U.S. DEPARTMENT OF HOMELAND SECURITY U.S. Customs and Border Protection

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ORIGINATING OFFICE: OS/OCMO

SUPERSEDES: N/A

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ADMINISTRATION OF NASAL NALOXONE PROGRAMS

1. PURPOSE

During day-to-day operations, U.S. Customs and Border Protection (CBP) personnel may be exposed to fentanyl or other opioids or encounter an individual experiencing an opioid overdose. CBP personnel can provide potentially lifesaving care to individuals in the first critical minutes of an opioid overdose if properly equipped and trained in the administration of naloxone. The safety and health of the CBP workforce, and those in the care and custody of CBP, is paramount. Despite the potency of some opioids, the risk of clinically significant exposure of personnel is extremely low.

This Directive establishes policy and guidance for CBP offices to develop, implement, and maintain a nasal naloxone program for non-health care providers in the CBP workforce. Principal field managers should use the guidance outlined in this Directive along with guidance provided in U.S. Department of Homeland Security (DHS) Policy Directive No. 247-01 (Department Policy Regarding the Administration of Naloxone by Non-Healthcare Providers) to assist in determining requirements for their naloxone program.

2. BACKGROUND

Opioids are a class of potent, effective pain-relieving medications with a high abuse potential. The misuse and abuse of opioid drugs, including legally prescribed painkillers, illegal narcotics such as heroin, and illicitly manufactured opioids (for example, the increasingly prevalent fentanyl), pose a serious and growing threat to public health. Employees who encounter opioids should be trained to protect themselves and others, recognize opioid intoxication signs and symptoms, have naloxone readily available, and be trained to administer naloxone and provide active medical assistance as appropriate.

According to the CDC:

- More than 1,000,000 people have died between 1999 to 2021 from a drug overdose in the United States.
- In 2021, more than 106,000 drug overdose deaths occurred in the United States.

- Opioids—mainly synthetic opioids (other than methadone)—are the main driver of these drug overdose deaths with 70,601 overdose deaths reported in 2021.
- The number of reported deaths involving prescription opioids totaled 16,706 in 2021.

Protection of CBP personnel is vital to enable its law enforcement operations. The risk of unintentional exposure to law enforcement and frontline personnel is low, but not zero. Whether inspecting an inbound cargo container, searching a person encountered at the border or port, or performing myriad other CBP responsibilities, CBP personnel should remain vigilant, monitor threats to their safety, and be aware of procedures and tools that are available to them, such as personal protective equipment (PPE).

PPE best practices to protect CBP agents and officers include the proper utilization of gloves, eye protection, coveralls, and N95 respirator or more protective masks, based upon exposure risk. Although incidental dermal absorption is unlikely to cause opioid intoxication in CBP personnel, nitrile gloves provide adequate protection when employees routinely handle opioids. Although it is an infrequent and exceptional circumstance for drug particles to be suspended in the air, an N95 respirator provides sufficient protection.

Nasal naloxone should be administered to any person who demonstrates active objective signs of opioid overdose, as timely administration of nasal naloxone can counter the effects of an opioid overdose. Nasal naloxone combined with Cardiopulmonary Resuscitation (CPR) and rescue breathing are key steps to a successful resuscitation of someone experiencing an opioid overdose, because naloxone could take up to 20 minutes or longer to take effect. By displacing opioids from opioid receptor sites in the brain, naloxone can reverse the respiratory depression that is usually the cause of overdose deaths. Nasal naloxone is not intended to replace the Basic Life Saving (BLS) care provided by first responders. Properly administered BLS care can provide a lifesaving bridge for patients experiencing respiratory depression from an opioid overdose while the naloxone is taking effect.

3. SCOPE

This Directive specifies effective protocols and procedures for the safe handling of potential synthetic opioids, including fentanyl, by the CBP workforce to reduce the risk of injury or death resulting from the accidental opioid exposure and enhance post exposure management in accordance with 6 U.S.C. § 216, "Protection against potential synthetic opioid exposure."

