



Receiving,



Distributing,



and Dispensing



Strategic National



Stockpile Assets:

**A Guide to Preparedness,
Version 11**



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Introduction to the Strategic National Stockpile

The Centers for Disease Control and Prevention (CDC)'s Strategic National Stockpile (SNS) is a repository of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency in which local supplies have been or may be depleted. The SNS program has grown over the years to encompass a wide range of medical countermeasures (MCMs) and response capabilities. *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness, Version 11*, is intended to help public health and emergency management personnel at the state, local, tribal, and territorial (SLTT) levels of government prepare to request and make effective use of MCMs to prevent, mitigate, or treat adverse health effects from an intentional, accidental, or naturally occurring public health emergency.

Building the Strategic National Stockpile Program

The SNS program was established with nominal funds in 1999 as part of the nation's preparedness against potential incidents involving select Category A agents (e.g., botulism, anthrax, smallpox, plague, and tularemia). Following the deployment of SNS assets to New York City to mitigate effects of the September 11, 2001, terrorist attacks on the World Trade Center and in response to the anthrax attacks in October of that year, the program grew exponentially. Those incidents prompted federal legislation and directives that rapidly facilitated and strengthened public health emergency preparedness efforts and the SNS program. Such legislation and directives included the Pandemic and All-hazards Preparedness Act (PAHPA)¹ of 2006, which introduced benchmarks for public health preparedness, and Homeland Security Presidential Directive 21 (HSPD-21),² which specifically addressed preparedness for

Medical Countermeasures

According to the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), medical countermeasures (MCMs) include both pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins) and non-pharmaceutical interventions (e.g., ventilators and personal protective equipment [PPE]) that may be used to prevent, mitigate, or treat adverse health effects from an intentional, accidental, or naturally occurring public health emergency.

¹ www.phe.gov/preparedness/legal/pahpa/pages/default.aspx

² www.fas.org/irp/offdocs/nspd/hspd-21.htm

catastrophic health events and stressed the importance of ensuring communities can “distribute and dispense countermeasures to their populations within 48 hours after a decision to do so.”³

In addition, the National Health Security Strategy (NHSS)⁴ refocused the various existing strategies for “public health and medical preparedness, response, and recovery to ensure that the nation is prepared for, protected from, and resilient in the face of health threats or incidents with potentially negative health consequences”⁵ and includes an effective countermeasure enterprise as one of the 10 strategies designed to support its goals. This strategy has guided the creation, development, manufacture, staging, maintenance, and prioritization of MCMs, as well as their timely distribution, delivery, and dispensing. In addition, this strategy requires SLTT officials to set priorities for how their jurisdictions will allocate MCMs when the supplies are limited.

Presidential Policy Directive 8 (PPD-8) was signed in March 2011 and serves to strengthen the nation’s security and resilience through systematic preparation for the threats that pose the greatest risk, such as acts of terrorism, pandemics, and catastrophic natural disasters. The PPD-8 implementation plan includes the National Preparedness Goal,⁶ which sets the overall strategic vision for national preparedness and establishes core capabilities used to drive preparedness activities nationwide. The National Preparedness Goal reflects the policy direction outlined in the National Security Strategy (May 2010),⁷ applicable PPDs, HSPDs, National Security Presidential Directives, and national strategies.

This legislation serves to strengthen the SNS program, which not only stockpiles the nation’s cache of pharmaceuticals and medical supplies but also develops rapid response capabilities to support the delivery of SNS assets to locations in which they may be needed. Since the program’s inception, CDC has deployed federal assets in response to large-scale incidents, such as the 2009 – 2010 H1N1 influenza pandemic, and to smaller incidents that affect a single person, such as the delivery of vaccinia immune globulin (VIG) to treat adverse reactions related to smallpox vaccination.

Connecting CDC’s Oversight and Support Structures

CDC’s Office of Public Health Preparedness and Response (OPHPR) has primary oversight and responsibility for all programs that comprise CDC’s public health preparedness and response portfolio. Through an all-hazards approach to preparedness – focusing on threats from natural, biological, chemical, nuclear, and radiological incidents – OPHPR helps the

³ www.fas.org/irp/offdocs/nspd/hspd-21.htm

⁴ www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf

⁵ Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR). National Health Security Strategy [online]. Available at URL www.phe.gov/Preparedness/planning/authority/nhss/Pages/default.aspx.

⁶ www.fema.gov/pdf/prepared/npg.pdf

⁷ www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf

nation prepare for and respond to urgent threats to the public's health. OPHPR carries out its mission by emphasizing accountability through performance, progress through public health science, and collaboration through partnerships.

Within OPHPR, two main divisions provide oversight and support to state and local jurisdictions related to an MCM response: Division of Strategic National Stockpile and Division of State and Local Readiness.

Division of Strategic National Stockpile

The **Division of Strategic National Stockpile (DSNS)** includes specialists in emergency response, logistics, science, and public health preparedness who manage the SNS formulary, staff the DSNS operations center, and provide training and exercise support to SLTT public health departments. The DSNS mission is to prepare and support partners and provide the right resources at the right time to secure the nation's health.

DSNS' organizational structure includes three branches under the Office of the Director: Logistics Branch, Program Planning and Analysis Branch (PPA), and Response Branch.

DSNS Mission

Prepare and support partners and provide the right resources at the right time to secure the nation's health

The **Office of the Director** is comprised of the Science Team, the Healthcare Preparedness Activity (HPA), and the Community Resilience Activity (CRA). The **Science Team** manages the medical, pharmaceutical, and scientific oversight of the SNS formulary and ensures the scientific review of all medical assets. **HPA** works to improve the healthcare delivery system's ability to respond to potential natural disasters and public health threats and provides tools and other resources intended to enhance preparedness from multiple sectors that affect healthcare and public health. CRA serves as a point of contact for federal agencies, non-governmental organizations, and partners for initiatives and issues relating to the contents, management, deployment, and use of SNS assets. CRA also develops and implements innovative strategies and solutions to reduce the burden of MCM distribution and dispensing on state and local public health agencies.

PPA supervises the design, implementation, and day-to-day execution of processes and systems to improve cost analysis, cost evaluation, planning, and financial management for DSNS.

The **Logistics Branch** is responsible for the procurement, management, and maintenance of SNS assets, including quality control. This branch also manages the CHEMPACK and Federal Medical Station (FMS) programs, which are described in **The Strategic National Stockpile Formulary** section of this guide.

The **Response Branch** is responsible for planning related to the management of SNS activities during a public health emergency and provides information to SNS leadership that informs strategic decision-making. The Response Branch includes the Current Operations Team, the Deployment Coordination Team, the Training Team, and the Exercise Team. The Current

Operations Team is responsible for the day-to-day operational activities of DSNS. These activities include monitoring news, weather, and information outlets for incidents, maintaining the DSNS Team Room in the CDC Emergency Operations Center and alternate emergency operations sites, and managing asset deployment missions. The Deployment Coordination Team supports, trains, and equips the teams of deployable personnel designated to provide SNS-specific assistance to state and local officials during a public health emergency. The Training Team develops and implements training for SNS personnel and SLTT partners. In addition, the Exercise Team provides support for national, state, and local SNS exercises.

Division of State and Local Readiness

The **Division of State and Local Readiness (DSLRL)** administers CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement.⁸ PHEP supports preparedness activities and provides technical assistance to 62 state, local, and territorial PHEP awardees, including the 50 states, four major metropolitan areas (Chicago, Los Angeles County, New York City, and Washington, D.C.), and eight U.S. territories and freely associated states (American Samoa, Guam, U.S. Virgin Islands, Northern Mariana Islands, Puerto Rico, Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau). The mission of DSLRL is to assure the nation's public health system is prepared and capable to respond to and recover from public health emergencies.

DSLRL's organizational structure includes three branches: Applied Science and Evaluation Branch, Field Services Branch, and Program Services Branch.

The mission of the **Applied Science and Evaluation Branch (ASEB)** is to strengthen public health preparedness, response, and recovery through science and evaluation. ASEB focuses on the effectiveness of the PHEP cooperative agreement, interdisciplinary preparedness science, collaboration with health security partners, and evidence-based recommendations to improve the quality of decision-making on preparedness and response activities.

The **Field Services Branch (FSB)** supports state, local, and territorial health departments with field-based staff, including preparedness

DSLRL Mission

Assure the nation's public health system is prepared and capable to respond to and recover from public health emergencies

DSNS PPB Moves to DSLRL

In April 2012, DSNS' Program Preparedness Branch (PPB) was realigned with the Division of State and Local Readiness (DSLRL)'s Program Services Branch (PSB). CDC implemented this transition to better align and support the technical assistance it provides to state and local public health partners. PSB continues to provide technical assistance for medical countermeasure distribution and dispensing (MCMDD) planning and assist the 62 jurisdictions that are funded through the PHEP cooperative agreement. The PPB data team is now aligned within DSLRL's Applied Science and Evaluation Branch (ASEB), where it continues collecting and monitoring data associated with MCMDD planning and operations.

⁸ <http://www.cdc.gov/phpr/coopagreement.htm>

field associates (PFAs) and members of CDC's Career Epidemiology Field Officer (CEFO) Program. FSB staff work directly in jurisdictions to enhance state, local, and territorial public health preparedness and assist in developing DSLR's science agenda and strategies.

The **Program Services Branch (PSB)** provides programmatic oversight and coordinates technical assistance (TA) for PHEP awardees. PSB project officers work with state, local, and territorial health agencies to clarify PHEP program requirements and provide guidance regarding program implementation activities designed to build and sustain the 15 public health preparedness capabilities, including MCM distribution and dispensing (MCMDD) planning.

Each jurisdiction receives MCMDD technical assistance from public health advisors who are subject matter experts on SNS/MCMDD operations, the emergency response infrastructure, and PHEP cooperative agreement requirements. Project officers provide guidance on how to improve preparedness and plan coordinated and efficient responses. These project officers serve as the jurisdictions' conduit for many different types of TA, including

- Access to program guidance documents, planning tools, and templates;
- Review and assessment of MCMDD plans;
- Support for exercises and evaluations;
- Access to SNS-specific online resources including the SNS Extranet⁹ and SNS SharePoint¹⁰ sites;
- Training;
- Direct consultation and guidance with planning staff; and
- Support for conducting distribution and dispensing modeling to test and refine plans.

Public Health Emergency Preparedness (PHEP) Cooperative Agreement

The PHEP cooperative agreement is a critical source of funding to assist state and local public health departments in building and strengthening their abilities to respond effectively to the public health consequences of infectious disease outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies, as well as terrorist threats. The PHEP cooperative agreement also provides dedicated funding for the Cities Readiness Initiative (CRI),¹¹ which supports MCMDD planning for all hazards in 72 metropolitan areas. CRI is intended to help jurisdictions develop the capabilities needed for "U.S. cities to respond to a large-scale biologic attack, with anthrax as the primary threat consideration" (Executive Order 13527).¹²

⁹ www.orau.gov/snsnet/default.htm. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or DSLR project officer.

¹⁰ www.orau.gov/snsnet/sharepoint-site.htm, registration is required for the SNS SharePoint site and instructions for registration are available on the front page.

¹¹ www.cdc.gov/phpr/stockpile/cri

¹² www.fas.org/irp/offdocs/eo/eo-13527.htm

In March 2011, CDC released *Public Health Preparedness Capabilities: National Standards for State and Local Planning*¹³ to assist awardees in their public health preparedness planning. This guide established national standards for state and local public health preparedness capabilities-based planning and assists state and local public health planners in identifying gaps in preparedness, determining specific jurisdictional priorities, and developing plans for building and sustaining public health capabilities. Two of the 15 public health preparedness capabilities include standards for MCMDD. The PHEP cooperative agreement provides funding, technical assistance, and other resources that support state, local, and territorial public health departments in demonstrating measurable and sustainable progress toward achieving the 15 public health preparedness capabilities.

Medical Countermeasure Operational Readiness Reviews

DSL project officers assess jurisdictional MCMDD planning and preparedness through annual reviews that aid jurisdictions in identifying gaps in their plans to receive and manage MCMs. Project officers work collaboratively with jurisdictions to schedule and conduct these reviews and assess each jurisdiction's planning efforts. For over ten years, CDC conducted SNS technical assistance reviews (TARs) to assess state, local, and territorial MCM plans and provide a score between 0 and 100 using the state, local, or island TAR tool. Effective July 2014, CDC is updating the medical countermeasure assessment to facilitate review of MCM plans for operational capability. CDC designed the updated operational readiness assessment to improve and advance state, local, and territorial MCM planning and response and to align MCM planning with the 15 public health preparedness capabilities.

Using This Preparedness Guide

Previous versions of this guide focused significantly on the scenario of a release of aerosolized anthrax, which would require jurisdictions to prepare for dispensing MCMs within 48 hours. However, *Version 11* takes into account a growing range of threats, changes to the amount and variety of stockpiled assets, and the existence of more comprehensive planning and preparedness processes in many jurisdictions. Considering the wide variety of potential public health threats and MCMs available to mitigate those threats, planning for this type of emergency response should be scalable and flexible.

Maintaining a state of readiness through constant planning is a central theme of this guide, but planning alone is not enough. The purpose of MCMDD preparedness planning is to build the capability to respond effectively, save lives, and prevent disease. Once the jurisdiction develops an MCMDD plan, it should implement the plan with people and resources identified to support it. Jurisdictions should maintain preparedness through regular

- Planning and review of existing plans;
- Training of the primary and back-up personnel who will staff the plan functions;
- Exercising the functions in the plan;
- Evaluating staff readiness and whether plans are operational;
- Assessing the adequacy of facilities vital to the jurisdiction's infrastructure; and

¹³ www.cdc.gov/phpr/capabilities

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- Reviewing and updating written agreements that will ensure use of any facilities or equipment.

To foster an all-hazards approach to planning, the chapters of this guidance do not mirror previous versions. Chapter 1 of this guide outlines the concept of operations for a large-scale response in which jurisdictions may request federal assets, while Chapters 2 through 13 represent the 12 functional areas of MCMDD planning. CDC removed the repackaging function as DSNS established contingency contracts with firms that can repackage tens of thousands of regimens per day and have agreed to use their production lines to repackage SNS assets during a large-scale public health emergency. The components of the SNS formulary mentioned in this overview are described in greater detail in the following chapters and appendices.

Realizing that most planners will not read this guide in a single sitting, each chapter is designed to stand alone – with individual page numbers and acronyms defined – to facilitate use by and sharing among various public health and emergency response partners. Planners may choose to print this guide, along with its table of contents and title page, and keep in a notebook with separate tabs for each chapter, or planners can use the electronic version, which has bookmarks for each chapter. The developers of this document (representatives from DSNS and DSLR) sincerely hope that this updated guidance provides a comprehensive picture of the MCMDD planning process and assists SLTT partners in developing scalable and flexible MCMDD plans.

12 Functional Areas of MCMDD Planning

- **Developing a Medical Countermeasure Response Plan**
- **Management of Medical Countermeasure Operations**
- **Requesting Strategic National Stockpile Assets**
- **Receiving, Staging, and Storing Medical Countermeasures**
- **Managing Medical Countermeasure Inventory**
- **Distributing Medical Countermeasures**
- **Dispensing Medical Countermeasures**
- **Public Information and Communication**
- **Strategic and Tactical Communications**
- **Securing Assets, Personnel, and Operations**
- **Hospital and Treatment Center Coordination**
- **Training, Exercising, and Evaluating Plans**

The Strategic National Stockpile Formulary

The items included in the Strategic National Stockpile (SNS) are referred to as its formulary. Various federal workgroups and agencies collaborate to determine which items to include in the formulary based on specific threats to the United States as well as other factors. The SNS formulary has grown to encompass a wide range of medical countermeasures (MCMs), including both pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins) and non-pharmaceutical interventions (e.g., ventilators and personal protective equipment [PPE]). These MCMs can be used to prevent, mitigate, or treat adverse health effects from any type of public health emergency, whether man-made or naturally occurring. The SNS formulary is configured in various response capabilities to facilitate rapid movement around the nation. Understanding how the SNS formulary is selected, what assets are available, and how the Centers for Disease Control and Prevention (CDC) will deploy those assets can aid jurisdictions in developing plans for requesting, receiving, distributing, and dispensing MCMs.

Understanding SNS Formulary Development

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)¹ determines which products to include in the SNS formulary. PHEMCE is a federal interagency working group consisting of members from the Department of Health and Human Services (HHS), including members from CDC, the National Institutes of Health (NIH), and the U.S. Food and Drug Administration (FDA); the U.S. Department of Homeland Security (DHS); the Veterans Administration (VA); and the Department of Defense (DoD). PHEMCE subject matter experts review threat assessments, collaborate to determine specific MCMs required to respond to those threats, and recommend specific MCMs for inclusion in the SNS formulary.

While many countermeasures included in the SNS formulary are readily available, the Biomedical Advanced Research and Development Authority (BARDA)² assists in obtaining products that are not available in the marketplace by facilitating the development of new MCMs to treat specific disease conditions. BARDA was established through the Pandemic and All-hazards Preparedness Act (PAHPA)³ of 2006 as the focal point within HHS for the

¹ <http://www.phe.gov/Preparedness/mcm/Pages/default.aspx>

² www.phe.gov/about/barda/Pages/default.aspx

³ www.phe.gov/preparedness/legal/pahpa/pages/default.aspx

advanced development and acquisition of MCMs. BARDA manages Project BioShield,⁴ which includes the procurement and advanced development of MCMs for chemical, biological, radiological, and nuclear (CBRN) agents. Project BioShield also includes the advanced development and procurement of MCMs for disease outbreaks outside of its CBRN scope, such as influenza pandemics and other emerging infectious diseases. In addition, BARDA manages PHEMCE.

While PHEMCE identifies the most effective MCMs, other factors are considered when selecting items for the SNS formulary. Consequently, each item included in the SNS formulary is selected based on specific criteria, which can be defined by the mnemonic REASON (See Figure F-1).



Figure F-1: REASON mnemonic

Each item considered for inclusion in the SNS formulary is reviewed under **REASON** to determine its **rotation** capability for going back into the commercial market; its **effectiveness** against specific disease agents; its supply **availability** in the commercial market; its **storage considerations**; **other considerations**, such as the costs for obtaining and maintaining the product, the multiplicity of the product use against various disease agents, and the regulatory requirements; and what **ancillary supplies** (e.g., intravenous sets, needles, etc.) are needed to support product use.

In general, the SNS contents are categorized based on specific threats, including Category A agents, radiological and nuclear, chemical, bacterial, and influenza (see Table F.1).

While it is important to note that Table F.1 depicts the broader category of assets in the SNS, a variety of planning considerations can impact a jurisdiction's ability to receive, distribute, and dispense certain items to the affected populations quickly and efficiently. For example, certain vaccines deployed from the SNS require special cold chain management and

⁴ www.medicalcountermeasures.gov/barda/cbrn/project-bioshield-overview.aspx

temperature monitoring throughout all levels of distribution to help ensure product stability. Additionally, some countermeasures, such as anthrax immune globulin, may be delivered from the SNS directly to hospitals as opposed to receipt, stage, store (RSS) facilities.

Table F.1: SNS Formulary by Specific Threat*

Threat	Key SNS Products to Treat/Prevent Illness from Threat
Anthrax	Antimicrobials (ciprofloxacin, doxycycline, amoxicillin, penicillin, clindamycin, rifampin, vancomycin, levofloxacin); anthrax immune globulin (AIG); raxibacumab; and anthrax vaccine adsorbed (AVA)
Plague	Antimicrobials (ciprofloxacin, doxycycline, gentamicin, levofloxacin)
Tularemia	Antimicrobials (ciprofloxacin, doxycycline, gentamicin)
Smallpox	Vaccine (ACAM2000, Aventis Pasteur-WetVax, Modified Vaccinia Ankara) Treatment of adverse reactions to vaccine: vaccinia immune globulin (VIG); cidofovir; tecovirimat for treatment of smallpox and treatment of complications from smallpox vaccine
Botulism	Antitoxins (Heptavalent A and botulinum antitoxin)
Chemical	CHEMPACK – atropine, pralidoxime, diazepam, Mark 1 kits/DuoDotes
Radiation	Prussian blue; calcium- (Ca) and zinc (Zn)-Diethylenetriamine pentaacetic acid (DTPA); granulocyte colony-stimulating factor, such as Neupogen® (filgrastim); antiemetics; limited IV antimicrobials for secondary infections
Burn/Blast	Medical/surgical supplies; IV fluids
Influenza (Pandemic)	Antiviral drugs (oseltamivir and zanamivir); personal protective equipment (PPE) (gloves, N-95 respirators and surgical masks, gowns); limited IV antimicrobials for secondary infections
Natural Disasters	Medical/surgical supplies and equipment; IV fluids; Federal Medical Stations (FMS)

* The SNS has medical supplies and equipment, including a limited number of ventilators, to support all threats listed in Table F.1.

Anthrax Vaccine Adsorbed (AVA), ABthrax, and Anthrax Immune Globulin (AIG)

Anthrax vaccine adsorbed (AVA) can be used as pre- and post-exposure prophylaxis for people who potentially may be exposed to *Bacillus anthracis* and, in some cases, people who are suspected of having been exposed to *B. anthracis*. Pre-exposure vaccine use is limited to military personnel and laboratorians working directly with the disease agent, though may be soon become available to emergency responders. Only pre-exposure

vaccination is FDA approved. SNS holds a limited supply of AVA. Jurisdictions should be aware that during an anthrax response, AVA can be administered to all adults (those over 18) under an Emergency Use Authorization (EUA)⁵ for post-exposure prophylaxis, but for pediatric patients, AVA will require an Investigational New Drug (IND) protocol.⁶ **Chapter 8: Dispensing Medical Countermeasures** provides further information on INDs and EUAs.

ABthrax[®] (raxibacumab) is FDA approved for prophylaxis and for treatment of severe anthrax disease following exposure to *B. anthracis*. Raxibacumab can be used for treatment of inhalation anthrax in combination with appropriate antimicrobial drugs, as well as for prophylaxis of inhalation anthrax when alternative therapies are not available or appropriate. A limited supply of raxibacumab is available from the SNS on a patient-by-patient basis.

Anthrax immune globulin (AIG) can be used for the treatment of severe anthrax disease following exposure to *B. anthracis*. A limited supply of AIG is available from the SNS under an EUA on a patient-by-patient basis.

Smallpox Vaccine, Modified Vaccinia Ankara (MVA), Tecovirimat, Vaccinia Immune Globulin (VIG), and Cidofovir

SNS maintains enough **smallpox vaccine** and the required ancillary supplies to immunize the entire population of the United States, its territories, commonwealths, and freely associated states. Should distribution and dispensing of smallpox vaccine become necessary, CDC's National Center for Immunization and Respiratory Diseases (NCIRD)⁷ will prioritize the vaccine distribution for jurisdictions with confirmed cases of smallpox and/or confirmed contacts to smallpox cases in accordance with the CDC Smallpox Response Plan.⁸ CDC will receive a smallpox vaccine deployment order from federal authorities once specific criteria have been confirmed.

Smallpox vaccine also can be used for pre- and post-exposure prophylaxis for people who may be or have been exposed to variola major. Pre-exposure vaccine use is limited to military personnel and laboratorians working directly with the disease agent.

Modified Vaccinia Ankara (MVA) is an attenuated vaccine that can be used under an EUA as prophylaxis for specific immune compromised persons (those with certain T-cell counts and atopic dermatitis) who may be or have been exposed to variola major. The SNS has limited quantities of MVA.

Tecovirimat can be used under an IND protocol to treat smallpox, monkeypox, and other orthopox virus symptoms, as well as complications from the smallpox vaccine. The SNS has limited quantities of tecovirimat.

⁵ www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm

⁶ www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm

⁷ www.cdc.gov/ncird

⁸ www.bt.cdc.gov/agent/smallpox/response-plan/files/cover.pdf

Vaccinia Immune Globulin (VIG) is FDA approved to treat people who experience an adverse reaction after receiving a smallpox vaccination or being exposed to someone else's smallpox vaccination site. The SNS contains limited quantities of VIG.

Cidofovir can be used under an IND protocol to treat people who experience an adverse reaction after receiving a smallpox vaccination or after being exposed to someone else's smallpox vaccination site. The SNS contains limited quantities of cidofovir.

Appendix E: Cold Chain Management contains further information on shipping and storing vaccines and biologics.

Ventilators

The SNS contains a limited number of ventilators. Jurisdictions and their healthcare partners can request ventilators in response to a public health emergency, but CDC will recover these items once the public health emergency has been resolved.

Appendix B: Ventilators provides additional information on ventilator use, models included in the SNS formulary, and links to manuals and instructional videos.

Categorizing SNS Response Capabilities

The SNS is organized for scalable response to a variety of public health emergencies. SNS assets are stored in facilities that meet conditions compliant with Title 21 of the Code of Federal Regulations (21CFR205.50)⁹ and are positioned in strategic locations across the nation. Once a jurisdiction makes a formal request for federal assets and assistance, CDC considers a variety of distribution methods depending on the threat and number of people affected. In some cases, SNS is the only repository of certain medications used to treat rare conditions, such as treatments for those with reactions or exposures to smallpox vaccine. In such cases, CDC might deploy these assets to treat a single person. For large-scale incidents, CDC can distribute assets through 12-hour Push Packages, managed inventory, or rapid purchasing power. For other events, SNS may be the only source of large quantities of required materials or may be the only source able to move materials rapidly enough to meet the needs of the jurisdiction and affected population. In addition, because of the need for immediate administration of some MCMs, such as antidotes to chemical agents, some assets are pre-positioned in states and localities to allow for immediate use following an incident in which local supplies are depleted or do not exist.

⁹ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=205.50

12-hour Push Package

If a community experiences a large-scale public health incident in which the disease or agent is unknown, the first line of SNS support most likely would be a 12-hour Push Package. The 12-hour Push Package is so named because it can be delivered anywhere in the contiguous United States within 12 hours of the federal decision to deploy. This distribution method ships, or “pushes,” a variety of items to the state, which allows jurisdictions to begin or sustain response efforts without the need to request specific items.

SNS has multiple 12-hour Push Packages located around the country to facilitate meeting this timeline. Each 12-hour Push Package contains a 50-ton cache of broad-spectrum medical supplies, including oral antimicrobials, intravenous supplies and medications, respiratory supplies, pediatric supplies, and medical/surgical supplies designed for rapid deployment. All items in a 12-hour Push Package are packed in 130 clear plastic Lexan® containers on casters to facilitate rapid movement on and off transportation vehicles and within a warehouse. Each container is color coded and numbered to facilitate rapid organization of materials by those who are receiving the shipment.



A 12-hour Push Package

Each 12-hour Push Package includes

- 33 containers of oral antimicrobials (color coded red);
- One container of medical/surgical supplies (color coded white);
- 23 containers of respiratory supplies (color coded blue);
- Four containers of pediatric supplies (color coded pink); and
- 69 containers of intravenous supplies and medications (color coded yellow), including one container that holds controlled substances.

In addition, pediatric oral antimicrobial suspension is shipped separately when CDC deploys a 12-hour Push Package.

Chapter 5: Receiving, Staging, and Storing Medical Countermeasures provides further detail on 12-hour Push Package space and warehouse requirements.

A specific listing and pictorial guide to items in the 12-hour Push Package is available in the *Strategic National Stockpile 12-hour Push Package Product Catalog* on the SNS Extranet.¹⁰

¹⁰ www.orau.gov/snsnet/default.htm. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

Controlled Substances

The SNS contains a variety of drugs classified as controlled substances and each 12-hour Push Package arrives with one container of controlled substances. Officials who receive and distribute SNS controlled substances should be advised that they must adhere to all pertinent local, state, and federal regulations regarding the distribution and dispensing of controlled substances. These regulations require tracking of distribution and dispensing of controlled substances from the federal level down to the patient level. Planners should contact the local Drug Enforcement Administration (DEA)¹¹ office for additional information to ensure that they meet these federal requirements.

Further information on DEA requirements is available in **Chapter 5: Receiving, Staging, and Storing Medical Countermeasures** and in **Chapter 6: Managing Medical Countermeasure Inventory**.

Managed Inventory (MI)

12-hour Push Packages, while a large and significant resource, only make up approximately 2% of the total available SNS medical materials. The majority of SNS assets are kept as managed inventory (MI), which is held in storage sites managed by others for CDC. MI can be used to provide additional specific items following deployment of a 12-hour Push Package or as an initial response, depending on the situation. MI will arrive within a medically relevant timeframe after the federal decision to deploy MCMs.

Additional information on MI appears in **Chapter 5: Receiving, Staging, and Storing Medical Countermeasures**.

Purchasing Power

When tasked by HHS to provide materials not in the SNS inventory, CDC can make purchases directly from vendors. CDC is able to provide additional medications and medical supplies through existing contracts with prime vendors. CDC can use this mechanism during an emergency to rapidly procure additional medications or medical supplies that are not typically part of the SNS formulary. Direct purchases can take longer to deliver than 12-hour Push Packages or MI because CDC cannot control product availability and shipping. Also, certain required formal requisition and approval procedures during a large-scale incident may affect the speed with which CDC is able to act on a request for assets. Because of these factors, CDC cannot provide specific timeframes for direct purchase actions.

Federal Medical Station (FMS)

Federal Medical Stations (FMS) are designed for deployment when communities experience a widespread terrorism incident or a large-scale natural disaster that incapacitates or overwhelms the affected area's medical care delivery system. CDC maintains FMS assets as deployable 250-bed medical units equipped to provide shelter and care for displaced individuals who have non-acute medical and mental health or other health-related needs

¹¹ www.justice.gov/dea/about/Domesticoffices.shtml

not provided for by a general shelter. Each FMS is a flexible, modular, and scalable unit that can be staged in a large local facility within a jurisdiction. HHS directs the deployment of FMS based on a request from state officials, which follows the same request process as for other SNS assets. Once the FMS is deployed and set up, it can be operated with a combination of federal, state, and local staff.

Appendix A: Federal Medical Stations provides further information on the FMS and **Chapter 4: Requesting Strategic National Stockpile Assets** provides further information on the request process.



An FMS staged in an athletic facility

Identifying SNS Response Strategies

In a health emergency, state, local, tribal, and territorial responders will work with HHS, CDC, and SNS experts who will determine the best method to deploy assets from the SNS. If the health threat has not been identified, federal authorities might send a 12-hour Push Package to provide a broad spectrum of MCMs until the specific disease or agent is determined. If the state or local jurisdiction has already determined the health threat, the federal decision might be to deploy MI. When it is obvious that a 12-hour Push Package alone would not meet the needs of the affected jurisdiction, CDC may deploy MI following a previously deployed 12-hour Push Package. The timeframe in which CDC sends follow-on MI is determined by its capability to deploy and the evolving or ongoing needs of the jurisdiction. As mentioned, CDC might obtain some products through rapid purchase power at the time of the incident and the timeframe for delivery of these assets cannot be predicted.

Forward Placement of SNS Assets

Some public health emergencies require administration of antidotes or treatments in timeframes that would make waiting for delivery of SNS assets impractical. For response to two such incidents, chemical or radiological releases, CDC forward placed MCMs so they will be available in communities should such incidents occur.

CHEMPACK Program: Exposure to nerve agents requires nearly immediate administration of chemical antidotes to mitigate illness and injury from exposure. CHEMPACK is a program for the forward placement of nerve-agent antidotes. CHEMPACK procures and provides jurisdictions with caches of prefilled syringes of chemical antidote (auto-injectors) and bulk treatment supplies to care for individuals exposed to nerve agents. The distribution of these caches provides a sustainable, reliable resource for nerve-agent treatment supplies and also improves local responders' capability to respond quickly to a nerve-agent attack.

Appendix C: CHEMPACK contains additional information on this program.

Diethylenetriamine Pentaacetic Acid (DTPA) Forward Placement Program: Internal contamination with radioactive materials can result in exposure to life-threatening doses of ionizing radiation. Removing radioactive material from the body is the best way to reduce such radiation exposure. Diethylenetriamine pentaacetic acid (DTPA) is an MCM currently approved by the FDA to treat suspected or known internal contamination with specific radioactive materials (americium, curium, or plutonium). DTPA is a chelating agent that binds to these specific radioactive materials so they can be excreted from the body. Forward placing DTPA allows jurisdictions to mitigate possible health effects of suspected or known internal contamination to americium, curium, or plutonium due to a radiological incident.

Appendix D: DTPA contains additional information on this program.

Asset Deployment Strategy for Influenza Pandemics

A major component of CDC’s influenza pandemic plan includes large-scale deployment of federal MCMs to all jurisdictions. This strategy would be accomplished using a population-based (pro-rata) distribution plan that pushes MCMs to the jurisdictions rather than waiting for individual requests for assets. CDC maintains MCMs for influenza pandemics as part of SNS MI. Consequently, jurisdictions should be prepared to receive MCMs, including antiviral drugs, PPE (including face shields, gowns, and gloves), and respiratory protection devices (RPD) in three parts. Jurisdictions will receive a percentage of their allocated countermeasures in each part. Parts 1 and 2 take approximately seven days each for delivery. Part 3 takes approximately 14 days for delivery (See Table F.2).

Table F.2: Influenza Pandemic Asset Deployment Strategy

Part 1	Part 2	Part 3
25% Antiviral Drugs	25% Antiviral Drugs	50% Antiviral Drugs
25% PPE	25% PPE	50% PPE
25% RPD	25% RPD	50% RPD
25% Antimicrobials	25% Antimicrobials	50% Antimicrobials

CDC Deployment Teams

CDC has the ability to efficiently and effectively deploy personnel to assist jurisdictions during emergencies. The current deployment strategy allows CDC to respond to up to three simultaneous events with a mix of technical expertise specific to each event. The decision to deploy SNS technical staff will follow consultation with the affected jurisdiction.

Stockpile Services Advance Group (SSAG): Due to increasing capacities of jurisdictions to receive, distribute, and dispense SNS assets, DSNS created Stockpile Services Advance Group (SSAG), a tailored pool of specialized responders to assist jurisdictions during a public health emergency. SSAG is scalable according to the needs of the project area during a specific incident.

The SSAG will be able to provide subject matter expertise on MCM operations and offer technical assistance to the jurisdiction while on site or from the CDC Emergency Operations Center (EOC). They can answer questions concerning SNS assets and response activities, assist with requests for additional supplies, and provide information on the status of incoming supplies. SSAG can deploy quickly with needed communication equipment, but the number of SSAG members deployed will depend on the situation and the type of assistance requested. Besides using the SSAG, CDC also may provide on-the-ground technical assistance to jurisdictions through an RSS Task Force or FMS Strike Team.

RSS Task Force: An RSS Task Force includes technical specialists deployed to assist in the RSS function (see **Chapter 5: Receiving, Staging, and Storing Medical Countermeasures** for further information) based on their specific skills to assist in receiving, staging, and storing SNS assets.

FMS Strike Team: An FMS Strike Team includes technical specialists deployed to provide assistance to jurisdictions and the U.S. Public Health Service Rapid Deployment Force responsible for the set up and operation of an FMS.

Chapter 1: Concept of Medical Countermeasure Operations

During large-scale emergencies, all partners in the jurisdiction must be aware of their roles, from whom they will receive information and directives, and to whom they should report. This is true for a single person in the local health department all the way up to a large federal agency. In response to a large-scale incident in which medical countermeasures (MCMs) may be requested, distributed, and dispensed, it is vital that everyone involved in the response understands how information and materials will move and what their roles will be. Understanding the overall concept of operations for an emergency response will aid jurisdictions in developing MCM distribution and dispensing (MCMDD) plans and executing those plans should it be necessary.

Understanding Federal Response Plans

Since 2001, the federal government has developed multiple strategies, guides, and systems to assist the nation in preparing for, responding to, and recovering from national emergencies. Some of these include the National Response Framework (NRF),¹ the National Incident Management System (NIMS),² and presidential directives. All of these fall under the National Strategy for Homeland Security,³ which provides a common framework through which the entire nation, including federal, as well as, state, local, territorial, and tribal (SLTT) governments; private and nonprofit sectors; communities; and individual citizens should focus homeland security efforts.

Federal Preparedness Directives

Presidential Policy Directive 8 (PPD-8)⁴ is intended to strengthen the nation's "security and resilience through systematic preparation for the threats that pose the greatest risk to the security of the Nation, including acts of terrorism, cyber attacks, pandemics, and

¹ www.fema.gov/pdf/emergency/nrf/nrf-core.pdf

² www.fema.gov/emergency/nims

³ www.dhs.gov/national-strategy-homeland-security-october-2007

⁴ www.fas.org/irp/offdocs/ppd/index.html

catastrophic natural disasters.”⁵ The PPD-8 implementation includes three major components: a national preparedness goal, a national preparedness system, and national planning frameworks.

Released in September 2011, the **national preparedness goal** establishes the overall concept for national preparedness and defines core capabilities that to promote preparedness activities nationwide. The national preparedness goal reflects the policy direction outlined in the National Security Strategy (May 2010),⁶ applicable PPDs, HSPDs, National Security Presidential Directives, and national strategies.

Released in November 2011, the **national preparedness system** is designed to help guide the preparedness efforts of all levels of government, the private and nonprofit sectors, and the public to build and sustain the capabilities outlined in the national preparedness goal. The national preparedness system includes “guidance for planning, organization, equipment, training, and exercises to build and maintain domestic capabilities.”⁷ It provides a strategic approach to build and sustain a cycle of preparedness activities over time.

The national preparedness system includes a series of integrated **national planning frameworks**⁸ that cover “prevention, protection, mitigation, response, and recovery”⁹ capabilities. These frameworks are being built on “scalable, flexible, and adaptable coordinating structures to align key roles and responsibilities to deliver the necessary capabilities.”¹⁰ The frameworks will “be coordinated under a unified system with a common terminology and approach, built around basic plans that support the all-hazards approach to preparedness and functional or incident annexes to describe any unique requirements for particular threats or scenarios, as needed. Each framework shall describe how actions taken in the framework are coordinated with relevant actions described in the other frameworks across the preparedness spectrum.”¹¹

Comprehending the Federal Response Framework

⁵ Department of Homeland Security. Presidential Policy Directive / PPD-8: National Preparedness [online]. March 30, 2011. Available at URL www.dhs.gov/xabout/laws/gc_1215444247124.shtm.

⁶ www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf

⁷ Department of Homeland Security. Presidential Policy Directive / PPD-8: National Preparedness [online]. March 30, 2011. Available at URL www.dhs.gov/xabout/laws/gc_1215444247124.shtm.

⁸ www.fema.gov/national-planning-frameworks

⁹ Department of Homeland Security. Presidential Policy Directive / PPD-8: National Preparedness [online]. March 30, 2011. Available at URL www.dhs.gov/xabout/laws/gc_1215444247124.shtm.

¹⁰ Ibid.

¹¹ Ibid.

The Homeland Security Act of 2002¹² created the Department of Homeland Security (DHS) and assigned the role of principal federal official for domestic incident management to the DHS Secretary. To support the secretary's role and facilitate coordinated national responses, Homeland Security Presidential Directive 5 (HSPD-5)¹³ directed DHS to develop a single, comprehensive management system for responding to incidents. Thus, NIMS¹⁴ was created to provide a consistent template for all levels of government, the private sector, and nongovernmental organizations (NGOs) to work together to reduce the effects of incidents, regardless of their cause, location, size, or complexity. NIMS provides the groundwork for agencies and organizations to collaborate "to prevent, prepare for, respond to, and recover from terrorist attacks, major disasters, and other emergencies."¹⁵ HSPD-5 also assigns roles to other federal officials for oversight and authority over various parts of NIMS.

DHS developed the NRF as a guide for national responses to any type of hazard. NRF emphasizes a coordinated federal response requiring layers of mutually supporting capabilities. SLTT governments develop functional capabilities and identify resources that may be required during an incident. In 2003, the Homeland Security Council and DHS developed 15 National Planning Scenarios for use in national homeland security preparedness activities, including all levels of government from federal and state, down to local, territorial, and tribal levels. These scenarios are broadly applicable; focus on a range of capabilities; represent baseline conditions that are likely to overwhelm SLTT governments; and represent threats or hazards of national significance.

The NRF describes in detail how the federal government will conduct all-hazards response operations. The NRF builds on NIMS to provide standard command and management structures that apply to response activities. This consistency serves as the foundation for utilization of NIMS for all incidents, ranging from responses to daily occurrences to

15 National Planning Scenarios

- Scenario 1:** Nuclear Detonation – Improvised Nuclear Device
- Scenario 2:** Biological Attack – Aerosol Anthrax
- Scenario 3:** Biological Disease Outbreak – Pandemic Influenza
- Scenario 4:** Biological Attack – Plague
- Scenario 5:** Chemical Attack – Blister Agent
- Scenario 6:** Chemical Attack – Toxic Industrial Chemicals
- Scenario 7:** Chemical Attack – Nerve Agent
- Scenario 8:** Chemical Attack – Chlorine Tank Explosion
- Scenario 9:** Natural Disaster – Major Earthquake
- Scenario 10:** Natural Disaster – Major Hurricane
- Scenario 11:** Radiological Attack – Radiological Dispersal Devices
- Scenario 12:** Explosives Attack – Bombing Using Improvised Explosive Devices
- Scenario 13:** Biological Attack – Food Contamination
- Scenario 14:** Biological Attack – Foreign Animal Disease (Foot and Mouth Disease)
- Scenario 15:** Cyber Attack

¹² http://www.dhs.gov/xlibrary/assets/hr_5005_enr.pdf

¹³ <http://www.fas.org/irp/offdocs/nspd/hspd-5.html>

¹⁴ <http://www.fema.gov/emergency/nims>

¹⁵ <http://mmrs.fema.gov/emergency/nims/FAQ.shtm>

incidents requiring a coordinated response between SLTT and federal agencies and organizations. The NRF, through its emergency support function (ESF) annexes, also provides details on specific capabilities of various federal agencies and outlines which agencies are responsible for oversight of certain aspects of the federal response. For public health emergencies, Emergency Support Function #8 – Public Health and Medical Services Annex (ESF 8)¹⁶ delegates responsibility to the Secretary of the Department of Health and Human Services (HHS). Following the signing of the Pandemic and All-Hazards Preparedness Act (PAHPA)¹⁷ in 2006, public health preparedness and recovery activities have been led by the HHS Secretary's Office of the Assistant Secretary for Preparedness and Response (ASPR).¹⁸

Integrating the Public Health Response at All Levels

Because SNS is one of the federal resources ASPR may deploy in response to incidents at the SLTT levels, it is important that SLTT planners, officials, and responders understand the federal response structure and how their response capabilities should be constructed to fit into that structure. The NRF and NIMS are designed to assist planners and responders at all levels in integrating their plans for a seamless response during large- or small-scale incidents.

Federal Response

As previously mentioned, federal assistance to supplement SLTT resources is directed by HHS through ASPR, which coordinates response and recovery actions. Resources will be furnished when SLTT resources are unavailable or the jurisdiction is overwhelmed and public health or medical assistance is requested from the federal government.

HHS may direct the Centers for Disease Control and Prevention (CDC) to deploy SNS assets and appropriate CDC personnel (if required) to assist the affected jurisdiction. Initial shipments of pre-selected MCMs from the SNS could arrive in varying configurations depending on the type of MCMs needed for the response. CDC and the Division of Strategic National Stockpile (DSNS) will activate CDC's emergency operations center (EOC) and the DSNS Team Room to manage the deployment of these assets and communicate with the affected jurisdiction and other federal departments and agencies. **Chapter 4: Requesting Strategic National Stockpile Assets** provides further information on the request process and the response teams.

State, Local, Tribal, and Territorial Responses

Incidents typically begin and end locally. However, large-scale incidents can involve jurisdictions and organizations at multiple levels. In the early stages of a response, authorities at local or other levels (depending on the scope of the incident) will need to assess the situation and determine the appropriate response. Initial actions will include establishment of an incident command (IC) center and identification of an incident commander. For a small

¹⁶ www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf

¹⁷ www.phe.gov/preparedness/legal/pahpa/pages/default.aspx

¹⁸ www.phe.gov/about/aspr/Pages/default.aspx

incident, the incident commander might fulfill all roles required to manage the incident, including operations, public information, safety, and planning. As the size or scope of the incident increases, the incident commander may expand the response structure. For a large multijurisdictional or statewide incident, the IC could quickly become a unified command (UC).

The response structure should be built to bring support down to the lowest level. A state response structure could institute a state EOC to support the local EOC. The local EOC supports the local area command (e.g., local public health EOC, if established) and the IC or UC post, such as points of dispensing (PODs) in the case of an incident requiring dispensing of MCMs. Similarly, the state-level response structure might include a state public health EOC with liaisons deployed to the state EOC (multi-area command centers) and other command sites, such as local EOCs and the receipt, stage, store (RSS) facility.

Whether or not response to an incident requires MCMs, planners in the jurisdiction must ensure plans are in place for the management of receiving, distributing, and dispensing MCMs from the SNS, or other sources, under the functional areas of the incident command system (ICS).¹⁹ Managing these activities will include

- Coordinating with subordinate or higher level organizations/agencies for personnel, material, or other resources;
- Mobilizing personnel and resources to sites of operation;
- Managing communications and reporting systems between the various lead personnel for MCM activities;
- Operating an RSS site to receive and process MCMs for distribution;
- Distributing MCMs from the RSS to points of use, including PODs, hospitals, and treatment centers;
- Establishing and maintaining communication between command management and supporting activities;
- Activating and operating PODs;
- Providing information to the public; and
- Providing security for all MCMDD-related activities.

CDC has identified activities critical to the successful management of operations involving the receipt, distribution, and dispensing of MCMs and these can be incorporated under the functional areas of ICS for broader all-hazards responses.

Using the Incident Command System and Unified Command

The Federal Emergency Management Agency (FEMA) describes the incident command system (ICS) as “a standardized, on-scene, all-hazards incident management approach that

- Allows for the integration of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure;
- Enables a coordinated response among various jurisdictions and functional agencies, both public and private; and

¹⁹ www.fema.gov/emergency/nims/IncidentCommandSystem.shtm

- Establishes common processes for planning and managing resources.”²⁰

ICS is flexible; can be used for incidents of any type, scope, or complexity; and can be applied across disciplines. ICS is used by all levels of government and by many NGOs and the private sector. The typical ICS structure facilitates activities in five major functional areas: command, operations, planning, logistics, and finance/administration. Depending on the type and scope of the response, some functional areas may not be used. A potential sixth functional area, Intelligence/Investigations, is activated on a case-by-case basis.²¹ Figure 1-2 shows a sample ICS structure.

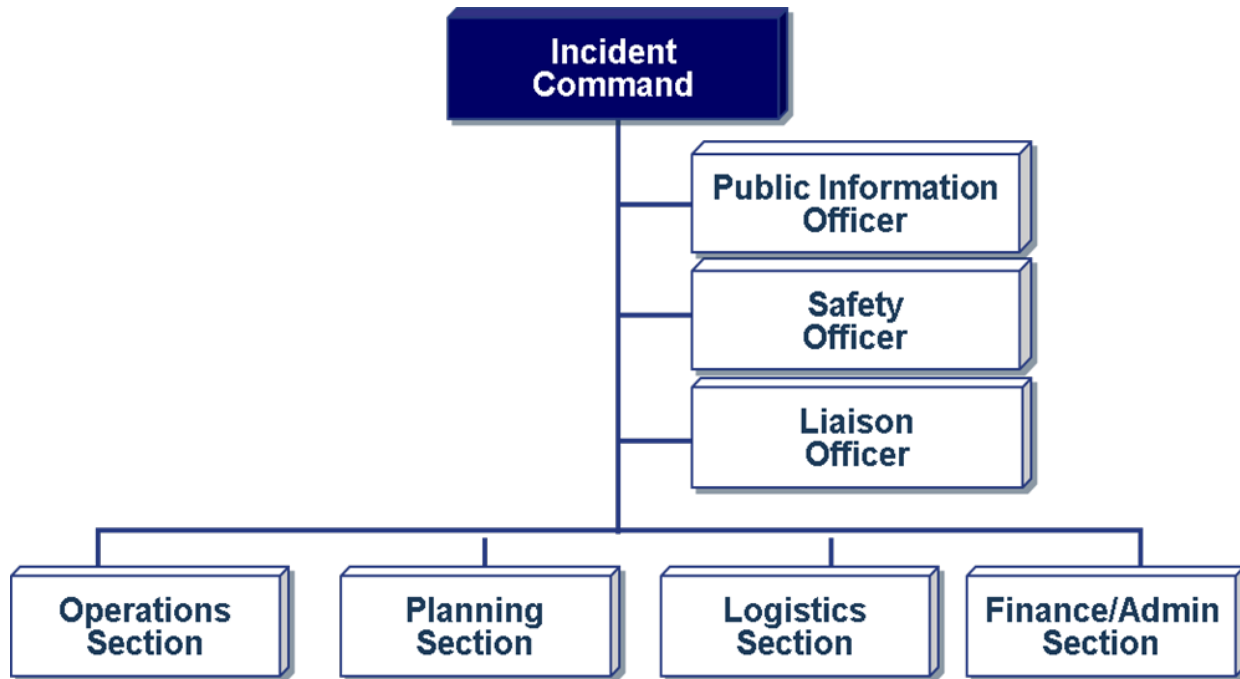


Figure 1-2: Sample ICS structure

During an emergency response, the jurisdiction (whether federal, state, local, territorial, or tribal) will likely activate an incident command (IC). The public information officer, the safety officer, and the liaison officer, report directly to IC. Because multiple agencies may have leadership responsibilities during a large-scale incident, ICS uses a unified command (UC) model that allows multiple stakeholders to simultaneously participate in incident management, which in turn supports consistent actions within the response system and provides a cohesive response system between a variety of agencies, jurisdictions, and response partners.

²⁰ Federal Emergency Management Agency (FEMA). ICS Overview [online]. Available at URL www.fema.gov/emergency/nims/IncidentCommandSystem.shtm.

