



Standard Operating Guidelines

SOG#: A101 – Medical Countermeasures Program, Biological Agent Prescription Procedures

Created: June 22, 2012, Updated: 04/14/2020, Version 3.0

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Purpose

The purpose of this program is to enhance the Region's biological response readiness by developing a process for prompt access to prophylactic antibiotics to protect Emergency Responders. These guidelines are based on the June 14, 2012 memo from OEM transmitting the *Anthrax Medical Countermeasures Prescription Program for Obtaining, Activating and Maintaining Scripts* (Appendix A) and the current prescription distribution process communicated by the Acting Deputy Director of the Safety and Sustainability Division on January 9, 2020.

Obtaining a Prescription

A prescription will be issued to the Region's Safety Health and Environmental Program Manager (SHEMP) by Federal Occupational Health (FOH) after the Emergency Responder completes their annual medical monitoring physical. The prescriptions will be stored electronically in a secure OneDrive Folder - https://usepa.sharepoint.com/sites/errpb_osc/OSC_MCM_Prescriptions/. Access to this folder will be restricted to the Branch Chief, Section Chiefs, and the Branch Safety Officer. The Region's SHEMP will keep a backup copy of the prescriptions in a separate secure location.

Should a biological agent emergency occur, or a specific deployment require the prescription, FOH will be available to issue a prescription to Emergency Responders who have an expired prescription or are overdue for their annual physical.

Deploying the Prescriptions

Following notification of an emergency involving Anthrax or Tularemia, Branch Management or their designee, will contact the FOH Emergency Response Call Center (24-hour) at 240-286-5676 and discuss the response. If FOH recommends the use of the prophylactic antibiotics, Branch Management, or their designee, will access the prescriptions and issue to the responding OSC(s).

Use of the Prescription

1. Responders, prior to leaving their Duty Station, will go to a convenient pharmacy and fill their prescription. Pay for the prescription using the Government Travel Card and account for it in the CONCUR System. The receipt must be retained for recordkeeping.
2. The Emergency Responder will receive further instruction on when to take the antibiotic.
3. If directed to take the antibiotic, the OSC shall take the antibiotic as instructed on the prescription/label.
4. The Emergency Responder should follow up with their personal physician or FOH for subsequent prescriptions or if complications or symptoms of exposure present.

Emergency Responder(s) who have had changes in their prescribed medicine or health since their last annual physical must contact FOH at 240-286-5676 prior to filling the prescription to discuss their condition and potential side effects or drug interactions.



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Created: June 22, 2012, **Updated:** 03/13/2012, 01/07/2015, 0813/2015, 04/01/2016, Version 2.0

Appendix A

Anthrax Medical Countermeasures Prescription Program for Obtaining, Activating and Maintaining Scripts





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 14 2012

MEMORANDUM

SUBJECT: Transmittal of the Anthrax Medical Countermeasures
Prescription Program Procedures for Obtaining, Activating and Maintaining
Scripts

FROM: Dana Tulis, Deputy Director 
Office of Emergency Management

Wesley J. Carpenter, Director 
Safety, Health, and Environmental Management Division

TO: Superfund National Policy Managers, Regions 1-10

PURPOSE

This memorandum transmits the EPA's *Anthrax Medical Countermeasures (MCM) Prescription Program Procedures for Obtaining, Activating and Maintaining Scripts* including:

- Process to obtain script
- Notification and trigger process to fill prescription
- Maintenance of the program

BACKGROUND

The *Anthrax MCM Prescription Program Procedures for Obtaining, Activating and Maintaining Scripts* was developed by the Headquarters MCM Workgroup consisting of representatives from the Office of Homeland Security, Office of Emergency Management (OEM) and the Safety, Health and Environmental Management Division (SHEMD). It is being issued jointly by OEM and SHEMD to meet requirements of Presidential Executive Order 13527, *Establishing Federal Capabilities for the Timely Provision of Medical Countermeasures Following a Biological Weapons Attack in the United States*. The procedures enhance EPA's overall biological response readiness by focusing on expediting the provision of medical countermeasures for our responders.