4. POLICY

Nasal naloxone programs established under this Directive will fall under the medical direction and oversight of the CBP Chief Medical Officer (CMO) or designee. CBP shall only implement nasal naloxone programs that have been developed and are consistent with this Directive. A uniform approach to the deployment of CBP nasal naloxone programs ensures that implementation occurs at all locations, CBP personnel are trained in the safe handling of synthetic

¹ The CDC's wide-ranging online data for epidemiologic research (WONDER) databases can be found at http://wonder.cdc.gov. See also Drug Overdose Death Rates, National Institute on Drug Abuse (NIDA), nih.gov (last visited August 11, 2023).

opioids as well as access to and proper use of nasal naloxone, and applicable inspections and inventory management are performed.

Component offices that regularly handle illicit narcotics during the performance of their primary duties will implement, organize, and administer their respective nasal naloxone programs under the supervision and authority of the CBP Office of the Chief Medical Officer (OCMO) or designee. Training will be documented in the CBP system of record for training, currently ACADIS. Other component offices that maintain stores of naloxone for use in response to a suspected overdose victim should implement, organize, and administer a nasal naloxone program in the same manner.

Component office leadership for non-law enforcement and non-laboratory offices will be the deciding official regarding if their office, or portions of their office (e.g., no locations, individual locations, or all locations) will implement a naloxone program. Each location with a nasal naloxone program will develop appropriate operational procedures. These will be developed in coordination with, and will comply with, this Directive and any other related CBP policies or Standard Operating Procedures (SOPs) issued by OCMO. Component offices that are not required to but choose to implement a naloxone program at individual locations may collaborate with another component office in their immediate area to ensure full compliance with this directive.

CBP personnel will be trained by approved instructors and supervised in compliance with this Directive. CBP-supplied nasal naloxone should only be administered in accordance with this Directive. Local Emergency Medical Services (EMS) must be contacted by CBP employees administering Naloxone to provide a medical assessment and determine appropriate transport needs or requirements in accordance with its protocols. Nasal naloxone deployment/administration shall be reported via a SITROOM report by field personnel in accordance with CBP Directive 3340-025F (Section 5.14) or subsequent revisions.

5. AUTHORITIES/REFERENCES

- 5.1. 6 U.S.C. § 216, "Protection against potential synthetic opioid exposure"
- **5.2.** DHS Policy Directive No. 247-01, "Department Policy Regarding the Administration of Naloxone by Non-Healthcare Providers" (April 26, 2017)
- **5.3.** DHS Standard Operating Procedure (SOP): Administration of Naloxone by Non-Healthcare Providers (December 24, 2017)
- 5.4. DHS Office of Health Security PowerPoint, Recognition and Response to Opioid Overdoses and Occupational Intoxications (December 2021)
- 5.5. CBP Occupational Safety and Health Division, Job Hazard Analysis & PPE Assessment, Exposure to Narcotics and Synthetic Opioids (Fentanyl) (April 9, 2023)
- **5.6.** Centers for Disease Control and Prevention (CDC), *Understanding Drug Overdoses and Deaths*, https://www.cdc.gov/drugoverdose/epidemic/index.html (May 8, 2023)

- **5.7.** U.S. Department of Health and Human Services, *U.S. Surgeon General's Advisory on naloxone and Opioid Overdose*, https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html (April 8, 2022)
- **5.8.** U.S. Food and Drug Administration (FDA), *Information about Naloxone and Nalmefene*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-naloxone (July 28, 2023)
- **5.9.** National Alliance for Model State Drug Laws, *Naloxone Access Statutes*, https://namsdl.org/naloxone-access-statutes/ (March 1, 2016)
- **5.10.** The Network for Public Health Law, *Legal Interventions to Reduce Overdose Mortality:* Naloxone Access Laws, https://www.networkforphl.org/resources/legal-interventions-to-reduce-overdose-mortality-naloxone-access-and-good-samaritan-laws/ (February 2, 2021)
- **5.11.** Rachel P. Winograd, et al., *Training to reduce emergency responders' perceived overdose risk from contact with fentanyl: early evidence of success*, Harm Reduction Journal 17:58 (August 24, 2020)
- **5.12.** Elizabeth Saunders, et al., "You can see those concentric rings going out"; Emergency personnel's experiences treating overdose and perspectives on policy-level responses to the opioid crisis in New Hampshire, Drug Alcohol Dependence. Vol. 204 (November 1, 2019)
- **5.13.** Michael J. Moss, ACMT and AACT position statement: preventing occupational fentanyl and fentanyl analog exposure to emergency responders, Clinical Toxicology, 56:4, 297-300 (August 24, 2017)
- **5.14.** U.S. Department of Justice, Bureau of Justice Assistance, National Training and Technical Assistance Center, *Law Enforcement Naloxone Toolkit*, https://bjatta.bja.ojp.gov/tools/naloxone/Liability-and-Risk