²¹ From the Federal Emergency Management Agency (FEMA), ICS overview; available at URL www.fema.gov/emergency/nims/IncidentCommandSystem.shtm.

The UC concept is particularly relevant to public health and medical partners whose primary responsibilities during emergencies include the safety and welfare of responders and the general public. In addition, the UC model provides a mechanism for public health and medical practitioners to be directly involved in decisions related to the response.

UC facilitates an effective coordinated response by bringing together all incident managers involved in the response, while simultaneously allowing them to continue to perform the duties of their own jurisdiction or discipline. UC provides a platform for the leaders of various agencies and organizations to work jointly on decision-making and sustain an integrated response. UC allows responders to overcome barriers that may exist due to

- Geographic boundaries;
- Government levels;
- Functional and/or statutory responsibilities; or
- Any combination of the above.²²

During an incident, members of the UC should develop an incident action plan (IAP), which documents incident-specific objectives and the agencies and organizations to which those objectives are delineated. UC provides guidance throughout an incident by using

- A single integrated management structure for the emergency response;
- Shared or co-located management facilities;
- A single planning process and IAP (single set of goals and objectives); and
- A coordinated process for requesting and managing resources.²³

The UC concept is particularly relevant to public health and medical partners whose primary responsibilities during emergencies include the safety and welfare of responders and the general public.

State and local SNS planners, working through ICS and incorporated in the UC, can assist other partners in determining specific IAPs for an MCMDD response. **Chapter 3: Management of Medical Countermeasure Operations** provides more specific information on the MCM operations team and where they fit into the ICS structure.

Requesting Assistance

During an incident, jurisdictions should quickly assess all available resources and capabilities. When the jurisdictional resources and capabilities are depleted or unavailable, the jurisdiction should know where to turn for assistance and to what agencies or organizations to direct requests. The IC/UC and emergency operations center (EOC) should be the central point of contact for information and requests coming into and leaving the jurisdictional level, regardless of whether it is the local, territorial, tribal, state, or federal jurisdiction.

²² Health and Human Services. Medical Surge Capacity and Capability: A Management System for Integrating Medical and Health Resources During Large-Scale Emergencies (2007). Available at URL www.phe.gov/Preparedness/planning/mscc/handbook/chapter1/Pages/theincidentcommand.aspxf.

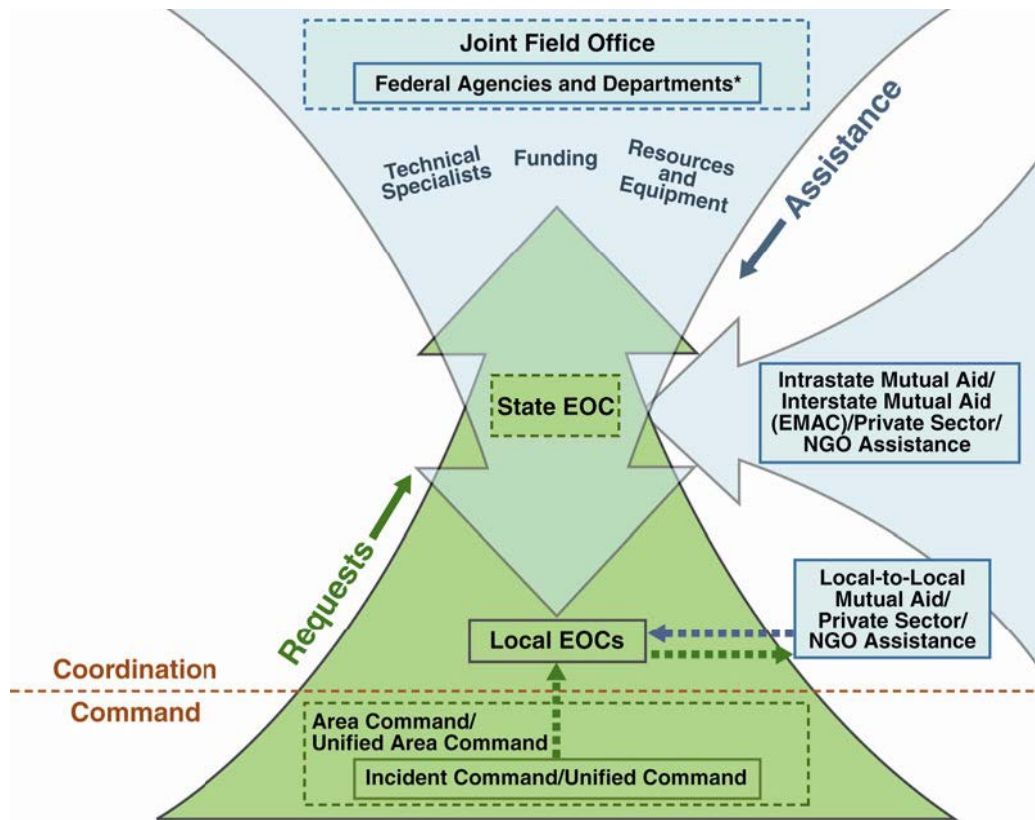
²³ Health and Human Services. Medical Surge Capacity and Capability: A Management System for Integrating Medical and Health Resources During Large-Scale Emergencies (2007). Available at URL www.phe.gov/Preparedness/planning/mscc/handbook/chapter1/Pages/theincidentcommand.aspxf.

During a response, IC/UC will identify resource requirements and communicate needs through the area command (if established) to the local EOC. If possible, the local EOC will fulfill the need, but if local resources are unavailable, the EOC may request assistance through mutual aid agreements and assistance agreements with private-sector partners and NGOs.

In most incidents, local resources and local mutual aid and assistance agreements will provide the first line of emergency response and incident management. If the local jurisdiction is unable to sustain the response, they may request assistance from the state, which in turn will supply resources, if possible. However, if the state cannot meet the needs of the local jurisdiction, then officials may arrange support from another state through an agreement, such as the Emergency Management Assistance Compact (EMAC), or through assistance agreements with NGOs. If additional resources and/or capabilities are required beyond those available through interstate agreements, the governor (or his/her designee) may ask for federal assistance.

The federal government will collaborate with SLTT officials on the decision to deploy assets. Federal assistance may be provided under various federal authorities. If a governor (or his/her designee) requests a disaster declaration, the president will consider the entirety of the situation, including damage assessments and needs, and may declare a major disaster under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act).²⁴ However, the HHS Secretary, or the Assistant Secretary for Preparedness and Response (ASPR) under the HHS Secretary's authority, may direct CDC to deploy SNS assets prior to receiving a formal request or before a federal disaster or public health emergency declaration. Also, HHS/ASPR may direct CDC to deploy SNS assets before the president initiates a coordinated federal response. In cases in which there is time to assess the requirements and plan for a catastrophic incident (e.g., a major hurricane or flooding), in coordination with SLTT jurisdictions, federal assets may be pre-positioned in the anticipated affected area and tailored to address the specific situation. Depending on the specifics and magnitude of the incident, officials may establish a joint field office (JFO) to manage federal assistance (e.g., technical specialists, funding, and resources and equipment). Figure 1-3 illustrates how DHS envisions the flow of resources and requests for assistance between SLTT jurisdictions and the federal government.

²⁴ www.fema.gov/about/stafact.shtm



***Some Federal agencies (U.S. Coast Guard, Environmental Protection Agency, etc.) have statutory responsibility for response and may coordinate and/or integrate directly with affected jurisdictions.**

Figure 1-3: Flow of requests and assistance during large-scale emergencies (From Department of Homeland Security. National Incident Management System. 2008 [online]. Available at URL www.fema.gov/pdf/emergency/nims/NIMS_core.pdf.)

In a large-scale emergency in which SNS assets are required, planners will need to activate the MCM operations team to coordinate SNS activities throughout the jurisdiction. **Chapter 3: Management of Medical Countermeasure Operations** details the organization and structure of the MCM operations team. However, it is important to note here that this team will need communications and reporting systems at all jurisdictional levels (federal, state, local, territorial, regional, and tribal) to ensure orders and directives are received and information flows throughout the affected jurisdiction and back to the federal level.

Regardless of the type of incident, officials should quickly assess and clearly identify capability shortfalls and accurately communicate the jurisdiction's requirements during the request process. This is especially important for requests sent to the federal government as it will enable federal officials to identify resources and support SLTT responders as quickly and efficiently as possible. It is important to note that during the request process, states should

request a capability, not a specific resource. For example, in a large-scale disease outbreak, the state can request additional MCMs from the federal government without specifying a source (e.g., a 12-hour Push Package from the SNS). The federal government will then determine available resources for delivery to the affected area in the shortest timeframe.

Chapter 4: Requesting Strategic National Stockpile Assets provides further detail on the federal request process and specific detail on requesting MCMs.

Learning NRF, NIMS, and ICS

FEMA offers courses through the **Emergency Management Institute (EMI)** to assist planners in learning ICS. Courses offered through EMI meet the requirements specified in NIMS and are developed collaboratively with the National Wildfire Coordinating Group (NWCG), the United States Fire Administration, and the United States Department of Agriculture (USDA). This site also identifies those courses critical to train personnel capable of implementing all functions of emergency management. To view coursework offered through EMI, visit <http://training.fema.gov/IS/NIMS.asp>.

EMI also provides **ICS Training Courses** that establish the NIMS core curriculum to train emergency and incident response personnel on all concepts and principles of each NIMS component and recommends ICS coursework for various response levels. To view coursework, visit <http://training.fema.gov/EMIWeb/IS/ICSResource/TrainingMaterials.htm>.

EMI also offers many courses online through its **Independent Study Program (ISP)**. To view or register for online courses, planners can visit the ISP website at <http://training.fema.gov/IS>.

In addition, FEMA's **Integrated Emergency Management Course (IEMC)** introduces the NRF and reinforces the understanding of the roles and relationships among federal and SLTT emergency management organizations, as well as private sector agencies and NGOs. IEMC emphasizes the requirement for all emergency management stakeholders to operate in an integrated, collaborative environment when responding to any incident. Planners can find further information on IEMC at the FEMA website, www.fema.gov/emergency/nims/NIMSTrainingCourses.shtm#item4.

Chapter 2: Developing a Medical Countermeasure Response Plan

The threat of a large-scale public health emergency is of great concern to federal, state, local, tribal, and territorial authorities. In the event of a chemical, biological, radiological, nuclear (CBRN) incident, the rapid dispensing of medical countermeasures (MCMs) may be essential to reduce morbidity and mortality in the affected community. Developing comprehensive, written plans to receive, distribute, and dispense Strategic National Stockpile (SNS) assets is imperative to the mission of getting MCMs to the affected population as quickly and efficiently as possible.

While there are special considerations involved in preparing for a large-scale public health emergency in which MCMs would be required, planning for such an incident will involve multiple agencies and disciplines and should be included in the all-hazards plans for the jurisdiction. Many other agencies and organizations are planning for emergency responses, and the Centers for Disease Control and Prevention (CDC) recommends that plans to receive, distribute, and dispense MCMs be part of state and local all-hazards response plans. By coordinating with other agencies, planners can ensure that the MCM distribution and dispensing (MCMDD) plan integrates into the state and local response structures.

State and local MCMDD plans should address all of the functions required to receive, distribute, and dispense MCMs, including

- Managing MCM operations;
- Requesting SNS assets;
- Receiving, staging, and storing MCMs;
- Managing MCM inventory;
- Distributing MCMs;
- Dispensing MCMs;
- Public information and communication;
- Strategic and tactical communications;
- Security;
- Hospital and treatment center coordination; and
- Training, exercising, and evaluating plans.

The MCMDD plan, including these functional elements, should be written; contain the goals and objectives of each of the functions; list the actions, procedures, or processes required to

achieve those goals and objectives; align with the all-hazards response plans within the jurisdiction; and be operational.

Working with the Planning Process

Many federal resources exist to assist planners in developing comprehensive preparedness plans, including plans for the receipt, distribution, and dispensing of MCMs. Using these resources, planners can ensure that their written plans align with federal plans for the smoothest transfer of MCMs from the federal government, to the state or territory, for distribution down to the local level.

Planning is the continuous process through which jurisdictions develop, validate, and maintain plans, policies, and procedures. The jurisdictional planning effort should include federal, state, local, tribal, and territorial governments, non-governmental organizations (NGOs), and the private sector. The Federal Emergency Management Agency (FEMA) and the Department of Homeland Security (DHS) both state that “Strategic and operational planning establishes priorities, identifies expected levels of performance and capability requirements, provides the standard for assessing capabilities and helps stakeholders learn their roles.”^{1,2}

The plans, policies, and procedures developed through the planning process should describe how jurisdictions will prioritize, coordinate, manage, and support personnel, information, equipment, and resources to prevent, protect, mitigate against, respond to, and recover from catastrophic incidents. When accomplished properly, planning provides a methodical way to work through the entire life cycle of a potential crisis, determine required capabilities, and help stakeholders learn and practice their roles. A well-developed plan directs the way in which a jurisdiction envisions and shares a desired outcome, selects effective ways to achieve it, and communicates expected results.

An effective written plan conveys the goals and objectives of the intended operation (e.g., the receipt, distribution, and dispensing of MCMs) and the actions needed to achieve it. However, the process of planning is just as important as the written plan that results from it. Consequently, the planning effort should not focus strictly on the act of developing a written plan to support MCMDD response operations, but should focus more on the ability of the plan to achieve its concept of operations. Coordination among multiple response agencies will ensure that MCMDD plans will result in successful operations because all entities involved will know their roles, accept them, and understand how they fit into the overall plan. In developing the written MCMDD plan, planners also should remember that plans are not scripts followed to the letter but rather are flexible and adaptable to the actual situation.

An effective written plan conveys the goals and objectives of the intended operation and the actions needed to achieve it.

¹ www.fema.gov/national-preparedness/plan

² www.dhs.gov/topic/plan-and-prepare-disasters

During the planning process, planners should ensure that the plans support the intended operational capabilities given the current resources available within their jurisdictions. Plans also should ensure that in the absence of sufficient resources, or in those areas where gaps exist, jurisdictions are able to successfully obtain resources through the appropriate coordination, whether through emergency agreements or requests for assistance.

To develop effective MCMDD plans, planners should look to FEMA's *Developing and Maintaining Emergency Operations Plans: Comprehensive Preparedness Guide 101, Version 2.0* (CPG 101).³ CPG 101 provides information on developing strategic plans through horizontal coordination and vertical integration of plans among all levels and sectors. CPG 101 includes concepts from operations planning research and day-to-day experience that can assist planners in integrating plans throughout the jurisdiction. In addition, CPG 101 guides planners in developing plans for the three tiers of planning: strategic planning, operational planning, and tactical (incident scene) planning (see Figure 2-1). According to CPG 101, this type of strategic planning sets the context and expectations for operational planning, while operational planning provides the framework for tactical planning and all three tiers of planning occur at all levels of government.



Figure 2-1: Relationship between strategic operational and tactical planning (From Federal Emergency Management Agency [FEMA]. *Developing and Maintaining Emergency Operations Plans: Comprehensive Preparedness Guide 101, Version 2.0*. 2010)

Determining Planning Jurisdictions

When it comes to planning for large-scale public health emergencies, it is often difficult to determine where one planning jurisdiction ends and the next begins. State and territorial planners may find that they need to work with neighboring states and even neighboring countries or territories. At the same time, city, county, and other local planners may find that their jurisdiction continues to expand beyond the originally defined borders. Planners who are aware that their jurisdiction may overlap several neighboring jurisdictions can use this to their advantage by coordinating with neighbors to share plans and resources.

³ www.fema.gov/pdf/about/divisions/npd/CPG_101_V2.pdf

For example, metropolitan statistical areas (MSAs) generally are comprised of multiple overlapping geographic, political, jurisdictional, and planning boundaries divided into counties, regions, or districts. These boundaries typically are developed for the purpose of satisfying legislative or political requirements or organizational, operational, and planning needs for local, county, regional, or state agencies.

In the midst of a public health emergency, especially one that requires the dispensing of MCMs, working through multiple planning jurisdictions with autonomous response plans may lead to confusion and delays in the response. By integrating and regionalizing response plans, jurisdictions can ensure continuity of operations across an MSA, state, or multiple states within a planning jurisdiction. This type of regionalization also allows jurisdictional partners to pool resources for the benefit of everyone in an affected area.

Additionally, with recent budget cuts and the loss of public health personnel, eliminating jurisdictional and political boundaries for the purpose of developing a joint, singular planning jurisdiction will benefit planners by allowing for a single plan requirement and a single jurisdictional operational requirement for drills and exercises as defined in the 2012 Public Health Emergency Preparedness (PHEP) cooperative agreement.⁴ **Chapter 13: Training, Exercising, and Evaluating Plans** provides further information on drill and exercise requirements.

Consequently, CDC encourages Cities Readiness initiative (CRI)⁵ jurisdictions to consider opportunities for planning coordination that involve regionalization, coalition building, and partnering to distribute MCMs within a single plan. With this in mind, CDC provides the following criteria for meeting the 2012 – 2017 PHEP cooperative agreement requirements as a single, combined MCM dispensing planning jurisdiction:

- All entities within the planning jurisdiction will adhere to one basic MCM response plan with overarching guidance provided by the state.
- Individual planning nuances may be captured in planning annexes.
- One local MCM operational planning assessment (formerly known as local technical assistance review, or LTAR) will be conducted in the jurisdiction.
- All local planning jurisdictions will participate in the planning and execution of all required operational drills.
- All local planning jurisdictions will participate in the planning and execution of all required full-scale dispensing exercises in accordance with Homeland Security Exercise and Evaluation Program (HSEEP)⁶ standards.
- During an actual or exercised MCM response, all local planning jurisdictions will pre-designate, in the MCM response plan, representation to serve in a unified command (UC) structure.
- The UC will operate in accordance within National Incident Management System (NIMS)⁷ and the Incident Command System (ICS).⁸

⁴ www.cdc.gov/phpr/coopagreement.htm

⁵ www.bt.cdc.gov/cr

⁶ https://hseep.dhs.gov/pages/1001_HSEEP7.aspx

⁷ www.fema.gov/emergency/nims/AboutNIMS.shtm

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- The UC will develop operational objectives that encompass the entire planning area for the Incident Action Plan.⁹
 - The UC will establish the ICS structure for the MCM response.

Identify Unique Planning Jurisdictions

For state and local jurisdictions that include military installations, tribal nations, and federal agencies, a unique set of challenges can arise for coordinating the receipt, distribution, and dispensing of MCMs. While planners sometimes mistakenly believe that these unique jurisdictions are autonomous or will be covered by federal agencies during an emergency, responsibility for these entities actually falls to the state and local jurisdictions in which they are located. Another population segment, those with functional needs (e.g., those who have difficulty communicating or have mobility challenges), can be difficult to reach, especially during an emergency. Therefore, plans should provide specific details for addressing these additional segments of the population and planners should work with appropriate contacts within these unique jurisdictions to coordinate planning efforts.

Military Installations

The Department of Defense (DoD) issued an instructional memo, DoD Directive 6200.3 (Emergency Health Powers on Military Installations),¹⁰ that establishes a DoD policy under applicable law, to protect installations, facilities, and personnel in the event of a public health emergency due to biological warfare, terrorism, or communicable disease epidemic or other public health emergency. However, it is important to note that military installations do not have MCMs available to protect active duty personnel, contractors, or the family members living in these communities. It is the role of state and local public health to include the staff and family members of military installations in the total population for the jurisdiction and plan for distribution and dispensing of MCMs for that portion of the community. DoD Directive 6200.3 requires military commanders to designate a public health emergency officer (PHEO). The role of the PHEO is to maintain close contact and seek close coordination with the local and state health departments and CDC concerning all actions taken under this directive. Planners should contact their state or local emergency management officials for a list of DoD liaisons or their jurisdiction's PHEO, if needed.

⁸ www.fema.gov/emergency/nims/IncidentCommandSystem.shtm

⁹ www.phe.gov/Preparedness/planning/mscc/handbook/pages/appendixc.aspx

¹⁰ www.dtic.mil/whs/directives/corres/pdf/620003p.pdf

Employees of Federal Agencies

Many planners mistakenly believe that federal agencies have access to MCMs separate from the state or local plan, either through caches at their facilities or direct federal delivery. However, it is important to note that there is no federal-to-federal delivery mechanism and just as with DoD, federal agencies do not typically have their own caches of MCMs. When the state receives SNS assets, planners should have a plan for dispensing to everyone residing in or visiting the state, regardless of employer. However, CDC has been reaching out to federal employers to encourage federal agencies to work with their local health departments to develop plans for dispensing to their employees by setting up internal dispensing sites at their facilities. Further information on dispensing to businesses is included in **Chapter 8: Dispensing Medical Countermeasures**.

Tribal Nations

Jurisdictions should coordinate and collaborate with American Indian and Alaska Native (AI/AN) tribes through a memorandum of agreement (MOA) or memorandum of understanding (MOU) that ensures those living on tribal lands will receive MCMs. AI/AN tribal members may receive MCMs through a local health department point of dispensing (POD); hosting their own PODs on tribal lands; or arranging with the Indian Health Service to provide MCMs. Regardless, the state is responsible for developing the MCM distribution system and it is vital that state and local planners coordinate with their tribal populations to ensure everyone in the affected communities has access to MCMs during an incident.

At-risk Populations

HHS defines at-risk populations as people with needs in five functional areas.¹¹ These needs can make people more vulnerable before, during, and after an incident. According to HHS, members of at-risk populations may have additional needs in one or more of the following functional areas:

- **Maintaining Independence** – Individuals in need of support that enables them to be independent in daily activities
- **Communication** – Individuals who have limitations that interfere with the receipt of and response to information
- **Transportation** – Individuals who cannot drive due to the presence of a disability or who do not have a vehicle
- **Supervision** – Individuals who require the support of caregivers, family, or friends or have limited ability to cope in a new environment
- **Medical Care** – Individuals who are not self-sufficient or do not have or have lost adequate support from caregivers and need assistance with managing medical conditions

¹¹ RAND Health for the Department of Health and Human Services (HHS) under contract #HHS-100-03-0010. Analysis of Risk Communication Strategies and Approaches with At-Risk Populations to Enhance Emergency Preparedness, Response, and Recovery: Final Report (2008) [online]. Available at URL <http://aspe.hhs.gov/daltcp/reports/2008/emergfres.htm>.

In addition to those individuals specifically recognized as at-risk in the Pandemic and All-Hazards Preparedness Act (PAHPA)¹² (i.e., children, senior citizens, and pregnant women), individuals who may need additional response assistance could include those who have disabilities; live in institutionalized settings; are from diverse cultures; have limited English proficiency or are non-English speaking; are transportation disadvantaged; have chronic medical disorders; and have pharmacological dependency.

To reach these communities, planners can work with local hospital associations, private or nonprofit community clinics, and other healthcare stakeholders, such as home health agencies, homeless shelter clinics, and migrant clinics. **Chapter 8: Dispensing Medical Countermeasures** and **Chapter 9: Public Information and Communication** further address these populations and provide guidance on how to reach them.

Coordinating Planning Efforts

Plans should specify not only the processes and tasks involved in the response but also how agencies within the planning jurisdiction (whether state, local, tribal or territorial) will interact with each other during a public health emergency. The planning process should include documentation of structured interactions (meetings, conference calls, training, etc.) with all agencies that support the plan and have a role in the response effort. Partners who are involved in the planning process can assist in identifying and resolving potential support problems.

Form a Multidisciplinary Advisory Group

The planning process requires a collective effort of many diverse agencies that will support a public health emergency response. Working together, state, local, tribal, and territorial (SLTT) public health planners can coordinate with various public and private sector partners to develop a comprehensive MCMDD operations and response plan that specifies how all agencies and organizations will work together.

Public health should familiarize partner agencies with the specific emergency response requirements of a public health response. From there, the planning process should include frequent discussions with agencies designated to support the plan. It is imperative that planners form planning groups with representatives who would respond during a public health or other type of emergency. Possible agencies, representatives, and organizations to include on the MCMDD planning committee include

- Public health departments;
- Emergency management;
- Homeland security office;
- State and local public health lawyers;
- Mental and behavioral health/crisis professionals;
- Public information officers (PIOs);
- Departments of transportation;

¹² www.phe.gov/preparedness/legal/pahpa/pages/default.aspx

- Hospitals, treatment centers, urgent care facilities, and other health care organizations;
- Pharmacists;
- Departments of administration/finance;
- Departments of corrections;
- HHS regional emergency coordinator (REC);
- National Disaster Medical System (NDMS) representatives;
- Medical Reserve Corps (MRC) representatives;
- Law enforcement (federal, state, and local);
- Public works departments;
- School superintendents/education departments;
- Private businesses (developing closed PODs and a volunteer base);
- Emergency medical services (both public and private);
- Fire departments;
- Medical professional organizations;
- Colleges and universities;
- Military installations;
- Tribal nations;
- Metropolitan Medical Response System (MMRS);
- Volunteer groups (American Red Cross, Salvation Army, etc.); and
- Nongovernmental organizations with ties to at-risk populations.

Table 2.1, located at the end of this chapter, provides details on how these organizations can assist in a planning for an MCMDD response.

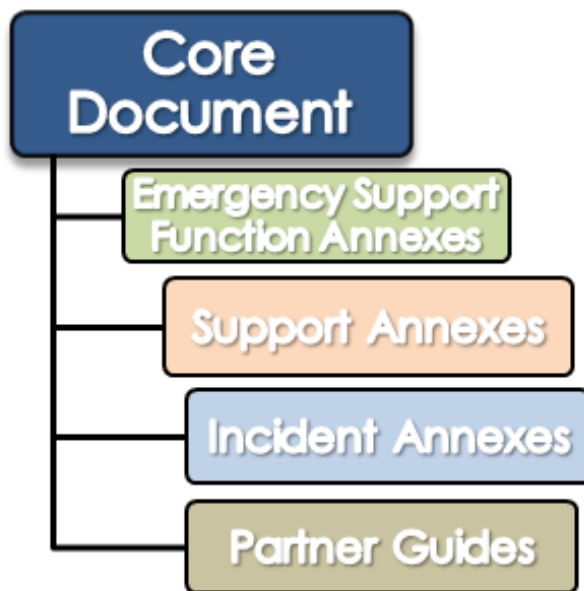
This list cites partners to consider for planning collaboration and each particular jurisdiction may require additional partners. Planners should canvas specific stakeholders and determine who should be a participant in the multiagency planning process. Additionally, many agencies are single-source, resident experts for the services that they provide, so including their expertise in the planning process can leverage local knowledge and resource capabilities.

As planning becomes more robust, the list will expand to engage more strategic partners from the public and private sectors, which may include local businesses and multi-national corporations. Developing mutually beneficial relationships with the private business sector may provide the opportunity to leverage resources and gain professional expertise that may not normally exist in traditional emergency planning channels. Similarly, jurisdictions can enhance the strength of their planning by diligently and proactively engaging volunteer groups and organizations. These groups often bring a wealth of experience from involvement in similar responses and their experience can assist in building more comprehensive and flexible plans.

Formatting the MCM Distribution and Dispensing Plan

The MCMDD plan should be part of a more comprehensive state or local all-hazards plan, perhaps in the form of an annex to that plan. One possible format for the plan could mirror the structure of the National Response Framework (NRF).¹³ Many state-level emergency operations plans use this format. The NRF begins with a core document, addresses individual tasks through Emergency Support Function (ESF) Annexes, includes unique support and incident appendices that support the core document, and then attaches separate partner guides. In a corresponding state or local MCMDD plan, the core document would be the overall MCMDD plan, the ESF Annexes would be replaced with the MCMDD functional areas, which would be followed by support annexes, appendices, and partner guides. Figure 2-2 shows a side-by-side comparison of the NRF structure and an MCMDD plan structure.

NRF Structure



MCMDD Plan Structure

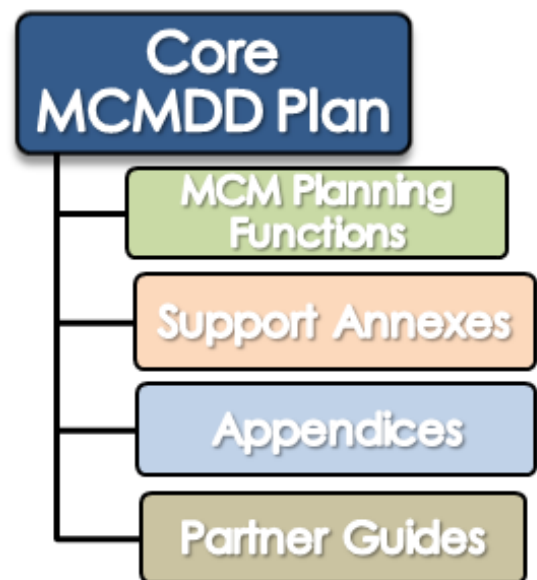


Figure 2-2: Comparison of NRF and MCMDD plan structures.

The **core plan** provides an overview of the jurisdiction's emergency management system and structure and briefly explains the hazards faced, capabilities, needs, and demands. It also reviews expected mission execution for each emergency phase, identifies the agencies that have the lead for a given support function, and outlines the support functions that will be activated during an emergency.

¹³ www.fema.gov/pdf/emergency/nrf/nrf-core.pdf

The **MCMDD planning functions** include the functional areas of an emergency response in which the jurisdiction requests and utilizes MCMs. These include, but are not limited to, the functions listed in this guide.

The **support annexes** describe the framework through which a jurisdiction's departments and agencies, the private sector, non-profit and volunteer organizations, and other NGOs coordinate and execute the common emergency management strategies. The actions described in the support annexes apply to nearly every type of emergency. Each support annex identifies a coordinating agency and cooperating agencies. In some instances, two or more departments or agencies share coordinating agency responsibilities.

The **appendices** provide relevant information not already addressed in the core plan. Typically, this includes commonly referenced information such as a list of terms and definitions, guidelines for plan revisions, or a plan exercise and evaluation program. It also may include forms used for managing emergencies.

The **partner guides** describe key roles and actions for SLTT, federal, and private sector response partners.

Regardless of the form the MCMDD plan takes, CDC recommends that state and local planners write a plan in which the body contains actions that typically do not change and the appendices and indices contain information that may change frequently, such as names and contact information for personnel in specific roles.

Writing an Operational Plan for MCM Distribution and Dispensing

While the planning process is vital in developing plans, it is essential that plans be written so that all partners will know and can agree to their roles in each phase of an emergency. Because the task of writing the MCMDD plan can seem overwhelming, CDC encourages planners to work with members of the multi-disciplinary advisory group to assist in writing the formal plan. If the writing task is broken down into the base plan, followed by the MCMDD functional annexes, it will make the writing task feel more manageable. Members of the planning group can provide content for the functional annexes, review the written plan, and offer suggestions for additional materials.

Developing a Scalable Plan

One of the key tenants of planning is to develop scalable plans. As incidents change in size, scope, and complexity, the public health response must be flexible and easily adaptable to meet changing requirements. The number, type, and sources of resources must be able to expand or retract rapidly. For example, during a large-scale response, the plan should be able to guide the mobilization of large numbers of resources including staff, volunteers, equipment, and facilities. This type of response may be required to support an incident that requires the jurisdiction to provide MCMs to its entire population within a short timeframe, such as the release of aerosolized anthrax. However, the plan should be flexible enough to guide the public health response for those events that pose serious threats to public health, but on a smaller scale, such as a meningitis outbreak that requires vaccination of students

from one high school or one county. Planning also should account for incidents that may be longer in duration, such as influenza pandemics, which may cause outbreaks of illness that occur in multiple waves over several months. In addition, the overall response should be flexible as it transitions from the response effort to the post-incident recovery phase.

Emergency response plans should be able to adapt to changing situations, including changes within the jurisdiction, the organization, and any emergency response partners. In addition, the plan should contain contingencies for changes in the organization's infrastructure, response capabilities, emergency responder levels, and services, which may cause new vulnerabilities or affect the mode of response. One example currently impacting many health jurisdictions across the nation is the decrease in staffing within the public health department. This has caused public health planners to adjust their plans in such ways as expanding recruitment efforts for volunteers or incorporating additional alternate methods of dispensing that would not rely solely on public points of dispensing (PODs).

Determine Policies and Procedures

Jurisdictional policies and procedures serve as the basis for how the jurisdiction will conduct response operations. As plans are developed, it is important that specific policies and procedures are included in the plan, and more importantly that all stakeholders are aware of these policies. For example, dispensing laws within a jurisdiction govern how medical professionals can dispense medication, but during emergency declarations, there may be laws within the jurisdiction that allow for modifications that help support more rapid MCM dispensing to the public. Since some policies and procedures may affect key components of the public health response, it is important to include them in the plan and reference any changes that might occur during an emergency declaration.

Determine List of Tasks

By collaborating and sharing plans, agencies can create comprehensive all-hazards plans that include a listing of the tasks to be performed during an emergency response involving SNS assets. This task list can outline which procedures and tasks are designated to participating agencies or organizations, including those organizations not under jurisdictional control (e.g., American Red Cross). When two or more organizations perform the same kind of task, planners should designate one as the primary responder and give the other(s) a supporting role. For the sake of clarity, the list should include an at-a-glance matrix or chart of organizations and areas of responsibility (including functions) that shows the primary and supporting roles covered by partner agencies and organizations.

Share Plans among Partners

As agencies develop emergency response plans, it will be important for partners to share their plans with all the members of the multidisciplinary advisory group and with neighboring jurisdictions. Depending on the jurisdictional level, such neighboring jurisdictions could be comprised of other states, counties, cities or townships, and even countries. Partners and neighboring jurisdictions can share plans at regular meetings, through training and exercising together, and via online collaborative venues, such as Microsoft SharePoint®. By sharing plans, partners can integrate planning efforts into viable, flexible, and operational plans. Additionally it is important that all participating agencies and jurisdictions record

concurrency with plan expectations to ensure the tasks assigned within the plan are acknowledged by the partnering agencies.

Integrate the MCMDD Plan into Existing Response Planning Infrastructure

The federal government has encouraged state and local jurisdictions to have a standard emergency planning framework through the National Incident Management System (NIMS)¹⁴ and Incident Command System (ICS).¹⁵ Emergency management and public health planners should work together to integrate their MCMDD procedures within their all-hazards planning. This can be either an annex, appendix, or stand-alone document within the all-hazards plan.

Delineate State and Local Responsibilities

An emergency will require the coordinated efforts of SLTT public health officials to get assets quickly to those in need. To achieve that coordination, public health response plans must clearly identify both the state and the local responsibilities during an MCMDD response. The efforts of the different jurisdictions should complement one another to avoid the omission or duplication of key actions.

By breaking down the process to receive, distribute, and dispense MCMs, planners can readily recognize and address their jurisdictional responsibilities. Figure 2-3 displays the federal, state, and local activities associated with a MCMDD response.

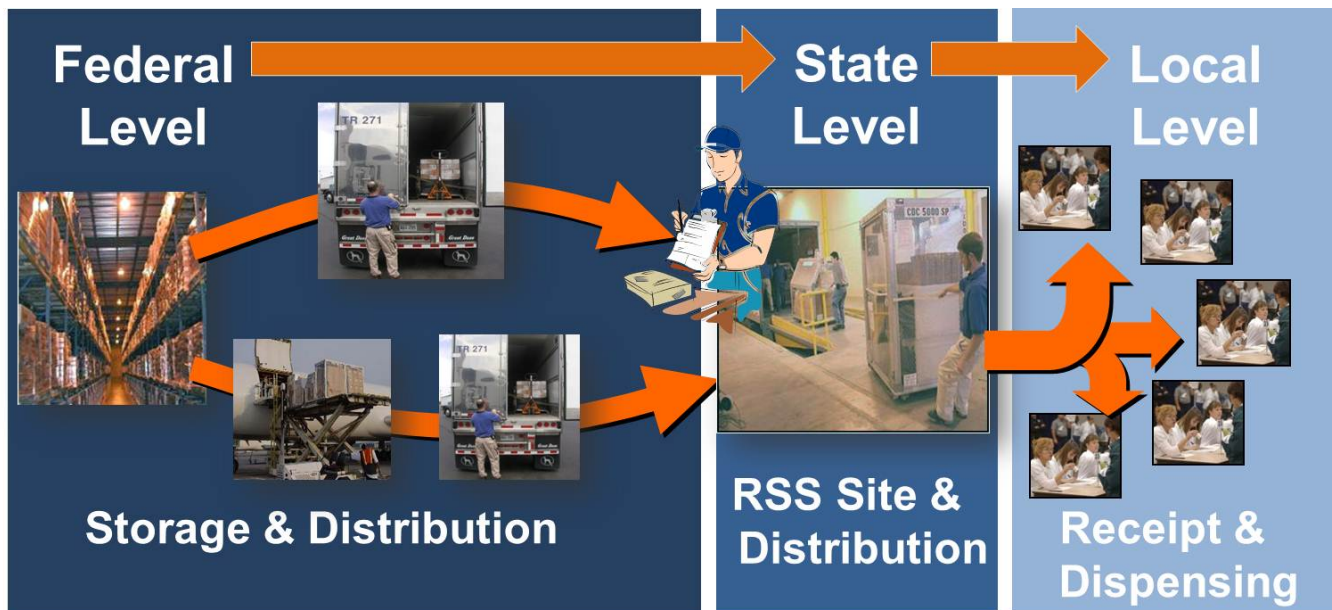


Figure 2-3: Federal, state, and local activities during an MCM response.

¹⁴ www.fema.gov/pdf/emergency/nrf/nrf-core.pdf

¹⁵ www.fema.gov/emergency/nims/IncidentCommandSystem.shtm

State Responsibilities

In most instances, the primary premise for receiving SNS assets from the federal government is that CDC will deliver assets to the state, which will then further distribute assets to the affected jurisdiction based on established distribution plans. Some states plan to receive assets and immediately turn them over to an intermediate site in the local jurisdiction for staging, distribution, and dispensing during an emergency. Other states plan to configure assets at the state warehouse facility and deliver them directly to points of dispensing (PODs), hospitals, or other dispensing sites. Each state is responsible for determining the best model for their unique circumstances and resources, which includes transfer of assets and integration of plans between the various jurisdictions. If the state cedes planning responsibilities to local jurisdictions, the state must assist local jurisdictions in understanding and conducting those responsibilities.

State SNS coordinators should be able to assist and guide local public health planners in developing plans that promote the seamless transfer of SNS assets from the state to the local jurisdiction and down to the people who need them.

Some considerations in determining responsibilities include

- The ability of a state governor or his/her designee to request federal assistance and to waive or suspend state laws and regulations in the event of an emergency;
- The ability of a governor or his/her designee to direct the efforts of state agencies, such as the National Guard, state police, and transportation department; and
- The need to coordinate efforts across adjacent state borders.

Local Responsibilities

Local public health planners have the responsibility to receive and dispense necessary MCMs in a timely and efficient manner. Local public health officials must develop partnerships within the community to assist with accomplishing these responsibilities. Local public health planners should establish relationships with agencies, entities, and organizations within the jurisdiction, including local hospitals, health care providers, POD partners, public safety/security officials, and media outlets, to name a few. The methods the jurisdiction uses to provide MCMs to the public will depend on the incident. Mass vaccination clinics and PODs are resource-intensive operations and require detailed pre-incident planning. Planners must select locations, establish facility use agreements, and coordinate staffing and security plans. The relationships developed by local public health agencies during the planning process will be vital to staffing and managing a full-scale MCM response.

Special Planning Considerations

State and Local Stockpiles or Caches

Depending on the threat, many health departments explore whether or not to stockpile MCMs at the state and/or local level. Some jurisdictions purchase medication caches for first responder communities for immediate prophylaxis during a large-scale inhalation anthrax

attack or pandemic influenza. Planners may find that they face additional planning considerations associated with such caches, such as political guidance, cost, storage, and regulatory issues that influence this decision.

State and local jurisdictions can use these caches to provide MCMs to first responders and essential personnel as the response effort gets underway, but they also may have MCM caches to begin the dispensing process prior to the arrival of MCMs from the SNS. State and local planners should work together to determine how much medication is needed and how much can feasibly be stored and maintained in state or local caches. To leverage buying power partner agencies and organizations may decide to establish an agreement to make a collective purchase versus multiple smaller purchases. A single storage and maintenance agreement also might make the management of procured countermeasures a cost savings for the community.

Regulatory and Legal Considerations

During a large-scale public health emergency, dispensing MCMs as rapidly as possible could be one of the primary ways public health officials are able to save lives. The timeframe needed for the jurisdiction to distribute and dispense MCMs will depend on the incident. In the case of an aerosolized release of anthrax spores in a populated area, the jurisdiction needs to distribute and dispense MCMs rapidly as people would need to begin a course of antimicrobials within 48 hours of exposure to prevent the onset of disease. However, to dispense medications in this condensed timeframe, the jurisdiction may need to alter and/or eliminate standard dispensing procedures in order to save time and in turn, save lives. Consequently, state and local SNS planners should be aware of regulatory requirements and legal protections the federal government may put into place during an emergency declaration and how these can affect MCM dispensing. For instance, the jurisdiction may have legal protection under federal legislation, such as the Public Readiness and Emergency Preparedness (PREP) Act,¹⁶ during some incidents. In addition, MCMs dispensed under an Emergency Use Authorization (EUA)¹⁷ or Investigational New Drug (IND)¹⁸ protocol require the jurisdiction to follow specific FDA procedures or protocols. Therefore, planners should be familiar with federal legislation and FDA guidelines and develop plans that are capable of being adapted for various scenarios.

Chapter 8: Dispensing Medical Countermeasures provides further information on legal and regulatory considerations.

State dispensing laws

It is important for planners to be aware of the laws that govern who can legally dispense medications within the state. In addition, planners need to be familiar with laws governing who can issue standing orders for medication dispensing and whether that authority is

¹⁶ ftp://ftp.hrsa.gov/countermeasurescomp/Public_Readiness_and_Emergency_Preparedness_Act.pdf

¹⁷ www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm

¹⁸ www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm

suspended or changes during an emergency declaration. Planners also should determine whether their jurisdictions contain enough licensed medical professionals to assist in responding to a large-scale public health emergency that requires MCM dispensing. Planners may need to pursue ways in which dispensing laws can be rewritten or amended during an emergency to facilitate large-scale MCM dispensing operations. Planners should work with their public health law professionals to determine the needs of their jurisdictions.

Staff Compensation

Plans should include information regarding whether and how the jurisdiction will compensate staff and volunteers for their efforts during a public health response. Some questions to consider include:

- How will staff be paid for the time they work on the response?
- How will staff log hours worked for compensation?
- Will volunteers be compensated? If so, how will they be compensated? (For example, during a large-scale dispensing operation, people may volunteer to help in the PODs if they will receive MCMs for themselves and their families first)
- How will workers' compensation be handled for injuries that occur to staff or volunteers during a response?
- Will entities that permit use of their facilities (e.g., warehousing companies, school districts, businesses) be compensated? If so, how will they be compensated?
- Is there a means in which private property can be procured for an emergency response? If so, how will the property owner be compensated?

Planners should work with their public health law professionals to determine how compensation will occur and clearly include the compensation mechanisms in the plan. In addition, planners should document any memoranda of agreement (MOA) or memoranda of understanding (MOU) with entities that will participate within their jurisdiction during a public health response and those MOAs or MOUs should clearly define whether and how the jurisdiction will provide compensation.

Identify First Responder and Critical Infrastructure Personnel

Homeland Security Presidential Directive-8 (HSPD-8)¹⁹ defines first responders as those individuals who, in the early stages of an incident, are responsible for the protection and preservation of life, property, evidence, and the environment. This includes emergency response providers as defined in section 2 of the Homeland Security Act of 2002 (6 U.S.C. 101),²⁰ as well as emergency management, public health, clinical care, public works, and other skilled support personnel (such as equipment operators) that provide immediate support services during prevention, response, and recovery operations. Emergency response providers are federal, state, and local emergency public safety, law enforcement, emergency response, emergency medical (including hospital emergency facilities), and related personnel. As broad as these definitions read, it is imperative for jurisdictions to clearly identify who qualifies as a first responder within their communities and what protective

¹⁹ www.fas.org/irp/offdocs/nspd/hspd-8.html

²⁰ www.dhs.gov/xlibrary/assets/hr_5005_enr.pdf

measures the jurisdiction will provide to ensure that these responders are safely equipped and able to conduct their duties during a public health emergency. Equipping responders may include, but is not limited to, providing personal protective equipment (PPE), vaccinations, or prophylactic medications. Based on lessons learned from the response to Hurricane Katrina in 2005, health officials may also want to consider planning for first responders to have access to prophylactic medications for their family members to help ensure that these essential groups of workers are able to respond without family-related reservations.

In addition to first responders, it is equally important for planners to determine the critical infrastructure systems and personnel within the community and how the jurisdiction will provide MCMs to these groups during an emergency. Critical infrastructure includes assets, systems, and networks, whether physical or virtual. These systems are vital to communities and their incapacitation or destruction would have a debilitating effect on security, the economy, public health, safety, or any combination thereof.

Homeland Security Presidential Directive 7 (HSPD-7)²¹ established U.S. policy for enhancing critical infrastructure protection by establishing a framework to identify, prioritize, and protect critical infrastructure within communities. HSPD-7 primarily refers to protection against terrorist attacks, but the protection is necessary regardless of the specific type of emergency. Most commonly recognized critical infrastructure assets are facilities and systems for

- Electricity generation, transmission, and distribution;
- Gas production, transport, and distribution;
- Oil and oil products production, transport, and distribution;
- Telecommunication;
- Water supply (drinking water, waste water/sewage, stemming of surface water);
- Agriculture (food production and distribution);
- Heating (e.g., natural gas, fuel oil, district heating);
- Public health (including hospitals and ambulances);
- Transportation systems (fuel supply, railway network, airports, harbors, inland shipping);
- Financial services; and
- Security services (including police and military).

Continuity of Operation Plan (COOP)

Continuity planning is a fundamental responsibility of public institutions and private entities to the nation's citizens. Continuity planning facilitates the performance of essential functions during an emergency that disrupts normal operations and/or the timely resumption of normal operations once the emergency has ended. A strong continuity plan provides the organization or community with the means to address the numerous issues involved in performing essential functions and services during an emergency. Without detailed and coordinated continuity plans and effective continuity programs to implement these plans, jurisdictions risk leaving their residents without vital services in what could be their time of greatest need.

²¹ www.dhs.gov/xabout/laws/gc_1214597989952.shtm#1

The goal of continuity planning is to reduce the consequence of any disruptive event to a manageable level. The specific objectives of a particular organization's continuity plan may vary, depending on its mission and functions, its capabilities, and its overall continuity strategy. In general, continuity plans are designed to

- Minimize loss of life, injury, and property damage;
- Mitigate the duration, severity, or pervasiveness of disruptions that do occur;
- Achieve the timely and orderly resumption of essential functions and the return to normal operations;
- Protect essential facilities, equipment, records, and assets;
- Be executable with or without warning;
- Meet the operational requirements of the respective organization (continuity plans may need to be operational within minutes of activation, depending on the essential function or service, but certainly should be operational no later than 12-hours after activation);
- Meet the sustainment needs of the respective organization (An organization may need to plan for sustained continuity operations for up to 30 days or longer, depending on resources, support relationships, and the respective continuity strategy adopted);
- Ensure the continuous performance of essential functions and operations during an emergency, including such instances as pandemic influenza that may require additional considerations beyond traditional continuity planning; and
- Provide an integrated and coordinated continuity framework that takes into consideration other relevant organizational, governmental, and private sector continuity plans and procedures.

Maintaining and Reviewing the Plan

It is important to note that plans should adhere to a regular cycle of updates. Public health planners should review plans to receive, distribute, and dispense MCMs at least annually to ensure that information is current. Every update of the plan should include a review, evaluation, and approval by responsible agencies.

Portions of the plan might be shared among agencies, so planners should consider how to protect any confidential information in the plan. For instance, planners might wish to share the body of the plan with appropriate government agencies but keep personnel contact information or the exact location of PODs or other facilities in an addendum that is kept confidential. Regardless of what information is shared, each agency involved with executing the plan needs to have a copy of the portion that pertains to their particular responsibilities.

The planning process does not end with a written document. Planners must ensure thorough dissemination, coordination of resources, execution of agreements, volunteer coordination, training, exercising, and plan improvement and updating. Planners should remember that the MCMDD plan is never finished; it will continue to evolve as new information becomes available, new partners are recruited, and best practices are identified and adopted. Once a formal plan is developed and written, jurisdictions should have regularly scheduled reviews of the written plan to update information, add new partners, and include changes gleaned from exercises and after action reports. Ideally, each jurisdiction should review and

update their plan at least annually and share any pertinent changes with neighboring jurisdictions and response partners. See **Chapter 13: Training, Exercising, and Evaluating Plans** for further information on exercising, evaluating, and updating the plan based on after action items from drills and exercises.

Medical Countermeasure Planning Assessments

For over 10 years, CDC conducted technical assistance reviews (TARs) of state, local, and territorial MCM plans. The purpose of the TAR was to review the jurisdiction’s planning efforts as related to SNS functional elements. Effective July 2014, CDC is updating the medical countermeasure assessment to facilitate review of MCM plans for operational capability. CDC designed the updated operational readiness assessment to improve and advance state, local, and territorial MCM planning and response and to align MCM planning with the 15 public health preparedness capabilities.