IMPLEMENTATION

The *Anthrax MCM Prescription Program Procedures for Obtaining, Activating and Maintaining Scripts* are to be used in the event of an anthrax incident requiring the activation of the written prescription program. While participation in the EPA's anthrax MCM prescription program is **voluntary**, we are hopeful that all of our responders will have a prescription by September 30, 2012.

Process to Obtain Script: To obtain a prescription, the EPA responder will be evaluated during his/her annual medical monitoring exam to determine if he/she is suitable to take the medication. Suitable responders will then receive a prescription from the Federal Occupational Health (FOH) doctor, along with an official letter indicating they are part of an emergency response community. The responder should request the prescription if it is not offered as part of the examination process. If the responder has already had his/her medical monitoring exam and not received a prescription, they may make a separate appointment with the FOH physician for the purpose of receiving a prescription.

Notification and Trigger Process to Fill Prescription: The regional or Headquarters Emergency Operations Center will be notified of an anthrax incident. The Responsible Removal Manager(s) will notify FOH. Personnel from the FOH's Emergency Response Team will discuss the situation with the RM(s) and provide medical direction. Upon receiving the FOH medical authority's recommendation to activate the prescription plan, the EPA RM(s) will contact their prescription program employees selected to deploy and/or support the EPA's response and instruct them to contact the FOH medical authority on call if they have had any health or medication changes since their annual exam. Unless otherwise indicated by the FOH medical authority, the EPA responder may then fill and self-administer the prescriptions. Each employee will also be required to bring to the pharmacist the official letter written by the FOH indicating that he/she is part of the EPA emergency response group.

Maintenance of the Program: OEM will maintain an anthrax MCM prescription program participant list of all eligible On Scene Coordinators and Special Team members enrolled in the medical surveillance program for the purposes of supporting an emergency biological response. This list will be updated annually and shared with SHEMD and regional Safety, Health and Environmental Management Program Managers. Each script must be turned in at the employee's annual medical exam, where a new script will be provided. FOH will notify SHEMD and the local SHEMP manager of any personnel who cannot receive a script due to health reasons.

Please share this memorandum and the attached procedures with your Removal Managers, OSCs, Special Team Members and SHEMP Managers. A copy of this document is available on the EPA's website at the www.epaosc.org. General questions should be referred to Mark Mjoness at (202) 564-1976 or Craig Beasley at (202) 564-2087.

Attachment

cc: Mathy Stanislaus
Barry Breen

Lisa Feldt
Assistant Regional Administrators
Regional Removal Managers
SHEMP Managers
OSRTI Managers
OEM Managers
Mike Flynn, ORIA
Henry Barnet, OCEFT



EPA Anthrax Medical Countermeasures (MCM) Prescription Program Procedures for Obtaining, Activating and Maintaining Scripts

Participation in the EPA's Anthrax MCM prescription program is voluntary. The regional Removal Managers (RMs) and special team managers reserve the right to determine which personnel to deploy in response to an anthrax incident. In the event of an anthrax incident requiring the activation of the written prescription program for the EPA On-Scene Coordinators (OSCs) and Special Team Members enrolled in the medical surveillance program, the following procedures must be followed:

Process to Obtain Script

- During the annual medical monitoring exam, the EPA responder will be evaluated by a Federal Occupational Health (FOH) medical doctor to determine suitability to take doxycycline (doxy) or ciprofloxacin (cipro) antibiotics in the event he/she is deployed to an anthrax incident.
- All eligible responders will then be provided with a medical script for either doxy or cipro and an official letter from the FOH medical authority indicating they are part of the EPA emergency response community.
- EPA employees enrolled in this program are required to safeguard their medical script and letter until they either need it for a response (see trigger process below) or the next annual exam takes place, at which time the script and the letter must be returned to the FOH medical authority to receive a new script.

FOH will provide a list of employees issued a medical script to the Safety, Health and Environmental Management Division (SHEMD) and the regional and local Safety, Health and Environmental Program (SHEMP) Managers. SHEMD will share this information with the Office of Emergency Management (OEM) and the SHEMP Managers will provide this information to the RMs to facilitate response, as appropriate.