6. DEFINITIONS

- **6.1.** The Office of the Chief Medical Officer (OCMO) Provides medical guidance and direction to all CBP components and offices, including for the purpose of nasal naloxone deployment, storage, inventory, and ordering.
- **6.2.** The Chief Medical Officer (CMO) Serves as the overall medical prescriptive and purchase authority for all naloxone within CBP and shall designate the CBP Naloxone Medical Director. The prescriptive and purchase authority may be delegated, at the discretion of the CMO, to the CBP Naloxone Medical Director.
- **6.3. CBP Nasal Naloxone Program Medical Director** Designated by the CBP CMO and will provide medical direction and oversight to the naloxone program for CBP personnel. Additionally, shall designate the CBP Nasal Naloxone Coordinator.

- 6.4. OCMO Chief Quality Officer (CQO) Provides quality management review of medical incidents, including naloxone usage in all environments within CBP and provides administrative feedback to the field to improve the quality of care provided by CBP personnel in coordination with the CBP Naloxone Medical Director.
- **6.5. CBP Nasal Naloxone Coordinator** Serves as the primary point of contact (POC) for CBP Components and offices for the CBP Naloxone Program.
- 6.6. Component Nasal Naloxone Coordinator Provides oversight of the naloxone programs within their component (e.g., Office of Field Operations, Air and Marine Operations, U.S. Border Patrol) and shall be designated by the appropriate executive level management official in the respective component.
- 6.7. Local Nasal Naloxone Coordinator Provides oversight of the local nasal naloxone program within their area of responsibility. This coordinator will typically reside at the Sector, Field Office, Branch, or equivalent level.
- **6.8. Medical Direction** Provided through the Office of the Chief Medical Officer and monitors and evaluates the naloxone program through regular assessments and advises on proper use of naloxone.
- 6.9. Approved Instructors For the purpose of this Directive, approved instructors are either current CBP personnel who have an active EMS credential from DHS or are a certified CPR instructor from one of three certifying authorities (American Safety and Health Institute (ASHI), American Red Cross (ARC), or American Heart Association (AHA).
- 6.10. Naloxone Naloxone, sometimes referred to as Narcan, is a safe drug that has no risk of abuse or dependency and that reverses an opioid overdose. Naloxone displaces (or "kicks out") the opioids from the receptors, and then blocks the receptors (and the effects of the opioid) for roughly 30-90 minutes.
- 6.11. Opioid Opioids are substances (naturally derived or synthetic) that act on opioid receptors to produce morphine-like effects, and are most often used medically to relieve pain, but also used to suppress coughs and alleviate diarrhea. Opioids include opiates, a term that refers to drugs derived from the fluids of the poppy plant.
- 6.12. Overdose A drug overdose results from taking too much of a substance, whether it is prescription, over the counter, legal, or illegal. Drug overdoses may be accidental or intentional. An overdose can lead to serious medical complications, including death. The severity of a drug overdose depends on the drug, the amount taken, and the physical and medical history of the person who overdosed.

7. RESPONSIBILITIES

7.1. CBP CHIEF MEDICAL OFFICER

7.1.1. Designate a <u>CBP Nasal Naloxone Program Medical Director</u> to provide medical direction, guidance, and oversight of the nasal naloxone program. This position will

- report to the CBP CMO.
- **7.1.2.** Ensure establishment, maintenance, and execution of policy and procedures for the CBP Nasal Naloxone Program.
- **7.1.3.** Ensure appropriate funding is identified by components for nasal naloxone training and supplies.
- **7.1.4.** May delegate prescription authority, within regulations, to a designee.

