

Defense Health Agency PROCEDURAL INSTRUCTION

NUMBER 6025.07 June 19, 2018

Healthcare Operations

SUBJECT: Naloxone Prescribing and Dispensing by Pharmacists in Medical Treatment

Facilities (MTFs)

References: See Enclosure 1.

- 1. <u>PURPOSE</u>. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) through (c), and in accordance with the guidance of References (d) through (h), establishes the Defense Health Agency's (DHA) procedures for prescribing and dispensing naloxone by pharmacists in MTFs to eligible beneficiaries, upon beneficiary request, or when the pharmacist determines the beneficiary meets the established criteria for being at risk for a life-threatening opiate overdose.
- 2. <u>APPLICABILITY</u>. This DHA-PI applies to the Defense Agencies and the DoD Field Activities (referred to collectively in this DHA-PI as the "DoD Components").
- 3. <u>POLICY IMPLEMENTATION</u>. It is DHA's instruction, pursuant to References (e) through (g), that access to opiate reversal kits should be expanded to MTF beneficiaries who meet the established criteria and are determined to be at risk for potential overdose.
- 4. <u>RESPONSIBILITIES</u>. See Enclosure 2.
- 5. PROCEDURES. See Enclosure 3.
- 6. <u>RELEASABILITY</u>. **Cleared for public release**. This DHA-PI is available on the Internet from the Health.mil site at: www.health.mil/DHAPublications.

7. <u>EFFECTIVE DATE</u>. This DHA-PI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with DHA-Procedural Instruction 5025.01 (Reference (c)).

R C. BONO VADM, MC, USN Director

Enclosures

- 1. References
- 2. Responsibilities
- 3. Procedures

Glossary

Attachments:

- 1. Example of Standing Order for Naloxone
- 2. Patient Education Materials on Opioid Safety and Naloxone Administration
- 3. Instructions on Accessing CarePoint and Verifying Account
- 4. Step by Step Screen Shots for Using the Patient Look Up Tool
- 5. Naloxone Evaluation Criteria and Prescription (paper form)

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
- (b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
- (c) DoD Instruction 1010.04, "Problematic Substance Use by DoD Personnel," February 20, 2014
- (d) DHA-Procedural Instruction 5025.01, "Publication System," August 21, 2015
- (e) National Defense Authorization Act for Fiscal Year 2017
- (f) Executive Action, "JOINT FACT SHEET: DoD and VA Take New Steps to Support the Mental Health Needs of Service Members and Veterans," August 26, 2014
- (g) Executive Action, "FACT SHEET: Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin Use," October 21, 2015
- (h) DoD Pharmacy and Therapeutics Committee Minutes and Recommendations, August 2016 Basic Core Formulary decision signed November 8, 2016
- (i) Increases in Drug and Opioid Overdose Deaths United States, 2000-2014, Morbidity and Mortality Weekly Report, 64(50); 1378-82, January 1, 2016
- (j) Boston University, Prescribe to Prevent: Overdose Prevention and Naloxone Rescue Kits for Prescribers and Pharmacists, October 15, 2014¹
- (k) Substance Abuse and Mental Health Services Administration, Opioid Overdose Toolkit²
- (l) Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Prescription Opioid Overdose Data, December 16, 2016³

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¹This reference can be found at: http://www.opioidprescribing.com/naloxone module 1-landing

²This reference can be found at: http://store.samhsa.gov/shin/content//SMA16-4742/SMA16-4742.pdf

³This reference can be found at: https://www.cdc.gov/drugoverdose/data/overdose.html

ENCLOSURE 2

RESPONSIBILITIES

- 1. <u>DIRECTOR, DHA</u>. The Director, DHA, will identify the key DHA and component heads or officials of the same level to carry out the procedures in this DHA-PI.
- 2. <u>DEPUTY ASSISTANT DIRECTOR, HEALTHCARE OPERATIONS</u>. The Deputy Assistant Director, Healthcare Operations, will have oversight of the program implemented in accordance with the procedures in this DHA-PI.
- 3. <u>DIVISION CHIEF, DHA PHARMACY OPERATIONS DIVISION</u>. The Chief, DHA Pharmacy Operations Division, will assess the utilization of the program, including measures of performance and measures of effectiveness, implemented in accordance with the procedures in this DHA-PI.
- 4. <u>SERVICE PHARMACY CONSULTANTS</u>. The Service Pharmacy Consultants provide this DHA-PI to all Department of Pharmacy Directors for implementation at their respective MTF site(s).
- 5. <u>DIRECTORS, MTF DEPARTMENT OF PHARMACIES</u>. Through Service Components, Directors, MTF Department of Pharmacies, obtain approval to dispense naloxone and disseminate this DHA-PI to Section Supervisors at respective sites in order to implement the procedures included.
- 6. <u>MTF PHARMACY DEPARTMENT HEAD/SECTION SUPERVISORS</u>. Through Service Components, MTF Pharmacy Department Head/Section Supervisors provide training to ensure their staff comprehends the appropriate use of the procedures in this DHA-PI in order to effectively implement them.
- 7. MTF PHARMACISTS. Through Service Components, MTF pharmacists:
- a. Ensure naloxone is available in the pharmacy according to the Basic Core Formulary determination by the DoD Pharmacy and Therapeutics Committee (P&T) (Reference (h)).
- b. Follow procedures included in this DHA-PI to prescribe and dispense naloxone in the MTFs to eligible beneficiaries, upon beneficiary request, when the beneficiary meets the established criteria for being at risk for a life-threatening opiate overdose or based upon an assessment and professional judgment.