Notification and Trigger Process to Fill Prescription

- The Headquarters (HQ) Emergency Operations Center (EOC) and/or regional EOC will be notified of an anthrax incident resulting in a potential need for responders to fill their scripts. This notification will be relayed to the appropriate regions and HQ, respectively, as part of normal notification standard operating procedures. The trigger process to fill prescriptions is initiated in the region as part of the response decision making process as outlined below.
- The responsible RM will notify the FOH of a suspected or actual biological incident by contacting the FOH's Emergency Response telephone line at (240) 286-5676, a 24-hour access service for activating FOH's Emergency Response Team. Personnel from

the FOH's Emergency Response Team will discuss the situation with the RM(s) and provide medical direction.

- Upon receiving the FOH medical authority's recommendation to activate the prescription plan, the EPA RM(s) will contact their prescription program employees selected to deploy and/or support the EPA's response and instruct them to contact the FOH medical authority on call if they have had any health or medication changes since their annual exam. Unless otherwise indicated by the FOH medical authority, the EPA responder may then fill and self-administer the prescriptions according to the instructions on the label and senior agency officials. The responders are authorized to use their travel cards to fill their medical scripts. All receipts for scripts must be kept for recordkeeping.
- To ensure that pharmacists understand why prescriptions are being filled later than the date on the script, each employee will also be required to bring the official letter written by the FOH indicating that he/she is part of the emergency response group for the EPA. This letter is provided to the EPA personnel at the same time they receive their script.
- When prescription program personnel are given the direction to self-administer medication, they should follow up with their personal physicians for subsequent prescriptions and for any required symptomatic care.
- Deployed personnel who cannot follow up with their personal physicians should coordinate with their RM(s), who will convey this information to the FOH directly or through the SHEMP manager. SHEMD will work with the FOH to ensure that all prescription program personnel receive subsequent prescriptions that go beyond the initial 10-day prescriptions, as needed.

Maintenance of the Program

- OEM will maintain an anthrax MCM prescription program participant list of all eligible OSCs and Special Team Members enrolled in the medical surveillance program for the purposes of supporting an emergency biological response. This list will be updated annually and shared with SHEMD and regional SHEMP managers.
- The individuals on the program participant list will receive a script and letter addressed to the pharmacist at the time of their annual medical monitoring exam.
- All enrolled employees with a script are expected to safeguard their script and pharmacist letter; each script must be turned in at the employee's annual medical exam, where a new script will be provided. Employees that do not turn in their script at their annual exam will be reported to their respective managers. Disciplinary actions will be enforced.
- If an employee loses their script, they must immediately notify their manager, and a determination will be made as to whether or not the employee can continue to participate in the MCM program.
- FOH will notify SHEMD and the regional SHEMP manager of any personnel that will not receive a script due to health reasons.

From: [Weisberg, Skip](#)
To: [Scott, Barbara](#); [Eichinger, Kevin](#)
Subject: RE: Updates to Medical Countermeasure Program and DuoDote Program
Date: Thursday, January 9, 2020 5:01:06 PM

I've asked Kovak to share the information below with all the Response Managers, so feel free to tell the OSCs.

SHEMs, OSCs and the RM need to discuss the new MCM process for their region. Think about whether the RX's need to be printed and stored, kept electronically, who should have access, who notifies Doc Lewis if they are needed, etc...

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From: Scott, Barbara <Scott.Barbara@epa.gov>
Sent: Thursday, January 9, 2020 3:43 PM
To: Weisberg, Skip <Weisberg.Skip@epa.gov>; Eichinger, Kevin <Eichinger.Kevin@epa.gov>
Subject: RE: Updates to Medical Countermeasure Program and DuoDote Program

Thank you so much, Skip!!!! Even though it's more work for the SHEM, it will help keep things straight. I wish we could have a conference where all the SHEMs could share how they are handling this added work load - BMPs. I am doing all of mine electronically – nominations, exam forms, and clearances all in separate folders and it's working pretty well.

Kevin – I'll just send the scripts to you. I wonder if there is PII on the scripts?