7.2. CBP NASAL NALOXONE PROGRAM MEDICAL DIRECTOR

- 7.2.1. Provide medical direction and oversight of CBP Nasal Naloxone programs.
- **7.2.2.** Review and approve internal CBP written nasal naloxone programs, SOPs, in coordination with the CBP CMO. The CBP CMO has final review and approval authority for nasal naloxone programs and SOPs submitted by CBP components and offices.
- **7.2.3.** Participate in quality assurance protocols of the nasal naloxone program and conduct post-incident follow up. Use post incident follow up and quality assurance to conduct reviews of the nasal naloxone program.
- **7.2.4.** If needed, and delegated from the CBP CMO, provide prescription and associated documentation for the purchase of nasal naloxone through the appropriate vendor, in accordance with current purchasing guidance.
- **7.2.5.** Designate a <u>CBP Nasal Naloxone Coordinator</u> to serve as the primary POC for component personnel and exercise technical oversight and implementation of the nasal naloxone program.

7.3. CBP NASAL NALOXONE COORDINATOR

- **7.3.1.** Serve as the POC for the CBP Naloxone Program.
- **7.3.2.** Provide consistent application and technical oversight of the nasal naloxone program, which includes a triennial (and as needed) review of the nasal naloxone program status, guidance, updates, and compliance evaluation.
- **7.3.3.** Implement, in conjunction with the CMO, this Directive consistent with Federal acts and mandates, industry standards, DHS policies, and best practices.
- **7.3.4.** Assist local sites with program development to ensure compliance with the established guidelines.
- **7.3.5.** Review and approve written nasal naloxone programs and SOPs submitted by CBP components and offices, in coordination with the CBP Nasal Naloxone Program Medical Director.

- **7.3.6.** Ensure compliance with protocols and participate in post-incident debriefing sessions and reviews.
- 7.3.7. Ensure all naloxone supplies are kept current per FDA rules and regulations for medication. Supplies should be replaced no later than 30-days before the expiration date unless an expiration extension is granted by the appropriate authority.
- **7.3.8.** The CBP Nasal Naloxone Program Manager will provide guidance to the Component Nasal Naloxone Coordinators in ordering naloxone to ensure nasal naloxone purchased is compliant with this Directive.
 - 7.3.8.1. Coordinate with the CBP Nasal Naloxone Medical Director to obtain the prescription letter for purchases if requested by the Component Nasal Naloxone Coordinators.
 - 7.3.8.2. Assist Component Nasal Naloxone Coordinators to identify appropriate annual funding for purchase of naloxone on a recurring and rotating basis to ensure available nasal naloxone is not expired or otherwise unserviceable.
- **7.3.9.** Participate in medical quality management review process with the Chief Quality Officer and Nasal Naloxone Medical Director.
- **7.3.10.** Work with appropriate stakeholders to establish and maintain a database for tracking all nasal naloxone inventory, deployment, and disposal.
 - **7.3.10.1.** Database shall include all pertinent information (location, lot number, expiration date, and disposal/deployment date) on naloxone.
 - 7.3.10.2. Database will be accessible at the local site level to allow for data input which will facilitate regular inventories which will be conducted, at a minimum, annually.

7.4. CHIEF QUALITY OFFICER (CQO)

- 7.4.1. Coordinate with the CBP Nasal Naloxone Program Medical Director to conduct medical quality management reviews of nasal naloxone usage, as appropriate.
- 7.4.2. Coordinate with the CBP Nasal Naloxone Program Manager and the CBP Nasal Naloxone Program Medical Director to ensure compliance with protocols, policies, and directives.
- 7.4.3. Participate in post-incident debriefing sessions and reviews.

7.5. COMPONENT NASAL NALOXONE COORDINATOR

7.5.1. Facilitate coordination and communication between the CBP Nasal Naloxone Program

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- Manager, CBP Nasal Naloxone Program Medical Director and their respective Field Offices, Sectors, Air and Marine Regions and other facilities where nasal naloxone programs have been established.
- 7.5.2. Ensure the naloxone inventory database is maintained and regularly updated (at least quarterly) to provide the most accurate and current data regarding naloxone located at field locations.
- 7.5.3. Provide nasal naloxone program information (e.g., local written policies, inventory or inspection records, and other related nasal naloxone program information) when requested by the CBP CMO, CBP Nasal Naloxone Program Medical Director, CBP Nasal Naloxone Program Manager, or the CQO.
- 7.5.4. Identify and provide appropriate component level budget to supply nasal naloxone to field elements, including resupply, and to provide the appropriate initial and recurring training.