Table 2.1: Partner Organizations

Individual/Organization	What They Bring to the Planning Table
<p>Chief health official, health director, senior health official (elected or appointed), or designee</p>	<ul style="list-style-type: none"> • Knowledge of policy for the emergency response organization • Knowledge and expertise of the overall response and recovery operations • Knowledge of guidelines for authorization with mitigation strategy for recovery • Knowledge of title or position of individuals responsible for serving as incident commander(s), emergency operations center (EOC) manager, health and medical coordinator, communications coordinator, warning coordinator, public information officer (PIO), evacuation coordinator, mass care coordinator, and resource manager • Familiarity with and ability to coordinate the use of health and medical resources and personnel involved in providing medical assistance to disaster victims • Knowledge of information acquired from the heads of local public health, emergency medical services (EMS), hospital, environmental health, mental health, and mortuary services, or their designees • Provide advice on preparation of emergency health and medical plans to ensure practicality and interoperability • When appropriate, ability to include information on local representatives of professional societies and associations in these meetings to gain members’ understanding of and support for health and medical plans • Knowledge of record keeping related to morbidity and mortality • Knowledge of the jurisdiction’s public health and medical surge capacity • Understanding of the special medical needs of the community • Knowledge of historic infectious diseases and syndromic surveillance and sampling procedures • Knowledge and expertise to gather information from

Individual/Organization	What They Bring to the Planning Table
	<p>representatives of fire and police departments, emergency management agencies, military departments, state and federal agencies to discuss coordination of plans</p> <ul style="list-style-type: none"> • Ability to make recommendations regarding thresholds for re-ordering MCM • Knowledge of title, position, and responsibilities of the individuals assigned to work in the EOC during emergencies
<p>Homeland security</p>	<ul style="list-style-type: none"> • Knowledge of coordination and comprehensive federal response to mount a swift and effective recovery effort • Ability to assume primary responsibility for ensuring that emergency response professionals are prepared for any situation, if required
<p>Emergency management</p>	<ul style="list-style-type: none"> • Ability to designate emergency management agency staff to serve in key posts, as appropriate • Ability to advocate that mitigation concerns be addressed appropriately during response and recovery operations • Experience and knowledge of working with the public information officer (PIO) to develop emergency information packets and emergency instructions for the public • Familiarity with and ability to coordinate with local volunteer organizations, such as the American Red Cross, Salvation Army, other public service non-profit organizations, as well as volunteers from outside the jurisdiction and unaffiliated volunteer and neighborhood groups within the jurisdiction • Knowledge of managing the EOC as a physical facility (e.g., layout and set-up), expertise to oversee its activation, and ensure the resource support for response and organizational needs • Familiarity of management of resource staffing for communications and Information Processing sections in the EOC • Knowledge of how to ensure necessary planning considerations for the EOC • Ability to identify and designate private and public service agencies, personnel, equipment, and facilities that can be used to augment the jurisdiction's communications capabilities (For example, developing procedures with Radio Amateur Civil Emergency Service (RACES) or other available local communications resources and arranging for emergency augmentation of communications capabilities) • Ability to coordinate planning requirements with the emergency management staff in neighboring jurisdictions that have been identified as potentially hazard-free and have agreed to house evacuees in their mass care facilities • Knowledge of coordinating emergency communications and warning frequencies and procedures with EOCs at higher levels of government and with neighboring communities • Knowledge of coordinating the provision of mass care needs

Individual/Organization	What They Bring to the Planning Table
	<p>for personnel performing medical duties during catastrophic emergencies</p> <ul style="list-style-type: none"> • Knowledge of reviewing and updating listings including phone numbers of emergency response personnel to be notified of emergency situations
<p>State and local public health lawyers</p>	<ul style="list-style-type: none"> • Ability to provide recommendations to state and local public health departments on legal considerations surrounding MCM operations • Provide legal language for inclusion in MOUs/MOAs with partner organizations • Ability to provide information on tort protection for partner organizations, staff, and volunteers • Ability to provide recommendations on compensation for volunteers, partner organizations, and staff • Ability to analyze public health law to determine whether legislative changes may be necessary to support MCM operations
<p>Public information officers (PIO)</p>	<ul style="list-style-type: none"> • Specialization and expertise on matters of public information and crisis and emergency risk communication (CERC) • Knowledge of preparation and delivery of emergency information packets for release of pertinent materials to local media prior to emergencies • Ability to act as liaison with media and the public to communicate messages • Knowledge of and techniques on how to ensure that information needs of special, at-risk, and vulnerable populations are met
<p>Mental and behavioral health/crisis professionals</p>	<ul style="list-style-type: none"> • Knowledge of the provision of emotional support, stabilization, and assistance as needed to keep affected people calm during an emergency event • Ability to provide guidance and recommendations for developing plans for providing emotional support and calming fears during a large-scale emergency
<p>Transportation department</p>	<ul style="list-style-type: none"> • Knowledge of transport into or through the communities, states, and counties • Knowledge of transportation and shipping regulations • Provide roadblocks or traffic signs, if needed, during a response • Ability to analyze traffic patterns and transportation routes for POD and distribution plans • Ability to provide transport vehicles and personnel
<p>Hospitals, treatment centers, and other health care organizations</p>	<ul style="list-style-type: none"> • Knowledge and ability to provide medical assistance and ensure receipt and dispensing of MCM • Ability to provide medical staff for MCM dispensing operations • Capability to transport or relocate residents as necessary to designated emergency shelter or alternate locations

Individual/Organization	What They Bring to the Planning Table
Pharmacists	<ul style="list-style-type: none"> • Knowledge of pharmaceutical distribution and control, including federal and state distribution and dispensing laws • Knowledge of drug therapy management of patients • Ability to assist jurisdictions in selecting MCM for stockpiles and emergency inventories as part of emergency-preparedness programs • Ability to assist in developing education materials for those receiving MCM • Ability to assist in preparing appropriate education and training materials for dispensing personnel
Administration/finance department	<ul style="list-style-type: none"> • Ability to provide recommendations on reimbursements for expenditures incurred by private sector partners (e.g., businesses, colleges and universities, or medical facilities) • Ability to provide record keeping for MCM distribution and dispensing-related services (e.g., printing, food service, payroll, etc.) • Ability to track expenditures associated with MCM operations
Corrections department	<ul style="list-style-type: none"> • Ability to care for and provide MCM to populations under their jurisdiction (e.g., inmates), possibly staff and family members • Ability to provide transportation as necessary for large groups or vulnerable populations
HHS regional emergency coordinator (REC)	<ul style="list-style-type: none"> • Knowledge and coordination experience with medical and logistic distribution and managing consistent functions of operations in their jurisdiction • Ability to serve as liaison between federal officials and neighboring jurisdictions
National Disaster Medical System (NDMS) representatives	<ul style="list-style-type: none"> • Ability to supplement an integrated national medical response • Capability to assist state and local authorities in dealing with the medical impacts of major disasters • Ability to provide support to the military and the Department of Veterans Affairs medical systems in caring for casualties
Medical Reserve Corps (MRC) representatives	<ul style="list-style-type: none"> • Knowledge and ability to identify, screen, train, and organize volunteers utilized for support of routine public health activities and augment preparedness and response efforts • Knowledge of office activities that include strategic planning, intra- and interagency coordination, communications, policy development, program operations, grants management, contract oversight, technical assistance, and deployment operations
Law enforcement (federal, state, local)	<ul style="list-style-type: none"> • Knowledge of law enforcement and protection • Provide security walk-through of RSS and POD facilities and make security recommendations • Provide recommendations for security screening and identification badge requirements of warehouse, POD, and

Individual/Organization	What They Bring to the Planning Table
	transportation personnel <ul style="list-style-type: none"> • Knowledge of law enforcement resources and law enforcement operations • Knowledge of ESF #13 – Public Safety and Security Annex
Community emergency response team (CERT)	<ul style="list-style-type: none"> • Ability to provide CERT members to assist in the community or workplace in support of emergency response and preparedness projects • Ability to provide CERT members to assist with documentation, logistics, and comforting others • Assist with keeping databases, writing notes for tracking purpose
Public works department	<ul style="list-style-type: none"> • Knowledge of the jurisdiction road and utility infrastructure • Knowledge of how to manage public works resources and direct public works operations (e.g., water supply/treatment, road maintenance, trash/debris removal) • Knowledge of coordination with private sector utilities (e.g., power and gas) on shutdown and service restoration • Knowledge and ability to assist, as appropriate, in animal care and control agency staff's efforts to coordinate the preparedness actions needed to protect and care for animals during and following catastrophic emergencies • Knowledge of private sector utilities and contractors for use of private sector resources in public works-related operations
Education department, school superintendents, or designers	<ul style="list-style-type: none"> • Knowledge about school facilities • Knowledge about the hazards that directly affect schools • Knowledge of specialized personnel and equipment resources (e.g., buses)
Private businesses	<ul style="list-style-type: none"> • Ability to partner with public health to become POD sites for their employees and family members (i.e., closed PODs) • Ability to provide volunteer staff to assist in MCM distribution and dispensing • Ability to provide facilities for use as closed or open PODs • Ability to provide services (e.g., printing, transportation, food, etc.) in support of MCM operations
Emergency medical services (both public and private)	<ul style="list-style-type: none"> • Knowledge and expertise on providing medical care • Ability to provide personnel and vehicles during a public health response • Can provide emergency medical services at POD locations
Fire departments	<ul style="list-style-type: none"> • Knowledge of fire department resources and fire department operations • Supports Emergency Support Function (ESF) #4 – Firefighting
Medical professional organizations	<ul style="list-style-type: none"> • Knowledge and ability to provide medical assistance and ensure receipt of MCM

Individual/Organization	What They Bring to the Planning Table
	<ul style="list-style-type: none"> • Ability to provide volunteer medical staff for MCM dispensing operations • Capability to transport or relocate residents as necessary to designated emergency shelter or alternate locations
Military installations	<ul style="list-style-type: none"> • Ability to assist in coordinating and integrating chemical, biological, radiological, nuclear and high-yield explosive (CBRNE) installation response plans as necessary • Ability to dispense MCM to service members and possibly family members • Familiarity with coordination and integration in receiving assets as part of the distribution plan
Tribal nations and U.S. territories	<ul style="list-style-type: none"> • Experience with assisting in consultation in the form of communication to emphasize trust, respect, and shared responsibility • Ability to collaborate and provide informed decision making for tribal populations
Metropolitan Medical Response System (MMRS)	<ul style="list-style-type: none"> • Ability to integrated the state and local medical response systems • Ability to assist and/or provide detailed system response and operations plans • Ability to provide specially trained responders at all levels • Knowledge of and ability to supply specialized response equipment • Ability to provide specialized medical equipment and pharmaceutical cache • Ability to enhance medical transport and treatment capabilities
Volunteer groups (American Red Cross, Salvation Army, etc.)	<ul style="list-style-type: none"> • Ability to coordinate and delegate volunteers to assist with MCM operations • Ability to provide services to volunteers (e.g., food, shelter, etc.) during MCM operations
Colleges and universities	<ul style="list-style-type: none"> • Ability to coordinate and delegate students and staff members with assisting in documentation, logistics and distribution or coordination • Ability to serve as closed PODs for employees, students, and possibly family members • Ability to assist with delivery of public information in school system network
Private contract warehouse and transportation companies	<ul style="list-style-type: none"> • Manage the coordination of receiving, shipping, and distribution of MCM • Familiarity on how to coordinate with the transportation contractors and law enforcement officials to move MCM to other states or locations

Individual/Organization	What They Bring to the Planning Table
Nursing, assisted living, and residential care facilities	<ul style="list-style-type: none">• Knowledge and ability to provide medical assistance to the vulnerable population and ensure receipt of medication or emergency countermeasures• Capability to transport or relocate residents as necessary to designated emergency shelter or alternate locations

Chapter 3: Management of Medical Countermeasure Operations

Managing medical countermeasures (MCMs) deployed to an affected area involves coordination and oversight of the distribution throughout the jurisdiction, dispensing to the affected population, and sustainment of operations until the situation is contained. The management of MCM receipt, distribution, and dispensing activities requires collaboration, coordination, and cooperation from political leadership, emergency management, public health, law enforcement, and other groups. Jurisdictions can develop effective MCM management operation by integrating their MCM distribution and dispensing (MCMDD) plans into existing all-hazards plans and by following the Incident Command System (ICS)¹ at the jurisdictional level.

Building the Medical Countermeasure Planning and Response Teams

The jurisdiction should identify dedicated personnel for both MCM planning and operations. During the planning phase, the jurisdiction's staff should determine the functional roles that need to be filled; identify and assign the specific tasks that need to be accomplished; and assign individuals and back-up personnel to serve in functional roles during an MCM response and the subsequent recovery phase. During MCM operations, which include activation through the recovery phase, identified staff must fill their functional roles, follow the jurisdiction's ICS, and complete the tasks assigned to their specific roles.

Building the teams that will manage MCM planning and operations is similar to building the multidisciplinary advisory group, as discussed in **Chapter 2: Developing a Medical Countermeasure Response Plan**. Many of the partners that assist in the process of writing the MCMDD plan also will fill roles in planning for and responding during MCMDD operations. Working together, state, local, tribal, and territorial (SLTT) public health planners can coordinate with various partners to form an MCM planning team, specify the roles and responsibilities required for MCM operations at the jurisdictional level, and outline how all team members will work together.

¹ www.fema.gov/emergency/nims/IncidentCommandSystem.shtm

In many cases, team members who serve on the MCM planning team also will transition to serving as leads or team members during a response that requires activation of MCMDD operations. However, it is possible that members of the team that coordinates planning for MCMDD operations may have other key roles and responsibilities and will be unable to serve in specific MCMDD operational roles during a response. Nonetheless, these team members can bring their knowledge and expertise to the planning table to assist in identifying individuals that can serve in roles for management of MCMDD operations.

Public health planners will need to familiarize partner organizations with the specific emergency response requirements of a public health response and MCMDD operations. From there, the planning process should include frequent discussions with organizations designated to support MCMDD operations to determine the roles on the MCM team, identify individuals to fill those roles, and establish MCMDD operations response and recovery plans.

Determining Medical Countermeasure Team Roles

The jurisdiction should incorporate positions on the MCM team into the jurisdiction's ICS structure based on the actions required at the jurisdictional level to complete the mission. During a response, individuals should move from their daily roles and responsibilities into roles assigned to them as part of the ICS structure.

Depending on a state's operational plans, MCM response activities at the state level may only involve receiving MCMs from the federal government or other sources, then distributing these assets down to the affected jurisdictions. Therefore, members of the MCM response team at the state level should be capable of performing specific, pre-identified tasks in support of activities related to receipt and distribution of MCMs. Likewise, MCM response teams at the local level will focus on those missions involved in receiving MCMs from the state and operating the different dispensing modalities necessary to provide MCMs to people in the affected jurisdiction.

MCM team roles might include, but are not limited to, the following:

- MCM team lead
- Staffing/volunteer coordinator
- Communications and information technology (IT) coordinator
- Security coordinator
- Receive, stage, store (RSS) lead
- Inventory management lead
- Distribution leader/manager
- Dispensing supervisor/leader
- Hospital and treatment center coordinator
- Public information and communication lead

Once the jurisdiction determines specific roles on the MCM team, team members should work together to create a list of tasks to be accomplished and assign responsibility for those tasks to individual roles. The chapters of this guide that correspond to the SNS functional areas can assist in determining specific tasks at the jurisdictional level. These tasks may overlap between jurisdictions (e.g., from the state to the local level or between neighboring

counties or cities), so it can be beneficial for planners to coordinate their efforts between these jurisdictions and see where potential roles can be combined and resources shared. The SNS state and local Technical Assistance Review User's Guides² can assist in developing the tasks associated with each of the SNS functions and the corresponding MCM operations team roles. All team members, as well as alternate or back-up team members, should be familiar with their particular roles and responsibilities during a response. In addition, the MCM team members should develop job action sheets (JAS) that outline those tasks for each position on the team.

Identifying MCM Operations Team Members

As tasks are identified for the specific roles on the MCM operations team, planners can begin to identify individuals and back-up personnel to fill those roles. It is important to ensure these roles are filled by individuals who both possess skills appropriate for the position **and** are available to fill the position during a response. For example, the head of the jurisdiction's law enforcement agency might have all the skills required to serve as the security lead, but he or she may have duties during a large-scale emergency that would prevent serving in that role on the MCM operations team.

In addition to ensuring that individuals on the MCM team will be available to serve on the MCM operations team during a response, the roles in the MCM team should have built-in redundancy with back-up and alternate individuals identified during the planning process. Planners should look to the agencies and organizations that participate in the multidisciplinary advisory group and associated partner agencies listed in Table 2.1, located in **Chapter 2: Developing a Medical Countermeasure Response Plan**, to identify individuals to fill roles in the MCM team. Team members selected from knowledgeable personnel within the jurisdiction bring skills and expertise that can be incorporated into the overall construction and execution of the plan. For instance, all areas have law enforcement agencies that are familiar with security and tactical communication systems and many have a transportation department that is familiar with dispatching and tracking vehicles for distribution efforts. Personnel from these agencies can easily fill roles in the security and distribution functions of the MCM operations team.

While the jurisdiction will be creating a new team to manage an MCMDD response, this team will consist of positions that crossover between other areas of the all-hazards plan. For example, partners who would lead and coordinate volunteer management during one type of emergency could perform the same role for an MCMDD response. The SNS or Cities Readiness Initiative (CRI) coordinator can serve as the team lead and as a facilitator in getting existing agencies to contribute their respective skills to the management of MCMDD operations. As the MCM team identifies individuals to fill roles, it should develop a team roster that names the primary and back-up individuals for each position and lists contact information.

² www.orau.gov/snsnet/guidance.htm#TAR. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

The following guidelines suggest key positions for MCMDD operations. Planners can add or subtract positions; divide activities; and modify the team structure in any way that best supports the jurisdiction's plan.

MCM Team Lead

The jurisdiction's SNS and/or CRI coordinators are the best candidates to fill the lead position on the MCM planning and operations teams as they already are responsible for developing the jurisdiction's MCMDD plans. The SNS and CRI coordinators within the jurisdiction also are the most knowledgeable people concerning the MCMDD plan and will have worked directly with all supporting agencies, as well as planners and responders, to develop the jurisdiction's MCMDD plan. Local jurisdictions involved in the response will need an individual who interacts with the state MCM team to ensure an effective and efficient response. The MCM lead will

- Act as the representative for the MCM team;
- Interact with incident command;
- Resolve problems and issues; and
- Determine how best to respond to the situation in the absence of guidance from the incident commander.

Staffing and Volunteer Coordinator

MCMDD operations will be especially labor intensive, so coordination of volunteer and professional staff is a critical role. The staffing and volunteer coordinator must have strong knowledge of volunteer recruitment and coordination, the ability to manage and assign tasks to staff from a variety of disciplines, familiarity with dispensing laws and regulations in the jurisdiction, and the ability to determine staffing needs for the jurisdiction, be it the state, local, or dispensing level. The staffing and volunteer coordinator will

- Develop volunteer recruitment and training plans;
- Develop just-in-time training for spontaneous volunteers; and
- Determine credentialing procedures and licensing requirements for medical volunteers.

Possible sources for staffing and volunteer coordinators include health department personnel, emergency management agencies, and volunteer and community service organizations.

Strategic and Tactical Communications Coordinator

Communications during MCMDD operations will be vital to a seamless flow of information between all members of the team, incident command, the emergency operations center, and all sites involved in the response. Fortunately, states have emergency communication systems that allow for diversity and redundancy. Regardless of whether the backbone of the communications system is a law enforcement agency, state emergency management, or a department of transportation, any communication system must have the capability to transfer information from all levels and all players in the response community. To lead communication efforts, the jurisdiction will need someone who is familiar with the primary communication system and has a wide background and knowledge in other systems. This

position is a technical position and is not a public information specialist. The strategic and tactical communications coordinator will

- Coordinate and facilitate the communications between lead personnel for each of the MCMDD activities;
- Receive requests, send situational reports, and exchange information;
- Ensure MCMDD teams have communication equipment and can connect to communications networks and systems;
- Arrange for or carry out any equipment or system repairs or replacements;
- Maintain awareness of problems and be able to expedite solutions; and
- Interact with incident command and the emergency operations center (EOC) to request support from other response functions, such as law enforcement.

To ensure these actions take place, the strategic and tactical communications coordinator must develop detailed communication networks and support plans. These plans should provide incident command and the EOC with information and timely, accurate data from other MCMDD activities. **Chapter 10: Strategic and Tactical Communications** provides additional information that can assist in determining the lead for this position.

Security Coordinator

Security provides a safe environment for response activities and the person who fills this role should possess a law enforcement background. The primary purpose of the security coordinator is to interface with the assigned law enforcement agency (LEA) or agencies responsible for security for the entire MCMDD operation. In many instances, the security manager will be a law enforcement official acting as a liaison between LEAs and the MCM team. Security leads should have a strong knowledge of facility and personnel security, law enforcement security policies and procedures, traffic management, and personnel identity and badging procedures. The security lead coordinates

- Personnel identification within the jurisdiction;
- Security for assets in the jurisdiction, whether at the state-, local-, RSS-, or dispensing-level;
- Security for staff and volunteers in the jurisdiction;
- Security of clients in the points of dispensing (PODs); and
- Coordination of traffic management for RSS and POD locations.

Regardless of how the jurisdiction arranges its security, the security manager will be able to work with LEAs to ensure that all security matters are handled quickly and efficiently. Jurisdictions may identify security team leads from state or local law enforcement professionals, private security professionals, or the National Guard.

Receive, Stage, Store (RSS) Lead

The receiving, staging, and storing of medical material is integral to the success of an MCMDD response. Management of RSS activities should fall under the operations function area of the jurisdiction's ICS. The RSS lead should be an individual with experience in warehouse management. Jurisdictions may find it advantageous to partner with or contract professional warehouse managers to fill this position. Based on the size of the management staff, the lead for managing RSS activities also may be the person in charge of the RSS

operations. The MCM team must ensure that the RSS facility is performing the actions needed to receive, store, and process orders for MCM distribution to local jurisdictions. Some states have chosen to establish regional distribution sites (RDS) as part of their distribution strategy. These sites would receive MCMs from the RSS for further breakdown and distribution to pre-determined dispensing sites, such as PODs. RDS leads coordinate with the state's RSS lead, who has overarching responsibility for RSS activities in the state.

Inventory Management Lead

The lead for inventory management activities provides inventory status, including supply, resupply, allocations, and possible shortages to incident command during an incident. The individual in this capacity must have a strong knowledge of inventory management requirements; familiarity with inventory management software; and a working knowledge of the RSS site. Additionally, this position should have the ability to coordinate with distribution partners and have strong knowledge of RSS and product-picking functions. Individuals with the skill set for this position could be professional inventory managers, health department personnel, and pharmacy managers.

Distribution Leader/Manager

Managing distribution activities at the state level involves coordinating transportation of MCMs between RSS and RDS facilities (where applicable), PODs, and hospitals and treatment centers. At the local level, the activities could involve coordinating the distribution between the RDS and PODs and other dispensing sites. Individuals in this position should have a background in transportation; knowledge of shipping and receiving regulations and requirements for the jurisdiction; experience in and knowledge of route development; and be familiar with multiple distribution modalities for the jurisdiction. Partners that may be able to supply individuals with the skill set to serve in this position include state or local departments of transportation, private sector transportation partners, and private sector shipping partners.

Dispensing Supervisor/Lead

Dispensing is the act of directly providing MCMs to those people affected by the incident. Dispensing activities may fall under the operations functional area of the jurisdiction's ICS. The jurisdiction should identify lead and back-up positions for managing dispensing activities. The lead and back-up should have knowledge of jurisdiction's POD plans and alternate methods of dispensing, as well as knowledge of state and local dispensing regulations and laws. During operations, the dispensing lead's responsibilities vary depending on the jurisdictional level. At the state level, the dispensing lead interacts with the dispensing leads in the local jurisdictions' ICS. At the local level, the dispensing lead serves as point of contact for all POD managers in the jurisdiction. Within the POD ICS, the dispensing lead coordinates activities within the POD. Potential candidates may be state or local public health professionals, private medical partners, and pharmacy professionals.

Hospital and Treatment Center Coordinator

Hospitals and treatment centers may have large requirements for a variety of medications, supplies, and medical equipment during an incident. Coordination must exist between incident command, the EOC, and the hospitals and treatment centers within the jurisdiction to procure emergency medical material as needed. Hospitals and treatment centers need to have designated leads or operate under a hospital incident command system (HICS) and to interact with the MCM operations team. The individual in this role must have a good working knowledge of the jurisdiction's overall MCMDD response activities, a background in healthcare, familiarity with healthcare facilities within the jurisdiction, and the ability to foster and maintain relationships with healthcare facilities, hospitals, assisted living facilities, or similar organizations within the jurisdiction. The hospital and treatment center coordinator will facilitate the request process and coordinate MCM distribution to hospitals and treatment centers, as well as identify sites and staffing pools for treatment centers should hospitals be overwhelmed or incapacitated. Possible candidates include public health nurses, hospital professionals, or members of state or local hospital associations.

Public Information and Communication Lead

Public information and communication (PIC) is a key element in MCMDD operations. PIC leads will coordinate information with participating agencies and local media so that clear and consistent messages direct the public to take correct actions to protect their health in an emergency. Public information officers (PIOs) are generally assigned these responsibilities and their activities may be coordinated through a joint information center (JIC).

Including MCM Operations Roles in ICS

As stated in **Chapter 1: Concept of Medical Countermeasure Operations**, the incident command system (ICS)³ is a standardized, on-scene, all-hazards incident management approach that

- Allows for the integration of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure;
- Enables a coordinated response among various jurisdictions and functional agencies, both public and private; and
- Establishes common processes for planning and managing resources.

Public health emergencies, such as an influenza pandemic or a biological emergency, may require extraordinary coordination. Managing the distribution and dispensing of MCMs, including those from the SNS and other sources, may involve multiple jurisdictions, several levels of government, and diverse emergency response agencies. The movement of MCMs from the RSS to PODs in local jurisdictions requires coordinated activities involving government and private sector organizations. Managing these activities will be most effective if all responders use the common core set of concepts, principles, procedures, organizational processes, and terminology of the ICS.

³ www.fema.gov/emergency/nims/IncidentCommandSystem.shtm

ICS enables effective incident management even when the incident involves diverse agencies and response organizations with numerous facilities, a variety of equipment, specialized personnel, organizationally specific procedures, and different communications systems. ICS also enables incident managers to identify the key concerns associated with the incident without diminishing specific attention to any component of the command system.

Government agencies at all levels use ICS to manage incidents. Jurisdictions should manage MCMDD operations under the jurisdiction's established ICS and within its existing functional areas. Using ICS provides the consistency and flexibility needed to facilitate effective incident management.

During MCMDD operations, the jurisdiction should integrate the MCM operations team into its ICS, along with the state or local EOC, to ensure that those who are most familiar with MCMDD operations are available to direct and assist in the response. If activated, the EOC should assign the MCM operations team members to the appropriate sections in the jurisdiction's ICS structure.

The jurisdiction might consider MCMDD operational sites, such as the RSS facility or dispensing sites, as "incident sites" in the ICS structure. The management of operations at these sites should be accomplished under the ICS functional areas and staffed as necessary with qualified personnel functioning under the direction of the area command. In some instances, on-site management of these activities may be accomplished using incident management teams (IMTs) of designated personnel that have trained and operated together for managing a specific MCMDD operational function.

SNS planners at all levels must ensure that the activities associated with the management of MCMDD activities apply the same management characteristics (i.e., common terminology, span of control, etc.) as response plans for other hazards. Plans for the management of MCMDD operations should illustrate how the functional areas assigned the responsibility for managing these activities will be staffed and incorporated into the broader ICS for response to all types of hazards.

The jurisdiction's ICS provides the structure in which the MCM team will operate during an emergency. The plan for managing MCMDD operations should outline where the jurisdiction will place the specific MCM operations roles in its ICS structure during a response. By making these determinations during the planning phase, the MCM operations team will know in advance under which ICS position they will be located, to whom they will report, and where to report during an activation. Figure 3-1 shows the ICS structure with a sample of how the MCM operations team could be placed during a response.

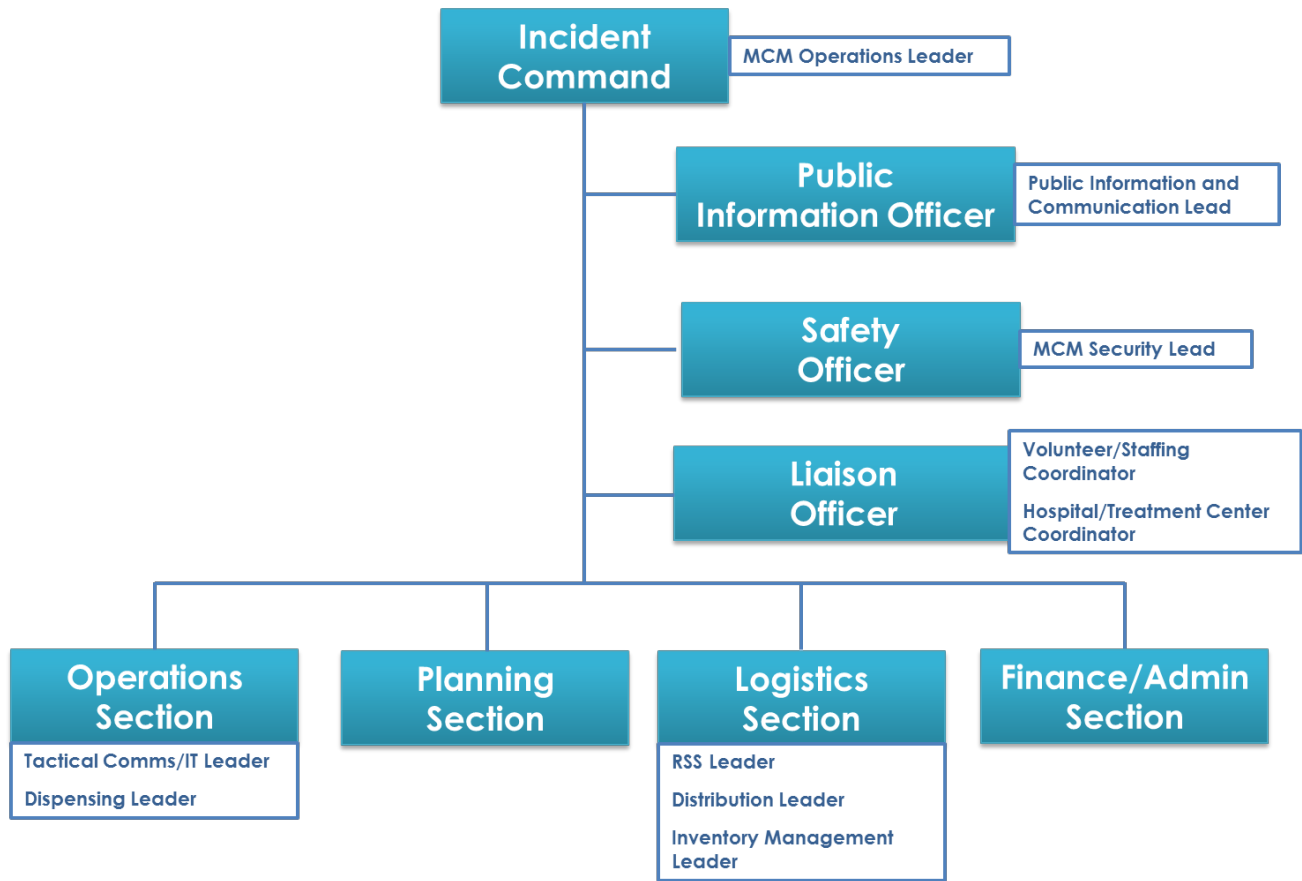


Figure 3-1: MCM Operations Team in the ICS Structure

Determining the Alert Notification Processes

The alert notification process is an important component in MCMDD operations management. Organizing the MCM operations team in the initial hours of a response starts with an activation, which is accomplished using an established alert notification process. If the MCM operations team is integrated into the jurisdiction's ICS, the individuals on the MCM operations team should be incorporated into the notification roster(s) the jurisdiction uses to alert all emergency response personnel. Jurisdictions employ various methods to alert their emergency response personnel; the most common method is by telephone to a listed emergency contact number, but also could include using local Health Alert Networks (HAN).

Quarterly Call-down Drills of Leadership Positions

Conducting quarterly call-down notification drills of leadership positions on the MCM operations team allows for validation of contact information in the system (manual or automated). Call-down drills also provide an opportunity to assess personnel response times by requesting leadership to respond with their availability and estimated time of arrival should they need to report to their response duty location. Responsibility for planning and

conducting routine call-down drills can be a duty for the MCM team lead or the MCM communications/IT lead. The MCM team lead also could coordinate with the jurisdiction's emergency management agency to get the MCM team call-down roster included in any regularly scheduled call-down drills conducted by partner agencies. Routine call-down drills provide an opportunity for members of the MCM operations team to clarify their roles in the EOC or public health EOC and provide added awareness of the role of public health and MCMDD operations within the jurisdiction's emergency management agency.

Exercise Notification and Activation of MCM Operations Staff

Training for individuals in non-leadership positions on the MCM operations team is also an important component of maintaining the MCMDD operations plan. Staff turnover can affect the ability to fill positions within the team with MCM operations staff, so conducting an annual notification and activation drill can allow planners to assess where staffing gaps exist and allow for recruitment of replacement staff. Annual notification and activation of non-leadership staff also allow partners to maintain involvement and provide orientation of newly hired staff into the MCMDD response plan.

Establishing Emergency Operations Capabilities

Because public health officials are responsible for managing numerous activities during MCMDD operations, the jurisdiction may decide to activate a public health emergency operations center (PH EOC), or equivalent organization, as part of the area command along with the state or local EOC. If activated, the PH EOC should ensure that liaisons are assigned to the state or local EOCs, where resource requests, law enforcement support, unified jurisdictional messaging, and other important response elements will be coordinated as part of the area command.

Dispensing or vaccination sites (e.g., PODs), and other MCMDD-related operations sites, such as the RSS or RDS, might be considered "incident sites." The management of activities at these sites should be accomplished under ICS functional areas and staffed as necessary with qualified personnel who operate under the direction of the area command. As previously mentioned, on-site management of specific MCMDD operations activities may be accomplished using IMTs of designated personnel that have trained and operated together specifically for the purpose of managing a specific function.

Assignment of an IMT is generally dependent upon the size and nature of the MCM distribution or dispensing activity. For example, a POD in which people walk through the steps required to receive MCMs would require different resources and corresponding supervision than a drive-through POD, even if some of the steps are the same. Consequently, the organization of these activities would be scaled to meet the site's specific requirements. Figure 3-2 shows how POD staff might be aligned according to ICS, with the POD considered as an incident site.

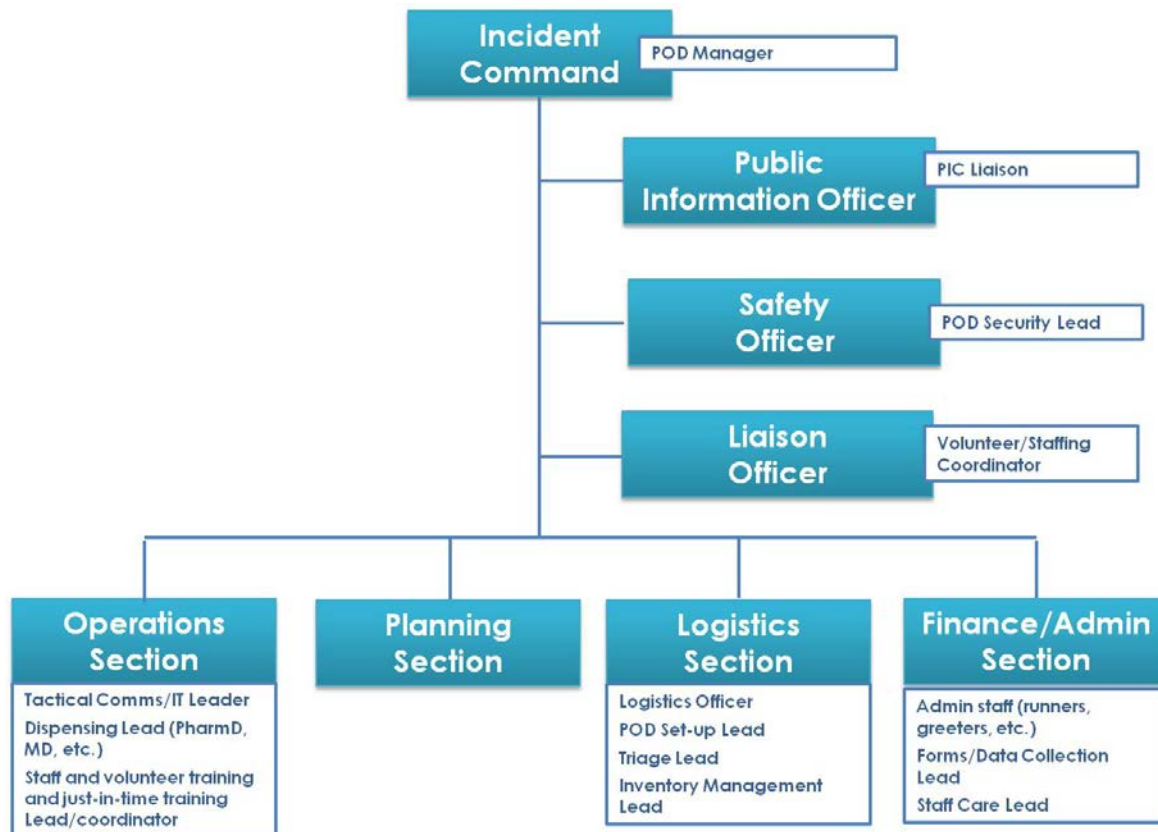


Figure 3-2: Sample ICS for POD as an incident site

Managing Medical Countermeasure Operations

A jurisdiction's ability to respond effectively to an incident that requires MCMs will depend in large part on the ability to manage MCMDD operations with a timeframe that includes the recognition of a declared public health emergency or other incident all the way through recovery operations. The response effort can be broken down into three phases: initial, sustained, and recovery. Recognizing that during large-scale emergencies, these phases may extend over days, weeks, or even longer, planners can develop comprehensive MCMDD operations plans that span the response activities required during each phase of a response.

During the initial phase of the response, critical activities of the MCM operations team include but are not limited to

- Alerting and activating response personnel;
- Staffing activities involved in the response (e.g., EOC, RSS, PODs, etc.);
- Establishing lines of communication between command management and all MCMDD operations units;

- Coordinating between command management and partner agencies/organizations, including both government and non-government entities;
- Developing and providing incident-specific public information;
- Coordinating integration and management of volunteer personnel and staff; and
- Providing MCMs to responders and their family members.

The jurisdiction can best sustain MCMDD activities during the response through continuous situation assessments; rotation of personnel; reordering of MCMs, supplies, and equipment; and other actions according to the guidance and directions outlined in the MCMDD plan. The critical activities of the MCM operations team during this phase include, but are not limited to

- Augmenting personnel and resources from outside agencies supporting the response (federal, state, local, and private sector);
- Addressing issues related to the safety and welfare of staff and volunteers;
- Ensuring the continued dissemination of timely and accurate information to the public and the public health responder force;
- Monitoring usage of MCMs, medical supplies, and equipment, and ensuring timely replenishment;
- Maintaining lines of communication between command management and other MCMDD activities managers (e.g., RSS manager, volunteer managers, POD managers);
- Providing security for MCMDD activities in accordance with established policies; and
- Maintaining partnerships and agreements with both government and private sector support agencies for use of facilities and other resources.

Once the incident has been contained, the MCM operations team plays a significant role in recovery activities. Much of the coordination needed to carry out recovery activities may begin well before entering the recovery phase of the response. It is important for planners at all levels to understand that actions during the initial and sustained phases of the response can affect the speed and effectiveness of the recovery. For example, the detailed agreements between public health and the owners of facilities used during the response (e.g., POD or RSS sites) can ensure those facilities are restored according to expectation during the recovery phase. In addition, accurate information reported by POD staff to public health leadership can ensure effective follow-up of exposed people. The critical activities of the MCM operations team during this phase include, but are not limited to

- Coordinating deactivation of MCMDD operations, such as RSS and dispensing activities, through the jurisdiction's EOC;
- Conducting inventory of MCMs, supplies, and equipment;
- Securing any records generated during the response;
- Coordinating transition of management of facilities used during the response back to facility owners; and
- Coordinating demobilization of resources with federal, state, and private organizations deployed to support the affected jurisdiction.

Involving CDC Personnel in the Response

In some instances, the Centers for Disease Control and Prevention (CDC) may deploy SNS technical teams to assist in a response, if requested. These teams – Stockpile Services Advance Group (SSAG), RSS Task Force, and Federal Medical Station (FMS) Strike Team – are described in **Strategic National Stockpile Organization and Formulary** at the beginning of this guide. Each team consists of specialized responders who can assist the jurisdiction during the response. These teams are designed to fit into the jurisdictional ICS structure and answer questions concerning SNS assets, requesting additional assets, and coordinating SNS response activities during a public health emergency.

In addition, CDC personnel will be involved in the response at the federal level through the DSNS Team Room located in CDC's EOC. The DSNS Team Room coordinates deployment of SNS assets and personnel and communicates with the state's or jurisdiction's SNS coordinator. The DSNS Team Room also coordinates with CDC's EOC and the Department of Human Services (HHS) Secretary's Operations Center (SOC),⁴ as well as other federal agencies. In addition, CDC likely will deploy personnel to the federal Incident Response Coordination Team (IRCT).

Maintaining Medical Countermeasure Management Capabilities

Collaboration among public health agencies, emergency management, law enforcement, the healthcare community, and other key partners and stakeholders is essential to maintaining the infrastructure that will support MCMDD operations and response efforts. Maintaining relationships with partners is one of the primary responsibilities of the jurisdiction's MCM operations team lead. To assist in maintaining the vital relationships required for successful MCMDD operations, the MCM operations management lead can plan and conduct regular meetings, workshops, training opportunities, and exercises.

Conducting training and exercises with the individuals identified to fill roles in the MCM operations team is an important part of maintaining capabilities. By following a prescribed exercise and training program developed in accordance with the Homeland Security Exercise and Evaluation Program (HSEEP),⁵ members of the MCM operations team can solidify their roles and become firmly integrated into the jurisdiction's ICS structure. **Chapter 13: Training, Exercising, and Evaluating Plans** provides guidance on developing and managing a training, exercising, and evaluation program. However, it is worth noting here three important reasons to provide a strong training and exercise program for the MCM operations team:

- 1) **Develop familiarity:** Exercising and training allows individuals who will work together during an emergency to develop familiarity with others on the MCM team. This familiarity will help individuals understand their roles and how these roles fit into the response.

⁴ www.phe.gov/Preparedness/responders/soc/Pages/default.aspx

⁵ https://hseep.dhs.gov/pages/1001_HSEEP7.aspx

- 2) **Build capacity:** Exercising and training allows individuals and teams to be prepared to respond, transforms an identified need or function within the written plan into a measureable capability, and determines whether additional capacity is needed by the team.
- 3) **Solidify plans:** Exercising and training allows MCM operations plans to evolve based on lessons learned prior to a response. These lessons can increase the team's planning efforts and solidify plans before the jurisdiction activates MCM operations.

Chapter 4: Requesting Strategic National Stockpile Assets

State, local, tribal, and territorial (SLTT) governments will be the closest to an incident and therefore will have the lead role in response operations. State governments will play a key role in supporting their localities and coordinating resources and capabilities throughout the state. If a state or territory anticipates that its resources may be overwhelmed during an incident, the state may choose to request assistance from other states using an Emergency Management Assistance Compact (EMAC) or other agreement; or alternatively, the governor or other authorized official can request assistance from the federal government. In the case of a large-scale public health emergency, the state may determine that it needs additional medical countermeasures (MCMs) to assist in response efforts. MCMs may include medications, medical supplies, equipment, or other capabilities and in some cases the Strategic National Stockpile (SNS) may be the best or only source for MCMs. The all-hazards plans developed by SLTT officials should have clearly defined processes for requesting assistance, including processes for how both public sector and private sector partners gain access to MCMs and other assets during a large-scale public health emergency.

Determining When to Request Federal Assistance

The Department of Homeland Security (DHS) developed the National Response Framework (NRF)¹ as a guide for how the nation conducts all-hazards responses. The NRF emphasizes a coordinated federal response requiring layers of mutually supporting capabilities. SLTT governments develop functional capabilities and identify resources required to respond to public health emergencies, including those of catastrophic proportions, such as technological or natural disasters, large-scale disease outbreaks, or terrorist attacks involving chemical, biological, radiological, nuclear, or high-yield explosive (CRBNE) weapons.

SLTT health officials may become aware of a public health concern before they fully recognize it as a public health emergency (PHE). As the situation evolves, state, local, regional, and federal public health officials, including the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and response (ASPR)² and

¹ www.fema.gov/emergency/nrf

² www.phe.gov/about/aspr/Pages/default.aspx

the Centers for Disease Control and Prevention (CDC), will use existing health information systems to share data and analyses. SLTT public health officials should request required federal assistance during the early stages of a PHE to maximize the amount of time available to provide MCMs to the endangered population. In scenarios other than isolated or small-scale incidents, the federal government will take actions, such as issuing a PHE declaration, national emergency declaration, or a presidential declaration of emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act).³ In such incidents, when state and territorial health officials request federal assistance the federal government may direct CDC to deploy SNS assets as part of a coordinated federal response.

Federal public health and medical assistance is available under Emergency Support Function 8 – Public Health and Medical Services Annex (ESF 8)⁴ of the NRF. Since the Pandemic and All-Hazards Preparedness Act (PAHPA)⁵ was signed into law in 2006, federal public health preparedness, response, and recovery activities have been led by HHS/ASPR. The Public Health Service (PHS) Act⁶ forms the foundation of HHS' legal authority for responding to public health emergencies. The PHS Act authorizes the HHS Secretary to

- Lead all federal public health and medical responses to public health emergencies and incidents covered by the NRF;
- Direct the U.S. PHS and other components of the department to respond to a public health emergency;
- Declare a PHE and take such actions as may be appropriate to respond to the PHE consistent with existing authorities;
- Assist states in meeting health emergencies;
- Control communicable diseases;
- Maintain the SNS;
- Provide for the operation of the National Disaster Medical System (NDMS);⁷
- Establish and maintain a Medical Reserve Corps;⁸ and
- To potentially provide targeted immunity for covered countermeasures to manufacturers, distributors, certain classes of people involved in the administration of a program to deliver covered treatments to patients, and their employees.

The PHS Act recently was amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013.⁹

During an incident, SLTT governments may request assistance from the federal government when response efforts challenge or exceed the medical or public health capabilities of the

³ www.fema.gov/about/stafact.shtm

⁴ www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf

⁵ www.phe.gov/preparedness/legal/pahpa/pages/default.aspx

⁶ www.phe.gov/Preparedness/planning/authority/Pages/default.asp

⁷ www.phe.gov/preparedness/responders/ndms/Pages/default.aspx

⁸ www.medicalreservecorps.gov

⁹ www.phe.gov/Preparedness/legal/pahpa/Pages/pahpra.aspx

jurisdiction. During the response, state and local officials will evaluate the capabilities of the jurisdiction's response agencies and the governor or other authorized official may or may not declare a state of emergency. If state officials determine that they lack sufficient capabilities or resources to carry out an effective response, the governor or other authorized official can submit a request for federal assistance. The Stafford Act provides the statutory authority for most federal disaster response activities. By working through the Federal Emergency Management Agency (FEMA) regional administrator,¹⁰ the governor or other authorized official can submit a request to the president for a disaster declaration. This request should outline the incident and certify that combined jurisdictional resources are insufficient to respond effectively. The president will then make the decision whether or not to declare a major disaster or emergency.

In most cases, jurisdictions must make a formal request; however, the federal government may deploy assets without a Stafford Act declaration. For instance, under an HHS Secretary's declared PHE, HHS can assist states in preventing and controlling disease outbreaks by providing personnel, equipment, medical supplies, and other resources from agencies that fall under the HHS Secretary's authority, such as CDC and the U.S. PHS. The HHS Secretary also may activate the NDMS and deploy SNS assets without a PHE declaration. In addition, authorized SLTT public health officials can submit a request to HHS for assistance in the absence of a Stafford Act declaration by working through the HHS ASPR Regional Emergency Coordinators (RECs).¹¹

Requesting Federal Assistance

If the state cannot meet the needs of a local jurisdiction during an incident, officials may arrange support from another state or through assistance agreements, such as the Emergency Management Assistance Compact (EMAC).¹² If additional resources and/or capabilities are required beyond those available through interstate agreements, the governor or other authorized official may ask for federal assistance. Prior to requesting assistance, SLTT officials should assess and clearly identify capability shortfalls, such as depleted supplies of MCMs. The request for assistance should then accurately communicate those shortfalls and the jurisdiction's requirements. **The distinguishing factor in determining how the state should route the request for federal assistance is established by the presence or absence of a federal disaster declaration for the incident.**

Request Process for Presidentially Declared Emergencies or Major Disasters

Once SLTT health officials recognize a public health emergency may overwhelm local, regional, and state pharmaceutical and medical material response assets, they should recommend that the governor, the governor's designee, or other health official request federal assistance through DHS/FEMA using the following process.

¹⁰ www.fema.gov/regional-operations

¹¹ www.phe.gov/Preparedness/responders/rec/Pages/contacts.aspx

¹² www.emacweb.org

State or territorial health officials should submit requests through their respective emergency management agency to DHS/FEMA per the established mission assignment request process during a declared federal disaster. During such federally declared disasters, all requests for assets should follow the prescribed request process as defined by DHS/FEMA in 44 Code of Federal Regulations (CFR).¹³ In that request process, the state or territory completes an action request form (ARF) that describes the federal assistance and capability required. This process is done at the state emergency operations center (SEOC) in conjunction with the DHS/FEMA regional response coordination center (RRCC) or a joint field office (JFO), if established, and submitted to DHS/FEMA. An HHS regional emergency coordinator (REC) may be located at the SEOC or the JFO or remotely available to assist the state or territory with the request process.

Upon submission of the ARF, DHS/FEMA may then direct HHS, through the mission assignment process, to provide the appropriate assistance. HHS will analyze the request and determine which operating division is best suited to fill the request and direct the deployment of assets. In some instances, HHS may determine that the best option is to purchase the assets directly from the vendor; in which case, the vendor would ship the assets directly to the SLTT and would not involve CDC. Figure 4-1 demonstrates this request process.