From: Weisberg, Skip <Weisberg.Skip@epa.gov>
Sent: Thursday, January 09, 2020 3:32 PM
To: OMS-ARM-OA-SSD-SHEMPMGRS <OMS-ARM-OA-SSD-SHEMPMGRS@epa.gov>
Subject: Updates to Medical Countermeasure Program and DuoDote Program

SHEMs:

There have been updates recently to both the Medical Countermeasure Program (MCM) and DuoDote Program (Nerve Agent Antidote) requirements under the Occupational Medical Surveillance Program (OMSP).

For the **MCM program**, here is a brief background on what we were doing previously:

On-Scene Coordinators (OSCs), Special Team members and hazmat divers were screened for MCMs at their health unit appointment and were given their prescription by the local FOH physician. However, there were several issues with this process that needed to be addressed (backup physicians unaware to deliver prescriptions, incorrect FOH prescription pads, being omitted due to FOH Unit personnel turnover, etc.), and our new FOH Occupational Physician (Reviewing Medical Officer, RMO) wanted to reduce the risk associated with providing prescriptions with individual employees. We needed a process that should ensure everyone who needs an MCM prescription has one, while satisfying FOH's desire to reduce their risk in distributing prescriptions.

What we're moving to (and FOH has already started) is basically that the RMO will take over writing the MCM prescriptions from the local FOH Physicians. The employee goes to the OMSP exam as normal and it's sent to FOH HQ and the RMO as normal. **The RMO will write a MCM prescription (for every employee noted on Page 11 by the SHEM under Special Programs as needing it), and FOH HQ will upload the prescription into our secure file transfer site (same place the pg 12 exam clearances statements are being uploaded).**

The SHEMP manager therefore now has control of the prescription. The next step is for the SHEMP manager to get the prescription to the local Response Manager (or their designee) who will be responsible for storing all the prescriptions for their site until an emergency occurs requiring distribution of the prescriptions. If an emergency occurs requiring distribution, the response manager (in conjunction with the SHEM Manager) would then contact the RMO to request an approval to release the scripts, have the employees fill them and take the MCMs.

We are currently working on updating our MCM protocol document with the new procedure, but since FOH has already changed the process they're following we felt it important to communicate what's happening.

DuoDote Program (nerve agent antidote kit):

Currently, lab employees in EPA's Ultra-Dilute Chemical Warfare Agent (CWA) laboratories, On-Scene Coordinators (OSCs), Special Team members and hazmat divers are evaluated for DuoDote kit use as part of the OMSP exam. There is a Duodote screening form that was supposed to be filled out by those employees prior to their exam. **SSD has been pushing for years to get rid of this superfluous form as there is no contraindication to using a DuoDote kit (last minute life saving intervention).**

Our new RMO agrees with this line of thinking and therefore, we'll no longer be using the Duodote screening form. What is important, is that all SHEM managers understand that they must make use of page 11 on the exam form for each OMSP exam. For page 11, you should always complete the entire page, which includes filling in the correct occupation of the employee and checking the special programs box (lists MCM, Duodote, Voluntary Exercise Program).

All SHEM managers should be filling out page 11, but last I heard from FOH we were only at

about 50% filling it out. As you check the boxes on pg 11, it communicates to the RMO what he should be looking for and what he is expected to clear the employee for on the page 12 clearance page. Assuming the right category of employee is selected and DuoDote is checked on page 11, the RMO will know to evaluate the employee for potential DuoDote usage, MCM, Respirator usage, etc., and provide the appropriate medical clearance (based on the medical history, medications, exam results, etc.).

These topics will be discussed in more detail by Josh McDonald and David Wynn on **January 15th (11:30 – 12:30 PM Eastern) during the OMSP Matrix and 2020 Exam Form training teleconference.**

If there are any questions, please feel free contact Josh McDonald or David Wynn.

Sorry for the length of this note.