7.6. LOCAL NASAL NALOXONE COORDINATOR

- 7.6.1. Facilitate communication among Component Nasal Naloxone Coordinator and appropriate Ports of Entry, Stations, Air and Marine Branches, or other facilities within their area of responsibility (AOR).
- 7.6.2. Maintain an inventory database of all nasal naloxone located in their AOR.
- **7.6.3.** Ensure all policies, procedures, and protocols are followed in any nasal naloxone deployment within their AOR.
- 7.6.4. Coordinate the collection of data and reports from responders and other personnel involved to ensure appropriate reporting is completed in a thorough and timely manner.
- **7.6.5.** Advise Component Nasal Naloxone Coordinator of any issues with nasal naloxone (e.g., 90 days to expiration).

7.7. INSTRUCTORS

- **7.7.1.** Instructors must meet the definition of Approved Instructor in Section 5.8 of this directive.
 - 7.7.1.1. Instructors conducting CPR certification for CBP employees must meet ASHI, ARC, or AHA instructor requirements and be in good standing with the certifying authority.
- 7.7.2. Instructors must be approved by their respective Component Nasal Naloxone Coordinators to provide nasal naloxone instruction in accordance with this Directive.
- 7.7.3. Instruction shall be provided in accordance with Section 7.6. of this Directive.

7.8. CBP OCCUPATIONAL SAFETY AND HEALTH DIRECTOR

- 7.8.1. Reviews and updates the CBP Job Hazard Analysis & PPE Assessment, Exposure to Narcotics and Synthetic Opioids (Fentanyl) (CBP Fentanyl/Opioid JHA), periodically as needed.
- **7.8.2.** Includes reference to this Directive in revisions to the CBP Fentanyl/Opioid JHA.
- **7.8.3.** Coordinates with OCMO on revisions to the CBP Fentanyl/Opioid JHA to ensure there are no conflicts with this Directive.

8. PROCEDURES

- 8.1. Medical Oversight A physician must have oversight in all phases of the nasal naloxone program. The CMO shall be the designated physician for this program and all CBP Nasal Naloxone programs will operate under this oversight.
- **8.2.** Written Policy Local and Component Level Standard Operating Procedures (SOP) may be developed, consistent with this Directive, to provide clarifying guidance and direction to personnel regarding the storage, inventory, and use of nasal naloxone within the AOR.
- 8.3. Inspection and Inventory A national database (developed by OCMO) will be maintained by the Local Nasal Naloxone Coordinators for their AOR. A monthly inspection and inventory shall be conducted by the Local Nasal Naloxone Coordinators for all nasal naloxone in their AOR.
- 8.4. Post Event Review Following any incident in which there is an administration of naloxone, a post-incident evaluation should be completed by the Local Nasal Naloxone Coordinator to identify any circumstances or issues that occurred during the event. Components will follow local Critical Incident Stress Debriefing (CISD), employee care, and procedures following any incident.
- **8.5.** Recordkeeping All records shall be maintained in accordance with CBP records management policies and directives.
 - **8.5.1.** Nasal naloxone inventory records shall be maintained for three (3) years.
 - **8.5.2.** Post Event Review documentation shall be maintained, electronically, for 20 years along with the associated Patient Care Report (PCR), if applicable, and the DHS Non-Healthcare Provider Naloxone Administration Reporting Form (see Attachment A).
 - **8.5.3.** Records must be stored in accordance with appropriate confidentiality and CBP privacy rules and regulations that may apply.
- **8.6.** Training Requirements Component and Local SOPs must ensure that the national training requirements for personnel are identified within their local SOPs.

- 8.6.1. Instructor Certification Instructors must be a current CPR instructor certified from one of the three CPR certifying authorities (ASHI, ARC, or AHA) or hold a current EMS license/credential that meets the requirements for employees to serve as CBP EMS personnel. Additionally, instructors must utilize the standardized training materials for nasal naloxone training, provided by CBP or DHS if CBP materials are not available.
- 8.6.2. Naloxone (non-healthcare provider) Personnel CBP employees must receive initial and follow-on CPR training. Additionally, during the training, instructors should provide any pertinent updates to nasal naloxone protocols, procedures and reporting requirements.
 - 8.6.2.1. Students will have training documented in ACADIS or the current CBP training system of record.
 - 8.6.2.2. Students will **not** receive a CPR certification, but will be instructed in CPR for awareness, unless training is provided by a CPR certified instructor **and** the class is offered as a CPR certification course meeting the requirements of the certifying authority.