¹³ http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title44/44cfr206_main_02.tpl

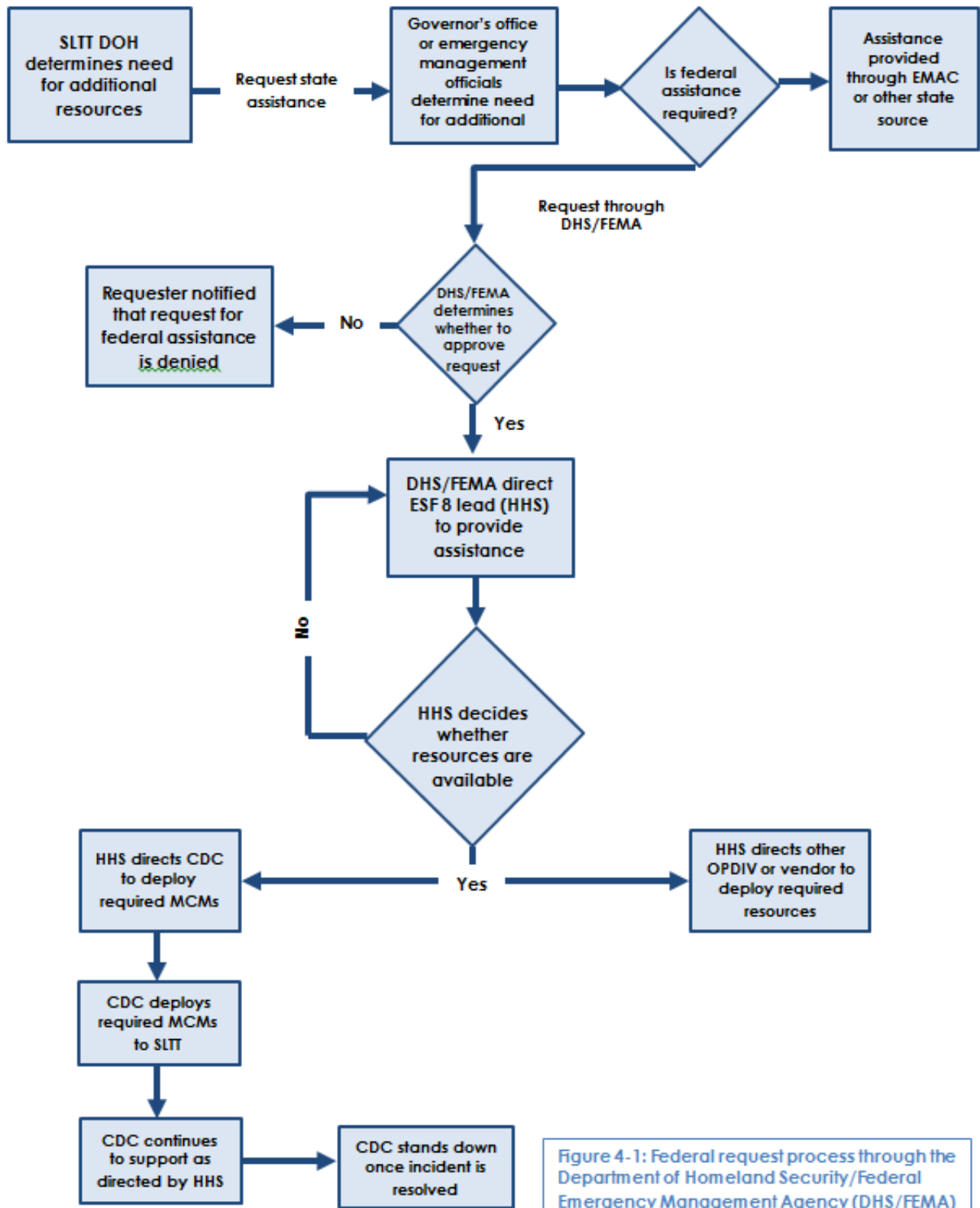


Figure 4-1: Federal request process through the Department of Homeland Security/Federal Emergency Management Agency (DHS/FEMA)

Request Process in the Absence of a Presidentially Declared Emergency or Major Disaster

In the absence of a federal disaster declaration, once SLTT health officials recognize a public health emergency may overwhelm local, regional, and state pharmaceutical and medical material response assets, they should recommend that the governor, the designated health official, or other designee request MCMs by calling CDC's emergency operations center (EOC) at **770-488-7100** or by working through their HHS ASPR REC.

In support of this request process, representatives from ASPR's regional and headquarters offices and CDC's Division of Strategic National Stockpile (DSNS) and Division of State and Local Readiness (DSLRL) will hold a conference call with the requesting SLTT officials to discuss the request and the specific situation. DHS also may be on the call, especially if the incident involves a known or suspected intentional release of a biological agent. During this conference call, participants will determine if federal assistance is required. HHS will analyze the request and determine which of its operating divisions is best suited to fill the request and direct the deployment of assets. In some instances, HHS may determine that the best option is to purchase the assets directly from the vendor; in which case, the vendor would ship the assets directly to the SLTT and would not involve SNS assets. Figure 4-2 demonstrates this request process.

During suspected incidents, isolated, individual, or time-critical emergencies, SLTT health officials can request MCMs by contacting the CDC Emergency Operations Center at 770-488-7100 or by working through their HHS ASPR REC.

Request Process for Isolated, Individual, or Time-critical Cases

During a suspected, isolated, minor, or time-critical incident, such as a single patient with botulism or an adverse reaction to smallpox or anthrax vaccine, health officials may request MCMs from the SNS by calling CDC's emergency operations center (EOC) at **770-488-7100**. In these instances, the request may come from an Epidemic Intelligence Service (EIS) officer in the field, HHS REC, a clinician, or a state or local health officer.

Once the request is initiated, CDC's EOC will quickly arrange a telephone conference call between the requesting representative(s) and the appropriate CDC clinicians and subject matter experts (SMEs). The purpose of this conference call is to collaborate with the clinicians to evaluate the request by assessing the detailed information related to the request, such as the patient's condition, urgency of the need for MCMs, and location to which MCMs will be delivered (e.g., hospital, pharmacy, or treatment facility) if the request is approved. Based on the recommendation of SMEs, the CDC Director or his/her designee can authorize the deployment of SNS assets. In many small-scale or single-patient requests, the DSNS Director is the CDC Director's designee for deploying SNS assets. Figure 4-3 illustrates the process for requesting assistance directly from CDC.

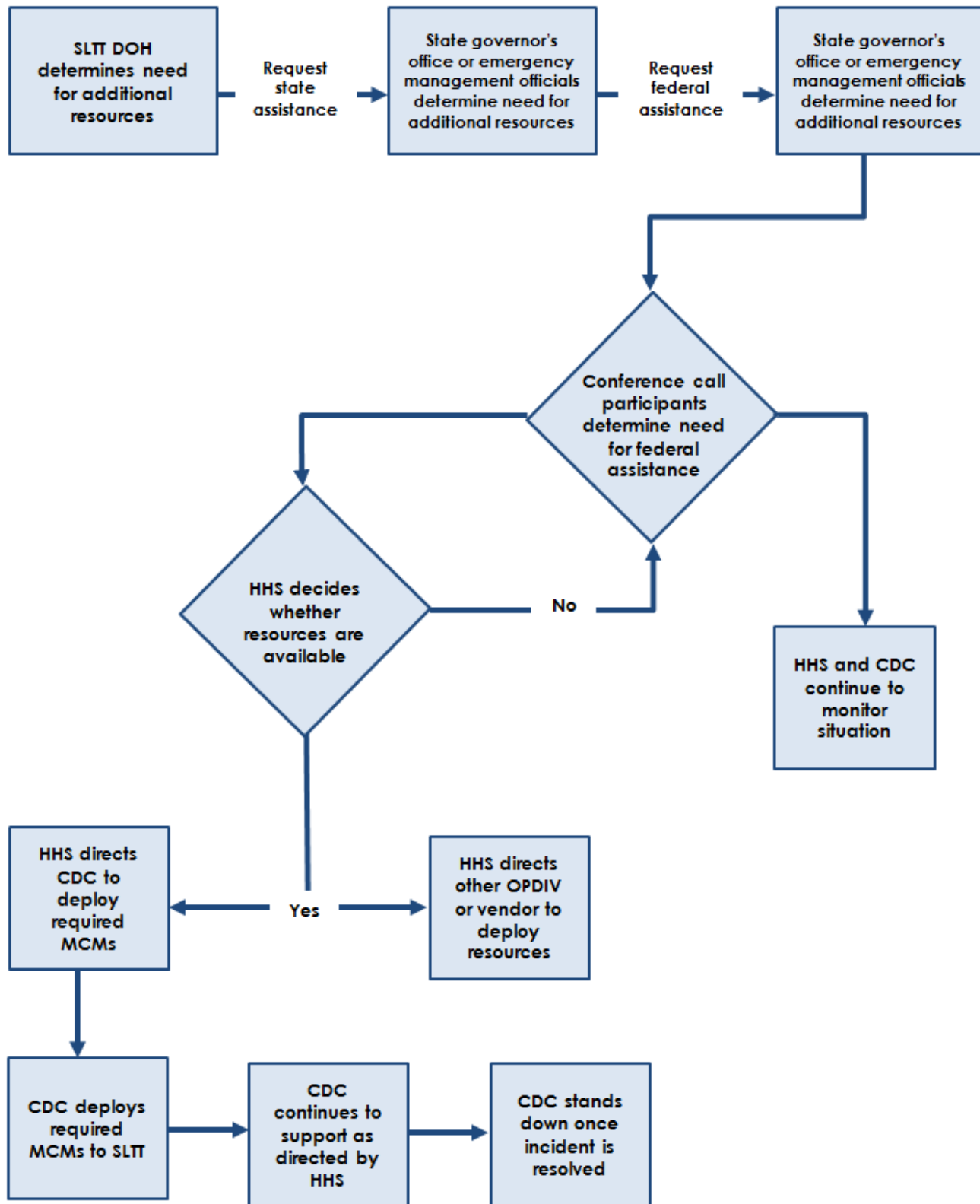


Figure 4-2: Federal request process through the CDC Emergency Operations Center (EOC)

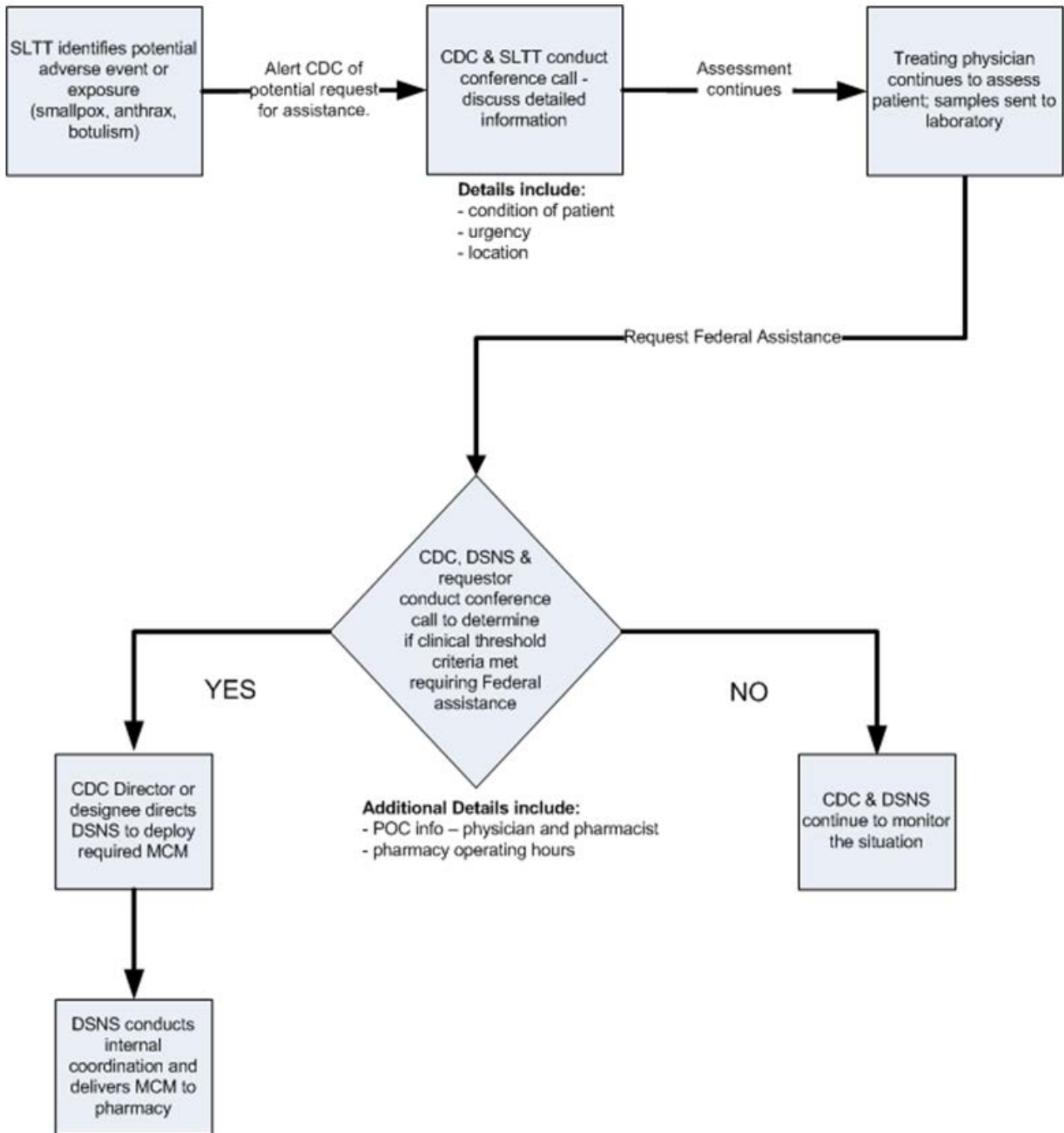


Figure 4-3: Request process for isolated, small-scale incidents.

Coordination with Tribal Governments

According to the NRF, federally recognized tribal governments can request SNS assets directly. However, CDC has been working to foster relationships in which tribal governments partner with state and local health departments to obtain the needed medications and assistance during an MCM response. Many tribes will find they can receive services and supplies from state and local governments much quicker than from federal sources because of their proximity to these entities.

State and local planners should work with American Indian/Alaska Native (AI/AN) governments and communities, as well as the Indian Health Service (IHS), to plan how to request, receive, distribute, and dispense SNS assets during a public health emergency.

CDC has worked with AI/AN governments to encourage tribal leadership to

- Designate a lead tribal liaison with the authority to speak on behalf of the tribe to help coordinate interagency responses and negotiate agreements with other state and local partners;
- Identify roles and responsibilities for people involved in emergency planning and response;
- Develop plans, procedures, and guidelines consistent with neighboring community agencies;
- Define what public health resources exist in the community and determine what support will be needed from sources outside the community;
- Identify at-risk or vulnerable community members who may have special needs during a public health emergency;
- Create mutual aid agreements that help with the exchange of resources and information between agencies during emergencies; and
- Exercise MCM distribution and dispensing responses and other all-hazards plans.

Deploying Strategic National Stockpile Assets

SNS assets can be deployed with or without a federal emergency or federal disaster declaration. The federal government may direct CDC to deploy SNS assets prior to receiving a state's request or prior to a federal emergency or disaster declaration, PHE, or an important event. HHS APSR also may direct CDC to deploy SNS assets prior to the president initiating a coordinated federal response under any of the following:

- **A credible threat exists, or a catastrophic incident or attack is imminent.** This federal decision to deploy can occur during certain incidents or threats, such as smallpox, a pandemic influenza outbreak, or in anticipation of a major storm or natural hazard.
- **A state makes a request for assistance.** CDC may deploy SNS assets based on a state's request for assistance if the state or a local jurisdiction identifies a potential or actual situation that may exceed their capabilities.
- **A clinician's request for assistance.** When the health of an individual is at risk, CDC may deploy assets based on a hospital clinician's request for products with no or limited commercial availability such as vaccinia immune globulin (VIG) and antitoxins or other specialized assets maintained in the SNS formulary.

National Special Security Event (NSSE)

The federal government may direct CDC to deploy SNS assets in support of a national security special event (NSSE). A NSSE is an event of national or international significance determined by DHS to be a potential target for terrorist or other criminal activity. These events have included national political conventions and presidential inaugurations. This directive may or may not be the result of a state's request. However, in some instances, a state will conduct a gap analysis to determine existing capabilities and the need for additional stand-by capabilities based on the threat analysis and estimated increase in population size due to the special event. If the state determines capability gaps exist, the governor or other authorized official may request support from the federal government to augment state or local resources.

Isolated or Small-scale Incidents

Isolated or small-scale incidents may occur that require CDC to deploy specific MCMs. In most small-scale or isolated incidents in which CDC deploys assets, SNS is the single source for necessary MCMs; for example, when a patient presents to a local hospital with a severe adverse reaction to a smallpox vaccine. The hospital clinician may contact CDC directly asking for assistance or go through local and state health officials to request MCMs directly from CDC. After consultation with CDC disease experts, the CDC Director or his/her designee has the authority to deploy the appropriate MCMs from the SNS. CDC experts also may help link the clinicians with other federal resources, such as the Oak Ridge Institute for Science and Education's Radiological Incident Management Consultation Group¹⁴ for medications specific to treating exposure to high levels of radiation or internal contamination with radioactive materials and, when these products are not available commercially, with the appropriate pharmaceutical manufacturer.

Developing the Request Plan

All jurisdictions should develop plans for the request process, which includes how the request goes from a local jurisdiction to the state or from the state to the federal government. SLTT planners should consult with their DSLR project officers and ASPR RECs for guidance in the development of plans for requests to the federal government. Plans also should include the process that dispensing sites, including alternate dispensing sites and other organizations (such as businesses, universities, hospitals, military installations, and other federal agencies) will use to request the MCMs they need to provide prophylaxis to their constituents. In addition, the request plan should include the process for points of dispensing (PODs), vaccination sites, and other dispensing sites to request additional assets from the local jurisdiction. The plan for requesting SNS assets can be included in the state's plan for requesting federal assistance or in the local jurisdiction's plan for requesting state assistance.

¹⁴ <http://orise.orau.gov/reacts/capabilities/radiological-incident-medical-consultation/default.aspx>

The Request Process

SLTT SNS planners should adhere to the request processes established in the jurisdiction's all-hazards plans and ensure that request processes unique to a public health incident have been established and integrated into their plans. When developing the request process for public health emergencies, SLTT planners also should collaborate with their respective emergency management agencies to determine the process for making formal requests for assistance. The process will require different steps depending on whether the jurisdiction is a city, county, region, territory, or state. Planners should be certain to include private sector partners in the request process, as well. Hospitals, clinics, and other medical treatment facilities may be the entities responsible for dispensing or administering MCMs and should be aware of how to request MCMs from the state or local jurisdiction, depending on the state's plans to support hospitals and treatment facilities. Planners and partnering organizations at all levels should be familiar with the process their jurisdiction will use to request assistance. In addition, it can be useful for planners to be familiar with the process for requesting assistance through the next tier of government so they can ensure that the initial request includes all information required for a request to be approved at the next tier.

State or territorial officials should assist planners in the local jurisdictions to create plans for requesting assistance that seamlessly coordinate with their respective plans. At the local level, the request plans should include

- The detailed process for how local jurisdictions will notify the state of the possibility that a request for state or federal assistance may be needed;
- The jurisdiction's justification process, which should mirror the state's process;
- Personnel (i.e., positions) at the local level who can request assets;
- Any forms that will be required to make the request;
- How tribal nations will request local, state, or SNS assets if they are not already working directly with state officials;
- The process for the jurisdiction's federal and private-sector partners (such as military installations, hospitals, closed POD sites, and alternate dispensing site partners) to request MCMs;
- Personnel (i.e., positions) at the state or territorial level to whom the request is forwarded;
- An annex containing the names and contact information for personnel in the request process; and
- How people at the local level, including POD managers, private-sector points of contact, hospitals, and other partners, will be informed, trained, and exercised on the request process.

To create a request process the state planners need to determine

- Which official can determine that a request for federal assistance or SNS assets should be made;
- How the request will be forwarded to the governor's office;
- What paperwork will be required to make the request;
- What information is required to justify a request for federal assistance;
- To whom at the governor's office the request should be sent; and
- How to train and exercise people on the request process.

The plans should include instructions or templates for justifying the state's request for federal assistance, including the request process for federal assistance in the absence of a federal emergency declaration. The justification should provide fact-based observations indicative of a significant public health threat or incident that would justify deploying federal assistance, such as

- A clear, concise description of the situation;
- Results of specimen testing, if any;
- Actions already taken or decisions that have been made at the jurisdictional level;
- Any mitigation measures that have been taken by the jurisdiction or state;
- An assessment of available state and local response assets; and
- A clear description of the capabilities needed to support the response.

The Written Plan

After determining the formal request process, planners should document the plan and ensure that it includes

- A signed copy of the memorandum of agreement between CDC and the jurisdiction (at the state or territorial level);
- A written process for key officials (jurisdictional leadership, SNS coordinator, public health emergency preparedness [PHEP] director, laboratory director, SLTT health officer, or governor's office, etc.) to communicate with one another regarding decisions to request assistance;
- A detailed outline of the request process, including to which organizations and personnel at those organizations requests are directed;
- Justification outlines for requesting MCMs;
- Personnel within the jurisdiction who are authorized to make the request (e.g., the state health officer may be the official in the public health office who sends the request to the governor's office);
- Personnel at the various levels through which the initial request must go (e.g., the local jurisdiction may forward their request to the state health officer or state public health director);
- Names and contact information for specific personnel filling the roles in the request process (to avoid revisions in the plan due to staff-turnover, this should be included in an annex that is reviewed, updated, and revised on a regular basis, at least annually);
- Written procedures for treatment facilities (such as hospitals) to request MCMs;
- Written procedures for requesting state-owned or state-managed assets, such as MCMs from CHEMPACK (for incidents involving chemical exposure) or previously placed diethylenetriamine pentaacetic acid (DTPA) (for treatment of people internally contaminated with specific radioactive materials);
- Written procedures for requesting additional or follow-on supplies; and
- Written procedures for dispensing sites (including closed PODs or treatment centers that might require MCMs) to request additional materials (at the local level).

Activating an SNS Response

Once a request is approved and HHS directs CDC to deploy SNS assets, DSNS will activate the DSNS Team Room, a section of the CDC EOC through which DSNS manages

deployments and incident responses. Personnel in the DSNS Team Room will coordinate through the designated CDC assignees (e.g., Division of State and Local Readiness [DSLRL] project officer) for the affected area and maintain contact with the state/tribal EOC or the state SNS coordinator to obtain situational information and provide the most appropriate and effective response. This coordination will help to

- Verify points of contact for SNS deployment, including the state SNS coordinator, the address of the receipt, stage, store (RSS) site, and the contact information for the RSS facility manager;
- Determine the location and any specific information about, or changes in, the state's preferred RSS facility;
- Assure that appropriate security is in place;
- Provide information on state policies and decisions concerning the use of MCMs, including any treatment or prophylactic regimens;
- Define the affected population;
- Determine the need for any media announcements, press releases, risk communications, or health alerts; and
- Discuss SNS asset transportation plans (from RSS to PODs).

Because the situation will likely be dynamic and information about the emergency will continuously develop and change, DSNS Team Room staff will seek updated information about the incident as assets are delivered to the affected jurisdiction. Consequently, state officials should be prepared to respond to queries regarding

- The status of critical resources or whether any additional resource shortfalls have become apparent;
- The status of critical facilities and distribution systems (e.g., operations centers or the RSS facility), including changes in locations, providers, or processes based on the evolving incident response;
- Significant changes in the status of the disaster or emergency, such as any change in the agent or any change in the known boundaries of the hazard;
- The need or rationale behind requesting items that are not part of the SNS;
- The agent involved in the incident and whether it has been identified;
- Whether a follow-on attack (in the case of suspected or known terrorism) has occurred or is suspected to occur;
- The safety and security of pre-identified RSS facilities, distribution routes, or surrounding areas;
- Hazards that may impede movement of federal personnel or assets;
- Any possible disruptions in connectivity between the affected area and federal personnel on the ground or in the DSNS Team Room; and
- Any obstacles that may exist between SNS-asset sites and the RSS facility.

Staff in the DSNS Team Room will continuously monitor and update CDC officials of the incident and the management and movement of SNS assets. DSNS Team Room staff also will maintain contact with personnel in the affected state to ensure that materials arrive, that SNS assets match the inventory list provided with the shipment, and whether and when the jurisdiction will request additional follow-on assets.

Requesting Additional Assets

If SLTTs require additional assets for response operations, health officials can request further assistance through the emergency management process or collaborate with the HHS REC responding to the incident for guidance on the request process. The level of federal response will determine the avenues used to request additional assets. For example, if there is a declared federal disaster, DHS/FEMA will establish an ESF 8 section responsible for public health and medical services at the state EOC, RRCC, or the JFO. The JFO would task HHS to provide the additional support and HHS would then direct CDC to deploy additional SNS assets or look for more efficient ways to provide follow-on material. To fulfill local and regional requirements for additional resources, local and regional managers must work with the state to determine methods and procedures for reordering materials and exchanging information.

Planners should be aware that during some incidents, MCMs may be available in limited supplies and may be available only on a pro rata basis. In such incidents, CDC will require additional data to justify release of further MCMs. CDC SMEs may require additional data from SLTT officials, which they will need to supply through the DSNS Team Room and other communication portals. Such additional data may include the number of people in the priority population who have received MCMs, the amount of MCMs on hand in the jurisdiction, and any relevant surveillance data. SLTT officials will provide data proactively to CDC through the SNS Inventory Management and Tracking System (IMATS). Further information on IMATS is available in **Chapter 6: Managing Medical Countermeasure Inventory**.

During an incident, state or territorial SNS coordinators can obtain guidance on the incident-specific process for requesting follow-on material by contacting the DSNS Team Room or CDC EOC. In addition, if SNS assistance teams are deployed (e.g., Stockpile Services Advance Group [SSAG] or RSS Task Force), they will work with state and federal partners to request additional assets from the federal government. To fulfill local and regional requirements for additional resources, local and regional managers must work with the state to determine methods and procedures for reordering materials and exchanging information. Again, to ensure complete coordination, all involved parties should be kept apprised of replenishment activities.

As is the case in all MCM planning, the process and procedure for requesting additional assets should be documented in the plan and shared with all participating partners at each jurisdictional level. It can be useful for the state to provide its local jurisdictions, the RSS site manager, and inventory control lead with a flow chart of the request process with contact names and numbers for agencies in the request process. In addition, local jurisdictions could provide a flow chart of the POD and dispensing site request process, including contact names and numbers, to POD inventory leads and managers, or any other personnel that the jurisdiction designates as a potential requester for additional federal assets.

Chapter 5: Receiving, Staging, and Storing Medical Countermeasures

Receiving, staging, and storing (RSS) functions generally are carried out at the state level, but depending on state, local, tribal, or territorial (SLTT) plans this responsibility also may be carried out in major metropolitan cities or regionally. The RSS facility will act as the hub of the distribution system for the state or jurisdiction to which Strategic National Stockpile (SNS) assets are deployed. As such, the jurisdiction should design and staff the RSS to facilitate rapid and efficient receipt and distribution of medical countermeasures (MCMs) to points of dispensing (PODs), treatment centers, and other locations during an emergency. The number of people to whom the jurisdiction can dispense MCMs, and ultimately the number of lives saved, will depend greatly on the location, staffing, equipment, and type of facilities selected for RSS operations.

Building the RSS Management Team

The RSS management team is responsible for developing the RSS plan, selecting RSS sites, and overseeing RSS operations during a response. The RSS management team should be fully integrated into the overall MCM distribution and dispensing (MCMDD) operations team and coordinated through the jurisdiction's incident command system (ICS),¹ as described in **Chapter 3: Management of Medical Countermeasure Operations**.

Building the RSS management team begins with the RSS lead. Ideally, the person filling the lead position on the RSS management team will be an experienced warehouse manager. The RSS lead typically will be in charge of all RSS operations and may be assisted by a deputy and an administrative assistant. During activation, the RSS management team lead will ensure that the RSS facility is performing the four basic functions of the RSS, which are

- Receiving material;
- Storing material;
- Filling orders (picking) for dispensing and treatment sites; and
- Shipping orders to those sites.

¹ www.fema.gov/emergency/nims/IncidentCommandSystem.shtm

Consequently, during a response, the RSS operations team should consist of leads and personnel for the following:

- RSS operations
- Security
- Inventory control
- Picking/storing
- Quality control
- Shipping/receiving

Each lead in the RSS operations team may have two to eight staff members under them, so planners need to ensure sufficient personnel, training, just-in-time training, and safety equipment for those involved in a response. As in all responses, these functions should be scalable and flexible to meet the needs of the jurisdiction at the time of activation. Table 5.1, located at the end of this chapter, provides a breakdown of the possible RSS roles, responsibilities, and the number of people per team during a full-scale MCM response.

Selecting a Receiving, Staging, and Storing (RSS) Site

As the hub of the jurisdiction's MCM distribution network, the RSS site will be one of the most important considerations in MCM distribution and dispensing (MCMDD) planning. When selecting an RSS site, planners should look for features that will enhance the speed and efficiency of both the receipt and the distribution of MCMs. In addition, planners should select at least one secondary RSS site to serve as a back-up should the primary site become unavailable or inoperable. When selecting RSS sites, planners will need to take into consideration physical locations, key characteristics of prospective sites, and operational equipment needed at each facility.

Some states plan to deliver SNS assets from the RSS to intermediate sites, known as regional distribution sites (RDS), which, in turn, will deliver the assets to local PODs, hospitals, and treatment centers. Depending on the population served, RDS sites may have the same staffing and location criteria as RSS facilities. Plans should include more than one RDS in a given region to ensure redundancy. However, planners should remember that having an RDS adds an additional step into the distribution process, which can significantly affect the time it takes to distribute and dispense MCMs to the affected population.

Facility Location

Since it is impossible to know exactly where incidents will occur, jurisdictions should develop plans for several, widely dispersed RSS sites that can be operational at the time of an incident. The Centers for Disease Control and Prevention (CDC) recommends at least two sites, a primary site and a back-up site, in two different locations to ensure the required redundancy. In addition, CDC encourages states that have large geographic areas to identify multiple RSS sites so that the site closest to the impacted area can receive MCMs at the time of an incident.

Some of the key considerations for determining RSS site locations include:

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- **Environmental conditions:** To mitigate the possibility of the facility being impacted by environmental conditions created by or subsequent to an incident, planners should evaluate potential sites for all weather and environmental conditions, such as fault-lines, floodplains, heat, wind, snow, or rain. Certain locations may increase the chance of encountering problems that could slow or halt RSS operations. For instance, low-lying areas may be at risk of flooding. To select locations least likely to be impacted by hazardous environmental conditions, SNS planners may wish to consult the U.S. Geological Survey earthquake hazards website² and the Federal Emergency Management Agency (FEMA) flood map website.³ In addition, planners can consult with local community planners who know the location of environmental hazards and local meteorologists who know weather patterns that may affect conditions of an RSS site during adverse weather.
 - **Proximity to potentially impacted areas:** Incidents can occur anywhere, however planners should assess the jurisdictions in the state and consider locating RSS sites close to those that could be more prone to incidents. For instance, areas that contain larger or more concentrated populations could be more vulnerable to certain incidents and low-lying areas may be more prone to flooding. Therefore, planners might select RSS facilities located near more susceptible jurisdictions throughout the state to facilitate MCM deliveries to the RSS closest to the impacted area.
 - **Site accessibility for selected distribution methods:** When selecting an RSS facility, planners also must consider the transportation methods (i.e., ground, air, water, rail) the jurisdiction will use for the distribution process. Since trucks probably will be the primary means of transport within the state, planners should select RSS facilities with close proximity and unrestricted access to interstate highways and major thoroughways leading to delivery locations. Other methods of transport will have their own planning considerations. For example, aircraft will need an adjacent space for taking off and landing, water transport will need a pier or dock, and rail will need a sliding or elevated-platform station. To ensure redundancy in traffic and security planning, each RSS and RDS facility should have multiple, secured transportation routes for entry and exit.

Facility Requirements

RSS facilities must be located in sound, secure structures with hard surface floors and adhere to Title 21 Code of Federal Regulations, Part 211 (21CFR211.56).⁴ 21CFR211 pertains to the current good manufacturing practices (cGMP) for pharmaceuticals. In particular, subpart C outlines the requirements for buildings and facilities used to manufacture, process, package, or store pharmaceuticals. 21CFR211.56 states that facilities should be “maintained in a clean and sanitary condition” and “free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed

² <http://earthquake.usgs.gov/hazards/qfaults>

³ www.fema.gov/hazard/map/index.shtm#flood

⁴ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=211.56&SearchTerm=sanitation

of in a timely and sanitary manner.”⁵ The facility also should be free of chemical and mechanical hazards. Other subparts of 21CFR211⁶ provide additional facility requirements and can aid planners in determining suitable RSS sites. In addition, ensuring that RSS sites are properly equipped will significantly reduce the time and effort required to process SNS assets for delivery to dispensing, treatment, and RDS sites. Jurisdictions should consider the following aspects when selecting RSS facilities.

Facility Type: The ideal RSS facility is a functional warehouse or similar structure. However, some jurisdictions choose to use convention centers or sports arenas when these sites are suitable for RSS operations. Any facility identified as an RSS should have multiple loading docks and unobstructed hard surface flooring to allow equipment to move unimpeded. Military facilities are viable options and are authorized by the Department of Defense (DoD) to serve as RSS sites through DoD Directive 6200.3.⁷

Many jurisdictions have identified airplane hangars as RSS sites due to the large floor space. While airplane hangars may provide the necessary floor space, planners need to consider how weather and environmental conditions may affect such facilities, as they may not have the climate-controlled features necessary to meet cGMP as outlined in 21CFR211. In addition, hangars do not have loading docks, so loading and unloading material will take longer and require more forklifts, material handling equipment, and staff. Hangars also have a door tracking mechanism comprised of an elevated steel tracking frame that forms deep ruts in the floor. This tracking frame can create a hazard and make it difficult to roll shipping containers or pallet jacks through the doors. Before selecting an airplane hangar as an RSS facility, planners should carefully consider all of the barriers to using the location, including the hangar door hazard, access to airport facilities, the need to clear traffic from active runways, and the need for employing multiple forklifts and drivers to unload material from and load material onto cargo trucks. In addition, planners should refer to 21CFR211.42⁸ for federal regulations on building design and construction features required for storing pharmaceuticals.

Utility Requirements: During RSS operations, facilities should have adequate power for lights, heating and air conditioning, computers, printers, radios, on-site and portable refrigeration units used to store product, and other electrical equipment. Ideally, the facility will have primary as well as back-up electrical power to ensure the facility’s continued operation should the area experience power failures. Owners of the chosen facility may consider installing generators to assure redundant electrical systems; however, this is not necessary if plans, contracts, or agreements are in place to supply redundant power sources and back-up lighting to the facility during an incident. For instance, planners may work with emergency management to have the RSS site identified as a critical infrastructure, which could make the site a priority for restoring electrical service if a disruption in power occurs while the facility is engaged in RSS operations.

⁵ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=211.56&SearchTerm=sanitation

⁶ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

⁷ www.dtic.mil/whs/directives/corres/pdf/620003p.pdf

⁸ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=211.42&SearchTerm=buildings

Climate Control: The building must be climate controlled or have heating and cooling equipment to maintain a temperature range of 58°– 86° Fahrenheit, the recommend temperature to maintain efficacy of MCMs. The U.S. Pharmacopeia defines this temperature as a “working environment of 20°C to 25°C (68°F – 77°F) that allows for brief deviations between 15°C and 30°C (59°F – 86°F) that are experienced in pharmacies, hospitals, and warehouses.”⁹ All locations that store or dispense MCMs (including the RSS facility, PODs, and hospitals or treatment centers) must maintain this temperature range.

When CDC ships items that require refrigeration, such as vaccines (smallpox vaccine or anthrax adsorbed vaccine) or other biologic products requiring cold chain management, Division of Strategic National Stockpile (DSNS) staff use cold chain packing protocols, temperature monitoring devices, and specialized shipping containers to ensure that the items remain at the proper temperature throughout the packing and shipping processes. CDC ships these items in either an electric/battery back-up refrigeration shipping container (Vaxi-Cool™) or a specialized foam shipping container (Endurotherm™). Planners should be aware that CDC will ship most SNS products requiring cold chain management in Endurotherms™ rather than in Vaxi-Cool™ containers. Endurotherms™ can maintain the required temperature for up to 72 hours without electricity or the need for additional refrigeration; however, RSS facilities should have plans for storing material requiring cold chain management in case the jurisdiction does not dispense the product within the timeframe for which shipping containers can sustain the required storage temperature. See **Appendix E: Cold Chain Management** for further information on the shipment of materials requiring refrigeration.

Security and Safety Features: To ensure security of personnel and MCMs, CDC strongly recommends that the jurisdiction not disclose location of the RSS to anyone other than authorized staff and volunteers. The RSS facility should have controlled and limited access to authorized personnel only. The RSS plan should include an access control system that utilizes staff rosters and/or identification badges. To control access, the facility’s perimeter should be secure with barriers or fencing. If the selected facility does not have an existing secure perimeter, the jurisdiction should develop a plan to move barriers and other security features into place during an incident. **Chapter 11: Securing Assets, Staff, and Operations** provides further information on security planning.

In addition to a secure perimeter, the facility should have locks on windows and doors. Ideally, windows will be protected from shattering, either with shatterproof glass or an external covering, such as iron bars. Planners should work with security partners (e.g., state or local law enforcement) to assess security of any potential RSS sites and determine whether additional security features might be necessary during a response. The facility also should have standard safety features for fire protection, such as extinguishers, sprinklers, smoke detectors, and fire alarms.

Jurisdictions must have further security considerations for receipt of pharmaceuticals classified under Title 21 of the United States Code, Controlled Substance Act. The U.S.

⁹ www.usp.org/about-usp

Department of Justice's Drug Enforcement Administration (DEA)'s Office of Diversion Control strictly monitors distribution and storage of scheduled pharmaceutical.

Parking Area: Ideally, the facility will have a parking area secured by a fence or wall, guards, and closed circuit video monitoring. It also should have adequate parking for all potential personnel needed during a response and for staging trucks for loading and unloading operations.

Loading Docks: RSS facilities with multiple docks will permit more rapid and efficient unloading and loading of trucks. Docks should be 48–50 inches high to accommodate unloading procedures. Dock doors should be 100 inches wide by 14 feet high (8-foot minimum height). In addition, the driveway to the docks must accommodate a 53-foot trailer with an 11-foot tractor, plus a turn radius for vehicles of that length.

DSNS recommends the RSS have five dock doors – two for receiving and three for shipping. Planners will need to determine the appropriate number of dock doors based on the estimated number of orders the RSS will fill and the number of trailers that must rotate through the shipping process. Planners should again look to population numbers to estimate how many docks the jurisdiction needs to accommodate the number of truckloads of material the RSS must ship during a full-scale incident.

Ideally, docks will have automatic dock levelers to bridge the gap between the warehouse floor and an open trailer to facilitate easy loading and unloading of trucks. Warehouses without automatic levelers, but with doors at roughly the height of a trailer, may be able to use dock plates between the warehouse floor and the trailer bed for movement of materials. If the RSS is located in a facility other than an operational warehouse, planners should ensure the facility has doors that are large enough to accommodate SNS12-hour Push Package containers, the largest of which is 43x62x80 inches.

Planners also should be aware that SNS transport trucks do not have lift gates, so the jurisdiction should plan for other means of unloading trucks at facilities without loading docks. For instance, the RSS would need a driveway large enough to accommodate tractor-trailers and have an additional area to unload assets. Without functional loading docks, RSS operations will require multiple forklifts and qualified forklift drivers to unload trucks, position assets in the warehouse, and load trucks distributing materials to PODs and other facilities. Planners should carefully consider how this option could significantly slow operations before selecting such facilities. Depending on the facility's characteristics, the state can purchase commercially available portable ramps to facilitate loading and unloading; however, ramps create an incline that staff must navigate, which risks worker safety.

Material-handling Equipment (MHE): Requirements for MHE (i.e., forklifts and pallet jacks) will vary depending on the type of loading docks available. The RSS management team lead should work with the managers of each facility to develop an inventory of MHE available and a list of materials/supplies that the jurisdiction will need to procure and/or deliver at the time of an incident.

- *Forklifts:* The number of forklifts required will depend on the availability of loading docks at the facility and the amount of material that the area needs (i.e., jurisdictions

with smaller populations may require less material and therefore less MHE). However, planners can assume that they will need four 3,000- to 5,000-pound-capacity forklifts – two for receiving assets and two for staging assets and loading outgoing trucks – and be aware that forklifts with larger than 6,000 pound capacity are not efficient for RSS operations.

- *Pallet jacks*: In general, RSS operations will need a minimum of six pallet jacks – three to support picking material, one for use in the quality control area, and two for staging, loading, and unloading assets onto trucks if forklifts are not available.

Office Space and Equipment: The ideal RSS facility will have separate office space and be equipped with standard office equipment. Because the RSS manager and other staff will need to conduct phone calls and other office duties, planners should locate the office in a secluded area that provides protection from the noisy environment of the warehouse floor.

Staff at each facility should have access to computers and printers for inventory management, printing forms, and communication, if e-mail is available. Basic software should include word processing, spreadsheet, database, and local inventory control and reporting software. RSS staff may require a facsimile machine to transmit orders and information from and to the command center. Planners may find it beneficial to have printers/copiers at both the picking and shipping stations to allow workers to print multiple copies of pick lists or shipping documents. This will be particularly important if the RSS has an automated inventory management system, such as the DSNS-supplied Inventory Management and Tracking System (IMATS). An ideal RSS facility will have at least three phone lines and phones available – two for voice and one for data. The facility also should have local area network, high-speed Internet connection, or wireless Internet connection with WPA2 encryption. RSS managers should take an inventory of office equipment for each RSS site and document any equipment, materials, or supplies that the jurisdiction must deliver or procure at the time of an incident to support operational RSS plans.

Staff Comfort Facilities: The RSS site should include bathroom facilities, drinking water, and break area where staff can eat and rest.

Facility Supplies

Some facilities may provide basic operating supplies, such as MHE and office equipment. When developing the memoranda of agreement or understanding (MOA/MOU) with a facility, SNS planners should clarify their needs by including specific items in the MOA/MOU. If the facility does not supply these items, SNS planners should develop a plan for how to obtain these items and transport them to the RSS at the time of activation.

- **Fuel for forklifts:** Forklifts that run on propane will require a tank of fuel for every 8 to 12 hours of use. Electric forklifts will require battery recharge every 8 to 12 hours and a charging station to supply replacement batteries. CDC does not recommend the use of gasoline-powered units inside a facility because emissions pose a health hazard in an enclosed space. Planners should work with forklift providers to obtain instructions and needed personal-safety supplies for filling tanks and charging batteries.

- **Pallets:** The RSS facility will need empty pallets for staging and distributing SNS materials. To fill orders for PODs, treatment centers, or RDS sites, the RSS team will pick assets (i.e., pull material from the storage area) from 12-hour Push Package containers or pallets of managed inventory (MI) and stack boxes of material onto pallets. They will then move these pallets to the shipping staging area and the shipping team will load completed orders onto delivery vehicles, which will leave pallets of material at delivery sites.

Because distribution drivers may not have time to return the empty pallets from delivery locations to the RSS facility, DSNS recommends that planners establish a contingency contract for 40×48-inch pallets. The contract should initially call for delivery of sufficient pallets at the time of RSS activation and provide for the delivery of additional pallets as required. The number of pallets necessary will vary depending on the scale of incident, the number of shipping locations (i.e., PODs, treatment centers, RDS sites, etc.), and the number of people who receive MCMs at each dispensing site. In addition, the number of pallets necessary will depend on whether the jurisdiction receives MCMs as MI or in a 12-hour Push Package. While the RSS facility is in operation, a team member, such as the inventory management lead, should be responsible for ordering more pallets when supplies run low and ensuring that the facility maintains enough pallets on hand.

A good rule of thumb for determining the number of pallets needed is to keep in mind that one pallet of prophylactic medications (approximately 96 cases) will provide 10-day unit-of-use bottles for 9,600 individuals. By using the jurisdiction's population, planners can calculate how many full pallets the jurisdiction will need to treat that population (further details of this calculation are on page 13 of this chapter).

- **Stretch wrap:** Stretch wrap is similar to the cellophane covering on many commercial products and can be wrapped around a pallet to secure the material for transit. Planners can order stretch wrap from warehouse supply companies. DSNS recommends 20 rolls per RSS facility to begin operations. If the RSS facility does not have an automated wrapping machine (found in professional warehouses), DSNS recommends ordering handles for manually wrapping pallets.
- **Shipping containers:** While CDC recommends shipping in whole cases whenever possible, some jurisdictions will need to split cases of material for smaller shipments. If a jurisdiction anticipates the need to split cases for multiple-facility shipments, planners should address in their RSS plans how they will ship this material. For instance, plans will need to include additional shipping containers (such as small cardboard or plastic boxes), additional packing materials (such as, bubble wrap or foam packing peanuts), and packing tape.
- **Cold chain management supplies:** Depending on the event and the required MCMs, planners should have a ready source or identified supplier of cold chain shipping supplies for vaccines or other biological products that require cold chain handling. Cold chain shipping supplies include polystyrene packing containers, dry ice or gel packs, and a temperature monitoring process. **Appendix E: Cold Chain Management** provides further information.

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- **Work gloves:** Planners should supply enough work gloves with rubber grips to provide each RSS team member with at least one pair per shift. Planners should look for gloves that have grip assists in the palm and are thick enough to protect workers from pallet splinters or sharp edges.
 - **Sturdy footwear:** DSNS recommends steel-toed boots to protect workers' feet. However, some staff or volunteers may not own such boots, in which case workers should be encouraged to wear work boots, hiking boots, or other sturdy closed-toe footwear.
 - **Disposable earplugs:** If the RSS facility utilizes propane-powered forklifts, staff will need ear protection. Planners should supply enough disposable earplugs to provide each forklift operator with at least one fresh pair per shift. If the facility utilizes electric-powered forklifts, workers will not need earplugs as these vehicles are much quieter than the propane-powered models.
 - **First aid kit:** Planners should supply each RSS facility with at least one kit containing basic first aid supplies, such as bandages, pain medication, and eye cleaner. RSS facilities also should have an automated external defibrillator (AED) and at least one staff member trained on its use.
 - **Office supplies:** Planners should ensure enough pens, pencils, paper, bills of lading, file folders, scissors, tape, staplers, staples, toner cartridges, clipboards, and pre-made signage (if pre-made signs are not available, include colored poster board and markers to create signs) for the duration of operations and have a plan for resupply of these materials.

Commercial Warehouse Partners

To simplify the RSS selection process, many jurisdictions turn to commercial partners for the use of facilities, personnel, and resources during an emergency. Most working commercial warehouses meet the criteria for an RSS without requiring modification. Many planners foster partnerships with professional warehouse partners by explaining the importance of the public health mission and offering to provide MCMs to warehouse staff (and possibly their family members) as public health responders during an incident. In addition, jurisdictions find partnering with professional warehouse staff a highly effective way to meet the needs of RSS operations as it relies on the proven capabilities of professional facilities and staff that receive, manage, and ship material every day.

Jurisdictions should look at the commercial warehouses in the preferred geographic locations to determine if they would be willing and available to serve as an RSS facility during an emergency. State SNS coordinators should use the RSS Site Survey¹⁰ to conduct preliminary reviews of all potential locations (including existing commercial warehouses). The

¹⁰ <https://www.orau.gov/snsnet/functions/receiving.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

state SNS coordinator should coordinate with the assigned Division of State and Local Readiness (DSLRL) project officer for follow-up verification of RSS facilities under consideration. Once a facility is selected and verified, planners should draft and have their warehouse partners sign, a memorandum of agreement (MOA), memorandum of understanding (MOU), or formal contract. To clarify the agreed upon arrangements, the MOA/MOU or contract should include potential plans for long-term storage of assets as well as any commercial warehouse personnel the facility will provide during an incident.

Verifying and Reverting RSS Facilities

To assist planners in determining the suitability of RSS facilities, CDC developed the RSS Site Survey.¹¹ CDC encourages planners to use the RSS Site Survey to identify, assess, verify, and revert their facilities. The RSS Site Survey defines the elements available in an optimal RSS site. CDC recognizes that some of the features described in the RSS Site Survey may not be on site, such as cold chain storage supplies or back-up generators, but that plans are in place to provide such equipment at the time of a response. CDC provides the list of features in the RSS Site Survey to assist planners in ensuring the RSS meets the minimal storage conditions (as established in 21CFR211), recognizing the items necessary for RSS operations, determining if the selected RSS location has necessary items on hand, and identifying items the jurisdiction needs to deliver during RSS activation.

Jurisdictions should submit a completed RSS Site Survey for each RSS and RDS (if applicable) to their assigned DSLRL project officer, who will then schedule a site visit with a U.S. Marshal to verify the facility. Planners should submit back-up plans, written agreements, MOUs/MOAs, and other information supporting the RSS verification to the DSLRL project officer before the site visit.

During the site visit, the RSS verification/reversion participants will sign the RSS Site Survey and include their titles and agency names. In addition, if the project officer notes any significant gaps or deficiencies during the review, the project officer and U.S. Marshal will work with the jurisdiction's SNS coordinator to identify a date for a follow-up visit to complete the verification/reversion process. Jurisdictions cannot consider their RSS locations verified or reverted until they receive the signature sheet containing both the DSLRL project officer's and U.S. Marshal senior inspector's signatures.

If the jurisdiction plans on adding or changing an RSS facility location, the addition or change must be coordinated with the DSLRL project officer, who will schedule a verification site visit. Planners should be aware that the DSLRL project officer must revert RSS facilities every three years.

