHR.

Have you ever used nasal naloxone before? Have you ever received nasal naloxone in the past?

Figure 2 *The Boston Medical Center's Nasal Naloxone Protocol*

Nasal Naloxone Protocol

Office-Based Addiction Treatment (OBAT)

INDICATIONS

- Patients presenting to the OBAT clinic at risk for opioid overdose.

TYPES

- Nasal Naloxone 4mg/actuation spray

MECHANISM OF ACTION: Mu-Opioid Antagonist

INDICATIONS (WHO)

- Patients diagnosed with an opioid use disorder.
- When patients are at risk for an opioid overdose:
    - Illicit substance use
    - A current opioid prescription
    - Previous opioid overdose
- When patients are at elevated risk to witness an opioid overdose:
    - Attends recovery support meetings
    - Lives or works in a residential treatment setting
    - Close family members or friends with an opioid use disorder.
    - Close family members or friends with a current opioid prescription.
    - Reports witnessing a previous opioid overdose.
    - Communal spaces that may require shared spaces with patients with opioid use disorder (eg, homeless shelter, mental health facility, public transportation, public restrooms, etc.)

EFFICACY (See references)

- Efficacy of bystander administered nasal naloxone has been a utilized intervention since the early 2000s to reduce mortality related to the opioid epidemic.
    - Bystander administered nasal naloxone administration has a greater than 92% rate of recovery from opioid overdose.

- Efficacy of nasal naloxone to reverse overdose may be negatively affected by polysubstance use of the patient with life threatening respiratory depression.

ELIGIBILITY

- A patient who is registered with the hospital and have their own medical record number.
- Patients who ask for nasal naloxone should be provided with the medication.
- Patients at risk to witness an opioid overdose:
    - Attends recovery support meetings

- Lives or works in a residential treatment setting
- Close family members or friends with an opioid use disorder.
- Close family members or friends with a current opioid prescription.
- Reports witnessing a previous opioid overdose.
- Communal spaces that may require shared spaces with patients with an opioid use disorder (eg, homeless shelter, mental health facility, public transportation, public restrooms, etc.)

- Patients at risk for an opioid overdose:
  - Diagnosis of an opioid use disorder
  - Illicit substance use
  - A current opioid prescription
  - Previous opioid overdose

SIDE EFFECTS

- Nasal naloxone
  - Recurrent sedation
    - In patients who are not monitored after nasal naloxone administration there is a risk that the patient will experience recurrent sedation and possibly overdose again.

  - Precipitated withdrawal
    - The emergent use of a mu-receptor antagonist in a patient with an opioid use disorder puts them at risk for precipitated withdrawal for the period of which the drug is active in the system.

WORK FLOW

- Storage and Inventory
  - Doses of nasal naloxone will remain locked in the medication room after they have been received from pharmacy.
  - A medication count and expiration review should occur upon delivery of medication from the pharmacy and at least once weekly and be signed by at least two staff members of the OBAT team.
  - Pharmacy should be notified of the need for additional nasal naloxone doses when only 10 doses of medication remain in the locked medication cabinet.
- RN visit
  - Offer nasal naloxone to all patients coming in for routine OBAT visits with RN.
  - Patients should be counseled regarding opioid overdose identification and reversal and provided with written or electronic materials regarding the use of nasal naloxone.
  - Patients should be alerted that the medication will be billed through their insurance.

- Nurses must document nasal naloxone 4mg/actuation nasal spray to the patient's historical medication list in the EMR.
- Nurses should affix a patient label to the Nasal Naloxone Distribution Tracking sheet and identify the number of doses provided to the patient.
- The charge nurse or nursing supervisor should collect Nasal Naloxone Distribution Tracking Sheets and fax them to the pharmacy for review and appropriate billing by RPh.
- Tracking sheets should be saved in a folder in a locked filing cabinet. Sheets should be scanned into secure folder in the G: Drive once monthly and hard copies should be destroyed.

Education from the Nurse

Review patient education materials and the information below:

Nasal naloxone is a mu-receptor antagonist, or the antidote to an opioid overdose. If you think a patient may be overdosing from opioids they will be taking slow, shallow breaths, may be turning blue or gray, and will not respond to painful stimuli. If you are concerned about an opioid overdose and the person is unresponsive to your questions regarding their well being, using your fingers in a fist apply pressure to the patient's sternum or their maxilla just below the nose. For patients that are unresponsive to painful stimuli send for help and then provide the person with some rescue breaths to ensure adequate oxygenation of the brain. At this point you can place the atomizer in the patient's nose and administered the dose of medication. It may take 1-2 minutes for the medication to begin to work, Don't Panic, continue to wait and provide rescue breaths as needed. When the patient is able to breathe again without assistance encourage the patient to seek evaluation by an emergency room or another medical professional for adequate work up of the consequences of an opioid overdose, specifically acquired or traumatic brain injury.

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