Skip

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Appendix B

Biological Agent Fact Sheets

Anthrax

Incubation and Symptoms of Organisms

Disease	Infectious Agent	Type of Infection	Incubation Period Typical (Range)	Symptoms
Anthrax	Bacillus anthracis	Cutaneous (skin)	1 day	<ul style="list-style-type: none"> Localized itching followed by bumps that become fluid filled and subsequent development of necrotic centers within 7-10 days of initial lesion Fever, malaise, and headache may develop
		Inhalational	1-7 days (1-60 days)	<ul style="list-style-type: none"> Initial: Non-specific, flu-like symptoms with mild fever, dry cough, malaise, and mild chest discomfort or pressure Subsequent (2-5 days later): Sudden difficulty breathing, high fever, and shock Death within 24-36 hours
		Ingestion (gastrointestinal)	1-7 days	<ul style="list-style-type: none"> Initial: Nausea, vomiting, lack of appetite, and fever Subsequent (2-4 days later): Severe abdominal pain, bloody stool and bloody diarrhea, and fluid collection in abdominal space Shock and death within 2-5 days
		Ingestion (oropharyngeal)	1-7 days	<ul style="list-style-type: none"> Initial: Fever and neck swelling, severe throat pain, and difficulty swallowing Subsequent: Ulcers may progress to necrosis (dead tissue) and swelling may compromise the airway

Treatment and Prophylaxis of Organisms

Disease	Treatment	Prophylaxis	Enhanced Surveillance Period*
Anthrax	<ul style="list-style-type: none"> Ciprofloxacin and doxycycline is FDA approved for adults and children Levofloxacin is FDA approved for adults If adverse reactions are suspected, therapy may be changed to amoxicillin or penicillin. 	<ul style="list-style-type: none"> No vaccine routinely available Ciprofloxacin and doxycycline Use of tetracyclines and fluoroquinolones in children must be weighed against risk of developing a life threatening disease. 	60 days

Tularemia

Incubation and Symptoms of Organisms

Disease	Infectious Agent	Type of Infection	Incubation Period <i>Typical (Range)</i>	Symptoms
Tularemia	Francisella tularensis	Glandular (fever without ulcers)	3-5 days (1-14 days)	<ul style="list-style-type: none"> Sudden fever and chills, headache, muscle aches, joint aches, sore throat, dry cough, lack of appetite, nausea, vomiting, diarrhea, abdominal pain, and swelling of regional glands
		Oculoglandular (eye)		<ul style="list-style-type: none"> Irritation and inflammation of eye, and inflamed, painful conjunctiva with pus
		Oropharyngeal (throat, mouth, glands)		<ul style="list-style-type: none"> Pain with seeing light and excess tearing
		Pneumonic (lung)		<ul style="list-style-type: none"> May develop eye ulcers and swollen glands in front of ears, under jaw, and neck (may mimic mumps)
		Ulceroglandular (skin)		<ul style="list-style-type: none"> Sore throat, mouth ulcers, tonsillitis, and swelling of the glands in the neck
				<ul style="list-style-type: none"> Cough, chest pain, and difficulty breathing
				<ul style="list-style-type: none"> Skin ulcer appears at site where organism enters body, accompanied by swelling of regional glands usually in the armpit or groin

Treatment and Prophylaxis of Organisms

Disease	Treatment	Prophylaxis	Enhanced Surveillance Period*
Tularemia	<ul style="list-style-type: none"> Gentomycin or streptomycin (10-14 days) Tetracyclines and ciprofloxacin are also effective (21 days) 	<ul style="list-style-type: none"> Doxycycline (FDA approved) or ciprofloxacin 	40 days

Glanders (Meliodosis)

Incubation and Symptoms of Organisms

Disease	Infectious Agent	Type of Infection	Incubation Period <i>Typical (Range)</i>	Symptoms
Glanders (Meliodosis)	Burkholderia mallei, Burkholderia pseudomallei	Acute, local	2 days - years	<ul style="list-style-type: none"> Fever and muscle aches may develop A bump (nodule) forms where bacteria entered the skin May progress to bloodstream infection
		Bloodstream		<ul style="list-style-type: none"> May have difficulty breathing, severe headache and disorientation, diarrhea, pus-filled skin lesions, and muscle aches Pus-filled lesions (abscesses) may develop throughout the body More common in patients with HIV, kidney disease, or diabetes May develop fever and shock
		Lung		<ul style="list-style-type: none"> Begins with high fever, headache, lack of appetite, and sore muscles Develops into cough and chest pain Progresses to severe pneumonia
		Chronic		<ul style="list-style-type: none"> Involves internal organs (liver, spleen, lungs, brain, glands) May have occasional relapses