¹¹ <https://www.orau.gov/snsnet/functions/receiving.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC DSLRL project officer.

Determining RSS Space Requirements

The amount of space required for RSS activities can vary greatly between jurisdictions. The size of the facility will depend on the volume of material that the jurisdiction expects to flow through the RSS and this in turn can vary by the population. Determining the space and layout of the RSS facility are important to minimizing the warehouse personnel requirements and time to process MCMs while maximizing the amount of material processed. While previous guidance emphasized planning RSS space allocation and layout for the 12-hour Push Package, CDC has since developed robust contracts with vendors and increased the amount of MI available. Consequently, jurisdictions should expect to receive more SNS assets as MI rather than in a 12-hour Push Package.

Planners should use a baseline estimate of **30,000 – 50,000 square feet** for planning the space for the RSS. This is the space needed to accommodate a full-scale response involving 12-hour Push Packages, MI, and any additional material. However, the following recommendations will assist planners in estimating the necessary RSS space based on the population size and amount of material the RSS would need to hold to treat the jurisdiction's population. In addition, planners should recognize that it is unlikely that all the required assets will arrive simultaneously at the RSS. It is more likely that SNS assets, probably from MI, will arrive in multiple shipments over a period of days or weeks, depending on the incident and the type of assets required.

Managed Inventory (MI)

MI will be shipped on pallets. Standard pallets are 48x40 inches; however, planners should calculate space requirements based on 48x48 inches to provide space on either side of a pallet to access all the cases. Considering half of a 10-foot aisle will be associated with each pallet, planners can estimate 36 square feet per pallet for determining space requirements.

To calculate the number of pallets of MCMs a jurisdiction might require (and therefore the RSS space requirements for MI), planners should consider that one standard pallet of doxycycline or ciprofloxacin from CDC-provided MI contains 96 cases, on average, and sometimes 104 cases. Each case contains 100 10-day unit-of-use bottles. Therefore, each pallet will provide a 10-day supply of prophylaxis for 9,600 individuals. Consequently, a population of 1,000,000 would require 105 pallets, which requires or 3,780 square feet of storage space, for ten days of prophylaxis.

In an anthrax incident, an individual exposed to the agent will require a 60-day course of antimicrobials. For follow-on pallets of 50-day unit-of-use bottles (100 tablets/bottle), 1,000,000 people would require 105 pallets of doxycycline or 193 pallets of ciprofloxacin. DSNS recommends that planners consider that the total number of pallets (both 10-day and 50-day unit-of-use bottles of antimicrobials) could range of between 255 and 298 depending on the how much of each available antimicrobial the jurisdiction requests. Consequently, the warehouse space required to store the entire 60-day course of antimicrobials for a population of 1,000,000 would range between 9,180 and 10,728 square feet.

Using these estimates, planners can develop a rough model of the space requirements for their RSS facilities. It is important to note that the example space calculation represents only

oral antimicrobial prophylaxis. Depending on the incident, the jurisdiction may require other formulary items from the SNS, such as intravenous (IV) tubing or IV needles, to treat symptomatic patients. Treatment items include pallets of multiple line items of various configurations and sizes. RSS teams will need to stage these assets so they can quickly identify, pick items, and link the appropriate ancillary supplies with other MCMs for rapid distribution to hospitals and treatments centers.

12-hour Push Package

Typically, additional product from MI will follow a 12-hour Push Package and will require additional warehouse space. However, for planning purposes, planners should be aware that each container in a 12-hour Push Package is 60.625 inches wide and 43 inches deep. Therefore, to accommodate just the 130 containers of the 12-hour Push Package, the RSS should have at least 12,000 square feet of open, level, smooth floor that is free of cracks, dips, and other structural barriers to allow for the following minimum spaces:

- 7,000 square feet for storage of the 130 containers in a 12-hour Push Package
- 2,000 square feet for receiving and staging assets
- 2,000 square feet for staging and shipping assets
- 1,000 square feet for office space to accommodate staff for inventory control and operations management

Information on the contents of the 12-hour Push Package is available in the *Strategic National Stockpile 12-hour Push Package Catalog*.¹²

Aisle Space

RSS space allocation must account for aisle width. Ideally, RSS space will provide for 10-foot aisles between rows of containers or pallets of MCMs, which allows RSS staff to use MHE to move pallets and accommodates two-way traffic in aisles when filling orders.

Staging Areas

Staging occurs in two areas within the RSS: receiving and shipping. For receiving, RSS staff will unload assets from vehicles and stage them near the dock for inventory (entering into inventory list) before they store them in marked locations within the facility. For shipping, RSS teams will fill orders by picking assets from their marked storage locations, placing the assets on pallets, updating inventory lists (reducing stock in storage), and staging orders in the loading area for shipping to PODs, hospitals, treatment centers, and other sites. Space requirements will vary based on the activities RSS planners determine each of these staging areas will carry out.

Receiving Staging Area: If space is limited, planners may choose to limit the staging area at each receiving dock to the space needed for one full 53-foot truckload of material, or 24 pallets, which requires 824 square feet, if the space includes ten-foot aisles, or 284 square

¹² https://www.orau.gov/snsnet/resources/snsFormularyFinal02-15-12_ac.pdf. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC DSLR project officer.

feet, if material is staged without aisles. Additional truckloads of material can wait on the trucks until staff clear the staging area.

Shipping Staging Area: The shipping staging area is where staff arranges pallets in a logical order (last location loaded first and first location loaded last) for shipping. Planners should base the size of shipping staging areas on the size and the numbers of trucks used for distribution operations. For example, if the jurisdiction uses 53-foot trucks for distribution, with three dock doors available to load three trucks simultaneously, the space requirement for 24 pallets per truck, with five-foot aisles between the three pallet groupings, equals 1,872 square feet ($\{6.5' \times 4'\} \times 24 \times 3$) of floor space.

If the RSS facility accommodates additional dock doors, planners could plan for additional shipping staging if the facility does not need the space for storage. This would allow staff to stage additional truckloads of product at multiple dock doors. Also, if the jurisdiction plans to use cross-docking for SNS assets, RSS planners should allow for additional staging space in proximity to the docks. Cross-docking will require space for staff to unload material from trucks, temporarily stage it at the loading dock, and then load it onto shipping trucks.

Space Marking

Planners will find it helpful to map out staging areas for assets, mark the warehouse aisles and pallet locations, and determine ahead of time where set-up will occur in designated staging, receiving, and office areas. Marking the space in this way, as well as taking pictures, will help planners orient warehouse personnel to the layout for RSS operations. Planners also must provide a drawing of the RSS facility layout for RSS verification and reverification (see the RSS Site Survey¹³).

Commercial facilities may have less floor space, but more “pallet locations” by having elevated storage racks, which can make mapping material storage plans especially beneficial for analyzing a facility as a possible RSS site. When the RSS facility has existing storage racks, these will have location numbers that allow the inventory management team to synchronize stored material with an inventory management system and track material locations.

However, when RSS operations are located in a facility that does not typically function as a warehouse, or if SNS assets must be stored in an open floor space, the RSS lead and SNS coordinator will need to determine how to position palletized material in the available space. Planners will find it helpful to map out how material locations will be identified (e.g., by aisle and/or row number) and develop a system for marking floor space (e.g., taping outlines for aisles and rows, placing numbers or letters on the floor, etc.) to identify the locations of stored assets. In addition, this storage system will need to be coordinated with the inventory management system to ensure staff can inventory assets in the proper locations and generate pick lists that accurately represent material locations.

¹³ <https://www.orau.gov/snsnet/functions/receiving.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC DSLR project officer.

Contingency Space

When planning the layout for space in the RSS facility, planners should be aware that a large-scale incident will involve multiple shipments of SNS assets. Assets possibly will arrive faster than staff can store, stage, and deliver them. Consequently, RSS sites should allow plans for a number of contingencies, including

- Back-up space to temporarily store SNS assets in
 - The RSS facility;
 - Unloaded trailers (temperature controlled, if applicable) parked at the facility, if space in the warehouse is not available (the trailers used to transport SNS assets to the RSS facility should *not* be considered for storage);
 - Tents outside the facility (temperature controlled, if applicable); and
 - Portable storage containers (temperature controlled, if applicable).
- Additional security if temporary storage is not available inside the secure RSS compound;
- Methods for moving assets from a temporary location to the RSS facility;
- Additional MHE to unload, relocate, and distribute assets at temporary sites; and
- Additional semi tractors to relocate any trailers dropped away from the loading dock.

Lessons Learned

Ideally, SNS assets that cannot be unloaded immediately into the RSS facility should be stored adjacent to the facility. In exercises, some jurisdictions have used tents and portable storage containers located adjacent to the RSS facility. Other jurisdictions have stored assets temporarily at a location distant from the RSS facility, which required additional security forces to protect the location and some means of handling and moving the material to the RSS facility when space was available. This option increased the amount of staff needed to operate the RSS facility and delayed the movement of SNS assets to delivery sites. Wherever assets are stored, that location must comply with the specific environmental conditions.

Determining RSS Layout

To design the layout of the RSS facility, planners may find it beneficial to create a scale drawing of the facility's space, including all obstacles (e.g., doors, posts, and walls), and then position templates of assets (12-hour Push Package containers, MHE, pallets, tables) on it. Figure 5-1 provides an example of an RSS layout design.

While designing the RSS layout, planners should consider the following:

- Space requirements for the receiving area (approximately 2,000 square feet), including
 - A loading dock area with at least 600 square feet of obstacle-free space for movement of MHE in and out of trailers;
 - An area outside of loading docks that is at least 100 feet deep to allow trucks with 53-foot trailers to back up to docks;
 - An in-bound staging area near the loading docks for temporary storage and inspection of material, as needed;

-
- An area for quarantined material (i.e., damaged pallets or materials, incorrect product, etc.);
 - A space for storage of up to 100 empty pallets; and
 - Aisles that allow the passage of pallets and pallet jacks.
- Space requirements for the storage and picking area (at least 7,000 square feet), including
 - Enough space to position the 130 containers of the 12-hour Push Package as well as pallets of material;
 - Space to hold unreleased material and receipts of supplies to support MCM operations;
 - Aisles between containers and pallets that allow for two-way traffic with pallet jacks; and
 - Space that allows the doors of all 12-hour Push Package containers to face the aisles for easy access to their contents.
 - Space requirements for the shipping area (approximately 2,000 square feet), including
 - Dedicated dock space for outgoing orders;
 - A staging area for outbound palletized material receiving quality control inspection prior to shipment; and
 - Aisles that allow the passage of pallets, pallet jacks, and forklifts (if used).
 - Space for a dedicated office area (approximately 1,000 square feet), located away from the noise of the warehouse floor, for command and management activities and to provide workspace for federally deployed personnel, if required or requested.
 - Space for the inventory control team that is conducive to internal communication, phone calls, and computer work. Planners might find it helpful to provide a space adjacent to the storage and shipping areas. This can enhance communication between these teams and increase movement of materials to fill orders. These teams also can work together to rapidly correct discrepancies in orders.

- While previous guidance required planning for a space within the RSS site for repackaging bulk MCMs, DSNS has since established enough contingency contracts with professional firms to repack tens of thousands of regimens per day, thus removing this space requirement.

Sample RSS Warehouse Floor Layout (Not drawn to scale)

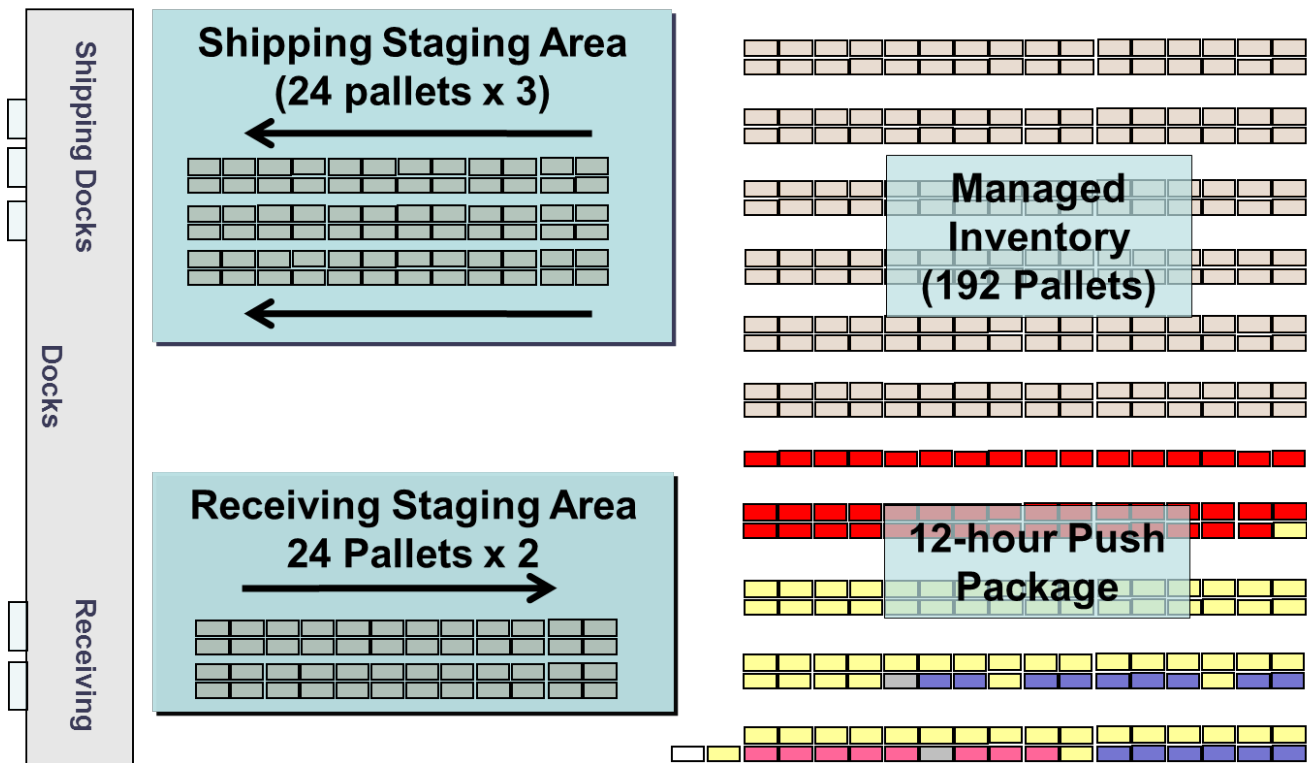


Figure 5-1: Sample RSS layout design. From *Field Operations Guide for Marking a Receive, Stage, and Store (RSS) Warehouse Floor*, available from DSNS.

Developing Receiving, Staging, and Storing Plans

As with all areas of MCMDD planning, the plans for operating and staffing RSS facilities must be both scalable and flexible to ensure the RSS facility can accommodate a rapid and potentially sustained response. Written RSS plans should include the following:

- The address of the RSS site
- The name and contact information for the facility manager
- The addresses for all back-up RSS facilities and contact information for facility managers

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- Photographs of the facilities, including satellite mapping photographs as well as interior and exterior photographs
 - Available square footage of the facility, and back-up facility, and maps of how material will be placed in the available space
 - Detailed security plan, security staffing requirements, and credentialing system
 - Mapped entrances and exits for routing vehicles
 - A list of MHE available at each facility
 - A list of available office equipment at each facility and any materials the jurisdiction will be required to supply when the RSS facility is activated
 - Training plans for staff
 - A plan for staff comfort management, including lengths of shifts, restroom and dining facilities, break areas, lodging, family care, etc.

RSS facility activation plans, including

- Incident-specific site selection criteria;
- Call-down rosters for staff and identified back-up staff;
- Site set-up plans;
- Names of lead personnel and RSS team members;
- Job action sheets for various staff positions;
- Just-in-time training materials and plans for staff;
- The name of the person authorized to sign SNS custody transfer forms;
- DEA distributor documents and chain of custody protocols and procedures for controlled substances, including the names of individuals or facilities authorized to receive and request controlled substances; and
- Plans for activating facility systems (i.e., electrical, phone, communications, etc.).

RSS facility demobilization plans, including

- Inventory of SNS assets;
- Plans for returning 12-hour Push Package containers or recoverable items;
- Plans for storage or reallocation of unused MCMs; and
- Staff debriefing.

Security

Because of the critical function that it performs, it is imperative for the jurisdiction to supply adequate security to protect the RSS facility and staff. Sabotage, maliciousness, and other acts could threaten the RSS and the entire MCMDD operation. **Chapter 11: Securing Assets, Staff, and Operations** provides further discussion of security to protect personnel, facilities, assets, and equipment, but important actions that the jurisdiction should take to ensure security of the RSS include

- Installing perimeter fences to keep unauthorized persons away from the site;
- Ensuring doors can be locked to prevent unauthorized entry;
- Ensuring that RSS facility lead and back up have keys, security codes, or other required access to unlock all gates, doors, and loading docks;
- Providing multiple access points at each RSS compound that allow multiple secure methods for entry and exit for personnel and vehicles; and
- Methods to secure controlled substances (Further discussion on controlled substances and DEA security and storage requirements appear later in this chapter).

Activating the RSS Facility

Activation is the first critical phase in the RSS operation. The amount of effort required to activate the RSS facility to receive SNS assets, store them temporarily, fill orders, and ship them to PODs and treatment centers can depend on how the facility functions before an emergency. If the facility typically functions as a warehouse, it most likely will have MHE, such as forklifts and pallet jacks, and personnel support services. If the RSS generally functions in another capacity, activation will require the delivery of MHE and other support before the facility can function as an RSS. If the facility is unused prior to an emergency, activation must also include the establishment of basic functions, such as electricity, lighting, heating or air conditioning, ventilation, phone lines, and personnel support services. If the facility actively works as a warehouse, depending on the space needs and the space available, staff may need to move out or relocate the goods stored in the facility. In addition, staff will need to relocate any trucks and trailers not involved in the immediate response.

The RSS lead should partner with law enforcement to perform a security screening of the facility prior to the arrival of SNS assets to ensure that no previously undetected security risks exist or that nothing impedes the plan for RSS activities. For example, the RSS plan may call for trucks carrying SNS assets to arrive via a surface street that is closed due to construction at the time of activation. Law enforcement officials may be able to have that area temporarily reopened or direct trucks through another route. Law enforcement also can assist in providing clearance and identification badges for personnel arriving at the RSS facility during activation.

The activation plan should include staff rosters and call-down lists. The plan also should note who is responsible for notifying staff (e.g., RSS, warehouse manager, etc.). Once activated, team leads should receive job action sheets defining their roles in RSS activities. As staff arrive, they should be assigned to teams and provided with just-in-time training (if they have not previously been trained or need a refresher) and job action sheets for their roles, including

- Receiving assets (i.e., unloading trucks);
- Controlling inventory (receiving, order fill, shipping);
- Staging received assets prior to storing on the shelf;
- Storing assets;
- Filling orders (i.e., picking products from the shelves, pallets, or 12-hour Push Package containers);
- Staging assets to be shipped;
- Quality control (QC) of orders before they are shipped;
- Shipping assets (i.e., loading trucks);
- Securing the site, assets, and personnel;
- Ensuring worker safety; and
- Providing communication/IT support.

Each of these considerations applies equally to the back-up facility (or facilities) that would be used if the primary location is unavailable.

Incident-specific Site Selection Criteria: During a response, planners should indicate which RSS facility is preferred for delivery of SNS assets. This may be the primary, back-up, or additional RSS site that best meets the needs of the jurisdiction for the incident. The preferred

RSS site must be able to operate fully and effectively and be located in an area out of the immediate incident scene. It might be the one central to the intended delivery points (PODs, treatment centers, or RDS); it may have more favorable agreements to meet the needs of the incident (e.g., space for long-term storage for a sustained response, such as a pandemic influenza); or it simply may be a site that can most rapidly mobilize for the response.

Distance to delivery sites might be a consideration during a public health emergency response since it can affect delivery time. In addition, material requirements of PODs and treatment centers may change rapidly. If an RSS facility is located far from these sites, travel time, traffic congestion, and the need for protecting delivery vehicles en route may hinder a rapid response. Longer distances also may interfere with the quality of radio communications between drivers, delivery locations, and RSS facility personnel.

Receiving SNS Assets

SNS assets will arrive at the RSS in 12-hour Push Package containers or, more likely, on pallets. The time and number of staff required to unload trucks will depend on the RSS facility's resources (e.g., loading docks and MHE) and the amount of material shipped from the SNS. For example, a 12-hour Push Package ships in at least eight 53-foot tractor-trailers carrying 16 to 18 cargo containers each and the number of trucks delivering palletized SNS MI will vary depending on the type and quantity of material delivered.

If the RSS facility has a standard-height dock with levelers or dock plates, a two-member RSS receiving team can easily unload and store a single tractor trailer load of 12-hour Push Package containers in less than 30 minutes by manually rolling containers off the truck and into pre-identified storage locations. The more docks and team members to assist in unloading, the faster the 12-hour Push Package can be unloaded and stored in its designated space.

In RSS facilities without standard loading docks, staff can unload SNS assets using other options, but planners should be aware that this will slow operations. Planners also should be aware that most CDC-provided trucks do not have lift gates, which means staff must use forklifts or other means to unload. Portable ramps are a viable option and can be purchased on the open market. As previously mentioned, ramps create an incline that staff must navigate both into and out of the tractor-trailers, so safety becomes even more important.

When staff use forklifts in the absence of standard loading docks, unloading 12-hour Push Package containers will require more people and time. To unload a 12-hour Push Package using forklifts, plans should call for at least four people per truck: one on the truck to position containers at the rear of the truck, one to drive a forklift, and two to move containers into place after the forklift drops them into the RSS facility. Unloading the 12-hour Push Package in this fashion takes approximately 45 minutes per truckload.

MI will require forklifts and/or pallet jacks to remove the pallets from the trucks and position them in the receiving staging area. A standard semi-trailer holds 24 pallets, which may be double stacked (i.e., 48 pallets) depending on the weight of the product and height of the pallets. One to two forklift drivers can efficiently unload a full semi-trailer and position material

in a short timeframe. However, if forklifts are not available, several staff members will be required to move material with pallet jacks. As previously mentioned, SNS assets may arrive in varying configurations from several different locations and not every vehicle that arrives at the RSS will be fully loaded. For instance, one truck may arrive with 20 pallets of material from one CDC facility, while another may arrive several hours later with the rest of the shipment from another CDC facility.

In addition to unloading material, the receiving team should have a process for

- Inspecting material and verifying packing list quantities before storing;
- Placing material of suspected condition or missing/incomplete documentation in quarantine; and
- Initiating the inventory control process by recording received products' storage locations, lot numbers, and quantities. This process also should include a method for deducting outbound shipments from the inventory balance. **Chapter 6: Managing Medical Countermeasure Inventory** provides further information on inventory management systems.

Accepting Custody of SNS Assets

Once staff has unloaded the shipment, a designated official from the jurisdiction must sign for custody of SNS assets before the jurisdiction can use them. An SNS technical advisor will provide a list of the items transferred to the jurisdiction and require a signature on the custody-transfer form.¹⁴ When CDC ships SNS assets without CDC personnel present, the receiver should sign the shipping documentation and send it to the DSNS Team Room Operations Manager. CDC will provide a fax number and e-mail address for return of signed documents when it ships SNS assets.

In addition to a signed custody-transfer form, states and territories must also sign a memorandum of agreement (MOA) obligating the state to adhere to handling instructions provided by CDC, maintain security of SNS assets, and to return SNS recoverable assets according to CDC guidance. An example MOA¹⁵ is available on the SNS Extranet. Planners should fill out the MOA during the planning phase and keep it on file until needed. CDC recommends that planners complete this agreement prior to an incident, but if a current copy is not available when the jurisdiction activates the RSS, the official who signs for custody of the assets also must sign the MOA.

The SNS contains a variety of drugs classified as controlled substances and each 12-hour Push Package arrives with one DEA-approved storage container (container number 100) that includes controlled substances. Federal and state officials responsible for receiving and distributing SNS-provided controlled substances must adhere to all pertinent local, state, and federal regulations regarding the distribution and dispensing of controlled substances. These regulations require tracking of distribution and dispensing at the federal, state, local, and

¹⁴ https://www.orau.gov/snsnet/resources/AppHCustodyTransferForm_ac.pdf. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC DSLR project officer.

¹⁵ https://www.orau.gov/snsnet/resources/AppISampleMOA_ac.pdf

patient levels. Planners should contact the local DEA office¹⁶ for additional information to ensure that they meet these federal requirements.

An authorized DEA registrant also must sign the SNS custody-transfer form and DEA Form 222¹⁷ for the Schedule II controlled substances in the shipment, including when a jurisdiction takes custody of a 12-hour Push Package. If the registrant is not present at the time of asset transfer, the jurisdiction can identify him/her on the SNS custody-transfer form and provide the appropriate signatures and DEA Form 222 later. Further information on receipt and handling of controlled substances appears below.

To reduce the time needed to transfer custody of SNS assets during an emergency, jurisdictions should supply CDC with the following items in advance of an incident:

- **A signed copy of the MOA** between the jurisdiction (state, tribal government, military installation, etc.) and CDC, which CDC will keep on file. Should the jurisdiction's legal counsel have objections or modifications to the MOA, they should send these in writing to the DSLR project officer. DSLR will forward these to the Department of Health and Human Services (HHS), Office of General Counsel for review.
- **A list of personnel authorized to sign for SNS assets** on behalf of the state, including DEA registrants. The jurisdiction should identify at least two individuals to ensure someone will be available to accept custody of SNS assets upon their arrival. The jurisdiction also should provide multiple methods for reaching each individual 24 hours a day, seven days a week.

Controlled Substances

The Controlled Substances Act (CSA) of 1970¹⁸ (21CFR, Part 1300) frames the federal drug policy on controlled substances and DEA is the lead federal law enforcement agency responsible for enforcing the CSA. The CSA requires special handling of controlled substances, including during RSS operations. Controlled substances can arrive at the RSS either in the 12-hour Push Package or on pallets from MI. The one DEA-approved container of controlled substances in a 12-hour Push Package (container 100) contains morphine sulfate, which is a Schedule II controlled substance, and diazepam and midazolam, which are Schedule IV controlled substances. DEA regulates the storage and transfer of Schedule II and Schedule IV controlled substances in accordance with 21CFR.¹⁹ The recipient must secure Schedule II and Schedule IV controlled substances in a cage, safe, vault, or locked drug cabinet. The size of the secured, locked enclosure is dependent on the amount of material stored.

DEA registers individuals and organizations, such as hospital pharmacies, to handle specific classes of controlled substances by issuing them a distributor's license. Members of organizations holding a distributor's license are known as agents. Licensees and agents

¹⁶ www.justice.gov/dea/agency/domestic.htm

¹⁷ www.deadiversion.usdoj.gov/faq/dea222.htm

¹⁸ <http://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm>

¹⁹ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm

(referred to here as “registrants”) who transfer controlled substances must ensure that recipients have the proper DEA authorization to receive them. They also must keep a detailed chain-of-custody record of all transfers. The person who receives Schedule II substances is required to initiate a request to transfer the material using a DEA Form 222. In addition, a designated state official (registrant representative) must sign for receipt of SNS assets containing controlled substances using DSNS Form 1237A, Controlled Substance DEA Custody Transfer Form.

DEA Distributor Registration: Each state participating in the SNS program should register as a distributor with DEA in order to provide a legal conduit for the shipment of controlled substances during an emergency. However, states **do not have to register each RSS** site with DEA for storage of controlled substances. With a few exceptions, states do not otherwise receive, stage, or store controlled substances at the RSS locations except in time of national emergency. DEA understands that states may not be able to determine which designated site to activate until the time of an incident and for this reason will permit RSS locations in each state, in time of national emergency, to receive, store, and distribute controlled substances under one centralized DEA distributor registration held by that state’s government.

State participants who stockpile any controlled substances at an RSS location prior to activation for a national emergency must first obtain a separate DEA Distributor Registration at that location and meet all security and recordkeeping requirements. Applications and detailed instructions on DEA distributor registration process are available on the DEA website.²⁰ DSLR project officers also can provide assistance on applying for the distributor registration.

Transfer Requirements: DEA recognizes that a large public health emergency may prevent its registrants from following normal recordkeeping requirements. In this case, DEA allows transfer of controlled substances during an emergency even if a DEA registrant is unavailable to accept them and sign a Form 222 for Schedule II substances. State DEA registrants eventually must provide CDC with signed Form 222s for each Schedule II transfer, but do not have to do so at the time they transfer SNS assets. Jurisdictions also must use DSNS Form 1237A for shipping and custody transfer of all controlled substances (Schedule II and IV) from DSNS-registered facilities to the supported registered site, such as a hospital or treatment center. For all Schedule II substances, jurisdictions should use DEA Form 222 in conjunction with DSNS Form 1237A for material transfer.

If CDC transfers controlled substances when the DEA registrant is unavailable, CDC

- Must know the name and DEA number of the person who will eventually sign the Form 222;
- Will require the person who receives the material to show a government-issued ID (e.g., a driver’s license) and sign copies of the manifest that itemizes the controlled substances transferred; and
- Will require the registrant to sign a DEA Form 222 for each transfer of Schedule II items as soon as practical after the physical transfer.

²⁰ www.deadiversion.usdoj.gov/drugreg/reg_apps/index.html

DEA will hold the registrant responsible until that person transfers the stock to another registrant (e.g., a pharmacy at a hospital or treatment center). DEA also will allow transfer of controlled substances to multiple facilities using a copy of the manifest (or another unofficial form) as long as a chain-of-custody record is maintained.

Storage Requirements: Because of the special security requirements of controlled substances, planners should consider storage options for those items that arrive from the SNS, such as

- Leaving controlled substances in the specialized hard-cased air cargo containers that DEA approves for secure storage;
- Using local law enforcement to provide security for controlled substances;
- Using a police evidence locker, portable lock box, or security cage for storing controlled substances; or
- Using a safe or vault at another facility (e.g., pharmacy, hospital, trauma center, methadone clinic, or wholesale drug distributor) that meets DEA standards.

Governing Laws: The controlled substance laws of the jurisdiction may be more stringent than 21CFR²¹ under which the requirement for DEA Form 222 falls. Planners need to work with the jurisdiction's public health legal advisors to review specific laws and ensure compliance. If state laws are more restrictive, public health law professionals can assist SNS planners in determining the effects of these laws on the ability to receive and dispense controlled substances and propose solutions to the state Board of Pharmacy.

For detailed information about federal controlled substance regulations, examine DEA's Diversion Control Program.²²

CDC Assistance: After drafting the proposed policy for storing and handling controlled substances, CDC (and DEA Headquarters) strongly suggest that jurisdictions meet with the local DEA Diversion Control Program Field Office (listed on DEA's website²³) or the state's Board of Pharmacy to gain concurrence. Jurisdiction representatives can contact their DSLR project officer for help in working with the Diversion Control Program office.

Storing SNS Assets

Upon receipt at the RSS, staff must transfer material to assigned storage locations. Jurisdictions may decide to pair job functions in the RSS based on the processes that they complete. One school of thought pairs storing and picking functions together and receiving and shipping together to complete typical warehouse processes. Another school of thought pairs storing and receiving functions together since these complete the receiving process and picking and shipping together since these complete the ordering process. The jurisdiction should organize staff using a method that works best for the particular RSS facility. Generally, the staff assigned to work on storage of material also is responsible for filling orders

²¹ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1305

²² www.deadiversion.usdoj.gov

²³ www.justice.gov/dea/agency/domestic.htm

(picking) received from the inventory control team. **Chapter 6: Managing Medical Countermeasure Inventory** provides guidance on the role of the inventory control team and use of inventory management systems for inventory control at the RSS.

Managed Inventory (MI)

Staff will need forklifts or pallet jacks to move MI (i.e., palletized material) into its storage locations. The SNS coordinator and RSS lead should work together to develop an inventory management process that assigns location identifiers to warehouse so that the pick team can readily locate material. When the RSS is located in a commercial warehouse, CDC recommends that RSS staff use the facility's existing system for identifying storage locations, provided it is compatible with the inventory management system (IMS) being used for RSS operations.

12-hour Push Package

The 130 containers of the 12-hour Push Package are numbered sequentially and color-coded by product type. The color-coded document pouches on the front of each container identify the type of product in the container:

- Red: oral antimicrobials
- Yellow: intravenous drugs and supplies
- Blue: airway supplies
- Clear: medical/surgical supplies
- Pink: pediatric supplies

The best way to organize a 12-hour Push Package in the RSS facility is by positioning the containers (i.e., storing them) by product type and sequentially by the container number printed *vertically* on the container (See Figure 5-2); note that the horizontal number is the container serial number. Staff should use the container numbers as storage location identifiers for inventory control, which will make it easier to locate specific products. Since containers most likely will not come into the RSS in sequential order, RSS staff should mark the floor with positions for each container number. This way, as each container comes off the truck, staff can easily roll it to its position, regardless of whether the neighboring containers are in place.

The document pouch on the container includes a list of its contents and a diagram of how the products are arranged in the container. Staff should position containers so the doors face the aisle to allow easy access and removal of the contents. When personnel are ready to begin picking material from a 12-hour Push Package, they should remove the container doors and place these to the right, between the containers, which will allow pick teams access to the document pouch when necessary.



Figure 5-2: SNS 12-hour Push Package container

Picking (Filling Orders)

Various locations, including PODs, hospitals, local health departments, or the state emergency operations center may generate requests. Once RSS staff receive orders and enter them into the inventory management system, they will generate documents for the pick team to use to pull assets from storage locations and fill the orders.

The RSS operations plan should address

- How orders will be routed to pick teams for filling;
- The size and number of pick teams (DSNS recommends three people per team, two to pick product and stack it on pallets and one to provide quality control of orders as they are picked); and
- Whether staff will conduct quality control of orders as they fill them or after they place completed orders in the shipping staging area. The pick team will circulate through aisles removing product from storage locations and placing it on a pallet to fill each request.

On each team, one person should track the requested material on the list and call out products to the team (quality control) while other team members pull required material from storage locations and stack it on the pallet. When the pallet is full or the order is complete, the team will take the pallet to the shipping staging area for preparation for shipment. A member of the quality control team may circulate with the pick team to ensure that all

requested items are included in the order, or the pallets may go through quality control after staff stage them in the shipping area.

If the incident requires dispensing of prophylactic medications, PODs will typically order unit-of-use oral antimicrobials or doses of vaccine, but depending on the incident, treatment facilities might order

- Intravenous medicines, intravenous administration supplies, fluids, life-support medicines, airway equipment, and medical or surgical items for treating casualties;
- Material or antidotes to care for people exposed to chemical or nerve agents; and/or
- Unit-of-use antimicrobials or vaccines for therapeutic treatment during a biological incident.

Staging and Shipping Assets

Once the pick teams fill orders for specific locations, they should stage pallets in the shipping area next to the loading docks to be loaded onto trucks. The shipping team should establish and mark staging areas for each shipping destination to ensure that the orders are not mixed during the staging process. The distribution lead should have identified routes for vehicles delivering assets to various sites within the jurisdiction. Shipping teams should stage orders so that orders for the last site on the delivery route are loaded onto the truck first. **Chapter 7: Distributing Medical Countermeasures** provides further distribution information.

The quality control team may check orders in the shipping/staging area or while embedded with the pick teams; either way this function should be performed before the shipment leaves the RSS. Some of the functions that staff should perform in the staging/shipping area include

- Verifying accuracy and correcting discrepancies in filled orders and reporting these to the inventory control team;
- Preparing material for delivery (stretch wrapping, marking pallets with shipping location and pallet number [e.g., Wilson High School POD, Pallet 1 of 3], and affixing shipping documents);
- Returning copies for filled orders to the inventory control team;
- Verifying delivery locations; and
- Assisting in loading material onto delivery trucks.

Determining Personnel Needs

RSS facility personnel are critical to operational success. Each staff member should be trained and attend RSS exercises to fully understand their responsibilities and the importance of the RSS functions to the MCM receiving and distribution process.

It is difficult to gauge how many staff RSS operations will require. As with all preparedness plans, the jurisdiction must develop scalable and flexible RSS staffing plans. This becomes particularly critical if the incident requires extended RSS operations, such as a pandemic influenza response, and the RSS plan must identify additional staff to assist in extended operations. In addition, a facility with too few personnel, or untrained personnel, can delay delivery of needed supplies to dispensing sites.

While staffing levels will vary depending on the incident and SNS assets shipped to the jurisdiction, Table 5.1 provides a list of possible personnel, staffing levels, and responsibilities for a full-scale RSS operation. Table 5.1 assumes the jurisdiction receives a 12-hour Push Package and follow-on MI. Planners need to determine their own staffing needs based on the characteristics of the RSS facility and response.

Table 5.1: RSS Roles and Responsibilities

Warehouse personnel roles	Responsibilities	Possible number of personnel per shift
RSS manager/leader	Facility management Has 24-hour authority and responsibility for all operations concerning the RSS site May sign for the assets	1
Inventory control team	Tracks inventory Receives SNS asset database and creates picking tickets based on requisitions and inventory supplies Updates inventory to reflect completed orders	Lead + 2 = 3
Storage/picking team	Stores material (rolls containers from the 12-hour Push Package into place or puts pallets of material on shelves or in assigned storage locations) Picks orders, builds pallets Labels pallets, records stock numbers, completes and copies the picking ticket to give to drivers	Lead + 12 = 13 (four teams of 3)
Quality control team	Checks inventory upon receipt Monitors picking and shipping processes	Lead + 1 = 2
Shipping/receiving team	Receives SNS assets, offloads into receiving (or staging) area Loads material onto the trucks	Lead + 2 = 3

Warehouse personnel roles	Responsibilities	Possible number of personnel per shift
Security manager/lead	Coordinates facility security and determines security staffing needs Checks/issues staff identification badges Works with and/or is a member of local law enforcement (See Chapter 11: Securing Assets, Staff, and Operations for further information on security roles)	1
Communications/IT	Ensures viability of facility's computers, communications devices, and internet connections Provides just-in-time training on computer software, if needed Troubleshoots computer and communication equipment issues (See Chapter 10: Strategic and Tactical Communications for further information on communications roles)	1
Safety Manager/Leader	Ensures staff have appropriate safety gear for warehouse operations (e.g., sturdy footwear, gloves, etc.) Provides just-in-time safety training Ensures functionality of facility's first aid kit and AED Ensures functionality of facility's back-up generators or other safety devices	1
Floater	Available to assist all teams as needed	2
Team lead supervisor	Supervises all teams and reports directly to the Warehouse/RSS Manager Verifies contents of the shipment once it has been released to the state Coordinates how shipment is sorted Oversees all activities of each team	1
TOTAL		28 per shift

Planners should work with the RSS management team to identify individuals to fill leadership positions and their back-ups in advance; provide these personnel with training on their roles; and include them in quarterly call-down drills to test response capability. An up-to-date call-down system is crucial to ensuring that contact information is accurate and personnel will report during RSS activation. The RSS management team should develop detailed job action sheets for each of the RSS functions and involve key individuals in training and exercise opportunities for their functions prior to an incident. The RSS management team also should develop just-in-time training materials for each of the RSS functions to familiarize personnel working within those functions. It is also important to provide training on safe use of MHE to personnel responsible for operating it.

Due to the possibility for extended operations and the need for trained and efficient personnel, partnerships with commercial warehouses may be useful to developing staffing plans. Planners should develop agreements to include pre-existing, trained warehouse staff while arranging for use of the facility. Commercial warehouse staff should already be familiar with the facility, processes, and functions described in this chapter and will likely need minimal training to run an efficient operation. If these personnel are available as part of the agreement, RSS plans should include them in call-down drills to ensure their ability to respond to an incident.

Demobilizing the RSS

RSS plans should include the actions required for demobilizing the facility once the response ends. Demobilization plans should include actions required for

- Returning SNS recoverable items (see the following section);
- Inventory of SNS assets;
- Storage or reallocation of MCMs not used during the response; and
- Staff debriefing.

Following response operations, the jurisdiction should conduct an inventory of SNS recoverable items. CDC retains ownership of durable assets, including

- 12-hour Push Package containers;
- CHEMPACK containers;
- Portable ventilators;
- Ventilator storage cases;
- Vaxi-Cool™ mobile refrigerators; and
- SNS equipment used to support deployed SNS personnel (e.g., laptop computers, communications equipment, etc.).

CDC spells out the terms of use for these items in Appendix I of the MOU that the jurisdiction signs with CDC for SNS assets. The jurisdiction must return durable assets to the CDC, at CDC expense, upon request or when no longer needed for the public health emergency response.

Each jurisdiction should determine, and include in the demobilization actions, plans for SNS assets that were distributed to PODs, treatment centers, or other facilities. For example, some states have determined that MCMs from the SNS will remain with the local health

department following a public health emergency. However, planners should be aware that MCMs distributed under an emergency use authorization (EUA) may have restrictions on how they can be used following the incident. Planners should work with public health law professionals and their DSLR project officer to determine whether and how the jurisdiction can use assets following an incident.

Once RSS operations end, staff at the RSS may need a debriefing and instructions on how to, whether, or when they will receive compensation, how to submit time sheets (if required), and what information they can share with friends or family members about their actions during the incident. The jurisdiction must decide whether staff debriefing is required and what should be included in plans for these debriefings.

Chapter 6: Managing Medical Countermeasure Inventory

Once medical countermeasures (MCMs) arrive at the state's receipt, stage, store (RSS) facility, they will need to be inventoried and broken down into shipments to go to dispensing sites. The RSS will utilize an inventory management process for receiving, storing, and locating assets to fill orders for shipment. This process relies on an inventory management system (IMS) to track the movement and storage of assets within the RSS and associated processes for managing MCMs, including receiving, storing, picking (i.e., pulling items from storage to fill orders), and shipping orders to dispensing sites. In addition, the jurisdiction can link its IMS to systems that will allow a line of site of available MCMs from the federal down to the local level. State Strategic National Stockpile (SNS) planners will need to build an inventory management team (IMT) and work closely with warehouse professionals to develop and utilize an IMS for MCM operations.

Understanding Inventory Management and Tracking

The inventory management process includes multiple steps, many of which occur simultaneously and cyclically as MCMs move from the federal level to the people who need them. Figure 6-1 illustrates these steps, which include

1. Mobilizing (activation)
2. Ordering/requesting resources
3. Approving requests
4. Receiving inventory
5. Storing inventory
6. Picking orders
7. Shipping inventory/orders
8. Dispensing MCMs
9. Demobilizing

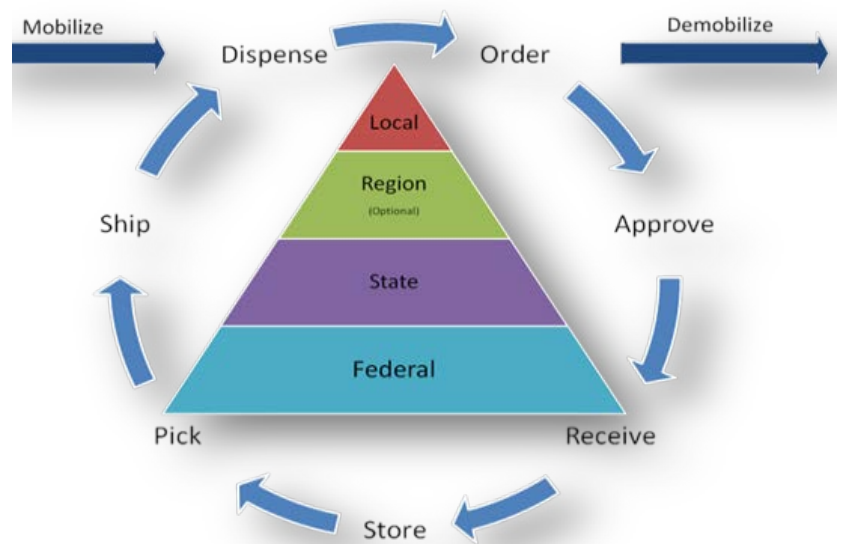


Figure 6-1: Inventory management process

To successfully respond during an emergency requiring dispensing of MCMs, all points of dispensing (PODs), treatment centers, hospitals, and alternate dispensing partners must receive the proper resources in the quantities they need and in configurations they can manage. To account for all available MCMs through the distribution and dispensing processes, the jurisdiction will need a system for tracking MCMs from the time they arrive in the state until they are dispensed to the people who need them. This tracking system will assist planners in documenting the chain of custody of all assets used to respond to an emergency.

Chain of Custody

Chain of custody refers to the chronological documentation, or paper trail, demonstrating the custody, control, transfer, and distribution of MCMs from the federal level, through the state, and to dispensing sites where people receive them. As an operational process, documenting the MCM chain of custody within the state or other jurisdiction is the responsibility of the IMT.

MCM chain of custody documentation is a requirement of Title 21 Code of Federal Regulations, Part 211 (21CFR211),¹ current good manufacturing practices (cGMP) for pharmaceuticals, to which all drugs and biological products must adhere. Specifically, Subpart J – Records and Reports² regulates the recordkeeping required for receipt, storage, handling, and transfer of MCMs. Various regulatory bodies enforce cGMP and it requires the validation of storage and distribution processes to ensure that there are no negative impacts to the safety, efficacy, or quality of MCMs. In addition to cGMP, state pharmacy boards³ may have additional data requirements for reporting chain of custody of pharmaceuticals included in any MCM shipments. Statutes and regulations often differ from state to state and coordinating with the state pharmacy board can ensure that the inventory management system (IMS) is equipped to receive any required data elements needed to produce chain of custody records, thus ensuring that the jurisdiction maintains chain of custody requirements throughout a response.

Certain items (e.g., vaccines or controlled substances) received at the RSS necessitate extensive additional chain of custody protocols due to specialized requirements for their safe handling, which are regulated by the U.S. Food and Drug Administration (FDA) and/or Drug Enforcement Administration (DEA).⁴ SNS contains certain controlled substances and items requiring cold chain management that are subject to these specialized chain of custody requirements to maintain the products in accordance with DEA regulations and manufacturer specifications during storage, distribution, and dispensing. To address these standards, written plans for inventory management should cover

¹ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=211

² www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=211.180

³ The National Association of Boards of Pharmacy website www.nabp.net/boards-of-pharmacy provides contact information for state pharmacy boards.

⁴ www.justice.gov/dea

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- Maintenance of packaging;
 - Storage of and access to controlled substances;
 - Cold chain management procedures, as required; and
 - Documentation procedures and forms (e.g., DEA Form 222) required for chain of custody.

Cold Chain Management

Cold chain management is an extension of cGMP that requires additional controlling of temperature, plus documentation and validation of temperature control to maintain the safety, efficacy, and quality of MCMs during the receipt, distribution, or dispensing processes. When the Centers for Disease Control and Prevention (CDC) ships items that require cold chain management, such as vaccines (e.g., smallpox vaccine, anthrax adsorbed vaccine, or other biologic products), it utilizes cold chain packing protocols, temperature monitoring devices, and specialized shipping containers to ensure that the items remain at the proper temperature throughout the packing and shipment processes. CDC ships cold chain items in either an electric/battery back-up refrigeration shipping container (Vaxi-Cool™) or, in most cases, a specialized foam shipping container (Endotherm™), which can maintain the required temperature for up to 72 hours without electricity or the need for additional refrigeration. The shipment also will contain a temperature monitoring device to record the temperature of the product during shipment. However, the jurisdiction's distribution plans should include plans for refrigeration trucks to maintain items in cold chain management in case the product is not dispensed within the timeframe for which shipping containers can sustain the required storage temperature. The jurisdiction's IMS will need to track and account for maintenance of the storage temperature of MCMs in cold chain management during RSS, distribution, and dispensing operations.

See **Appendix E: Cold Chain Management** for further information on the shipment and handling of materials requiring refrigeration.

Controlled Substances

In some instances, jurisdictions could receive controlled substances from the SNS. For instance, an SNS 12-hour Push Package contains one container (container number 100) of Schedule II (morphine) and Schedule IV (diazepam and midazolam) controlled substances and SNS burn and blast treatment supplies contain Schedule II (morphine and oxycodone/acetaminophen combination tablets) controlled substances. 21CFR1301.12⁵ outlines registration requirements for distribution and dispensing of controlled substances. States will need to register with DEA as distributors in order to be able to receive and transport controlled substances from the SNS. Even in an emergency, DEA regulations apply to controlled substances, which will require increased security in any site storing these items. Planners should be aware that DEA chain of custody protocols require stringent recordkeeping of inventory and security measures.

⁵ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

In recognition that strict adherence to some regulations at the time of an emergency would impede rapid deployment, DEA might grant exceptions to specific requirements under 21CFR1300 on a case-by-case basis for a specified period of time during an incident. These exceptions are not a release from the requirements but an extension in the timeline. To assist in meeting these regulations, CDC's Division of Strategic National Stockpile (DSNS) uses an internal document (DSNS1237A, Controlled Substance DEA Custody Transfer Form) when shipping controlled substances. A designated state official (registrant representative) must sign for receipt of SNS assets containing controlled substances and assume responsibility for all regulatory requirements, including security. Healthcare providers assisting in emergencies can act as an agent of the registrant to handle controlled substances; however, providers handling controlled substances should be diligent in documenting all activities relating to those substances.

For example, upon receipt of Schedule II and IV controlled substances, including those from SNS assets, DEA requires recipients to complete an accurate inventory – refer to 21CFR.1301.72(a) – and complete DEA Form 222, which must be kept when distributing or dispensing the Schedule II substances. DEA Form 222 acts as a receipt for Schedule II controlled substances and jurisdictions should keep it for chain of custody purposes. In addition, DSNS will provide DSNS 1237A and the recipient must sign this upon delivery of the 12-hour Push Package. In the event DSNS1237A is not included with a shipment of SNS assets, the invoice serves as proof of receipt for the Schedule IV products and can be considered as a substitute chain of custody form until the DSNS1237A can be provided.