ENCLOSURE 3

PROCEDURES

- 1. <u>OVERVIEW</u>. This DHA-PI provides guidance by which MTF pharmacists, at the point of reviewing opioid prescriptions, can identify, prescribe, and dispense naloxone to beneficiaries who meet the established criteria and are determined to be at risk for opiate overdose. These procedures include pharmacist training and patient education, such as opioid safety, risk factors, overdose symptoms, and treatment instructions.
- 2. <u>BACKGROUND</u>. Respiratory depression and death are common adverse effects resulting from opioid overdose. According to the Centers for Disease Control and Prevention, from 1999 to 2015, more than 183,000 people died in the United States from overdoses related to prescription opioids (Reference (1)). The Centers for Disease Control and Prevention and the Substance Abuse and Mental Health Services Administration, along with many other organizations, have called for expanded patient access to naloxone in efforts to save lives. Clinicians, including MTF pharmacists and caregivers of patients taking opioids, can mitigate these risks through education and expanded access to naloxone. Naloxone, an opioid antagonist, is an effective opioid reversal agent when administered upon recognition of an overdose. First responders, prescribers, and MTF pharmacists should provide broad access to naloxone to the community to increase the population health benefit and reduce adverse outcomes associated with opioid use (Reference (i)).

3. TIMELINE

- a. Pre-implementation activities will begin within 60 days from signature of the DHA-PI on naloxone prescribing and dispensing by MTF pharmacists.
- b. Prior to the implementation date, Pharmacy Section Supervisors are to ensure all personnel are trained, and that naloxone and beneficiary education materials are stocked and ready for distribution.
- c. Implementation will begin once MTF pharmacists are trained, and when naloxone and beneficiary education materials are available in the pharmacy.
- 4. <u>PRE-IMPLEMENTATION</u>. Describes activities MTFs will accomplish prior to MTF pharmacists dispensing.
- a. <u>Approval</u>. Each MTF will coordinate with the appropriate channels, to include their P&T and Medical Executive Board, for approval to implement this DHA-PI. If needed, MTFs will obtain a standing order for naloxone from provider(s) to authorize pharmacists to dispense naloxone when appropriate. Standing orders will allow pharmacists the authority to dispense

naloxone to eligible beneficiaries, upon beneficiary request, or when the pharmacist determines the beneficiary meets the established criteria for being at risk for a life-threatening opiate overdose. An example of a standing order is provided as Attachment 1.

- b. <u>Training</u>. Pharmacy Section Supervisors are to provide continuing education for MTF pharmacists to ensure competency for screening, counseling, administration, and dispensing of naloxone. Pharmacy Section Supervisors will use an industry standard continuing education course focused on overdose prevention and naloxone rescue, such as Boston University's "Prescribe to Prevent: Overdose Prevention and Naloxone Rescue Kits for Prescribers and Pharmacists" (Reference (j)). Another material that may be useful in educating MTF pharmacists is the Substance Abuse and Mental Health Services Administration's Opioid Overdose Toolkit (Reference (k)).
- c. <u>Naloxone Availability</u>. Ensure naloxone is available in the pharmacy according to the Basic Core Formulary determination by the DoD P&T (Reference (h)).
- d. <u>Beneficiary Education</u>. Ensure educational and informational materials for beneficiaries are available in the pharmacy for distribution (Attachment 2).
- 5. <u>IMPLEMENTATION</u>. With approval from the appropriate governing bodies at the MTF, i MTF pharmacists will offer naloxone to beneficiaries being prescribed an opioid prescription who have been identified in CarePoint through the Patient Look Up tool to meet the criteria for at risk for overdose.
- a. Naloxone Dispensing. MTF pharmacists will use the Patient Look Up tool available in CarePoint to determine if the beneficiary meets the eligibility criteria for being at risk for overdose. If the beneficiary meets the criteria, the screen will display a prompt in red colored font stating, "recommend naloxone". If naloxone is recommended, the pharmacists will review the patient's profile for any contraindications prior to offering naloxone to the beneficiary. If naloxone is not contraindicated, and the beneficiary meets the eligibility criteria for being at risk for overdose, MTF pharmacists will counsel the beneficiary on the availability of naloxone and dispense upon the beneficiary's or caregiver's request. If the beneficiary is pregnant or intends to become pregnant, do not dispense naloxone, but rather refer the beneficiary to his/her MD or OB/GYN. If the beneficiary is under 18 years old, the pharmacist should use their best clinical judgment and dispense naloxone, only when appropriate and in accordance with applicable federal, state, and local laws.
- (1) If the beneficiary accepts the naloxone prescription, the pharmacist will input a prescription, using a standing order for naloxone, and dispense to the beneficiary.