Treatment and Prophylaxis of Organisms

Disease	Treatment	Prophylaxis	Enhanced Surveillance Period*
Glanders (meliodosis)	<ul style="list-style-type: none"> At least 10 days for initial treatment, followed by a continued course of antibiotics for 20 weeks Sulfadiazines have been found to be experimentally effective. Reported to be sensitive to multiple antibiotics including tetracyclines, ciprofloxacin, streptomycin, novobiocin, gentamicin, imipenem, ceftazidime, and sulfonamides 	<ul style="list-style-type: none"> No vaccine available 	To be determined

Plague

Incubation and Symptoms of Organisms

Disease	Infectious Agent	Type of Infection	Incubation Period <i>Typical (Range)</i>	Symptoms
Plague	Yersinia pestis	Bubonic (skin)	1-7 days	<ul style="list-style-type: none"> • Acute onset of fever, painful swollen regional lymph nodes, usually in the groin, armpit, and neck • May progress to septicemic form
		Pneumonic (lung)	1-4 days	<ul style="list-style-type: none"> • Nonspecific symptoms including shallow rapid breathing, fever, and shock • Specific symptoms including difficulty breathing, non-productive cough, and watery blood stained sputum • May progress to septicemic form
		Meningeal (brain lining)	1-7 days	<ul style="list-style-type: none"> • Fever and chills, headache, nausea and vomiting, stiff neck, sensitivity to light, and change in mental status
		Septicemic (blood)	1-7 days	<ul style="list-style-type: none"> • Blood infection and shock • May also include low blood pressure, acute respiratory distress, and bleeding

Treatment and Prophylaxis of Organisms

Disease	Treatment	Prophylaxis	Enhanced Surveillance Period*
Plague	<ul style="list-style-type: none"> • 7-10 days • Streptomycin is the most effective treatment. • Gentamycin can be used if streptomycin is not available. • Tetracyclines, doxycycline, and chloramphenicol are also effective. 	<ul style="list-style-type: none"> • Tetracycline or chloramphenicol for one week after exposure 	14 days

Small Pox

Incubation and Symptoms of Organisms

Disease	Infectious Agent	Type of Infection	Incubation Period <i>Typical (Range)</i>	Symptoms
Smallpox	Variola minor, variola major	Typical	12-14 days (7-17 days)	<ul style="list-style-type: none"> • 90% of cases • Prodrome lasting 2-4 days includes fever, malaise, head and body aches, and sometimes vomiting • Early rash lasting for 4 days <ul style="list-style-type: none"> ○ Emerges as small red spots on tongue and mouth and develops into sores ○ After 24 hours, rash spreads to all parts of the body; fever decreases ○ By 3rd day, rash becomes raised bumps ○ By 4th day, bumps fill with thick, opaque fluid and often have a depression in the center that looks like a belly button ○ Most contagious period • On 5th day, pustular rash where bumps become sharply raised, firm pustules; pustules begin to form a crust and then scab <ul style="list-style-type: none"> ○ No longer infectious • Resolving scabs: scabs begin to fall off and leave pitted scars
		Hemorrhagic (bleeding)		<ul style="list-style-type: none"> • 5% of cases • Bleeding into skin lesions and internal bleeding • 95-100% mortality rate
		Malignant (flat)		<ul style="list-style-type: none"> • 5% of cases • Skin lesions do not progress to pustular stage but remain flat and soft • 95-100% mortality rate

Treatment and Prophylaxis of Organisms

Disease	Treatment	Prophylaxis	Enhanced Surveillance Period*
Smallpox	<ul style="list-style-type: none"> • Supportive care • Questionable use of anti-viral drug cidofovir 	<ul style="list-style-type: none"> • Vaccination with vaccinia within 4 days of exposure 	40 days