For 12-hour Push Package container 100 or Schedule II controlled substances in SNS burn and blast supplies, DEA Form 222 acts as an order/request form as well as a receipt and the recipient should provide CDC with the designated supplier copy. The inventory manager should keep invoices showing the receipt of Schedule IV substances, keep copies of DEA Form 222 as a receipt for Schedule II substances, and retain invoices for the distribution and dispensing of Schedule IV substances. In addition, jurisdictions should keep a copy of all documentation for chain of custody purposes. DEA may request records of controlled substances during an inspection in accordance with the U.S. Controlled Substances Act.⁶

Planners should develop contingency tracking procedures to document the transfer of controlled substances in the event that DEA Form 222 is not readily available at the time of transfer. Tracking information that must be present on any contingency form includes

- Shipper's name;
- Shipper's address;
- Shipper's DEA registration number;
- Ship to address; and
- Name of the responsible official taking possession of the controlled substances.

Federal and state officials responsible for receiving controlled substances from the SNS must adhere to all pertinent local, state, and federal regulations regarding their distribution and dispensing. Planners should contact the local DEA office for additional information to ensure that they meet all storage and handling requirements.

⁶ www.deadiversion.usdoj.gov/21cfr/21usc/index.html

Inventory Management Process

The state's inventory management process begins as soon as assets arrive at the RSS. For assets from the SNS, the state is responsible for the inventory management process as soon as it acknowledges receipt and verifies the inventory checklist that arrives from CDC. From the point at which MCMs are transferred from the federal government to the state's or territory's custody, the jurisdiction is responsible for using their IMS to track the MCMs as they are stored (i.e., put into storage locations) or apportioned (i.e., divided) into individual shipments, distributed to dispensing locations, and dispensed to the people in the affected area. The jurisdiction's IMS should be able to track the chain of custody of MCMs and maintain records on every bottle of pills or vaccine, including items in cold chain management, as it moves throughout the jurisdiction and into the hands of those who need it.

The RSS should have location identifiers, typically a system of letters and numbers (See **Chapter 5: Receiving, Staging, and Storing Medical Countermeasures** for more information on product location systems) that can be synchronized easily with an IMS to keep track of material storage locations. RSS operations that occur in a functional commercial-type warehouse space likely will have shelving or racks onto which staff will store material and note its location in the IMS. However, for RSS operations located in facilities that do not typically function as warehouses, or when MCMs must be stored in an open floor space, the RSS lead must develop a system for marking storage space (e.g., taping outlines for aisles and rows, placing numbers or letters on the floor, etc.). This system will identify material storage locations and be coordinated with the IMS.

An IMS requires physical storage sites, systematic or electronic tracking features, as well as personnel in order to function efficiently. For instance, within the RSS, location designations (e.g., aisle numbers, rack positions, or row numbers) provide a physical system to store and locate materials, while an electronic software program or paper-based tracking sheet provides a system to process warehouse transactions, and personnel move the inventory and enter information into the electronic or paper-based system.

The IMT, as mentioned in the **Chapter 5: Receiving, Staging, and Storing Medical Countermeasures**, is responsible for ensuring that dispensing, treatment, and distribution sites receive the appropriate supplies by performing the inventory management function.

Building the Inventory Management Team

The inventory management team (IMT) should consist of personnel who can develop and/or become familiar with the jurisdiction's IMS, regardless of whether it is computer- or paper-based. In jurisdictions that have contracted with a professional warehouse for RSS operations, the facility's staff may serve in this function and staff the IMT under the direction of the RSS lead or the IMT lead. The RSS site (typically a warehouse but in some cases another type of facility used for RSS operations) will include staff arranged into teams that perform specific functions, such as receiving, storing, picking orders, quality control, and shipping.

Responsibilities of the IMT include

- Establishing, adapting, or developing an automated or manual IMS prior to an incident;
- Documenting the addresses of all sites to which orders may be shipped;
- Recording the receipt, storage locations, and issues regarding all resources;
- Tracking the type, quantity, location, and configuration (i.e., package type) of the MCMs and other assets;
- Entering information into the IMS, such as the quantity, configuration, and source of each item received, from records supplied by the RSS staff;
- Processing apportionment orders, when necessary;
- Processing reorder requests from PODs, hospitals, treatment centers, and alternate dispensing partners;
- Issuing orders to the RSS staff to pick specific items for staging and delivery to specific customers;
- Monitoring inventory levels and ordering more inventory when levels are low;
- Recording the locations to which all assets, equipment, and SNS containers (e.g., 12-hour Push Package or refrigeration containers) are sent;
- Reconciling inventory records (i.e., comparing inventory lists to material on-hand, determining if material is in its designated location, and adjusting records/materials to reflect current inventory); and
- Tracking recovery of SNS-supplied equipment and containers, and unused or compromised MCMs (e.g., damaged or expired medications) after an incident.

Determining Data Collection and Tracking Elements

One of the most important components of running a successful MCM operation is having the ability to know where a product is at any given time. A robust IMS will be able to track receipts, on-hand balances, orders (for replenishment), and problems with shipments. In addition, the most useful IMS can track MCMs to the local level, maintain client data, and be able to track specific data to assist CDC in monitoring national inventory levels. Several unique systems are available, however not all systems have the capability to provide CDC with a snapshot of jurisdictional MCM supply levels on a weekly basis. By tracking national supply levels, federal officials will be able to spot shortages, respond to inquiries from multiple federal offices and agencies, and report on-hand quantities to CDC leadership to aid in making decisions to release additional SNS assets. The jurisdiction should identify their needs, become familiar with the type of data reporting that CDC might need, and explore options for an IMS or assess their existing IMS for gaps they can address.

Minimum Data Collection and Tracking Elements

MCMs may make several stops before reaching the client level and the jurisdiction must track MCMs from RSS operations through dispensing. CDC learned much about tracking MCMs during the 2009 H1N1 influenza pandemic response. CDC's after-action review of the response indicated that most jurisdictions were unaware of specific data elements that CDC needed to assess MCM inventory levels, which include the following minimum elements at distribution and dispensing locations.

Distribution

-
- Name of facility to which product is sent
 - Address of facility to which product is sent
 - Facility type (e.g., POD, hospital, private physician)
 - Product description
 - Manufacturer
 - Catalog/stock number
 - Product size (i.e., personal protective or non-pharmaceutical product sizes, e.g., small, medium, large gloves, masks, or gowns).
 - National Drug Code (NDC)
 - Lot number
 - Expiration date
 - Unit of issue (units/case; e.g., 100 unit-of-use bottles/case)
 - On-hand quantity (cases and/or units)

Dispensing

- Client Name
- Sex
- Date of birth
- Address, including street, city, state, and ZIP code
- Phone number
- E-mail address (optional)
- Drug name
- Dose
- Lot number
- Dispensed date
- Dispensing authority
- Information on whether the client falls into one or more of the following high-risk groups:
 - Pregnant women
 - Immune-suppressed
 - Children

Planners should be cognizant that the data collected on clients during dispensing is subject to privacy and security rules set down in Public Law 104 – 191: Health Insurance Portability and Accountability Act of 1996 (HIPAA).⁷ Data stored on an IMS will need to meet HIPAA standards for protecting the privacy of client’s identifiable health information and securing any electronic health information according to national standards.⁸

CDC recommends that client-level tracking be a function of a state, local, or regional IMS to facilitate client notification should a drug recall occur from dispensed MCMs. Since drug recalls occur by lot number, knowing who received MCMs from the recalled lot will make it

⁷ www.gpo.gov/fdsys/pkg/PLAW-104publ191/content-detail.html

⁸ Further information on HIPAA privacy and security rules is available from the Department of Health and Human Services (HHS) Health Insurance Portability and Accountability Act Health Information website. Available at URL www.hhs.gov/ocr/privacy/.

easier to issue recall information. Without the ability to identify locations from which a particular lot was distributed and dispensed, the state would need to issue a mass-broadcast for MCM recalls, which could cause an additional wave of confusion among recipients. CDC strongly recommends an IMS with the capability to record lot and client data to allow targeted recall notification, should it be necessary.

CDC also recommends tracking of certain high-risk groups and it is important to note that these groups will be defined by the type of incident. For example, during the 2009 H1N1 influenza pandemic response, high-risk groups were defined as adults over 65, children under five, pregnant women, people with neurologic and neuromuscular disorders, or those with chronic or immunosuppressive conditions, such as chronic pulmonary disease (including asthma). Being able to identify risk groups that receive a particular MCM can assist in adverse reaction tracking. CDC will only ask total regimens dispensed to high-risk groups not individual dispensing data.

A frequently overlooked IMS component is the ability to monitor inventory levels at local jurisdictions. For example, during the 2009 H1N1 influenza pandemic response, CDC requested inventory levels at the state, regional, and local jurisdictions as well as dispensing data. Many jurisdictions did not have the capability to track assets at the local level and did not have dispensing data (i.e., aggregate dispensing data). The ability to track inventory levels once MCMs leave the RSS will ensure quick response when supplies are low or assets need to be transferred elsewhere. Several jurisdictions utilize a single IMS to manage state MCM inventory as well as regional and/or local facility inventories, which is beneficial because it allows state officials to monitor MCMs across all public health jurisdictions, thus strengthening the emergency response capacity.

Providing National-level Countermeasure Tracking⁹

CDC's ability to respond to, manage, and reduce the impact of public health emergencies relies heavily on the ability to rapidly locate and provide MCMs to those affected by an incident. During a public health emergency, federal officials need to have a comprehensive picture of all available assets to make critical purchasing and distribution decisions. To do so, CDC depends on near real-time data on inventory and distribution of MCMs at the state and local level. Consequently, CDC has developed applications to assist in tracking MCMs at both the aggregate and individual level. Information on MCM inventory levels guides decisions for deployment and distribution of MCMs during an incident and can provide the ability for future follow up, reference, and safety in case of a drug recall. CDC's Countermeasure Tracking Systems (CTS) rely on state and local partners' existing information systems and standard information exchange with immunization information systems (IIS), IMS, and other relevant systems. During the 2009 H1N1 influenza vaccination campaign, CDC used multiple CTS components to assess MCM availability and coverage of target populations.

⁹ Information in this section is taken from the U.S. Centers for Disease Control and Prevention's Public Health Information Network website. Available from URL www.cdc.gov/phinf/tools/cts/index.html.

Through collaboration with state and local partners, the CTS team developed system features that map inventory through all the major steps of the inventory management process (see Figure 6-1). CDC's CTS consists of four components that allow tracking of MCMs and reporting of inventory levels from manufacturer, supplier, and retail levels; through distribution to the regional, state, and local level; and all the way down to dispensing to clients. The four components of CTS include

- Countermeasure Inventory Tracking (CIT) Dashboard;
- Countermeasure and Response Administration (CRA) system;
- Inventory Management and Tracking System (IMATS); and
- Communications Portal (CP).

These four components interoperate to enhance the capacity to track and manage MCM inventory and usage for support of all-hazards incidents, as well as day-to-day operations. Each component functions independently, but collectively the data consolidated from these systems can show population coverage, numbers of untreated individuals, drug and equipment shortages, need for resupply and more. All systems are free of charge and have a similar "look and feel" to facilitate ease of use. The Web-based applications are centrally located at CDC and require user security access through CDC's Secure Access Management Systems (SAMS).

Secure Access Management Services (SAMS)

As a government agency, CDC is bound by federal law to follow specific information security rules and processes. In accordance with federal information security requirements, CDC implemented safeguards to protect the data in its possession and the people and organizations that this information represents. Secure Access Management Services (SAMS) functions as the gateway to MCM tracking programs that require an identity proofing component by providing **authentication** and **authorization** for users.

- **Authentication:** Every individual system user must be uniquely identified (i.e., no two people may share a user ID). CDC must verify each user is actually the person they claim to be, through a process called Identity Proofing that must be performed before granting access to applications or to functionality within any system to ensure every action is correctly attributed to the person performing it.
- **Authorization:** Once a user has been authenticated, SAMS will ensure that users are only allowed access to systems or functionalities to which they have been explicitly approved.

Users for any of the four components of CDC's CTS applications must go through the SAMS authentication and authorization process prior to gaining access to CTS. Users must only go through this process once to have access to all the systems or functionalities that they are specifically approved to use.

Countermeasure Inventory Tracking (CIT) Dashboard¹⁰

CDC's Countermeasure Inventory Tracking (CIT) Dashboard is a national system that provides the ability to track the availability of critical medical and other countermeasures within the commercial drug sector as well as state public health agencies during public health emergencies. The primary purpose of the CIT Dashboard is to provide federal and state officials with situational awareness to assist in decision-making on the release of SNS assets. Using the CIT Dashboard, public health emergency managers will have a view of the overall commercial supply chain and public sector stockpiles, including data on production, current supplies, and ability of manufacturers and distributors to meet current demand. This information, combined with corresponding data from IMATS (including federal, state, and local stockpiles and vaccine supplies) can provide a complete picture of MCMs.

CIT data will provide critical information for situational awareness and emergency response to a natural disaster, pandemic influenza, or bioterrorism attack. During a public health emergency, decision-makers will be able to monitor the available inventory and location of MCMs within the supply chain and current distribution to affected areas to ensure that appropriate MCMs reach affected populations. During a public health incident, CDC may ask pharmaceutical and medical supply manufacturers, distributors, and retailers to contribute existing data voluntarily to CDC regarding current inventory and distribution of selected products. CDC personnel will view the data and make it available to public health partners, as appropriate. All uses of the data and potential disclosures will be covered in a Data Sharing Agreement that CDC will sign with each data source. CDC will use this data for public health preparedness and emergency response purposes only and a company's competitors will never have access to data provided to CDC. Use of data is strictly governed by the terms of binding legal data share agreements and the Trade Secrets Act.

Countermeasure and Response Administration (CRA)¹¹

CDC's Countermeasure and Response Administration (CRA) system is one tool public health partners may use to manage administration and tracking activities within their jurisdictions to support a full range of all-hazards incidents. CRA originated in the Pre-event Vaccination System (PVS) CDC implemented to track and monitor administration of smallpox vaccine as part of the National Smallpox Preparedness Program and was expanded for national, state, and local use to track vaccine doses administered during the initial weeks of the 2009 H1N1 influenza vaccination campaign.

CRA has the ability to track vaccine administration, as well as medical and other countermeasure dispensing at both the individual and aggregate levels. The primary objective of the system is to increase the capacity of all levels of public health to track and manage MCMs. In addition, CRA supports CDC's cross-jurisdictional reporting needs by providing flexible methods for accepting data from other systems or by extracting summarized data. CRA supports analysis of pharmaceutical safety, coverage, and

¹⁰ Information in this section is taken from the U.S. Centers for Disease Control and Prevention's Public Health Information Network website. Available from URL www.cdc.gov/phinf/tools/cit/index.html.

¹¹ Information in this section is taken from the U.S. Centers for Disease Control and Prevention's Public Health Information Network website. Available from URL www.cdc.gov/phinf/tools/cra/index.

effectiveness during an incident. CRA is a flexible all-hazards system that reduces the need for development of new applications each time there is a new incident.

CRA's advanced capabilities help ensure individuals receive recommended MCMs by tracking and managing information on vaccinations, dispensing of pharmaceuticals or medical equipment, treatments, and community mitigation measures. Key system capabilities include

- Management of multiple simultaneous events and countermeasures;
- Custom event creation and configuration;
- Flexible data entry screens for doses administered/dispensed information;
- Individual or aggregate level data collection;
- Data extracts for jurisdictional reporting; and
- Synchronization of data from off-line deployments.

Jurisdictions can use CRA as a Web-based application or offline, on a stand-alone basis, to support MCM operations. In addition, CRA supports file sharing, so that jurisdictions can utilize their own IMS and send data to CDC through CRA's file transfer (XML, pipe delimited) for the aggregate reporting; a feature needed for pandemic influenza and smallpox uploads. Future versions of CRA also will include HL7 messaging for data exchange.

Inventory Management and Tracking System (IMATS)¹²

The need for a mechanism to track MCM inventory down to the local level became apparent during the 2009 H1N1 influenza pandemic response. At that time, CDC needed inventory levels for antiviral medications and personal protective equipment (PPE) at the local level in order to make critical decisions on the allocation and distribution of these items. However, because effective inventory tracking mechanisms were not in place, this information proved very difficult to obtain. Following that incident, DSNS partnered with CDC's Office of Surveillance, Epidemiology and Laboratory Services (OSEL) CTS program to build a nationwide Inventory Management and Tracking System (IMATS).

The vision of IMATS is to increase the capacity of all levels of public health to track and manage inventory of medical and non-medical countermeasures during daily operations or an emergency response. IMATS provides planners with the capability to

- Create a line of sight for inventory (i.e., what is available and on-hand at all levels – state, regional, local, and/or dispensing sites), which allows federal officials to view inventory levels without the need to contact jurisdictions to request information;
- Identify point of delivery facilities where product is shipped (i.e., hospitals, county health departments, etc.);
- Determine how much of the product is used/dispensed at the point of delivery location, therefore extending the line of sight; and
- Facilitate RSS operations, including receiving, staging, and storing of inventory.

¹² Information in this section is taken from the U.S. Centers for Disease Control and Prevention's Public Health Information Network website. Available from URL www.cdc.gov/phinf/phin/tools/imats/index.html.

DSNS previously supplied stakeholders with an IMS known as RSS Inventory Tracking System (RITS). However, CDC discontinued RITS in 2011 and will no longer provide technical assistance for that system. The CTS development team created an inventory data exchange process, which will enable jurisdictions to report information from existing IMS to CDC. During an incident, jurisdictions that do not plan to use IMATS as their primary inventory tracking system will need to send inventory data to CDC via the protocol set in the IMATS data exchange specifications document. Project areas and localities using their own IMS can download an electronic copy of the data exchange specification document from the SNS SharePoint site¹³ or from the IMATS Web page.¹⁴

Communications Portal (CP)¹⁵

The Communications Portal (CP) is a content management system that consolidates important incident response information in one place, ensuring efficient communications during an incident. CP is a content management system complementary to IMATS, providing a central place for disseminating critical information to CDC partners regarding MCM tracking and usage during a public health emergency. However, planners should be aware that the CP is not a repository for documents (e.g., Emergency Use Authorizations or Investigational New Drug forms), but rather a central resource that directs users to source material related to the incident. Information included on the CP may include

- Emergency Use Authorization (EUA) and Investigational New Drug (IND) information (See **Chapter 8: Dispensing Medical Countermeasures** for further information on EUAs and INDs);
- Lot recalls;
- Announcements; and
- Related documentation and materials.

The initial version of the CP, released in 2011, includes the following functionalities:

- A spotlight feature highlighting the most current information and communication to state and local partners regarding the incident
- A general announcements section listing recent communications with hyperlinks to important documentation
- A calendar providing information about current and upcoming activities, webinars, and conference calls
- A document library containing all available documentation, presentation files, and more
- A resource section listing CDC contacts and other general information
- A management capability allowing jurisdictions to add users and customize information

¹³ The SNS SharePoint Site is a web-based collaborative workspace that allows users to share information and content. Planners can request access to the SNS SharePoint site by going to <https://www.orau.gov/sns> and following the prompts under "Request Access."

¹⁴ www.cdc.gov/phin/tools/imats/index.html

¹⁵ Information in this section is taken from the U.S. Centers for Disease Control and Prevention's Public Health Information Network website. Available from URL www.cdc.gov/phin/tools/cp/index.html.

The CP will streamline access to important and current communication and documentation during an emergency incident.

Developing an Inventory Management System

CDC encourages planners to adopt IMATS as their IMS and offers it free. In addition, IMATS provides CDC with a snapshot of the MCM supply on a weekly basis. IMATs, along with the inventory data exchange process, allows federal officials to better spot shortages lasting more than 24 hours, respond to inquiries from multiple federal offices and agencies, and report on-hand quantities to CDC leadership when making decisions to release additional SNS assets. However, some jurisdictions already have developed an IMS or partnered with professional warehousing companies to use an existing IMS. For jurisdictions that do not use IMATS, CDC recommends that planners evaluate their system's data collection and tracking capabilities to ensure that the minimal tracking elements listed on page 7 of this chapter are part of the IMS. These data elements will be vital to CDC in tracking national inventory levels during an emergency.

Inventory Management System Features

Inventory can be managed using manual or automated, commercial or created systems. The IMS also must have a backup, which can be inventory management software, electronic spreadsheets, or paper. An IMS should be simple to use and have the ability to support just-in-time training for any volunteers activated during an incident. Because items received at the RSS will likely be a variety of products and packaging, not just medical supplies, the jurisdiction's IMS should have the capability to track and manage inventory from various sources, besides the SNS. The IMS must be able to support medical and other countermeasures, as well as donated items, such as food, water, MCMs, or emergency supplies (e.g., flashlights, batteries, extension cords).

In addition, the IMS should be able to import the electronic file of the inventory list from a 12-hour Push Package, which CDC will provide prior to the arrival of assets. This file is in a pipe-delimited format that imports into most database programs, such as Microsoft Excel and Access, or most commercial IMS. Computer savvy members of the IMT can assist in using an electronic IMS and training others in its use.

The IMT should have the ability to continue RSS operations even if electrical power or Internet connectivity is unavailable, which in some instances could last for an extended period. Since redundant procedures are important to continued MCM operations, the jurisdiction should plan for a backup offline IMS that will enable users to synchronize data once power or Internet connectivity is restored. Some RSS facilities will have backup generators to ensure power when the main power supply is disrupted and the IMT should be aware of the procedures to continue to document inventory actions during power or Internet outages.

Activating Inventory Management Staff and Resources

Prior to the delivery of MCMs to the RSS or regional distribution site (RDS), if applicable, all staff, including the RSS team, should be activated, which typically occurs through state and

local agencies' call down lists. The recommended time to activate and fully staff the RSS is six hours from the approved request. Staff should activate the IMS, check staff identities and provide identification badges, conduct just-in-time training for any volunteers, and provide job actions sheets for inventory management positions. As the incident progresses, the IMT lead may need to adjust staffing to meet the number of asset requests received to achieve dispensing goals.

Assessing Inventory and Monitoring Local Requests

Upon activation, the IMT should assess the number and types of items in stock. The jurisdiction's established IMS will aid in determining existing inventory and the IMT can communicate with incident command to determine whether this inventory includes items that local areas will request or need. The jurisdiction's IMT should be capable of actively tracking and recording resources, completing and submitting request forms, reporting inventory levels, and documenting distribution.

To monitor and keep a continuous record of local requests, the RSS should have procedures in place to communicate with local jurisdictions, which in turn must be able to communicate to the RSS or emergency operations center with the type and quantity of available local inventory and any MCM needs. Jurisdictions should monitor MCM levels at dispensing sites, as well as health-related agencies and organizations, by collecting data on MCM levels at least once per week, but potentially more frequently as determined by incident needs. For instance, in the early stages of a large-scale incident, especially one in which everyone in the jurisdiction must receive MCMs, the inventory management plan should include data collection from dispensing sites at frequent intervals, perhaps on an hourly basis. Additionally, procedures should be in place for requesting state or federal assets when local resources are depleted.

Chapter 10: Strategic and Tactical Communications provides further information on developing communication systems and **Chapter 4: Requesting Strategic National Stockpile Assets** provides further information on developing the jurisdiction's request process.

Receiving SNS and Donated Products

CDC may deliver numerous types of products from the SNS to the RSS. Most pharmaceuticals in the SNS must be kept within specified temperature ranges (usually 68° F–77°F; see **Chapter 5: Receiving, Staging, and Storing Medical Countermeasures** for further information) according to cGMP. Because of these temperature-related controls, the IMT should work quickly with the RSS team to log the receipt of products into the IMS so that MCMs do not sit on loading docks, but are stored or transferred to an appropriate temperature-controlled environment.

During an emergency, a state or jurisdiction may receive MCMs as a package containing multiple types of MCMs in a single unit. For instance, the 12-hour Push Package and Federal Medical Stations (FMS) each arrive as one group of assets yet have different items within some packages. The IMT will have to open these packages, inventory the contents, and record all items in the IMS.

In other instances, MCMs will come from SNS managed inventory (MI) so that pallets may contain a single product and lot number, making entry of inventory into the IMS easier. However, the IMT should ensure that the RSS is activated and staffed at the time MI arrives. Therefore, it will be important that the IMT, RSS lead, and SNS coordinator maintain contact with one another and with CDC to ensure that staff is prepared to receive MCMs when deliveries arrive. The need for accurate communications became evident during the 2009 H1N1 influenza pandemic response when there was no system in place to accurately inform jurisdictions of when or what types of products would arrive and, at times, delivery drivers would arrive at an RSS and find no staff present to accept the shipments. To address this, CDC provided the SNS coordinators with driver contact information and detailed information of what items were in transit to the RSS to enable jurisdictions to communicate and coordinate with drivers en route.

In addition to SNS-provided MCMs, jurisdictions likely will receive donated products. CDC recommends that planners develop a system for accepting, storing, and distributing donated items, including a process for identifying items as donated within the IMS once a designated medical officer has inspected and quarantined them. The IMT should be aware of procedures for handling donated material and entering it as inventory in the IMS.

Apportioning Medical Countermeasure Assets

Apportionment is the process of dividing MCMs into initial allotments to send to PODs and treatment centers based on the epidemiology, intelligence, the number of people affected, or projected inventory. During an incident, particularly in the first several days of a large-scale incident, treatment centers may be overwhelmed with casualties, unable to determine their true requirements, and too busy to order and receive additional resources. The jurisdiction's incident command may respond to such a situation by directing the MCM operations management and IMT to issue specific quantities of MCMs to specific sites.

When certain sites receive more supplies, other sites may still be in need of and ordering assets and orders may temporarily exceed supplies. In such a case, the jurisdiction may decide to allocate available supplies among the remaining treatment centers. This approach can treat current patients while buying time for the PODs, treatment centers, and the IMT to order and distribute additional assets. The amount apportioned to each entity should not change whether a jurisdiction receives a 12-hour Push Package or MI. Being able to apportion assets removes the possibility of preferential treatment while waiting for additional assets to arrive.

When determining the allocation to each treatment center or POD, jurisdictions should consider

- The number of dispensing sites, including closed and open PODs, treatment centers, and any alternate dispensing partners;
- Actual and projected case counts in each dispensing site;
- Percentage of assets to be delivered;
- Previous deliveries to each dispensing site; and
- Distance and travel time to each delivery location.

If the incident command does not direct quantities going to specific sites, an IMT, using IMS, may have to give all major treatment centers equal proportions of available supplies or hold back some supplies until better information is available.

Demobilizing Inventory Management Operations

Prior to an incident, the IMT should develop procedures for demobilizing operations once the incident has been mitigated. The demobilization plan should include procedures for deactivating operations, reconciling inventory records, recovering items for storage within the jurisdiction or return to CDC, and backing up and securing all records.

Reconciling Inventory Records

Often when dealing with large amounts and numerous types of items, inventory losses occur whether through poor oversight, miscounting, or other factors. Reconciliation is the process of determining the true, “at-hand” inventory and comparing it with inventory listed in an IMS. Reconciling inventory records usually involves printing the list of items in the IMS and counting the inventory within a jurisdiction, but inventory also can be reconciled by referencing chain of custody forms. In reconciling inventory records, the IMT should ensure that items are present in the numbers listed in the IMS and that items are where they should be in the storage site (i.e., on the appropriate aisle and shelf location) or treatment center (i.e., hospital, etc.). The IMT lead should work with the RSS lead to determine the process and procedures for reconciling, document these procedures, and make sure the IMT members are aware of and understand their roles in the reconciliation process.

Recovering SNS Equipment and Containers

The signed memorandum of agreement (MOA) between the state and CDC stipulates that certain SNS equipment and containers (section III-E; III-F(2)) will be returned to CDC. Due to these responsibilities, the state and local jurisdictions must be able to account for assets sent to them (section III-C). Appendix I of the MOA contains a list of equipment, containers, and other durable assets, including contents of an FMS and other assets the jurisdiction must return at CDC’s request. Per the 2010 MOA, CDC is responsible for fees associated with return shipment of materials it requests. Planners should refer to the MOA for the detailed list, however, a few items include

- CHEMPACK and 12-hour Push Package cargo containers;
- Ventilators;
- Ventilator cargo containers and cases;
- Refrigeration systems;
- Miscellaneous general items;
- Medical and special needs equipment (e.g., suction units, bariatric sets); and
- Computer and communications equipment.

The jurisdiction’s IMS will need to be able to register the shipment of assets back to CDC. The chain of custody procedures will require quantity, tracking numbers (e.g., lot, equipment, or property), signatures, and shipment tracking numbers with release and receipt signatures. If assets are moved within a jurisdiction (e.g., from local warehouse to hospital or treatment

center) CDC recommends that the IMT record the names and contact information of individuals accepting the assets and ensure the receivers are aware that they may be responsible for returning any requested assets to the jurisdiction's RSS or other facility for eventual return to CDC.

Planners should note that **pharmaceutical items cannot be returned**. Planners should remember that once the state accepts MCMs from the SNS, any unused pharmaceuticals remain the property of the state and do not need to be returned to CDC.

Resources

A specific listing and pictorial guide to material in the 12-hour Push Package is available in the **Strategic National Stockpile 12-hour Push Package Product Catalog** on the SNS Extranet at www.orau.gov/snsnet/about.htm#formulary. The SNS Extranet is password protected and planners can contact the state SNS coordinator or Division of State and Local Readiness (DSLRL) project officer to obtain the user name and password.

U.S. Drug Enforcement Administration (DEA)

Local DEA office information is available on the DEA website at www.dea.gov/pubs/states/domestic.html.

Detailed information on DEA Form-222 is available on the DEA website at www.deadiversion.usdoj.gov/faq/dea222.htm.

Cold Chain Product Storage and Handling Information

CDC's National Center for Immunization and Respiratory Diseases' **Vaccine Storage and Handling Guidance** online at www.cdc.gov/vaccines/recs/storage/default.htm.

International Air Transportation Association **Perishable Cargo Regulations** are available online at www.iata.org/ps/publications/Pages/perishable-cargo.aspx.

U.S. Army Medical Department offers **Cold Chain Management Processes and Procedures for All Medical Temperature Sensitive Products**, which is available online at www.usamma.army.mil/cold_chain_management.cfm.

Chain of Custody

Environmental Protection Agency **Chain of Custody Guidelines** are available on the EPA website at www.epa.gov/apti/coc.

Countermeasure and Response Administration (CRA)

To utilize CDC's CRA application, planners can contact the CRA team through the CRA help desk at 800-532-9929 or e-mail PHINTech@cdc.gov.

Chapter 7: Distributing Medical Countermeasures

Once the state receives federal assets at its designated receipt, stage, store (RSS) facility, the state is responsible for moving those assets to dispensing sites and in some cases to an intermediate or regional distribution site (RDS). In many planning jurisdictions, trucks will be the primary method used to deliver medical countermeasures (MCMs) to the various locations for dispensing. Jurisdictions also might use aircraft, watercraft, and railways (including subway and commuter trains), if available, to move resources to various locations. Planners must develop a comprehensive distribution plan to ensure the jurisdiction distributes MCMs as seamlessly as possible from the state- to the local-level for dispensing to people in the affected area. The Centers for Disease Control and Prevention (CDC) recognizes that state and local Strategic National Stockpile (SNS) planners most likely do not have a background in distribution or logistics and encourages planners to partner with other government agencies and private and public sector organizations in the jurisdiction for assistance in this function.

Building the Distribution Team

A well-developed distribution team will consist of personnel who can work closely with members of the RSS, dispensing, and security teams to provide the smooth transfer of MCMs from the state level to the dispensing sites. The distribution team is responsible for

- Developing and implementing the distribution plans, policies, and protocols;
- Developing and maintaining current routing information;
- Coordinating security and communication procedures for the distribution network;
- Overseeing appropriate use of material handling equipment (MHE); and
- Coordinating effective loading and unloading of MCMs.

The distribution team will include

- A distribution manager and at least one back-up;
- Route developers;
- Dispatchers;
- Vehicle drivers;
- Security personnel; and
- Support personnel.

Distribution Manager

The distribution manager will coordinate distribution planning and oversee distribution activities at the state, regional, or local level, depending on the planning jurisdiction. This role

involves coordinating transportation of MCMs between RSS, RDS (where applicable), and points of dispensing (PODs), hospitals, treatment centers, and alternate dispensing partners. At the local level, activities could involve coordinating distribution between RSS or RDS and community PODs, closed PODs, hospitals, treatment centers, and alternate dispensing partners. Individuals in this position should have

- A background in transportation;
- Knowledge of shipping and receiving regulations and requirements for the jurisdiction;
- Experience in and knowledge of route development; and
- Familiarity with multiple distribution modalities for the jurisdiction.

Planners can look to partners from state or local departments of transportation, private sector transportation partners, and private sector shipping partners to find individuals with the skill set to serve in this position.

Route Developers

Route developers analyze available transportation routes and modes and determine the best ways for transport vehicles to travel to delivery sites and return to the RSS or RDS to pick up the next shipment. Route developers will develop preliminary routes and keep track of road closures, traffic patterns, and any incidents that may require vehicles to be re-routed. Route developers will work with dispatchers to assist in determining the best ways to route shipments and maximize transportation resources. The people in this position should have the ability to use and understand route development software, read maps, and comprehend traffic patterns. The distribution manager may serve as route developer or planners may enlist personnel from the jurisdiction's information technology (IT) resources. The jurisdiction's transportation or public safety departments also can provide personnel and resources for route development.

Dispatchers

Dispatchers assign deliveries to specific drivers and vehicles, track the movement of vehicles, and ensure vehicles arrive at delivery points and return to the RSS or RDS facility as expected. Dispatchers analyze the required shipment sizes (e.g., number of cases of MCMs), sizes of available vehicles for delivery, and delivery locations, then determine ways to load and route vehicles in order to maximize transportation resources. Dispatchers will work closely with route developers to determine the best transportation routes and best ways to load vehicles to ensure the most efficient routing of MCMs. In addition, dispatchers will work closely with route developers to keep track of preferred routes and locations of problems (such as contaminated areas, congestion, closed roads, and downed bridges) that may require rerouting.

Dispatchers will need a system for tracking shipments of MCMs as they are loaded at the RSS facility, in transit to the delivery sites (including the location of the delivery vehicle), and received at delivery points along the route. The least complicated dispatch system is a large wall chart that identifies all delivery locations and the preferred routes to those locations; however, jurisdictions also can purchase an automated system for this purpose.

In addition, dispatchers will need a clear system of communication with delivery drivers, the distribution manager, route developers, and the inventory supply lead at the RSS to ensure

coordination between orders of MCMs for shipment from the RSS to dispensing sites, empty vehicles arriving for loading at the RSS, and personnel who will receive MCMs at the delivery sites.

Chapter 10: Strategic and Tactical Communications provides information on communication systems and devices.

Vehicle Drivers

Vehicle drivers will transport MCMs from the RSS or RDS to the delivery sites, pick up compromised MCMs (e.g., MCMs with damaged packaging) and/or empty pallets from dispensing sites, and possibly deliver supplies (e.g., fact sheets, signs, etc.) to dispensing sites. Planners should work with the distribution manager to identify licensed drivers who are qualified to operate their assigned vehicles. In some cases, drivers may be owner/operators of vehicles, in which case they should have all required transportation department licensing. Where possible, drivers should go through security screening and receive identification badges prior to an incident.

Security Personnel

Security personnel will work with the distribution manager, route developers, and dispatchers to ensure that routes selected can be secured. Depending on the size and scope of the incident, security personnel may be assigned to accompany MCMs, drivers, and vehicles from the RSS, en route to delivery locations, and until shipments are received at dispensing sites. Security personnel at the RSS, RDS, and dispensing sites can ensure that distribution vehicles have clear access to docks or unloading areas during deliveries. In addition, security personnel also can verify identification (ID) and driver's or other operator's licenses for assigned vehicle drivers and provide incident-specific ID badges for personnel involved in distribution operations. Planners should work with the lead security planner for MCM operations to locate partners from state or local law enforcement, National Guard, and private security partners to serve in this position.

Chapter 11: Securing Assets, Staff, and Operations provides further guidance on security screening and requirements for ID badges.

Support Personnel

Support personnel will fill multiple roles on the distribution team, including recovering disabled vehicles, redirecting compromised MCMs, re-fueling vehicles, and possibly repairing vehicles that are broken down or sending appropriate support vehicles, such as tow trucks. Staff or volunteers from various backgrounds can fill support roles.

Developing Distribution Networks

A distribution network is a system of interrelated people, facilities, and transportation resources that work together to move assets efficiently from the state RSS facility to MCM dispensing sites, including PODs, hospitals, treatment centers, and alternate dispensing partners. In some jurisdictions, the distribution network forms a direct line from the RSS to the

dispensing sites; while in other jurisdictions, the distribution network will include one or more RDS. To design the jurisdiction's distribution network, planners will need to identify

- All destinations that will receive MCMs;
- All available transportation resources for delivery of MCMs; and
- Agencies that can serve as security resources to protect drivers and MCMs en route from the RSS to the delivery destinations.

Depending on the distribution plan, state planners will need to assign roles and responsibilities between state and local government agencies and work together to ensure the plans accommodate rapid transport of MCMs to the dispensing or treatment locations.

Identify Distribution Sites

To determine the routes, modes of transport, and number of personnel needed to distribute MCMs, planners will first need to determine all sites that will receive MCMs from the RSS. These sites include

- RDS (if applicable);
- PODs, including closed PODs;
- Hospitals;
- Treatment centers; and
- Any alternate dispensing partners, such as Meals on Wheels or home healthcare agencies.

Chapter 8: Dispensing Medical Countermeasures provides further information on possible dispensing sites and partners.

Information for delivery sites should include the facility name, a contact person's name and phone number, and an address for delivery. Locations should provide the exact address for delivery, which may differ from the facility's main address. For instance, a school used as a POD may have an address on the main street the school faces, but the loading dock for receipt of MCMs may be on the street behind the facility. It will be vital that delivery personnel know exactly where to deliver assets in order to ensure the most efficient distribution operations. Some jurisdictions have found the best way to identify unloading areas at delivery sites is by using GPS coordinates, which will route drivers directly to the designated unloading area rather than a street address.

In addition, information on delivery locations should include information on the unloading area, including whether the site has material handling equipment (MHE) to unload MCMs from delivery vehicles. For instance, on a distribution route, site A might have a loading dock that will accommodate a delivery truck, doors that are large enough for pallets, plus pallet jacks and people who can assist in unloading assets for that site; while site B may not have a loading dock, but have doors wide enough to accommodate shipping pallets. When dispatchers know facility specifics, they can determine distribution routes based on which vehicles can accommodate the unloading areas of the various sites. In this example, the dispatcher will need to make sure that the vehicles sent to these two sites have correct MHE. For instance, delivery site A can accommodate a standard delivery truck, which can back up to the loading dock for unloading, while site B will need a truck with a lift gate or ramp and a hand truck to unload materials, unless the facility has a forklift and operator to remove pallets from the truck.

Identify Transportation Resources

Planners will need to determine which transportation resources will be available during an emergency and reach out to organizations and agencies that supply those. Some sources for transportation resources include

- National Guard units;
- State, county, regional, or municipal department of transportation (including air, ground, rail, and water traffic management, where applicable);
- Public works department;
- Parks and recreation departments;
- Department of education; and
- Law enforcement agencies.

Many planning jurisdictions face the possibility that there may not be enough government-supplied transportation resources to support the delivery needs of the PODs and other MCM delivery sites. Due to this possibility, many planners augment vehicle fleet resources by forming partnerships with other organizations, such as

- Local retailers;
- Commercial grocery/pharmacy distribution chains;
- Commercial logistics companies; and
- Local trucking and delivery companies

These collaborative partnerships may provide primary or back-up transportation modes, personnel, vehicle repairs, and fuel sources. Planners will need to establish written agreements for any partners, including government agencies. In addition, any organizations that serve a function in the distribution network should participate in the jurisdiction's training and exercises for MCM responses.

Chapter 13: Training, Exercising, and Evaluating Plans provides further information on incorporating partners into training and exercises.

Identify Security Resources

The distribution manager will need to work with the jurisdiction's lead for MCM security planning to identify security resources and develop specific policies to protect the distribution network. Planners will need to work with security partners to determine policies, including

- How volunteer's and driver's IDs will be checked and how they will receive ID badges for the incident;
- Whether or not security escorts are needed;
- Whether security personnel will be stationed in distribution vehicles or in security vehicles (such as police cars or National Guard trucks) that serve as escorts for delivery vehicles;
- Whether to use lights and sirens for security escorts accompanying delivery trucks (some jurisdictions regard this as a risk as it makes delivery vehicles targets for those who might want to disrupt MCM distribution networks or hijack materials); and
- How to ensure access to all delivery points.

Determining Distribution Models

To maximize the efficiency of the established distribution network, planners must determine whether to use a direct shipment or multipoint distribution model. In a direct shipment model (Figure 7-1), assets move directly from the state's RSS facility to local PODs, hospitals, treatment centers, and alternate dispensing partners.

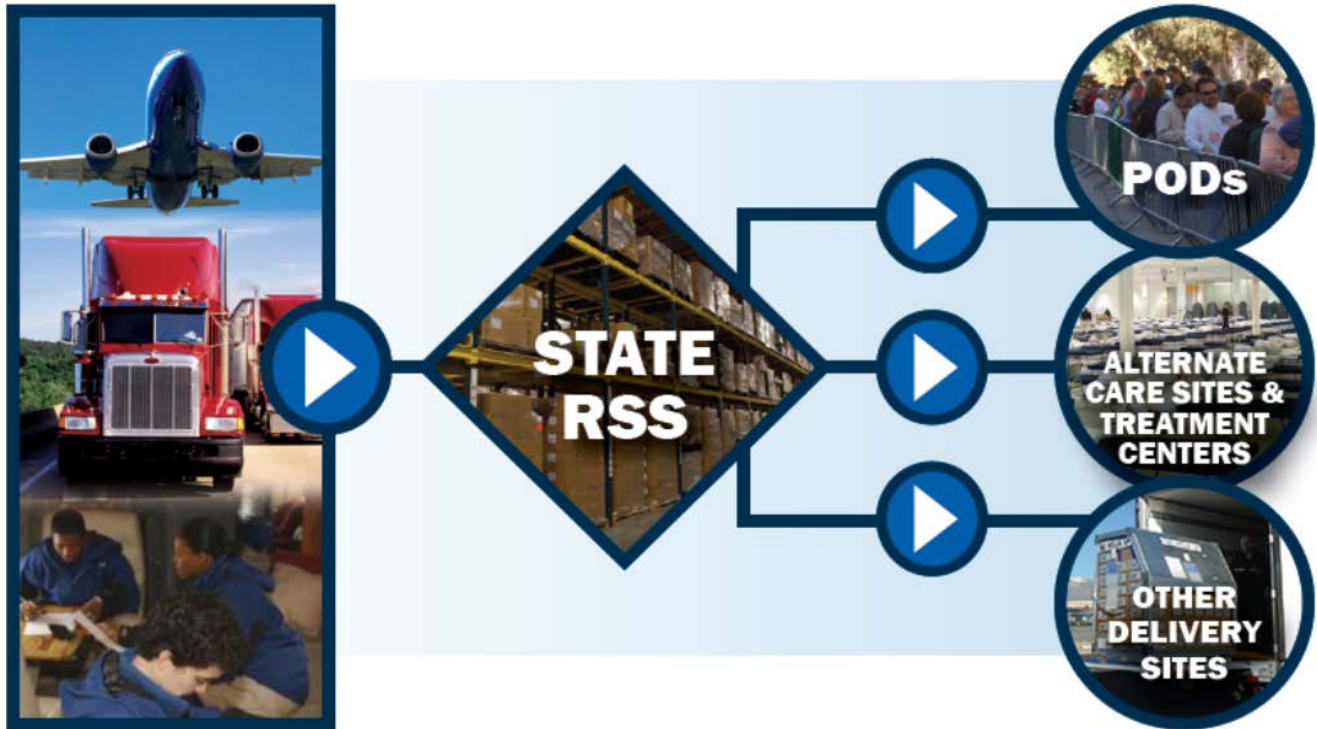


Figure 7-1: Direct shipment model.

In a multipoint distribution model (Figure 7-2), assets move from the state's RSS facility to an intermediate distribution site, such as a county or local facility, that serves as the RDS, which in turn delivers assets to local PODs, hospitals, treatment centers, and other dispensing sites. Some states also employ a multipoint distribution model that moves assets from the RSS to the RDS and further down to local intermediate distribution sites before transferring assets on to dispensing sites.

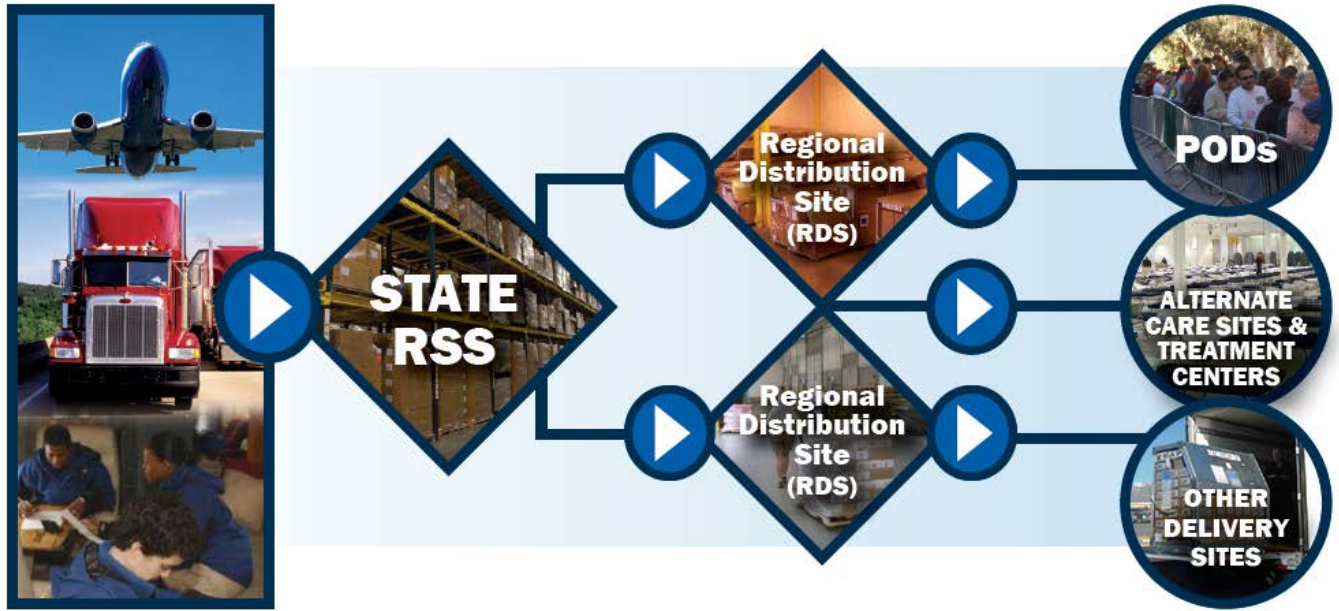


Figure 7-2: Multipoint distribution model.

States also have developed variations of the direct shipment and multipoint distribution models. In one variation, the hybrid distribution model (Figure 7-3), the RSS simultaneously moves assets to PODs and other dispensing sites closest to the RSS, while also distributing assets to an RDS that distributes to local dispensing sites.

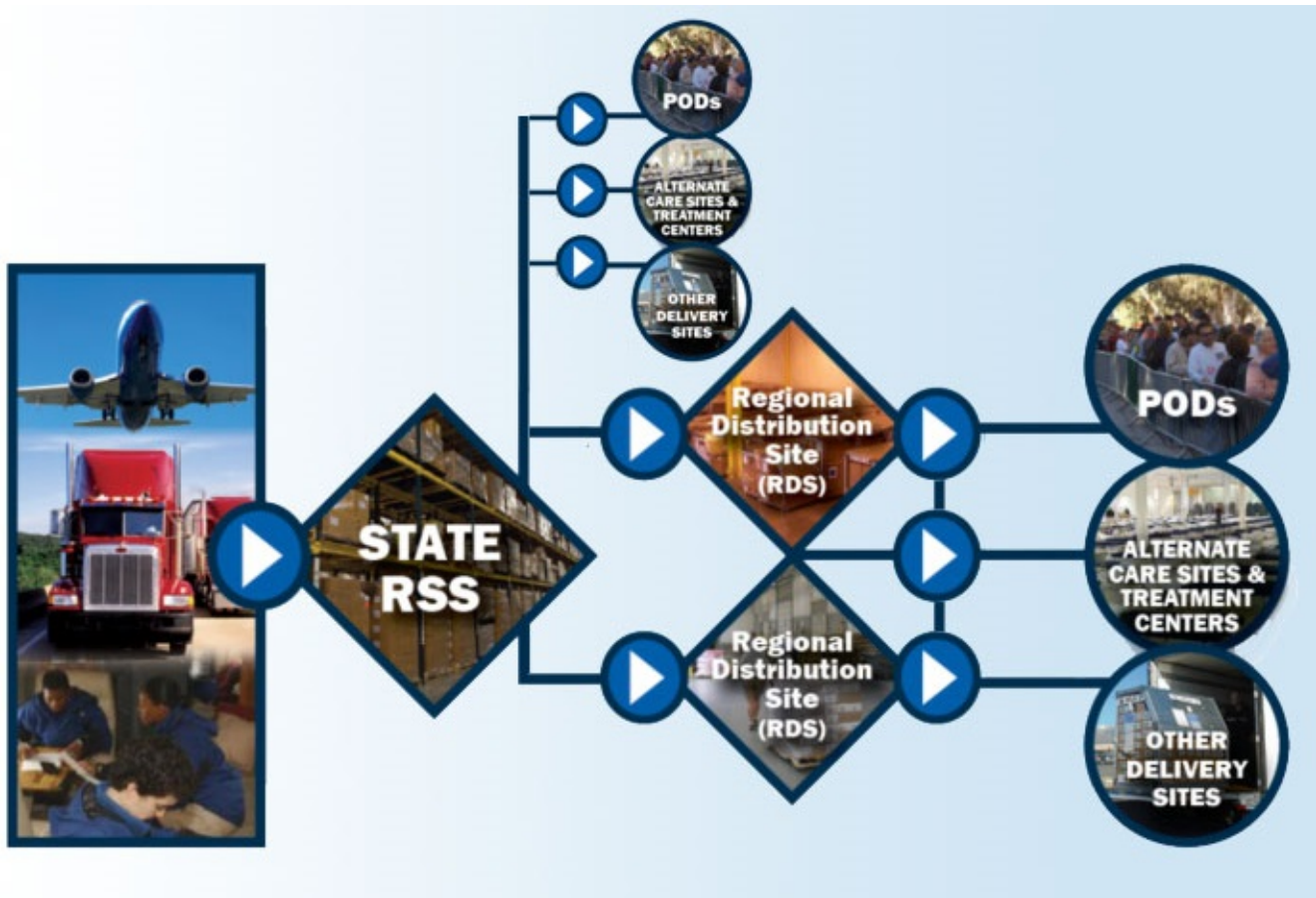


Figure 7-3: Hybrid distribution model.