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(2) If the beneficiary is requesting naloxone without filling an opioid prescription, the MTF pharmacists will go through the same process of inputting the prescription using a standing order for naloxone.

(3) If the beneficiary declines the recommended naloxone prescription, the MTF pharmacists will document the refusal.

Step by step instructions on how to gain access to CarePoint and the Patient Look Up tool are provided as Attachment 3. Once access to the CarePoint, Patient Look Up tool is complete, Attachment 4 provides screen shots of what the electronic process will look like. MTF pharmacists can scan the patient barcode using a barcode scanner, or manually input the beneficiaries' ID number.

- b. Naloxone Dispensing (Manual Method). If the MTF pharmacist does not have access to a computer and is unable to login to CarePoint, the following method can be used to dispense naloxone to beneficiaries. MTF pharmacists will screen/evaluate beneficiaries who are prescribed an opioid prescription, using the established screening criteria, to determine if they are at risk for overdose (Attachment 5). If the beneficiary meets the eligibility criteria for being at risk for overdose, MTF pharmacists will ensure there are no contraindications to naloxone, counsel the beneficiary on the availability of naloxone, and dispense upon the beneficiary's or caregiver's request. If the beneficiary accepts the naloxone prescription, the screening criteria form used to determine risk is to be completed, filed, and treated as a regular prescription (Attachment 5). To assist in determining eligibility, an opioid daily dose conversion chart is available for MTF pharmacists (Attachment 5).
- c. <u>Beneficiary Counseling and Education</u>. Beneficiaries, or caregivers, who request or are determined to meet the eligibility criteria and are prescribed naloxone by the MTF pharmacist, will be educated and counseled using the materials provided (Attachment 2). Beneficiary education is a requirement for beneficiaries receiving naloxone. When possible, caregivers will be educated using the same materials, and MTF pharmacists should stress the importance of knowing where the naloxone is stored in the home. Beneficiary education should focus on safe use of opioid medications, overdose prevention, overdose recognition, administration of naloxone, calling Emergency Medical Services, administration of the second naloxone dose (if necessary), and maintaining active relationships with prescribers. Updated patient education materials will be provided to the MTF pharmacists, by DHA, when available.
- d. <u>Prescriber Notification</u>. MTF pharmacists will review medication profiles for beneficiaries identified as at risk for overdose. If the beneficiary has already received two or more naloxone prescriptions within the last 6 months, or asks for a refill of naloxone, the MTF pharmacist will request rationale for multiple naloxone prescriptions (i.e., the naloxone expired, was used, misplaced, etc.). The beneficiary is not required to respond; however, if they do, the response will be documented. If necessary, the MTF pharmacists will contact the beneficiary's prescriber to discuss with/inform the provider of the beneficiary's opioid and naloxone use.
- e. <u>Performance Measures</u>. The DHA will utilize existing automated data collection capabilities to assess the utilization of the Patient Look Up Tool in accordance with the procedures in this DHA-PI.

f. <u>Effectiveness Measures</u>. The DHA will assess the effect this DHA-PI has on improving the safety of opioids among beneficiaries who receive opioids at an MTF Pharmacy.

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GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

DHA Defense Health Agency

DHA-PI Defense Health Agency-Procedural Instruction

MTF Medical Treatment Facility

P&T Pharmacy and Therapeutics Committee

PART II. DEFINITIONS

These terms and their definitions are for the purpose of this DHA-PI.

<u>Basic Core Formulary</u>. A list of medications required to be on formulary at all full-service MTFs.

<u>beneficiary</u>. A person eligible for health care services under the DoD health care program (TRICARE).

<u>CarePoint</u>. A DHA information delivery portal designed to promote self-service business intelligence, user collaboration, content delivery, and information transparency for the purpose of improving healthcare quality, access, and delivery across the Military Health System.

<u>naloxone</u>. An opiate antagonist which prevents or reverses the effects of opioids, including respiratory depression, sedation, and hypotension.

<u>opiate reversal</u>. When an opioid overdose is reversed by using an agent which blocks the effects of opioids.

opioid. Drugs that act on the nervous system to relieve pain.

<u>opioid antagonist</u>. A drug that blocks opioids by attaching to the opioid receptors without activating them.

<u>overdose</u>. Taking too much of a substance, whether it's accidental or intentional, to have a harmful effect on the body.

<u>P&T</u>. A DoD committee whose mission is to uniformly, consistently, and equitably provide appropriate drug therapy to meet the clinical needs of DoD beneficiaries in an effective, efficient, and fiscally responsible manner.

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<u>Patient Look Up tool</u>. A search tool in the CarePoint web portal that allows providers to view patients' medical profile, including percent risk for respiratory depression, morphine equivalence, etc.

<u>respiratory depression</u>. Unusually slow or shallow breathing, which can result in too much carbon dioxide and not enough oxygen in the blood and can be life-threatening.

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