8.6.3. Length of Training

- **8.6.3.1.** Initial training is recommended to be a minimum of 4 hours to allow for sufficient instruction time and skills practice. Training breakdown will be 2 hours for CPR instruction, 1 hour for airway management, and 1 hour for naloxone administration.
- 8.6.3.2. Follow-on training is recommended to be a minimum of 4 hours to allow for sufficient instruction time and skills practice. Training breakdown will be 2 hours for CPR renewal, 1 hour for airway management refresher, and 1-hour for naloxone administration refresher.
- 8.6.3.3. Follow-on training for naloxone will occur at a minimum of every 2 years. If CPR certifications are offered, they must be in accordance with a CPR certifying authority (ASHI, ARC, or AHA).
- **8.6.3.4.** As part of their training, participating personnel should be made aware of liability protections available to them when attempting to assist individuals in medical distress, including through the administration of nasal naloxone.

8.7. Reporting Requirements

- **8.7.1.** All local SOPs must contain guidance on reporting requirements for the AOR covered by the local SOP and must meet the minimum guidelines set forth in this Directive.
 - 8.7.1.1. A significant incident report (SIR) must be completed, in accordance

with current CBP guidance, for all naloxone deployments at any CBP location or by any CBP employee.

- **8.7.1.1.1.** Data required for inclusion in the SIR includes the information provided in the DHS Non-Healthcare Provider Naloxone Administration Form (Attached). This worksheet is provided as a guide to assist reporting and is not required for any other purpose.
- **8.7.1.2.** If nasal naloxone is deployed by CBP EMS trained personnel, a Patient Care Report is required as per DHS protocols.
- 8.7.1.3. Notification (SIR number, location of deployment, number of patients, number of doses administered, and if patient(s) was transported to the hospital) to the CBP Nasal Naloxone Coordinator (b) (7)(E) must be completed within 48 hours of the deployment, or sooner when practical.
- **8.7.2.** Components may include additional local reporting requirements in local SOPs for tracking purposes (e.g., written report of event(s), electronic incident log (IOIL), etc.).
- **8.7.3.** Local reporting guidance should also include local chain of command reporting as needed for the location.

8.8. PLACEMENT OF NALOXONE AT CBP FACILITIES

- **8.8.1.** Nasal naloxone locations shall be determined locally and based on operational needs for that location.
- **8.8.2.** Emergency Medical Services (EMS) trained CBP personnel should have nasal naloxone readily available to them. This can be accomplished in a variety of ways but will be the determination of the Local Nasal Naloxone Coordinator (e.g., placed in response bags or placed in locations that would have the most probable need for naloxone deployment).
- **8.8.3.** In determining locations for naloxone placement, the Local Nasal Naloxone Coordinator must ensure the following criteria are met. Naloxone must be:
 - **8.8.3.1.** Secured in a manner that prevents unauthorized access but allows ready access for trained personnel.
 - **8.8.3.2.** Easily identifiable through signage and other markings.
 - **8.8.3.3.** Stored in accordance with manufacturer guidelines for temperature controls.
 - **8.8.3.4.** Stored in locations that match location descriptions in the inventory

control database.

8.8.3.5. Made available for force protection (e.g., narcotic processing areas).

9. RECORDS MANAGEMENT

This policy creates records that require(s) a new file plan or potentially impact(s) an existing one. For records management purposes, electronic records will be completed in the appropriate CBP system of record, as outlined in the Office of the Chief Medical Officer File Plan.

10. NO PRIVATE RIGHT CREATED

This directive is an internal policy statement of CBP and does not create or confer any rights, privileges, or benefits upon any person, party, or entity.

11. POINT OF CONTACT

Direct all questions regarding this directive and the requirements it establishes to (b) (7)(E)

12. APPROVAL AUTHORITY



Troy A. Miller

Senior Official Performing the Duties of the Commissioner U.S. Customs and Border Protection

Attachments: DHS Non-Healthcare Provider Naloxone Administration Form