All distribution models have advantages and disadvantages. Some planners question whether a direct shipment network, with a single point of delivery at the RSS, is the most efficient means of distribution; while others wonder whether adding delivery points (e.g., RDS and local distribution sites) to the network will increase delays within the process. Planners should consider the following important factors related to the multiple stops that shipments could make when distributed through multipoint distribution networks:

- Multiple stops provide a greater opportunity for assets to be delayed, damaged, lost, or stolen.
- Multiple stops to transfer assets from one distribution mode to another (e.g., truck to warehouse to secondary truck) can cause slower distribution rates than a direct distribution network.
- Multipoint models require more distribution facilities, which will require more people, shipment tracking, and equipment for distribution operations than a direct shipment model.

After reviewing the distribution models, planners should build a distribution network for their jurisdictions by

- Identifying a distribution model that works best within the planning jurisdiction;
- Identifying and collaborating with well-established commercial transportation firms, where possible, to obtain advice and guidance;

-
- Developing a communication matrix that provides clear lines of communication between the state RSS, RDS (if applicable), PODs, hospitals, treatment centers, other delivery sites, security escorts, and vehicle drivers; and
 - Define the roles and responsibilities of people, agencies, and organizations within the distribution network.

Incorporating the Distribution Team into MCM Response Planning

The jurisdiction should incorporate the distribution team into its current incident command structure and communication matrix. During a response, the distribution team must be able to coordinate efforts with other MCM response teams, including the RSS team, security, POD managers, and tactical and strategic communications to ensure the most efficient distribution of MCMs. The jurisdiction should include any pre-identified distribution personnel in any training and exercises conducted prior to an incident. As with all areas of MCM response planning, planners should document any training and develop job action sheets for various roles on the distribution team.

In addition, because spontaneous volunteers, both professional and non-professional, may arrive to fill positions in the distribution team at the time of an incident, planners should work with the designated distribution manager to develop just-in-time training (JITT) materials for each of the distribution team positions and their individual functions. JITT materials should include information on the incident, MCMs and any special handling instructions, and the need for security around the RSS, transportation networks, and MCM delivery sites. Specifically, planners should develop a briefing handbook to provide to drivers at the time of activation. This briefing book should outline

- The MCM chain of custody procedure (i.e., receipt of shipment at RSS, signatory at delivery site, communicating with dispatch on location of shipment, etc.);
- Routing information including any specific areas to avoid and whom to contact should they need to change the designated route due to road closures or traffic;
- Specific security requirements for the incident (e.g., RSS and dispensing locations, transportation networks, etc.) and contact personnel for security of MCMs en-route;
- Communications procedures (e.g., name and contact information for dispatch and routing, specific radio frequencies [if using two-way radios], etc.); and
- Safety information for MHE.

Testing the recall of all team members will ensure viable communication lines and increase the probability that team members will arrive promptly during activation of the MCM response system. The distribution team should perform periodic communications checks with all members, including drivers, delivery locations, dispatch, inventory control, law enforcement or security support, supporting organizations, and the planning jurisdiction's emergency operations center. In addition, the jurisdiction should include all pre-identified distribution team members and partners in MCM exercises to orient staff and volunteers to MCM operations and determine gaps in training.

Determining Transportation Requirements

A well-developed distribution network will facilitate the most rapid delivery of MCMs with a fixed number of transportation resources. Planners should look at all possible sources for transportation resources and determine the number and hauling capacity of available vehicles and credentials of licensed drivers/operators. Planners, in conjunction with the distribution manager, route developers, and dispatchers, should determine how to utilize available resources and most rapidly move MCMs from the RSS to all dispensing sites. If partner agencies (e.g., public works, department of transportation, etc.) do not have sufficient resources to meet the jurisdiction's needs, planners should work with any identified transportation partners outside of government agencies to determine whether they can provide additional transportation resources during a large-scale incident. If so, planners can then determine how to allocate all transportation resources to maximize transportation assets and expedite the distribution process.

Each planning jurisdiction should consider the following requirements for both primary and back up transportation modes:

- Trucks
 - 10- to 24-foot cargo or "box" trucks with or without hydraulic lifts are the ideal workhorse for the distribution fleet and do not require commercially licensed drivers. These trucks are often available for rent by local rental agencies
 - Full-sized pickup trucks or cargo vans can be used alone or to tow trailers
 - Cargo or utility trailers, with or without ramps, also could be pulled by large sports utility vehicles, cargo vans, or pick-up trucks
 - Tarps to protect loads in open-bed trucks/trailers from the weather
 - Restraining straps to keep loads from shifting
 - Hydraulic lifts on the back of trucks to eliminate the need for a forklift or a loading dock at delivery locations
- Aircraft resources
 - Depending on aircraft type, nearby helipads or appropriate landing strips for winged aircraft
 - Slings for carrying loaded cargo containers under helicopters
 - Ground-to-air communication with pilots
 - Charts that identify delivery locations
- Rail (subway or railroad)
 - Rail sidings or elevated platforms
 - Transfer docks and forklifts for loading/unloading railcars
 - Freight-elevator access to subway platforms
- Watercraft
 - Piers or boat docks
 - Forklifts or cranes to load and unload materials

General distribution plans should include plans for 24-hour refueling, repairing, and recovery of vehicles, pallets, and containers (e.g., 12-hour Push Package containers from the SNS or other shipping containers, if used). If possible, drivers should have a credit card for the purchase of fuel at any commercial location in order to avoid delays related to returning to a jurisdiction's supplied source of fuel.

Distribution teams should assign tactical communication equipment to drivers or verify that such equipment is present in delivery vehicles to guarantee communication between drivers, dispatch, security, delivery site, and the RSS or RDS at all times. This could be as simple as providing a cellphone to drivers. In addition, some cellphones come equipped with GPS tracking, a feature that might be useful in assessing the locations of distribution assets, especially in the event that assets need to be deployed to a location other than the one to which they were originally routed or to transfer MCMs from one location to another.

When considering transportation modes to include in the distribution network, planners also should determine each mode's availability, lead-times, and hauling capacity for both MCMs and personnel. Planners also should explore the possibility of equipping vehicles with a GPS navigation system and live tracking systems to provide real-time status of vehicle location. Plans also should include standby vehicles to aid disabled vehicles and recover MCMs when vehicles break down during operations.

All transportation modes used should have the ability to maintain MCMs at appropriate temperatures according to Title 21 Code of Federal Regulations, Part 211 (21CFR211.56),¹ which pertains to the current good manufacturing practices (cGMP) for pharmaceuticals. However, some MCMs may come with special handling requirements, such as specific controlled substance regulations, and planners will need to have a variety of transportation modes to accommodate distribution and specific regulatory requirements of some MCMs, including refrigeration for some assets from the SNS.

When CDC ships items that require refrigeration, such as vaccines (e.g., smallpox vaccine, anthrax adsorbed vaccine, or others biologic products requiring cold chain management), staff use cold chain packing protocols and specialized shipping containers to ensure that the items remain at the proper temperature throughout the packing and shipment processes. CDC ships these items in either an electric/battery back-up refrigeration shipping container (Vaxi-Cool™) or, in most cases, a specialized foam shipping container (Endotherm™). These shipping containers can maintain the required temperature for up to 72 hours without electricity or the need for additional refrigeration. However, the jurisdiction's distribution plans should include plans for refrigeration trucks to maintain items in cold chain management in case the product is not dispensed within the timeframe for which shipping containers can sustain the required storage temperature. **Appendix E: Cold Chain Management** provides further information on the shipment and handling of materials requiring refrigeration.

Developing Distribution Routes

Once planners have determined distribution networks, shipment models, and transportation resources they will need to identify the primary and back-up route options from the RSS or RDS, to the PODs, hospitals, treatment centers, and other dispensing sites, including alternate dispensing partners. Route development will assist planners in determining the distance and delivery time between all sites in the distribution network and determine the best ways to apportion and allocate MCMs during an incident. Because no one can predict the nature of

¹ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=211.56&SearchTerm=sanitation

a possible incident, the distribution plan should identify primary dispensing sites that may be first in line for MCMs, such as the dispensing site for first responders or a large POD that will serve a significant portion of the population.

While the goal is to provide MCMs to all dispensing sites at roughly the same time, the reality is that, depending on the incident and the available transportation resources, trucks may have to make several stops along a delivery route and may be able to drop only partial shipments of MCMs in the early stages of an incident. Therefore, advanced planning in how to apportion MCMs and allocate resources can greatly improve the distribution process during an emergency. While the plan is for all dispensing sites to open for operations at the same time, the reality is that some PODs may receive MCMs 10 hours prior to opening to the public, while others may receive MCMs just an hour before doors open. Therefore, it is important for the distribution manager to work closely with the dispensing lead to determine priority sites that should receive asset deliveries in the first hours of an incident. State SNS planners should consider partnering with their state Department of Transportation (DOT) for developing and/or analyzing distribution routes. The state DOT will have the ability to assist in route planning and have the latest updates on road construction and closures. They also may have software to help develop a distribution plan.

To improve the route development process, planners can utilize route optimization software. CDC provides **TourSolver and TourSolver Regional**, software programs that enable planners to generate optimized distribution routes for the entire fleet of vehicles in their distribution network. The Stockpile Routing Web Portal, <http://cdcstockpilerouting.c2logix.com>, provides planners with free access to TourSolver software, which they can use to develop routes from the RSS or RDS to PODs, treatment centers, and any other dispensing sites.

Writing the Distribution Plan

Once the distribution team has outlined some of the basic principles of the distribution plan, they should capture these in a written plan. Distribution plans also should include a comprehensive guide outlining transportation requirements and resources. The team should develop this guide based on the availability of transportation partners and resources. The plan should identify vehicle types needed and a list of primary and secondary transportation partners and resources available. The written plan should include the following:

- Written agreements with any transportation partners, including government agencies, commercial partners, or volunteer organizations
- Roles on the distribution team, names of people or organizations that will fill those roles, contact information for those people, and locations where people will report during an activation (e.g., the distribution manager may report to the emergency operations center [EOC] or to the RSS or RDS, depending on the plan and what the MCM operations lead determines as best policy)
- Addresses, contact information, and specific site information for RSS, RDS, and any delivery sites for which the jurisdiction is responsible, including PODs, hospitals, treatment centers, and alternate dispensing partners
- The number, types, and descriptions of any known transportation vehicles
- A plan for how MCMs will be recovered if they have been damaged or compromised (e.g., will distribution vehicles pick up compromised MCMs while dropping off a

delivery to a POD or will one vehicle be sent to pick up all compromised MCMs from all dispensing partners?)

- A plan for support of vehicles and drivers, including
- How MCMs will be recovered if a vehicle breaks down en route to dispensing sites;
- How vehicles will be refueled during operations;
- How vehicles will be repaired during operations;
- Plans for drivers' breaks; and
- The length of a driver's typical shift.

A plan for communications during operations that includes the mode of communication (i.e., two-way radios, cell phones, etc.) and back up modes, plus specific communications channels including

- Whom drivers contact if their vehicles break down;
- How dispatch will communicate with drivers; and
- How the distribution manager will communicate with dispatch and dispensing site managers.
- Job action sheets and JITT for staff and volunteers
- A staff welfare-and-care plan that includes recommended lengths of shifts, breaks, available space for resting (e.g., a break room or lounge at the facility in which they are stationed), and plans for meals

The written plan also should include locations to which team members will report during activation and response. Depending on the jurisdiction, and working with the MCM operations lead, the distribution manager may report to and operate from the emergency operations center (EOC) or the RSS. As the MCM operations lead, dispensing lead, RSS lead, and distribution lead work through the planning process and exercise the plan, they will determine the most effective duty sites for everyone during a response.

Developing Action Item Lists

Prior to a public health emergency, the distribution team should develop an action item list that identifies items needed to distribute MCMs efficiently during an incident. The distribution team should list all actions that should take place during activation and assign roles to team members pre-incident. During activation, distribution team members will go through the action item list, compile information, and prepare for and manage movement of MCMs from the RSS to all the sites that will require them. Action Items in the list will include the following:

- Names, addresses, and multiple 24/7 contact telephone numbers for the RSS, plus delivery sites, including any RDS, PODs, hospitals, treatment centers, and other delivery locations, as well as specific information for each facility, including
 - Dispensing capability of the sites (the throughput, or capability, will determine the amount of MCMs needed);
 - Loading and unloading capability;
 - Number of and location of available loading docks;
 - Availability of onsite MHE, such as pallet jacks, hand trucks, and forklifts;
 - Security or other personnel that will keep the driveway and loading dock clear of vehicles, people, and other obstacles that would impede delivery; and

- Multiple support personnel to unload the truck including those trained to operate the MHE.
- Personal protective equipment (PPE) needed to protect workers within the distribution network
- Communication matrix and equipment for distribution network, including
 - Availability and lead times for two-way communications equipment (e.g., two-way radios) with redundant back-up capabilities (e.g., licensed truck drivers with cell phones, radios, etc.); and
 - Assigned radio frequencies for communications with vehicle drivers, dispatchers, delivery points, and security.
- GPS navigation systems and maps with primary and secondary routes to each location that
 - Identify areas to avoid due to contamination or major road, waterway, and bridge closures that may affect delivery routes; and
 - Provide GIS mapping of all delivery locations (if available).
- Transportation resources, including
 - Pre-identified, licensed drivers for trucks;
 - Number and types of available vehicles;
 - Location of nearby airports and any known air-traffic-control problems that may impair the use of aircraft;
 - Water transport systems and resources (if applicable); and
 - Rail systems with notes on any impediments that may affect their use.

Activating the Distribution Plan

When an incident occurs, the distribution manager will receive notification, most likely from the MCM operations lead. In turn, the distribution manager will notify the distribution team by activating the team's communication plan. The activation process should include who is responsible for

- Contacting or otherwise activating
- Transportation partners (who will activate drivers and other transportation systems) and provide information on the RSS for delivery pick-up;
- Security partners;
- Dispatchers;
- Route developers; and
- Support personnel.
- Assembling and delivering
- Driver handbooks,
- JITT, and
- Route maps.

The distribution manager will contact the RSS lead and determine when shipments will be ready to leave the RSS to ensure that the empty distribution vehicles arrive at an appropriate time and do not impede SNS delivery vehicles' arrival at the RSS. The distribution manager also will contact the dispensing manager to determine which dispensing sites will need MCMs first and provide an estimated time of delivery based on information received from the RSS lead regarding when first shipments would be ready.

All members of the distribution team will report to locations determined during the planning phase.

Demobilizing Distribution Operations

Depending on the incident, a response may end rapidly or operations may diminish over the course of days or weeks. The distribution team should develop processes for demobilizing operations that include

- How and when unused or compromised MCMs will be recovered from dispensing sites and returned to the RSS;
- How and when transportation resources will be scaled back to fewer daily deliveries and pick-ups;
- A hot-wash with drivers and transportation partners that reminds them of confidential information, such as location of RSS and dispensing sites;
- Whether and how distribution partners can apply for compensation for participation in the response (under a Robert T. Stafford Disaster Relief and Emergency Assistance Act [Public Law 93-288]² declaration those who assist in a public health emergency may be eligible for reimbursement); and
- After action reporting.

Resources

Lessons Learned Information Sharing (LLIS.gov) is a national, online network of lessons learned, best practices, and innovative ideas for the emergency response and homeland security communities. Developed and run by the U.S. Department of Homeland Security and the Federal Emergency Management Agency program, this provides federal, state, and local responders with a wealth of information and front-line expertise on effective planning, training, and operational practices across homeland security functional areas. LLIS.gov is available at URL www.llis.dhs.gov/index.do.

CDC's **Public Health Preparedness Capabilities: National Standards for State and Local Planning** provides guidance on 15 capabilities that state and local jurisdictions can use to identify gaps in preparedness, determine specific jurisdictional priorities, and develop plans for building and sustaining capabilities. Capability 9 provides information on functions and tasks associated with MCMDD planning, including distribution. Available on the CDC website at www.cdc.gov/phpr/capabilities/DSLR_capabilities_July.pdf.

CDC's **National Center for Immunization and Respiratory Diseases' Vaccine Storage and Handling Toolkit** provides information on maintaining vaccines according the current good manufacturing practice (cGMP) and is available at URL www2a.cdc.gov/vaccines/ed/shtoolkit/pages/introduction.htm.

² Information on the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Public Law 93-288) is available from URL www.fema.gov/about/stafact.shtm.

CDC's ***Selected Vaccine Storage & Handling Resources*** provides links to useful resources for determining storage and handling practices for vaccines. The resource links are available from URL www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/C/storage-handling-resources.pdf.

Planners can use **TourSolver and TourSolver Regional** to develop routes from the RSS or RDS to PODs, treatment centers, and any other sites. TourSolver is available at no charge on the Stockpile Routing Web Portal, <http://cdcstockpilerouting.c2logix.com>. TourSolver allows planners to customize parameters to reflect local conditions, run multiple scenarios, and ask "what if" questions that will simulate real world events. Planners, using multiple or as few constraints as desired, can quickly assess the impact of these conditions on the overall distribution operation.

International Air Transportation Association's ***Perishable Cargo Regulations (PCR)*** manual provides temperature control and cold chain management standards for goods from the health care and food sectors, including pharmaceutical products and non-hazardous biological materials. The PCR includes information that will assist planners to properly prepare, package, and handle time and temperature sensitive goods. Available for purchase at URL <https://www.iataonline.com/Store/default.htm>.

The ***SNS Extranet*** contains information on distribution and other SNS functions and can assist planners in developing MCM distribution plans. This site also includes Public Health Emergency Preparedness cooperative agreement guidance. Planners can access the SNS Extranet at URL www.orau.gov/snsnet, but this site is password protected. Planners can contact the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer to obtain the user name and password.

Chapter 8: Dispensing Medical Countermeasures

Dispensing is the most complex function in a medical countermeasure (MCM) response, as it requires considerations for how to provide MCMs rapidly and efficiently, possibly to everyone in the jurisdiction, while observing all the legal considerations of dispensing laws. In addition, dispensing plans must cover wide-ranging possibilities of MCMs and administration methods, such as oral medications or vaccinations. Previous Centers for Disease Control and Prevention (CDC) guidance primarily focused on strategies for mass dispensing of oral MCMs based on a worst-case scenario. However, CDC's updated guidance recognizes the need to develop scalable and flexible dispensing plans to meet the needs of smaller incidents, longer-term responses, or incidents requiring MCMs other than oral antimicrobials. Developing dispensing plans flexible enough to address an array of disease agents and possible MCMs for treatment or prophylaxis requires extensive, coordinated efforts between state and local public health, federal agencies, non-governmental organizations, businesses, and volunteers to provide the maximum public health protections in the community.

Understanding Dispensing as a Capability

Dispensing MCMs is one of the targets of the Public Health and Medical Services¹ capability of National Preparedness Goal,² which is:

A secure and resilient nation with the capabilities required across the whole community to prevent, protect against, mitigate, respond to, and recover from the threats and hazards that pose the greatest risk.³

To assist in preparing a resilient nation, the federal government provides funding through the Public Health Emergency Preparedness (PHEP) cooperative agreement⁴ and Cities Readiness Initiative (CRI).⁵ PHEP includes MCM dispensing as one of the 15 capabilities on

¹ www.fema.gov/core-capabilities#PublicHealth

² www.fema.gov/pdf/prepared/npg.pdf

³ From the Federal Emergency Management Agency *National Preparedness Goal* website. Available at URL www.fema.gov/national-preparedness-goal. (Accessed May 8, 2013)

⁴ www.cdc.gov/phpr/coopagreement.htm

⁵ www.bt.cdc.gov/cri

which state and local public health departments should focus their preparedness planning efforts.

Funded through CDC since 2004, CRI shaped much of the early dispensing planning by assisting states and large metropolitan statistical areas (MSAs) in developing plans “to respond to a large-scale biologic attack, with anthrax as the primary threat consideration.”⁶ Because of the nature of *Bacillus anthracis* (anthrax), a widespread release of aerosolized anthrax may require a jurisdiction to provide prophylaxis to everyone in the community within 48 hours.

This worst-case scenario prompted CDC to focus much of the early dispensing guidance on health departments providing an initial 10-day supply of oral antimicrobials (20 tablets) to everyone in the community. This guidance urged health departments to develop plans to provide prophylaxis at dispensing sites, often referred to as points of dispensing, or PODs, staffed and run by the health department.

What Is a POD?

A point of dispensing (POD) is a fixed, identified public facility in which medical countermeasures (MCMs) are given to people in response to a public health threat or emergency.

While early planning focused on this 48-hour dispensing scenario, CDC later recognized that jurisdictions needed to improve all-hazards planning and broadened dispensing criteria to support this activity. Consequently, CDC’s updated guidance encourages jurisdictions to develop the capability to dispense MCMs for a variety of incidents and timeframes. Jurisdictional dispensing plans should cover a widespread incident, such as a release of anthrax, but also be scalable to cover a smaller incident, such as a meningitis outbreak in a single school district, which may require screening and providing MCMs only to a localized population. In addition, dispensing plans should consider how the jurisdiction could maintain operations during a long-term response, such as an influenza pandemic, in which multiple waves of disease outbreaks may occur over several months.

Framing Liability Coverage for Dispensing

Early guidance helped prepare communities to receive, distribute, and dispense MCMs from the Strategic National Stockpile (SNS) within 48 hours of a federal decision to deploy assets. However, as medical countermeasure distribution and dispensing (MCMDD) plans evolved, public health departments realized they would not be able to attain their dispensing goals with their own limited resources. Subsequently, public health planners reached out to various agencies and organizations in the public and private sector to assist in providing prophylaxis as quickly as possible. As public health recruited more partners, especially private entities that may serve as PODs or assist in dispensing MCMs, those who might support dispensing operations raised many questions on their possible liability during a response, such as

⁶ From the Centers for Disease Control and Prevention Cities Readiness Initiative website; available at www.bt.cdc.gov/cri.

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- If I help the health department with dispensing, can I be sued if someone gets sick from taking the medication?
 - If I own the facility used as a POD and someone is injured during the dispensing process, am I liable?
 - How can I get compensated for providing resources to assist in dispensing operations?

In response to such questions, the federal government enacted legislation to maximize the nation's ability to rapidly respond to public health emergencies. This legislation provides liability protection for those who respond to and participate in public health emergencies and affords protection from tort actions related to an emergency response. State and local planners should work with public health law professionals to ensure that dispensing plans adhere to all regulations and allow for maximum protections afforded by these laws.

Public Readiness and Emergency Preparedness (PREP) Act

The Public Readiness and Emergency Preparedness (PREP) Act⁷ authorizes the HHS Secretary to issue a declaration (PREP Act declaration) specifically for the purpose of providing immunity from tort liability related to covered MCMs recommended in the declaration. The secretary can issue a declaration for any diseases, threats, or conditions determined to constitute a present or credible risk of a future public health emergency to entities and individuals. For example, as part of ongoing national emergency preparedness and planning efforts, the HHS secretary issued a declaration pursuant to the PREP Act to provide targeted liability protections for anthrax MCMs based on a credible risk that the threat of exposure to anthrax and the resulting disease constitutes a public health emergency. (See 73 Fed. Reg. 58239 [October 6, 2008]).⁸

Tort claims covered by a PREP Act declaration include all claims (except for willful misconduct) under federal or state law for any type of loss including death; physical, mental, or emotional injury; fear of such injury; or property damage or loss, including business interruption loss, with any causal relationship to any stage of development, distribution, administration or use of the covered MCMs recommended in the declaration. A secretarial declaration will specify the period for which liability protections are in effect, the population of individuals protected, and the geographic areas for which the protections are in effect. A PREP Act declaration is different from, and not dependent on, other emergency declarations. The PREP Act also authorizes an emergency fund in the United States Treasury to provide compensation for injuries directly caused by administration or use of a countermeasure covered by the secretary's declaration.

Staff and Volunteer Liability

Liability protection for staff and volunteers is an area of great concern for planners and is a complicated issue to address because different states and localities are subject to different liability laws and standards. Planners may find recruitment efforts are significantly impacted when potential volunteers are unsure of liability protections.

⁷ www.hrsa.gov/getthehealthcare/conditions/countermeasurescomp/prepact.pdf

⁸ www.gpo.gov/fdsys/pkg/FR-2008-10-06/content-detail.html

Section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d),⁹ as enacted by the PREP Act (Pub. L. No. 109-148),¹⁰ provides tort liability that covers entities involved in the development, manufacture, testing, distribution, administration, and use of MCMs. Planners should become familiar with protections afforded to *covered persons* involved in administration and use of an MCM recommended in a PREP Act declaration. *Covered persons* may, at the secretary's discretion, include

- Manufacturers of MCMs;
- Distributors of MCMs;
- MCM program planners (i.e., individuals and entities involved in planning and administering programs for distribution of MCMs);
- Qualified persons who prescribe, administer, or dispense MCMs (i.e., healthcare and other providers); and
- The United States.

Officials, agents, and employees of any of these entities also are considered "covered persons" and volunteers may be covered under the auspices of "qualified persons." This includes volunteers assisting in POD operations or volunteers participating in other aspects of responses involving a PREP Act declaration. The term also applies to businesses or other entities that volunteer to dispense MCMs to their employees at their facilities.

In addition to the PREP Act, other laws and provisions at the federal and state levels provide liability protection for staff and volunteers during a dispensing campaign. Planners should seek the assistance of their legal counsels to

- Identify the liability protections available for their jurisdiction;
- Ensure that their plans will facilitate operations during a PREP Act declaration; and
- Verify their dispensing plans fit within the scope of the liability coverage afforded by the PREP Act.

State and Local Legislation

In the absence of a PREP Act declaration (for instance a small-scale disease outbreak, such as meningitis in a high school requiring vaccination or dispensing of oral medications to all students and staff), planners should ensure that the plan identifies existing state and local liability coverage for staff, volunteers, and entities involved in the response. Coverage may come in the form of a public health emergency declaration by the governor, his/her designee, or the state or local health department. Planners should work with their public health law professionals to secure the necessary liability coverage for both large- and small-scale responses.

Local and state legislatures also have passed Good Samaritan and other types of legislation that impact local emergency response planning and may address policy and legal issues related to dispensing campaigns, such as prescribing authority and authorized dispensers during an emergency. Such legislation may provide additional liability protections to those

⁹ www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm

¹⁰ www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

offered under the PREP Act or a declared emergency. Therefore, planners should become familiar with any related state or local legislation in order to determine the best way in which the jurisdiction can provide liability protection for volunteers and other responders during an incident.

Additional Legislation

Additional information on federal legislation, including liability coverage and dispensing considerations for MCMs provided under Investigational New Drug (IND) and Emergency Use Authorization (EUA) protocols, are provided at the end of this chapter.

Delineating State and Local Responsibilities in Dispensing

While planning for dispensing MCMs to the public falls predominantly to local public health departments, planners at the state health department should provide guidance and assistance to their local counterparts on developing the MCM dispensing plan. The state health department also can facilitate coordination between local planners and non-governmental organizations and private entities that may play a role in an MCM response. In addition, state planners should develop clear guidance for local planners on the state's expectations for dispensing plans and ensure consistency in dispensing plans throughout the state. Ideally, state planners will have a system to track the progress of local planners to ensure that they have developed adequate dispensing capacity.

State planners should assist local jurisdictions in ensuring that they identify, assess, and prioritize legal and liability barriers to rapid dispensing strategies. State planners should work with those who have authority to address possible issues associated with dispensing MCMs, such as

- Standards of care;
- Documentation of care;
- Licensing;
- Civil liability protection for volunteers;
- Staff compensation;
- Rules governing when dispensing protocols can be changed from a medical model to a nonmedical model; and
- Appropriation of property needed for dispensing medications.¹¹

Local planners will need to assess the populations of their communities, determine the best dispensing strategies, develop plans, and create a comprehensive written dispensing plan along with site-specific plans for dispensing locations. In addition, local planners will need to assist any dispensing partners in developing plans that align with the local plan. Local planners are encouraged to partner with any agencies, organizations, or entities that they feel can assist in the dispensing process and provide clear roles and guidelines for those who agree to participate in the dispensing effort.

¹¹ From Recommended Infrastructure Standards for Mass Antibiotic Dispensing, RAND Corporation; Santa Monica, CA (2008). Available at www.rand.org/pubs/technical_reports/2008/RAND_TR553.pdf.

Forming MCM Dispensing Planning and Response Teams

In order to develop the dispensing plan and implement all of the possible dispensing methods, planners will need multi-tiered response and coordination efforts. Jurisdictions will need to take a whole community approach by bringing together expertise from a variety of professions and obtaining buy-in and support from other agencies and organizations. Members of the multi-disciplinary advisory group, mentioned in **Chapter 2: Developing a Medical Countermeasure Response Plan**, can assist in determining the best dispensing modalities, the number and locations of PODs, potential closed POD partners, and agencies and organizations that may be able to provide staff and resources for dispensing operations. Other government agencies, community-based groups, and private-sector organizations can support dispensing operations by providing POD facilities, volunteer staff, vehicles and personnel to move supplies and equipment to PODs, translation and interpreter services at PODs, reproduction services for printed materials, and support services to POD staff and volunteers.

Planners should review the list of organizations and roles included in Table 2.1 of Chapter 2 and include any possible partners in developing the dispensing section of the plan. For instance, if the jurisdiction plans to utilize local school facilities for dispensing, planners will need to work with the school board and/or the superintendent of schools to obtain the necessary permissions and written agreements for use of those facilities. In addition, planners should include law enforcement or other security professionals to assist in assessing security risks of possible POD sites, developing traffic plans, and securing assets and facilities during dispensing operations.

Planning for Whole-community Approaches to Dispensing

All of the functions in MCM response plans require considerations that affect the movement of MCMs from the federal level down to the people who would require them during an incident. This includes **everyone** in the community – residents, visitors, commuters, or anyone else in the affected area during an incident. However, because dispensing is the step that actually provides MCMs to the people who need them, planning for this function involves considerations for the unique populations that may be part of the jurisdiction. Providing MCMs to these populations may be required to maintain continuity of operations during the response (such as in the case of first responders) or may be affected by challenges related to the targeted population (such as at-risk individuals).

Responders and Critical Infrastructure Staff

Certain individuals in the community may serve essential roles during a response and the federal government recognizes these individuals as part of the critical infrastructure. Typically, responders and critical infrastructure staff include law enforcement, public health staff, firefighters, emergency management services, utility services, state and local government agency staff, elected officials, as well as others who are specific to the jurisdiction. Under the National Preparedness Goal,¹² protecting responders and critical

¹² www.fema.gov/national-preparedness-goal

infrastructure staff falls under the Physical Protective Measures of the Core Capabilities.¹³ For an MCMDD response, the jurisdiction may need to provide MCMs to several hundred or even thousands of people before opening PODs for the public. CDC recommends that jurisdictions identify the personnel and agencies to include as critical infrastructure early in the planning phase for an MCMDD response.

Some local jurisdictions maintain supplies and caches of MCMs to accomplish dispensing to critical infrastructure staff and responders before the arrival of federal assets and each of these jurisdiction will need to explore strategies for managing and dispensing local MCM caches. For instance, the jurisdiction could maintain its MCM cache in a central location and then deploy allocations to pre-determined sites for dispensing to responders upon activation. Alternatively, members in these groups could receive preliminary screening to determine the appropriate MCMs and quantities required so their respective agencies could receive pre-positioned MCMs.

Depending on the incident, local caches of MCMs may be covered under Emergency Use Authorizations (EUAs) that will provide protections under the PREP Act. For example, in July 2011 the FDA issued an EUA for doxycycline for post-exposure prophylaxis (PEP) for inhalation anthrax. This EUA covers oral formulations of doxycycline from local caches used for PEP as long as the terms and conditions of the EUA are met.¹⁴ However, state SNS planners should work closely with public health law professionals, state pharmacy boards, state medical directors, and legislators to ensure that dispensing plans, including plans for dispensing MCMs from state- or local-held caches, adhere to all regulations and allow for maximum protections afforded by the PREP Act and EUAs under a federally declared emergency.

Emergency Use Authorizations

An Emergency Use Authorization (EUA) allows the U.S. Food and Drug Administration (FDA) Commissioner to permit the use of unapproved medical products or unapproved uses of approved medical products in an emergency. An EUA authorizes the wide-scale use of unapproved, uncleared, or unlicensed MCMs in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. An EUA can be issued during a declared emergency involving a heightened risk of attack on the public or U.S. military forces. Authority for an EUA comes through Project BioShield Act of 2004 (Public Law 108-276).

Further information on EUAs is available in the Understanding How INDs and EUAs Affect Dispensing Section beginning on page 46 of this chapter.

At-risk Populations

At-risk individuals are those who have additional needs that may interfere with their ability to access or receive medical care, which can be of particular concern during an incident that requires quick action to receive life-saving MCMs. Therefore, planners must consider the needs of at-risk populations and involve representatives of these communities and their

¹³ www.fema.gov/core-capabilities#PhysicalProtect

¹⁴ From the U.S. Food and Drug Administration Emergency Preparedness and Response website, www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm269226.htm.

caregivers in their planning efforts. According to the Pandemic and All-Hazards Preparedness Act (PAHPA),¹⁵ at-risk populations are those who have additional needs in one or more of the following functional areas:

- Maintaining independence
- Communication
- Transportation
- Supervision
- Medical care

PAHPA's definition provides a flexible framework planners can use to address a wide range of needs while avoiding specific labels. **Chapter 9: Public Information and Communication** provides further information on reaching at-risk populations. In addition, planners can consult the *Public Health Workbook to Define, Locate and Reach Special, Vulnerable, and At-Risk Populations in an Emergency*,¹⁶ which provides information on how to develop a Community Outreach and Information Network (COIN)—a grassroots network of people and trusted leaders who can help with emergency response planning and delivering information to at-risk populations in emergencies.

Military Installations

As mentioned in **Chapter 2: Developing a Medical Countermeasure Response Plan**, state and local public health planners must include the staff and family members of military installations in the total population for the jurisdiction and plan for dispensing of MCMs to that community. Department of Defense (DoD) Directive 6200.3 Emergency Health Powers on Military Installations¹⁷ requires military commanders to designate a Public Health Emergency Officer (PHEO) to maintain close contact and seek coordination with the local and state health departments. State and local planners should work with the PHEO to determine how those stationed and/or residing on military installations will receive MCMs during an incident. Planners should contact their state or local emergency management officials for a list of DoD liaisons or their jurisdiction's PHEO, if needed.

Tribal Nations

As mentioned in **Chapter 2: Developing a Medical Countermeasure Response Plan**, jurisdictions should coordinate and collaborate with American Indian and Alaska Native (AI/AN) tribes for MCM response planning. Many planners mistakenly believe that these communities will receive MCMs from the Indian Health Service (IHS) or another federal agency. However, CDC's guidance calls for state and local health departments to coordinate with these communities, develop written agreements, and ensure those living on tribal lands will receive MCMs. AI/AN tribal members may receive MCMs through attending a local health department dispensing site; hosting their own dispensing sites on the reservation; or arranging with the IHS to provide MCMs in the community. Regardless of the dispensing

¹⁵ www.phe.gov/preparedness/legal/pahpa/pages/default.aspx

¹⁶ <http://emergency.cdc.gov/workbook>

¹⁷ www.dtic.mil/whs/directives/corres/pdf/620003p.pdf

option chosen, MCMs will be distributed through the system developed by the state health department once an emergency is declared and it is vital that state and local planners coordinate with their tribal populations to ensure everyone in the community has access to MCMs.

Determining Dispensing Policies

As mentioned, dispensing MCMs to the public is a function of local public health departments, but a number of crucial policy and planning decisions from the state level will have major influences on MCM dispensing planning and response. Some policy issues could include who is authorized to dispense medications and whether those authorizations can be suspended during large-scale incidents; what information is required on prescription labels; and what legal protections are offered to facilities and volunteers during a declared public health emergency. Planners will need to consult with authorized officials at the state level, such as the state health officer or medical director, on policy decisions and state SNS coordinators should assist local SNS planners in complying with these policies.

State SNS coordinators also can facilitate negotiations with state agencies in developing policies that may assist local planners in developing MCM dispensing plans, such as assisting in developing closed POD plans with state government agencies.

Local planners should contact their state SNS coordinator to identify available state planning resources and to understand the policies and procedures already in place to assist in dispensing operations. The following sections address a few possible policies and planning issues.

MCM Administration Routes

MCM administration routes (e.g., oral, intravenous, intramuscular) can affect the dispensing policies and authorized dispensers in the jurisdiction. Table 8.1 provides a list of MCMs available in the SNS and the associated administration routes. Planners should review these carefully and determine how the jurisdiction will plan for various scenarios in which MCMs could be requested and dispensed.

Table 8.1: MCMs from the SNS and Administration Routes*

Threat	MCMs	Administration Route	Other Information
Anthrax	Antimicrobials (ciprofloxacin, doxycycline, amoxicillin) <i>Post-exposure prophylaxis or treatment</i>	Oral	Most antimicrobials will be used under an EUA or IND
	Antimicrobials (ciprofloxacin, doxycycline, penicillin, clindamycin, rifampin, vancomycin, levofloxacin) <i>Treatment</i>	Intravenous (IV)	Most antimicrobials will be used under an EUA or IND
	Anthrax immune globulin (AIG) <i>Treatment for severe anthrax disease</i>	Intravenous (IV)	Will be used under a pre-EUA
	Raxibacumab (ABthrax) <i>Treatment for severe anthrax disease and prophylaxis following exposure to B. anthracis</i>	Intravenous (IV)	FDA approved
	Anthrax vaccine adsorbed (AVA) <i>Pre- and post-exposure prophylaxis</i>	Subcutaneous (SC)	Will be used under an EUA or IND for post exposure FDA approve for pre-event use
Plague	Antimicrobials (ciprofloxacin, doxycycline, gentamicin [IV only], levofloxacin [IV only])	Oral and Intravenous (IV)	Oral and IV ciprofloxacin, oral doxycycline, and IV gentamicin will be used under an EUA or IND; levofloxacin and doxycycline IV are FDA approved
Tularemia	Antimicrobials (ciprofloxacin, doxycycline, gentamicin [IV only]) <i>Post-exposure prophylaxis or treatment</i>	Oral and Intravenous (IV)	Oral doxycycline and oral and IV ciprofloxacin and IV gentamicin will be used under an EUA or IND

Threat	MCMs	Administration Route	Other Information
Smallpox	Vaccine (ACAM2000, Aventis Pasteur-WetVax, Modified Vaccinia Ankara [MVA]) <i>Post-exposure prophylaxis</i>	ACAM2000 and Aventis Pasteur-WetVax are administered via percutaneous route using a bifurcated needle. MVA is administered via subcutaneous injection route. Primary vaccinees are given 2 doses of vaccine 4 weeks apart. Previously vaccinated persons only require one dose of vaccine	Aventis Pasteur-WetVax and MVA will be used under an EUA or IND ACAM2000 is FDA approved
	Tecovirimat <i>Treatment of disease symptoms and adverse reactions to smallpox vaccine</i>	Oral	Will be used under an EUA or IND
	Vaccinia immune globulin (VIG), cidofovir, and <i>Treatment of adverse reactions to vaccine</i>	VIG and cidofovir are administered via intravenous (IV)	Cidofovir will be used under an IND or EUA
Botulism	Antitoxins (Heptavalent & A Botulinum Antitoxin) <i>Treatment</i>	Intravenous (IV)	Botulinum A Antitoxin will be used under an IND or EUA; Heptavalent botulism antitoxin is FDA approved
Chemical	CHEMPACK – atropine, pralidoxime, diazepam, atropens, and Mark 1 kits/DuoDotes <i>Treatment</i>	Intramuscular (IM) or intravenous (IV)	All drugs are FDA approved; Mark 1 kits and DuoDotes are not approved for use in children
Radiation	Calcium (Ca)- and zinc (Zn)- Diethylenetriamine pentaacetic acid (DTPA) <i>Treatment</i>	Intravenous (IV)	FDA approved
	Prussian blue <i>Treatment</i>	Oral	FDA approved

Threat	MCMs	Administration Route	Other Information
	Antiemetics	Oral	FDA approved
	Neupogen® (filgrastim) <i>Treatment</i>	Subcutaneous (SC)	Will be used under an IND or EUA
	Antimicrobials for secondary infections	Intravenous (IV)	
Burn/Blast	Medical/surgical supplies	Various	
	IV fluids	Intravenous (IV)	
Influenza (Pandemic)	Antiviral drugs (oseltamivir, zanamivir) <i>Treatment</i>	Oral Inhaled	FDA approved
	Personal protective equipment (PPE) (gloves, N-95 respirators, surgical masks, gowns, face shields)		N-95 respirators require fit testing to ensure proper use
	Antimicrobials for secondary infections	Intravenous (IV)	
Natural Disasters	Medical/surgical supplies and equipment	Various	
	IV fluids	Intravenous (IV)	
	Federal Medical Stations		Beds and medical equipment to support non-acute care, special needs care, or quarantine operations (See Appendix A: Federal Medical Stations for more information)

* The SNS has medical supplies and equipment, including limited amounts of ventilators, to support all threats listed in Table 8.1. CDC delivers ventilators kitted with enough ancillary supplies for one adult or pediatric patient. Additional ancillary supplies are available upon request.

Medical versus Nonmedical Dispensing Strategies

One of the first policy decisions jurisdictions will make is which dispensing model the jurisdiction will use during a public health emergency. Planners must determine whether dispensing sites will operate under the medical model or nonmedical dispensing model. In the medical model only licensed medical personnel can dispense MCMs, while the nonmedical model permits trained nonmedical personnel to dispense MCMs, thus streamlining the process. The nonmedical model is sometimes referred to as a rapid dispensing strategy. Planners should consider the following issues when determining whether dispensing operations will occur under a medical or nonmedical model.

Medical (Clinical) Model

In the medical model, each person receives a medical assessment and MCMs from a licensed medical professional. Jurisdictions typically would use the medical model in a dispensing operation that afforded ideal circumstances, such as adequate time and medical staff. Under this model, medical personnel would dedicate more time to providing a personalized medical evaluation and education on the agent and MCMs to each client at the dispensing site. The medical model makes several assumptions for dispensing operations, including

- Each individual is unique, therefore MCMs are provided on a personalized medical evaluation, even if only one or two MCM options are available;
- Few or no constraints exist for the type of medical staff who can dispense;
- No time constraints exist for conducting medical evaluations or providing MCMs; and
- All medical professionals have the necessary training and licensures to provide medical care based on current, best medical practices.

However, it would be difficult to meet all of these assumptions during a large-scale incident, especially one that requires the entire population of a jurisdiction to receive MCMs in the shortest timeframe possible. Consequently, planners should look to other possible dispensing strategies, which may require policy changes, in order to meet all possible MCM dispensing goals.

Nonmedical (Rapid Dispensing) Model

The nonmedical model refers to a modification of the medical model that streamlines dispensing operations in order to achieve rapid dispensing. The goal of rapid dispensing is to increase the number of people who can go through a point of dispensing (POD), known as POD throughput. POD throughput typically is expressed as people per hour, or PPH. In light of the anticipated large number of individuals requiring MCMs during an emergency and the timeframe in which the jurisdiction must accomplish dispensing, the nonmedical model takes into account limited medical staffing and decreased time to provide MCMs. In the nonmedical model, clients might receive a less comprehensive screening form; steps in the dispensing process might be combined or eliminated; or trained nonmedical personnel may dispense MCMs under limited supervision from licensed medical professionals.

State dispensing laws likely will dictate which dispensing model planners can use. Some states may allow only the medical model. Planners should consult with their legal counsel, state pharmacy boards, state medical directors, and legislators to determine whether the

state can take actions to allow for modification of the medical model in an emergency. For instance, SNS coordinators can work with legislators and legal counsel to develop legislative changes (such as an Emergency Powers Act) to allow individuals other than pharmacists to hand out prescription drugs at dispensing sites during an emergency. In addition, planners can prepare waivers for their governors (or appropriate governor designees) to sign that will allow for nonmedical dispensers during a large-scale public health emergency.

Planners also can refer to *Recommended Infrastructure Standards for Mass Antibiotic Dispensing*,¹⁸ sometimes referred to as the POD Standards, published by the RAND Corporation for further information on the rapid dispensing strategy.

Multiple versus Individual Regimens

Some jurisdictions have developed policies that permit a single adult person to pick up multiple regimens of MCMs for others who are not physically present at the POD, sometimes referred to as head-of-household (HOH) dispensing. In some cases, HOH dispensing may allow adults to pick up MCMs for their children, family members, or even others, such as an elderly neighbor who is unable to get to a POD. An HOH policy will reduce the number of people at the PODs and simultaneously increase the number of people receiving MCMs. Individuals picking up MCMs for others must still be able to complete the intake form for each person receiving medications. This may require them to provide the weights of any children for whom they are picking up MCMs. They also may need to provide other information on people for whom they are picking up MCMs, such as whether they have any contraindications to MCMs being dispensed, including allergies to the MCMs or are taking a medication that will interfere with the effectiveness of the MCMs.

CDC recommends multiple-regimen dispensing but encourages planners to set a limit on the maximum number of regimens that each person can receive without question. In addition, this limit should be standard throughout the jurisdiction and planners should devise a policy to address how to handle requests for more than the defined limit of MCMs at the PODs. For instance, those requesting more than the maximum number of regimens could receive additional questioning from POD staff, who have guidelines for determining when requests can exceed the dispensing limit and the type of evidence or information each person should provide to justify the number of regimens requested.

Note: Use of HOH pick up will not be possible in scenarios in which MCMs are dispensed under an Investigational New Drug (IND) protocol as each person for whom an MCM is dispensed must read and sign an informed consent form and parents must sign for any minor children. Further information on INDs appears at the end of this chapter.

Pediatric Dispensing

Dispensing plans will need to include pediatric dispensing considerations that align with state and local dispensing laws. For instance, some states have restrictions on who can dispense medications to children. Planners should include pediatricians in the planning process to

¹⁸ www.rand.org/pubs/technical_reports/2008/RAND_TR553.pdf

ensure that children receive the right MCMs, the correct doses, and that their parents are informed of how to properly administer MCMs.

In addition, for most MCMs children will require varying doses based on their ages and weights. However, planners will need to consider whether and how they will weigh children at the PODs. In lieu of taking time to weigh children, planners can use the average-weight chart available from the CDC.¹⁹ Ideally, parents will come to dispensing sites prepared to provide their children's weights and planners can develop the messages to encourage people to bring this type of information with them. **Chapter 9: Public Information and Communication** provides more information on developing messages, methods, and materials for dispensing campaigns.

Should the public health emergency require oral antimicrobials, it is important to note that SNS contains limited amounts of oral suspensions of ciprofloxacin, doxycycline, and amoxicillin, which will require mixing into a liquid suspension. Instructions for mixing these MCMs are available on the SNS Extranet.²⁰ In addition, the FDA provides pill crushing instructions²¹ for preparing pediatric doses of doxycycline.

Dispensing to Unaccompanied Minors

During large-scale emergencies, families may be disrupted or separated and many people from all walks of life may arrive at PODs to receive MCMs. In some instances, minor children may come to the POD alone because they have been separated from their parents by the incident or by other life circumstances, such as being orphaned or having run away from home. In addition, minor children may present to the POD as a head of household because their parents are ill, incapacitated, or perhaps do not speak English. Planners should work with state medical and legal professionals to determine

- The age limits for which children will be considered "minors" or "adults;"
- The criteria under which minor children will be able to pick up MCMs for themselves;
- Whether and under what criteria minor children will be able to pick up MCMs for family members or other adults; and
- Whether unaccompanied minors will require additional screening.

Planners may wish to review the Policy Statement on Consent for Emergency Medical Services for Children and Adolescents²² issued by the Committee on Pediatric Emergency Medicine to assist them in determining dispensing policies for unaccompanied minors at PODs.

¹⁹ www.cdc.gov/nchs/data/nhanes/growthcharts/set1/all.pdf

²⁰ <https://www.orau.gov/snsnet/default.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

²¹ www.fda.gov/downloads/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/UCM131001.pdf

²² Published in *Pediatrics*, Vol. 111(3). March 1, 2003; pp. 703 – 706. Available online at <http://pediatrics.aappublications.org/content/111/3/703.full.html>.

Drug Administration Fees

While partner agencies or organizations that provide MCMs cannot charge clients for the MCMs they receive from federal caches, private partners, such as commercial pharmacies or hospitals, may require a small administration fee to cover handling of the MCMs or related supplies, such as intravenous administration supplies. Planners need to determine whether partner entities will require administration fees and be certain to communicate clearly with clients what the fees are and why they are being assessed. Planners also must consider that the time required for collecting administration fees could impact the client flow at dispensing sites and impede dispensing operations.

Examining Dispensing Methods

Time and population are the two key considerations in developing dispensing plans – specifically, the amount of **time** required to accomplish the MCM dispensing operations and the jurisdiction's **population** demographics (size, age structure, socio-economic status, ethnic composition, dispersion, disease epidemiology, disability status, etc.). Time and population are the main factors that will drive the policies, guidelines, and methodologies established for MCM dispensing planning. In addition, planners must consider time and population in order to develop MCM dispensing plans that are scalable for a variety of response scenarios, as time and population can be highly variable depending on the cause of the incident.

During the first decade of MCM dispensing planning, the focus was on rapid dispensing of MCMs on a large scale (i.e., dispensing to everyone in the community within 48-hours) to meet the dispensing goal required for a release of *B. anthracis*. Because of the enormous wealth of resources dispensing will require, even in small communities, jurisdictions soon realized that the personnel of the health department alone will not be able to staff and operate all of the dispensing locations required to reach the entire population in the targeted timeframe should it be necessary. Planners soon recognized the need to simultaneously use multiple dispensing methods to provide MCMs to the entire population as rapidly as possible in a large-scale MCM dispensing campaign. Since that time, jurisdictions also recognized the need to be able to address smaller scale incidents that may not require the use of all possible dispensing methods. For instance, a meningitis outbreak at one school may increase the need to vaccinate or provide prophylactic medications to all the students of that school. Even though the affected school may not have been identified as a possible dispensing site for a full-scale incident, public health officials could use existing plans to set up a vaccination/prophylaxis center at that facility. Jurisdictions also recognized the need for dispensing plans that are flexible enough to address longer-term incidents, such as pandemic influenza outbreaks that could have multiple waves of outbreaks over an extended period of time.

In order to develop scalable, flexible dispensing plans, local jurisdictions will need to identify the appropriate dispensing methods, determine how to best integrate these methods, and form partnerships that will enhance their MCM dispensing campaigns.

Points of Dispensing (PODs)

Points of dispensing (PODs) are facilities or sites to which people will go to pick up MCMs for themselves and, in many cases, their family members. PODs use a series of steps to get people into the site, obtain information from them, provide them with MCMs, answer their questions, and deliver information on the incident and the MCMs they are receiving. PODs can use a variety of formats, may be open to the public or closed for a specific population, or even mobile and modular. Further information on POD design appears under **Outlining POD Operations** beginning on page 26.

While open PODs are the foundation for most MCM dispensing campaigns, limitations in time, personnel, and other resources could severely impact the ability to provide MCMs to the entire population within the required timeframe using only open PODs. By developing dispensing plans that include a variety of PODs and alternate dispensing methods, the jurisdiction can significantly decrease the time and staff needed to provide MCMs to the entire population.

Open (Public) PODs

Open PODs have been the primary focus of dispensing operations since the early days of planning for large-scale MCM dispensing campaigns. They are referred to as “open” because there are no restrictions on who can go to them; they are open to everyone. Open PODs should be located in pre-identified, community-based facilities that public health agencies can activate to serve the general public. Some typical facilities planners have identified as POD sites include public schools, sports arenas, gymnasiums, community centers, and other public buildings that are readily accessible. Through various public information methods, the jurisdiction encourages people to come to these locations to receive their MCMs. **Chapter 9: Public Information and Communication** contains detailed information on the messages, methods, and materials needed to get people to and through PODs.

Closed PODs

A closed, or private, POD uses the resources of partner organizations to set up PODs and dispense MCMs in their own facilities. Closed PODs remove the population of participating organizations from the total number of people that will need to go to public PODs.

PROMISING PRACTICE

Oklahoma City County Health Department Push Partner Program

The Oklahoma City County Health Department (OCCHD) partnered with agencies and organizations in the jurisdiction to develop a network of Push Partners that will serve as closed PODs. The concept of the “Push Partner” approach is to take advantage of businesses and other organized settings that can receive MCMs from OCCHD and dispense them to employees, employee family members, and other clientele. With some 173 different entities involved in the program, OCCHD has developed one of the most robust alternate dispensing strategies in the country. This network allows them the possibility to reach over 64% of the population in closed PODs, greatly reducing the population that will need to receive MCMs in public PODs. OCCHD’s website includes information for possible Push Partners at <https://www.occhd.org/community/emergency-response-program/push-partner-program>

Drive-thru PODs

Based on principles used by banks and the fast food industry, drive-thru PODs allow people to drive to a designated location, go through the steps for dispensing, and receive MCMs without leaving their vehicles. Many local public health jurisdictions have successfully used this concept in their annual influenza vaccination clinics and in MCM dispensing exercises.

Mobile dispensing sites

Mobile dispensing sites allow flexibility in dispensing site locations during an incident, especially in jurisdictions with an insufficient number identified, fixed POD sites pre-incident, or if pre-identified POD sites are not available when an incident occurs. A mobile dispensing site would include vehicles (trailers, vans, box trucks, etc.) that house and transport supplies needed to set-up and operate a fully functional POD.

In planning for mobile dispensing sites, planners must consider that vehicles and/or trailers included in the dispensing program must be able to store the necessary materials at all times, be organized efficiently to allow for easy-use, be kept at a secured location, be readily accessible to staff upon activation, and be easy to transport to each site. The jurisdiction should perform periodic maintenance checks on these vehicles and/or trailers to ensure their serviceability when needed (check tires, fuel, oil changes, etc.). The jurisdiction also should check supplies and materials stored in vehicles and/or trailers periodically for damage and to ensure that they contain the most up-to-date materials.

Alternate Methods of Dispensing

Alternate methods of dispensing can be used to reach those population groups that cannot access open PODs (e.g., those confined to long term care facilities) or that would be difficult to bring to open PODs (e.g., those who are homebound or incarcerated). These forms of dispensing are referred to as alternate methods of dispensing, since they are alternate methods to open PODs. While open PODs will be the cornerstone of any dispensing campaign, the more alternate methods of dispensing a jurisdiction can develop, the fewer people will need to go to public PODs, thus reducing the staffing and other requirements for those PODs.

The alternate dispensing methods adopted in a local planning jurisdiction generally are influenced by the unique challenges faced by that community. Each jurisdiction will have its own planning considerations related to PODs and alternate dispensing methods and CDC encourages local public health planners to enlist the assistance of their preparedness partners to examine each option carefully. Table 2.1 in **Chapter 2: Developing a Medical Countermeasure Response Plan** provides a list of possible planning partners.

Direct deliveries to residences

Some jurisdictions have developed models using government vehicles, such as school buses, to deliver MCMs to predetermined neighborhoods. In using this option, jurisdictions must determine the appropriate number of vehicles and drivers to cover the pre-determined neighborhoods and the skill sets of any team members on each vehicle. The team could

consist of medical (physician, pharmacist, or nurse), nonmedical, and security personnel, along with a driver. The make-up of the team can be influenced by local and state dispensing laws and availability of staff and volunteers. Additional planning considerations include the development of routes, provision of road maps or global positioning systems (GPS), communication systems for contacting the appropriate authority overseeing the dispensing campaign, as well as plans for pick-up sites for MCMs and for refueling vehicles.

Deliveries to Sheltered-in Populations

Sheltered-in populations are those confined to a facility (including their homes) because of disability, incarceration, or other circumstances. Examples of sheltered-in populations include

- Inmates of correctional facilities (jails, prisons, and juvenile-detention facilities);
- Patients in nursing homes, assisted living facilities, and other long-term care institutions;
- Hospitalized patients;
- Homebound patients who may or may not get care at home through local home healthcare service providers;
- Residents of half-way houses or mental health facilities; and
- Homeless and undocumented populations.

Pushing medications to the facilities or organizations that serve or house these populations allow trained lay persons (e.g., prison guards, office staff, social workers, or volunteers) to fill shortfalls in credentialed professionals that may not be available to staff the number of PODs needed. For instance, home health workers could deliver MCMs to their clients while performing their routine visits or people who provide daily visits, such as Meals on Wheels delivery drivers, could deliver MCMs to their clients along with their services.

Provision of Pre-incident MCMs to the Community

Jurisdictions can stockpile MCMs and planners may determine it is feasible to provide pre-incident MCMs to certain communities, such as first responders, or they may hold MCMs in a central location for dispensing during an emergency. For jurisdictions that have the resources to do so and plan to stockpile MCM caches, they should be prepared to

- Ensure MCMs are maintained in accordance with FDA guidance;
- Work with a professional pharmaceutical company to rotate out or dispose of expiring product in accordance with law; and
- Assume costs for storage, maintenance, and replacement of MCMs within their caches.

Determining the Number of PODs

One of the first steps in developing dispensing plans is to determine the number of PODs required to reach everyone in the community – residents, commuters, tourists, and visitors – within the targeted timeframe. Members of the Weill Medical College of Cornell University developed the Bioterrorism and Epidemic Outbreak Response Model (BERM)²³ to assist

²³ Bioterrorism and Epidemic Outbreak Response Model (BERM) developed by Dr. Nathaniel Hupert and colleagues at the Weill Medical College of Cornell University.

planners in determining the number of POD sites a jurisdiction will need to provide MCMs to the entire population within a 48-hour timeframe. Figure 8-1 provides an example that assumes a population of 500,000, a distribution and set-up time of 18 hours, a dispensing timeframe of 48 hours, and throughput (PPH) averaging 500 people/hour.

POD Formula Based on the Bioterrorism and Epidemic Outbreak Response Model (BERM)

$TP \div (HPP - S) \div PPH = \# \text{ of PODs required}$

TP = total population requiring prophylaxis

HPP = number of hours to provide prophylaxis to the population

S = amount of time required to distribute MCMs and set up the PODs

PPH = the number of people per hour who are provided prophylaxis in a POD.

The following example assumes a population of 500,000, a dispensing timeframe of 48 hours, a set-up time of 12 hours, and throughput (PPH) averaging 500 people/hour.

$(500,000) \div (48 - 12) \div 500 = 27.77 \text{ PODs, rounding up to 28 PODs}$

Figure 8-1: Formula for determining the number of PODs using an example of a community of 500,000 people.

The formula presumes that each POD has essentially the same design and staffing, will serve approximately the same number of clients, and therefore will produce roughly the same level of throughput. In some cases, larger PODs simply may be treated as multiples of small PODs: for instance, a baseline small POD may have a throughput of 500 people per hour, and thus a large 2000-person-per-hour POD may be considered equivalent to four small PODs.

Planners should use the estimated number of people who would go to an open POD as the total population (TP) in the BERM. Therefore, planners can subtract any population groups that would receive MCMs through any method of dispensing other than an open POD from the TP. For example, if the community of 500,000 in Figure 8-1 could use alternate methods of dispensing to reach 20% of the population, or 100,000 people, it would reduce the TP for open PODs to 400,000; reduce the number of PODs required from 28 to 22; and thus reduce the staff and supplies the health department needs to furnish for dispensing operations.

Jurisdictions should determine the number of PODs needed for a dispensing campaign well before an incident occurs to ensure enough available sites, resources, and personnel. As

plans develop and new partnerships form for closed PODs and other alternate dispensing methods, the number of open PODs may decrease. By identifying all possible POD sites and alternate dispensing methods, planners also will be able to scale back to just the most appropriate sites or dispensing methods to use in a smaller-scale incident or if previously designated sites are unavailable during a response.

Estimating Population

To determine the number of PODs needed in the jurisdiction, planners need to estimate the population of the community. As previously mentioned, dispensing plans must consider all the people who might be present during an incident, including residents, visitors, commuters, or anyone else who may be in the affected area. In developing population estimates, planners must consider how the population changes depending on the activities that take place in their communities. For instance, many cities see a daily shift in population due to commuters, conventions, and tourism. Some smaller cities may see shifts in population based on students attending colleges or universities and another increase in population related to collegiate sporting events associated with those institutions. Rural communities may hold agricultural events or fairs that bring together people who may typically be living far from each other, creating a temporarily dense population.

The RAND Corporation provides key guidelines for establishing a dispensing site network in the POD Standards.²⁴ Appendix A: Standard 1.1 of the POD Standards provides a sample spreadsheet planners can use for population estimates and to document the characteristics of the population their PODs will serve. Jurisdiction should review estimates annually and update estimates whenever new data are available (e.g., from the U.S. Census, from local metropolitan planning organizations, POD exercises, and CDC's Snap Shots of State Population Data [SNAPS]²⁵).

Selecting POD Sites

The ability of health departments to provide MCMs within the targeted timeframe will require them to develop a network of dispensing sites and alternate dispensing methods throughout the jurisdiction. Local health jurisdictions can meet dispensing requirements by assessing the resources available in the community that could support sustained dispensing operations for potentially indefinite periods. Highly urbanized jurisdictions may select pre-existing facilities, such as schools, community centers, religious centers, athletic complexes, health care systems/networks (e.g., clinics, nursing homes, assisted living facilities, etc.), businesses, and shopping malls as facilities for dispensing MCMs. Rural jurisdictions also may select existing facilities within their community or opt to establish mobile dispensing sites to deploy throughout the jurisdiction at the time of a public health emergency.

²⁴ www.rand.org/pubs/technical_reports/2008/RAND_TR553.pdf

²⁵ <http://emergency.cdc.gov/snaps>

Determining POD Locations

Planners must consider multiple factors when selecting sites for public PODs, including location in relation to population, physical characteristics, traffic patterns and parking, as well as required written agreements and facility security. Once planners determine the number of PODs that they will need to serve the total population (TP), they should look at population data to determine where to locate the required PODs to best serve the jurisdiction. In an area in which people live in dense clusters, such as a city with many people living and working within a few square miles, planners may need to position multiple PODs in a smaller geographic area so that people can access a POD closest or most convenient to them. In jurisdictions that have geographic features that may separate communities, such as a river, planners should be certain to position PODs to ensure that people are not cut off from dispensing sites due to geography.

Because of possible pre-existing agreements, planners should consider maximizing the use of publicly owned facilities, such as public schools, universities, or community recreation centers. The advantage of most public places is that they are familiar to the community, are readily available to as many people as possible, and have large parking facilities. Polling places are particularly attractive because the public uses them to vote, and they can come with a cadre of election volunteers to staff them. In addition, by partnering with agencies that control a number of facilities (e.g., school boards that control multiple school facilities or the parks and recreation department that controls multiple community recreation facilities), planners may need only one written agreement to cover access to numerous locations. Planners should make access to PODs as easy as possible by selecting sites within reach of the community and should consider whether people will be able to walk, use public transportation, or private automobiles to get to the PODs.

Some jurisdictions have hesitated to use sites that the public frequents because of the possibility that contamination by a contagious agent, such as plague or smallpox, could make these sites unusable until authorities could decontaminate them. Yet, the sites' familiarity and the convenience of these locations are precisely what make them so attractive as dispensing sites. Consequently, planners must balance the necessity of protecting the public during an emergency with the desirability of returning the jurisdiction to normal daily life after an emergency.

Note: CDC does not recommend using hospitals, commercial pharmacies, or other health care institutions as PODs except as closed PODs dispensing to their employees and employees' family members. Because hospitals and other healthcare facilities could be overwhelmed with an influx of additional patients due to an incident, as well as the patients already present in these facilities, they will not have the infrastructure to handle the added responsibility of dispensing MCMs to the public. Similarly, commercial pharmacies are not an ideal choice for public PODs because of their limited inventory, staffing, floor plan, and security.

Physical Characteristics of Facilities

Each POD, whether in a fixed structure or a drive-thru facility, must be large enough to handle several hundred (or even thousands) of people regardless of weather conditions.

Experience with exercises and the 2001 anthrax attacks have shown that the most successful POD sites are fixed structures ranging in size from 18,000 to 60,000 square feet. For PODs in fixed structures, planners should consider the following characteristics:

- Heat and air conditioning to maintain a controlled room temperature between 68° and 77° F (20° and 25° C) in accordance with the good manufacturing practices for pharmaceuticals outlined in Title 21 Code of Federal Regulations, Part 211 (21CFR211.56)²⁶
- Adequate bathrooms, water, and electricity
- Compatibility with Americans with Disabilities Act (ADA)²⁷ standards
- A public address or speaker system
- Wide hallways that easily allow for two way traffic
- An unloading area, such as loading docks or double doors, that will accommodate pallets of materials (for receipt of supplies)
- Storage space for MCMs and supplies away from the dispensing area
- Space for parking at or near the site
- Space for a staff break room/canteen

Site Security Considerations

Whether dispensing is occurring at a public POD or through alternate methods of dispensing, adequate security planning is essential for the safety of POD staff and clients, the sustainability of operations, and the safeguarding of the MCMs. In addition, planners must ensure that any closed POD sites have the same types of security measures required of public PODs.

Chapter 11: Securing Assets, Staff, and Operations provides detailed information on security planning, however, some considerations to mention here include

- Parking management;
- Protection of staff, MCMs, and the physical facility;
- Crowd and traffic control both inside and outside the POD; and
- Checking credentials of and providing identification badges to staff.

Jurisdictional law enforcement agencies may find it difficult to provide all the security needed for PODs and other dispensing methods. Law enforcement will be assisting with investigations, managing traffic control, providing security for treatment centers, as well as performing routine law enforcement duties. Therefore, public health planners may need to identify other potential security partners, such as contract security firms or members of the National Guard. Planners should enhance security resources, by

- Making sure all POD workers are aware of security concerns;
- Ensuring that POD workers know how to report suspicious individuals and activities;
- Using security personnel from the facility itself (planners should ensure this is included in any written agreements with facilities);
- Choosing POD locations with controllable entry and exit points (this assists security personnel in setting up entrance and exit security); and

²⁶ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=211.56&SearchTerm=sanitation

²⁷ www.ada.gov

- Planning an evacuation route for clients and personnel.

Closed POD Sites

Partnering with entities outside of the health department can help speed dispensing, especially in a large-scale incident in which everyone in the community must receive MCMs as quickly as possible. The state or local health department can obtain agreements from partner organizations such as private businesses, universities, or other organizations, which in turn receive MCMs from the state or local health department during an emergency and provide them to their designated populations. Some populations that could receive MCMs through closed PODs include

- Workers at large industries (hotels, utility services, businesses, etc.);
- Students, staff, and their family members at colleges and universities;
- Residents or employees of nursing or long-term care facilities; and
- Employees of federal, state, or local government agencies.

For closed PODs, occupational health or other healthcare providers in the partner organization will be able to dispense MCMs, including providing vaccinations. For organizations that do not have healthcare providers on staff, planning may include the use of trained volunteers overseen by a skilled, licensed healthcare professional.

Many jurisdictions have had success in recruiting closed POD partners from large employers in the jurisdiction by touting the benefits to the employers, such as

- Protecting employees and their family members by providing MCMs during an emergency;
- A positive public appearance because the business is helping the jurisdiction and their employees by assisting in dispensing; and
- Continuity of operations because
 - Employees know that they can get MCMs to take care of themselves and their family members if they go to work;
 - Employees will not have to go to open PODs and wait in line, thus getting them back to work sooner; and
 - Business operations can continue because employees feel that the business is taking care of them.

USEFUL TOOL

Community Partner Assessment Tool (cPAT)

Planners from the Las Angeles County Department of Public Health partnered with the Naval Postgraduate School to develop the Community Partner Assessment Tool (cPAT) to aid jurisdictions in determining the best closed POD partners in the community. The cPAT can help planners analyze the number of people that could be served by a closed POD and whether the site would benefit the community over an open POD. The cPAT along with a webinar featuring a demonstration of this tool are available on the SNS Extranet at <https://www.orau.gov/snsnet/secondWedWeb.htm>

Planners should analyze possible partners in the jurisdiction to determine whether they would make viable closed PODs. Some considerations for closed POD partners include

- The number of people they could serve (staff and staff's family members);
- Type and number of medical personnel (e.g., occupational health);

-
- How closed POD partners will receive MCMs; and
 - Site security.

Developing plans with potential closed POD partners requires planners to develop written agreements with the entities that volunteer to serve as closed PODs. In addition, plans should include how the closed PODs will integrate into the overall plans for distribution, training, staffing, security, dispensing, and public information. The Additional Resources section at the end of this chapter provides links to tools for recruiting closed POD.

Drive-thru POD Sites

When selecting sites for a drive-thru PODs, planners should consider additional factors to those for other POD sites. During site selection, planners should ensure that the location is adequate in size and layout to safely accommodate the movement of large numbers of vehicles. For instance, a drive-thru POD will need to be set up in a way that minimizes the impact on traffic flow around the dispensing area and avoids the possibility that cars lining up to enter the drive-thru POD will block the streets around the POD site. Planners also should consider including an on-site auto repair technician or tow truck to perform small repairs or remove vehicles that break down or run out of fuel.

Another consideration for drive-thru PODs is parking areas for people to wait. For instance, if one of the stations in the POD is backed up, people may need a place to park that does not impede cars entering, moving through, or leaving the POD site. Also, if the MCMs being administered require a vaccination, people may need to wait a prescribed amount of time for observation after receiving the vaccine to ensure that they do not have an adverse reaction. The drive-thru POD should have a designated parking/waiting area staffed with medical personal or trained nonmedical volunteers who can identify adverse reactions.

In addition, the staff and volunteers, as well as people being served by the POD, must be protected from any inclement weather. Some jurisdictions have acquired tents to use for drive-thru POD operations while others have opted to use large enclosed structures, such as parking decks or convention centers. If planners select an enclosed site for a drive-thru POD, they will need to ensure that the facility has adequate ventilation to protect clients and staff from engine exhaust. In addition, the jurisdiction may need to obtain and train staff on the use of carbon monoxide monitors for the site.

Outlining POD Operations

All PODs – open, closed, drive-thru, or mobile – will require the same basic operations. In addition, the way in which POD staff carries out these operations can affect the number of people who can receive MCMs at a POD; how long it takes those people to get through the POD; and how many people per hour each POD can process. Since knowing the estimated POD throughput is necessary for determining the number of PODs required, the jurisdiction will need to plan for and test (i.e., exercise) POD operations in order to estimate throughput.

Basic operations inside of each POD include

- Greeting clients;

- Providing client information forms (to collect client name and basic information for screening e.g., children's weights, client medication allergies and current medications, contact information);
- Screening information forms and sorting clients (i.e., determining which, or whether, MCMs at the POD are appropriate for each person);
- Dispensing MCMs (i.e., bottles of medication, vaccinations, etc.); and
- Providing information (e.g., medication fact sheets, hotline or phone numbers, websites, etc. for clients to use to obtain additional information).

Some of these steps may be combined, depending on the plans for each specific site and for the jurisdiction overall. Planners should attempt to ensure that all PODs within the jurisdiction operate in basically the same manner to avoid public perception that one POD site is more efficient than another or that one community is not being served the same as the rest of the jurisdiction. Planners will need to evaluate each possible POD site to determine the best ways to direct client flow through the POD.

Greeting Clients

Greeting clients that arrive at the POD is one of the easiest and yet most vital roles in dispensing. Greeters can serve in a triage role and reinforce public information messages, especially those that direct symptomatic people to treatment centers. In addition, greeters can assure people that they are at the right place to receive MCMs, give them an overview of what to expect in the dispensing process, answer some of their basic questions, and perhaps give them an estimate of the time it will take to go through the POD. Trained volunteers can act effectively in this role.

Distributing Client Information Forms

As part of the intake process, clients will need to provide some basic information to ensure that they receive the appropriate MCMs at the POD. Many jurisdictions find that trained volunteers can fill this function easily and often make it part of greeting clients as they enter the POD. By providing those who staff this area with background information on the data collection forms, they should be able to explain to clients why this information is necessary, including that the information will be used to

- Determine which medication each person should receive;
- Enable follow-up and monitoring in case public health officials determine there is a need to provide additional medication or change medications;
- Aid epidemiologists in the investigation of the disease outbreak or incident;
- Meet relevant state and federal regulations for medication dispensing documentation (e.g., date, time, location, dispenser, prescription number, etc.);
- Serve as a record of medications dispensed; and
- Track medications in case of recall.

The type and extent of data collected as part of the POD process will vary between jurisdictions. Therefore, state and local planners are responsible for determining the type and amount of information required and how the jurisdiction will collect this data (e.g., with paper documents, electronic programs, etc.).

Planners should be aware that the flow of clients through the PODs will decrease as the length of the information collection form increases. The time it takes people to move through a POD may not be significant during a small-scale incident, but slow client flow could seriously jeopardize a POD's ability to provide MCMs to many people during a large-scale incident. Therefore, planners should strive to create forms that are short, simple, and threat-specific. In addition, intelligent form design can speed the screening process because it allows volunteers, with medical professional oversight, to evaluate answers and direct clients to receive the correct medication.

Using computerized data collection forms can make it easier and faster to forward information to command and management activities and to epidemiologists investigating the exposure; however computerized forms may

- Require additional staff to perform data entry;
- Necessitate additional training for staff on the automated system; and
- Shut down if power interruptions and system failures occur.

Some jurisdictions may find that providing the data collection forms on a web site or in newspapers will allow clients to fill this information out in advance of arriving at the POD. If so, POD plans should include a way for these clients to skip the form completion step and move directly to the screening step at the POD.

Screen Client Information Forms and Sort Clients

Once clients have completed the information forms, POD staff should review (screen) these forms. Staff may sort clients into different dispensing areas depending on the MCMs being dispensed. For example, some clients may have allergies to the primary MCM being dispensed or be taking a medication that could interact with the preferred MCM; these clients may need to be directed to a dispensing station within the POD where they can receive an alternate MCM or be evaluated further by a medical professional. The screening area at the POD could require roles in addition to that of "screeners," who review the client information forms. Additional personnel could include

- A greeter to control the line of people into the area;
- Interpreters or translators for non-English speakers, hearing impaired, etc.;
- Roamers;
- First aid and medical transporters;
- Clinical professionals (physician or pharmacist); and

PROMISING PRACTICE

Online Screening and Electronic Applications for PODs

Many SNS planners are beginning to seek ways to tap into electronic technologies and devices, such as tablet computers and smart phones, as a way to streamline some processes that would take place at PODs, such as filling in forms, screening forms, and providing information to POD visitors. Some planners have already developed applications to assist in POD operations. For instance, planners from the Maryland Department of Health and Human Services, the San Francisco Department of Public Health, and Johnson County (Kansas) Health Department have created electronic tools, including online screening and smart phone applications. Planners from these areas shared their technologies and information about field testing on the *SNS Second Wednesday Webinars* program from March 12, 2012, which can be downloaded from the SNS Extranet at <https://www.orau.gov/snsnet/secondWedWeb.htm>. The SNS Extranet is password protected. To obtain login information, planners should contact their state SNS coordinator or DSLR project officer.

- Behavioral health counselors for those in need of it.

In addition, many project areas are turning to electronic methods to assist in decreasing the need to provide paper forms and even reducing the number of screeners at PODs. Some project areas have developed online screening forms that utilize an electronic algorithm to determine which MCM each client will need based on information they enter in an online system, see the “Promising Practice” on Page 28 for further information.

Dispensing MCMs

Once staff screen clients to determine which MCM, or whether an MCM, should be dispensed to them, they should be directed to a dispensing area. PODs should have multiple dispensing areas to serve as many clients as possible. Depending on the incident, more than one MCM might be available and dispensing stations will need to be set up for each of the available MCMs. Planners may determine that their PODs will have expedited dispensing stations for those clients whose information form demonstrates that they have no conflict with the most widely recommended MCM. In addition, those clients who have physical limitations may need to have a separate area in which to receive MCMs and avoid waiting in long lines or standing for long periods of time.

Staff requirements at the dispensing stations will be dependent on specific dispensing regulations in the jurisdiction. Some areas may be able to use trained volunteers under the supervision of a medical professional, while others may need to use licensed medical personnel according to state dispensing laws and regulations.

Providing Information and Education

Information is an important part of dispensing MCMs because people will need to know what has occurred, what the most effective treatment or prophylaxis is, why it is important that they receive MCMs and where they can receive them, and why it is important to take the MCMs according to recommendations from public health professionals.

An effective information and education plan begins before people arrive at the PODs, provides additional information at the PODs, and provides ways for people to have their questions answered after they receive MCMs and leave the PODs. In general, providing information and education does not need to be a standalone station within the POD, but instead should be a function that exists throughout the dispensing process. As part of the POD process, this step specifically refers to providing written fact sheets and oral information for people as they exit the facility. These fact sheets should provide basic information, including

- An explanation of the public health threat (e.g., Category A agents, disease outbreak, radiation threat, etc.);
- A description of the MCMs used for prophylaxis and treatment (under an EUA, specific FDA-approved fact sheet language about the MCMs may be required);
- Directions on how to properly use the MCMs; and
- Information people may need after they receive their initial course of MCMs, such as where they can receive further information or have their questions answered.

Chapter 9: Public Information and Communication provides detailed information for developing the messages, methods, and materials to provide information before, during, and after an MCM dispensing campaign, including any information sheets provided at the POD.

Staffing PODs

Planners will need to assess the steps in their POD plans and determine the types of people who will be able to staff those areas. For example, nonmedical volunteers could hand out information collection forms and help direct people through the PODs, while public health nurses may be required in the dispensing or screening areas. Planners will need to assess each POD site and determine how many people from various backgrounds or professions will be needed and then be sure to include that information in the site-specific POD plan, along with resources from which staff and volunteers will be drawn.

Staffing the overall dispensing operation may be the greatest challenge in conducting a mass dispensing campaign. Planners will need to recruit and maintain contact with staff and volunteers to ensure they are available when the jurisdiction activates the MCM dispensing plan.

To assist planners in meeting this challenge, the report *Recommended Infrastructure Standards for Mass Antibiotic Dispensing*²⁸ includes standards for determining

- The number of staff required for an MCM dispensing campaign;
- How to recruit staff for MCM dispensing operations; and
- How to assess the availability of staff during an emergency.

Some considerations for staffing requirements follow, but specific information on POD command structure can be found in **Chapter 3: Managing Medical Countermeasure Operations**.

Identify Dispensing Staffing Needs

In general, three types of people will be required to staff a dispensing system: professionals (physicians, nurses, pharmacists, public health workers, and social workers), management, and support staff, which can include both trained and untrained volunteers. Support staff should be familiar with the facility and/or the tasks involved in dispensing (providing information, directing clients through the POD, cleaning up, emptying trash, running errands, making copies, assisting professionals, helping the elderly, providing child care, moving MCMs and supplies, and annotating bottle labels). During POD operations, overlaps will occur among these types of workers. Physicians may have to pitch in to help unload trucks, and volunteers may have to help dispense MCMs.

During a large-scale incident, medical and pharmacy professionals will be in high demand. Planners should design PODs and alternate dispensing plans to maximize the use of these

²⁸ www.rand.org/pubs/technical_reports/2008/RAND_TR553.pdf

professionals by turning over any appropriate jobs to volunteers or nonmedical staff. Jurisdictions can improve POD operations significantly by having health professionals supervise volunteers. For example, every POD will have people come to the site with questions about the threat, the MCMs they will receive, and/or the process for getting MCMs. A well-prepared volunteer can use pre-scripted messages to provide that information, freeing a medical professional to perform other tasks.

Identify Sources for Staff and Volunteers

Planners should make every effort to partner with other agencies, professional organizations, volunteer societies, and the general public to recruit both professional and non-professional staff and volunteers for MCM dispensing campaigns. Some suggested sources for locating and recruiting professional and non-professional volunteers follow.

Medical staff could include professionals from

- Commercial pharmacies;
- State agencies that license doctors, nurses, and pharmacists;
- Professional associations to which these professionals belong;
- Universities;
- U.S. Department of Health and Human Services regional emergency coordinator (HHS REC);
- Regional health administrator; and
- Medical Reserve Corp (MRC).

Trained volunteers could fill additional roles in the POD, such as

- Spoken-language interpreters, who could be recruited from universities, ethnic organizations, and faith-based organizations; and
- Sign-language interpreters, who could be recruited through local schools for the deaf or associations for the hearing impaired.

Additional volunteers could include

- General disaster-relief volunteers, who could be recruited through the local chapter of the American Red Cross or public health mutual aid agreements with other governmental departments and jurisdictions;
- Civic and fraternal organization members, who could be identified and oriented before an incident;
- Employees of the locations selected to be PODs; and
- Walk-in or spontaneous volunteers that show up and volunteer to help.

Support staff may come from

- The facility at which the POD is operated;
- The broader institution that normally operates the facility (e.g., the Board of Education); and
- State and local government agencies.

Those who are familiar with the facility will know the locations of resources, any problems with the physical facility, and people with special skills or knowledge who can assist in POD operations. As part of the planning process, planners should be certain that the signed

written agreement documents any support services offered by the facility or requested by the health department.

Create and Manage Volunteer Registries

The ability to identify potential volunteers from sources, such as a volunteer registry, will decrease the amount of time needed to ensure adequate staffing levels for PODs during an emergency. Beginning in FY 2007, under the requirements of the CDC's PHEP cooperative agreement (mentioned on page 2 of this chapter), each state is required to develop an electronic registration system for recording and managing volunteer information.

By now, each state should have adopted their version of the national Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP).²⁹ Among the many advantages to this volunteer registry system is the ability consolidate information on volunteers from multiple local lists that may exist across the state. Planners can contact the volunteer program coordinator in the local jurisdiction or the state public health department for more information on ESAR-VHP and how to register and manage volunteers at the local level.

Developing Site-specific POD Plans

Once the jurisdiction identifies possible POD sites, planners will need to develop specific plans for each POD site. These plans should be clearly written to assist staff in the POD with setting up and running the facility in the absence of the lead planner. Planners should work with facility staff and security partners when developing site-specific plans to determine the best ways to use and secure the facility. Facility managers can assist by letting planners know which areas of the facility may be off limits to them during an emergency and pointing out additional options for facility use, such as storage rooms that lock or break rooms that would allow staff to rest away from the busy areas of the POD. Security partners can point out potential security risks of the facility and help plan to make operations at the site as secure as possible.

Site Surveys

Planners will need to take the time to walk through and assess each facility to determine the layout and client flow for each of the PODs, address any security concerns, and determine whether the possible sites can accommodate all clients. Planners should schedule routine, follow-up site visits to reassess the site-specific plans as construction or renovations may change the layout of facilities.

As well as assessing facilities with security partners and facility management, planners should conduct walkthroughs with planning partners, including community that have roles in emergency planning, such as members of the COIN³⁰ mentioned on page 8 of this chapter.

²⁹ Information on ESAR-VHP can be found at www.hhs.gov/aspr

³⁰ See the *Public Health Workbook to Define, Locate, and Reach Special, Vulnerable, and At-risk Populations* for more information on partnering with community groups and forming a community outreach and information

Physical walkthroughs are one way to work with community groups and their trusted leaders to determine issues with POD sites or planning, but virtual walkthroughs also can be useful. For instance, planners may invite representatives from these groups to a roundtable discussion, provide a sample POD flow chart, and discuss how POD operations will be conducted. In this forum, a COIN member may point out specific concerns their constituents may have in the POD and offer alternative planning considerations for the facility. These discussions epitomize whole community planning and help planners obtain buy in and cooperation from various groups whose constituents may be affected by a public health emergency and who otherwise may be hesitant to go to a POD.

Written Agreements

Once the planner selects dispensing sites, jurisdictions should enter into written agreements with any organizations and/or facilities that will be part of the dispensing campaign before an incident or emergency occurs. This includes organizations that will provide facilities for public PODs, such as school boards or civic organizations, as well as private entities that might serve as closed POD facilities, such as large businesses or government agencies.

Written documentation is vital because

- Considerable time may pass before access to this site is needed, and memories may differ on what was agreed to;
- Those who made the agreement may not be in charge when the need for dispensing arises;
- A large-scale public health emergency will not allow time for renegotiating access to vital facilities; and
- After the emergency, organizations or agencies providing facilities and resources may be eligible for reimbursement under a Robert T. Stafford Disaster Relief and Emergency Assistance Act (Public Law 93-288)³¹ declaration.

Written agreements should address considerations such as the health department's access to the site and any resources that would enable the location to operate effectively as a POD. Written agreements also should be in place for any services to support the overall dispensing operation, such as external security partners, organizations that will provide home delivery of MCMs (e.g., Meals on Wheels or home healthcare agencies), or organizations that will provide volunteers to assist in POD operations. CDC recommends that planners investigate forming mutual aid agreements (MAAs) with neighboring agencies and departments in the jurisdiction. MAAs are commonplace in emergency services such as fire and police protection.

At a minimum, written agreements should include language that addresses

- Immediate use of the facility or support service during an incident;
- Periodic access to the facility prior to an incident for inspections, exercises, and development of site-specific plans;

network (COIN). Available at <https://www.orau.gov/snsnet/resources/At-Risk-Populations-Workbook-FINAL9-13-10.pdf>.

³¹ Information on the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Public Law 93-288) is available from URL www.fema.gov/about/stafact.shtm.

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- 24/7 contact information for facility access;
 - On site resources that the POD staff will be able to access;
 - Financial compensation agreement (if any);
 - Liability or indemnification issues;
 - Authority for use of a facility or support service during exercises;
 - Services that will be provided by the agency or organization; and
 - Number and skill set of any personnel provided by the facility.

POD Flow Chart

Working with facility staff and security partners, planners should develop a detailed site map of both the exterior and interior of each POD site to determine the best layout and placement of POD operations for that facility. Aerial maps also can be useful to determine traffic flow and whether some streets may need to be re-routed during an emergency to maximize flow of traffic to and parking at the POD site.

Planners should use the jurisdiction's pre-determined POD steps to assess how clients will flow through the dispensing process in each facility. During the site surveys, planners should walk through the facility and determine the size, number, and placement of tables and chairs, staff, signs, etc. and the best ways in which to route clients through POD operations. Planners also should note how staff will bring MCMs and supplies into the site and ensure that client flow does not cross through MCM and supply routes, which could impede client or supply flows.

Site-specific Plans

Once the jurisdiction has identified POD sites and obtained signatures on written agreements, planners should develop plans for each site that are specific to how operations will run in that location.

Site-specific POD plans should include

- Written agreements for each identified location;
- Contact information for 24/7 access;
- Name and contact information of the designated POD manager and any alternate POD managers;
- Traffic flow patterns;
- Parking for staff and clients at the facility;
- Entrances and exits;
- Detailed maps for placement of signs inside and outside of the POD to facilitate client movement into, through, and out of POD facilities (specific information for the development of POD signs appears in **Chapter 9: Public Information and Communication**);
- Detailed maps of flow patterns for clients going into and through the POD;
- Identification of sites for POD staff break areas;
- Identification of sites for storing MCMs and POD supplies;
- Identification of locations within POD for a first aid station, one-on-one counseling room, and a post-vaccine waiting area (if needed);
- Identification of loading sites for MCMs and POD supplies;

- Specific security concerns; and
- Alternate plans in case of construction or other facility alterations at the time of an emergency.

Determining POD Segmentation Strategies

Another determination that affects POD site selection is whether planners opt to perform all POD steps in one place or to complete some steps (such as greeting, providing information collection forms, screening, and forms completion) at a central location and dispensing of MCMs in a separate location. PODs that are split among geographic locations are called **segmented PODs**. Complete PODs operating in just one location are called **nonsegmented PODs**. The reasoning behind the segmentation strategy is to control access to the POD by having a regulated system to bring clients to the dispensing site. The choice of segmented or non-segmented PODs can directly impact the transportation and traffic management of POD operations. Both strategies have advantages and disadvantages and these are listed in the following sections.

Non-segmented PODs

Non-segmented PODs have all dispensing operations conducted at one location. Members of the public drive themselves, walk, or take public transportation to the POD to receive MCMs. In general, this chapter addresses PODs under the non-segmented strategy. Figure 8-2 illustrates this strategy and Table 8.2 lists advantages and disadvantages of this strategy.

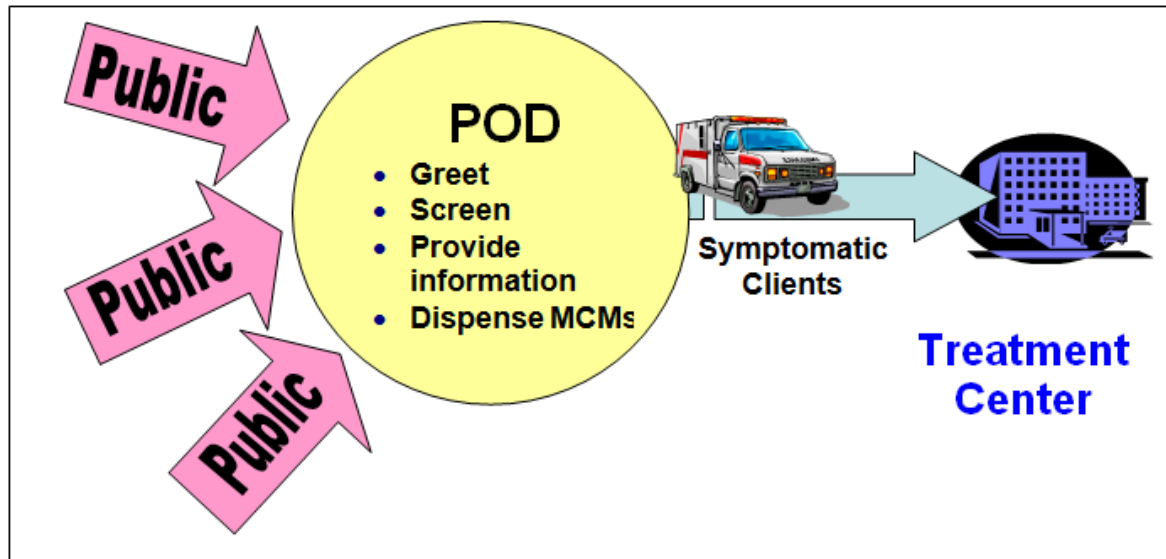


Figure 8-2: Non-segmented PODs.

Table 8.2: Advantages and Disadvantages of Non-segmented PODs

Advantages	Disadvantages
<ul style="list-style-type: none"> • Reduced need for resources compared to segmented PODs • All dispensing operations presented in a single location • May permit clients to walk, bicycle, or take other transportation methods to the dispensing site 	<ul style="list-style-type: none"> • Requires additional parking at the POD site • Requires additional emergency medical services (EMS) so that EMS units can be available at each POD • During a contagious outbreak, symptomatic clients may expose non-symptomatic clients to the agent at the POD, but this can also occur at staging sites for segmented PODs

Segmented PODs

For this strategy, the public will gather at a staging site that provides large amounts of dedicated parking, such as a shopping mall, convention center, or stadium. At the staging area, staff would greet, screen, and provide information on the incident and dispensing process to clients. Clients would then be transported in groups to the single POD where they would receive medication. Anyone who exhibits symptoms would be sent directly to treatment centers. A variation on the segmented model is to have one staging area for multiple PODs. Table 8.3 lists advantages and disadvantages of segmented PODs. Figure 8-3 illustrates the client flow for the single segmented POD model and in Figure 8-4 illustrates the multiple POD model.

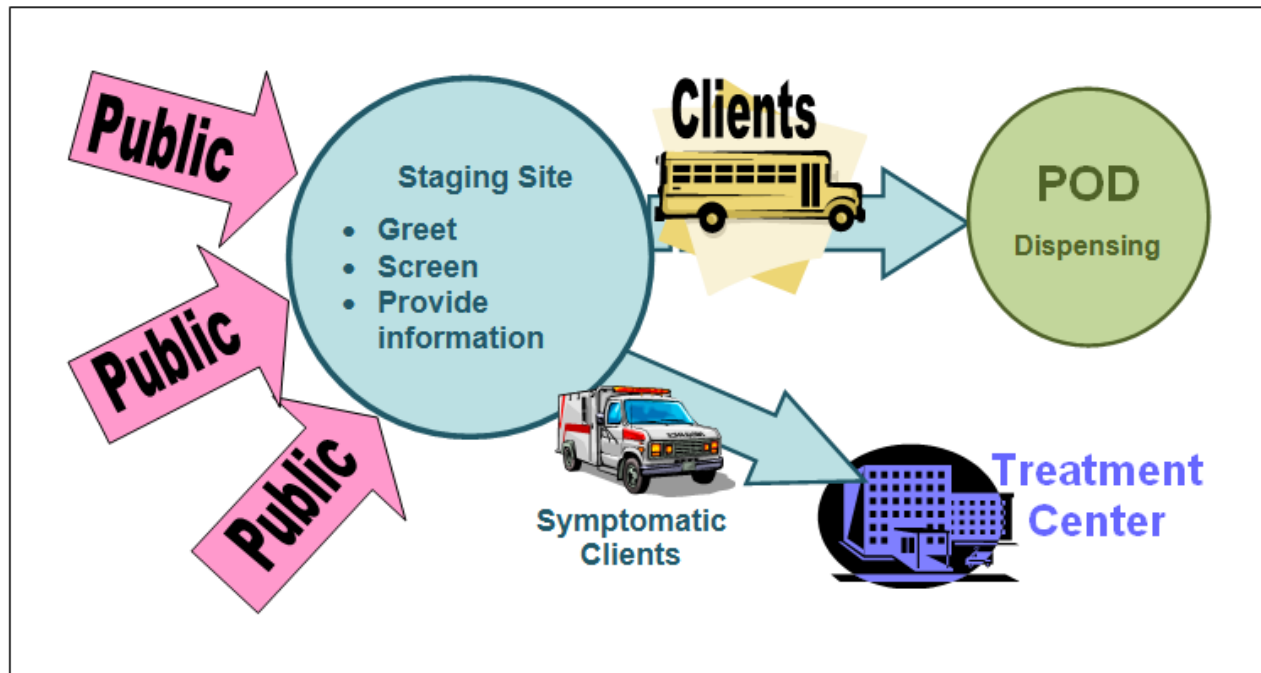


Figure 8-3: Basic segmented POD.

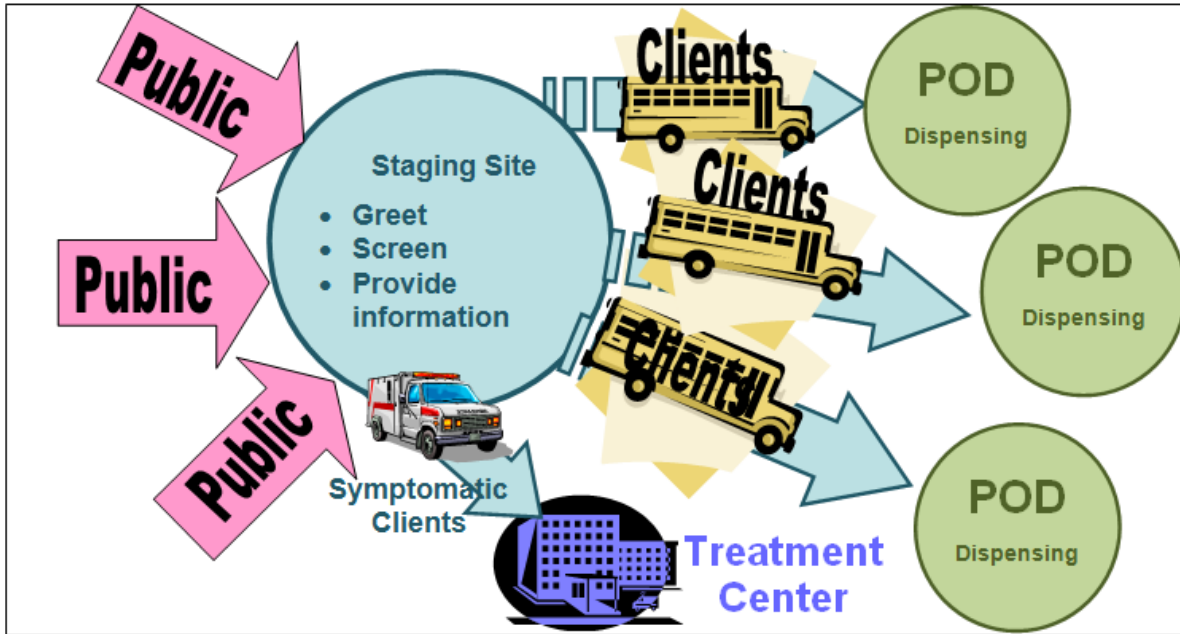


Figure 8-4: Multiple POD segmentation.

Table 8.3: Advantages and Disadvantages of Segmented PODs

Advantages	Disadvantages
<ul style="list-style-type: none"> • Regulated flow of clients through POD because people arrive in regulated groups • Reduced bottlenecks in the POD due to regulated flow of people arriving • Reduced parking and traffic congestion concerns at the POD • Improved security at the POD because of controlled access • Symptomatic people are kept out of the POD and transported directly to treatment centers 	<ul style="list-style-type: none"> • Additional planning to assure that PODs can handle the flow in batches (dozens to hundreds of people all at once, followed by a possible lull before the next batch arrives) • Requires exceptionally large parking area and traffic management plan for the staging area for multiple POD segmentation • Contagious clients may be interacting at staging area before triaged and sent to treatment centers • Requires additional staff and resources, such as vehicles, drivers, fuel, and maintenance for transportation vehicles • Requires additional planning and written agreements with transportation services • Requires additional training and exercising to ensure drivers understand their routes, how to interact with concerned clients, what information to provide clients en route to POD, etc. • May require additional security personnel to staff the staging area, control access to transportation vehicles during client loading, and secure transportation vehicles en route to POD • May not keep clients from traveling directly to POD sites and skipping the staging area

Planning for Prescribing and Dispensing MCMs

Every state has pharmacy laws that regulate who may dispense prescription drugs. The size and scope of an emergency may expand to the point where people other than pharmacists or physicians must dispense MCMs to the public. During a large-scale public health emergency, it is likely that jurisdictions may need to enlist the assistance of additional, non-licensed personnel to dispense MCMs under the instruction and supervision of credentialed professionals. CDC recommends that planners investigate legislative changes (such as an Emergency Powers Act) or waivers for their governors (or governor's designee) to sign that would allow individuals other than pharmacists to hand out prescription drugs at dispensing sites during an emergency.

Prescribing Authority and Prescribing Organization

Federal law requires that prescriber information be part of the label for a dispensed prescription drug. The jurisdiction should identify a prescriber, which may be the chief medical officer or lead public health official, before an incident since all MCMs dispensed in the jurisdiction will be under that prescriber's name.

Federal law also requires that the name and address of the dispenser (e.g., pharmacy) appear on the label of a prescription. To eliminate confusion, planners should consider using the name of a single organization, such as the state public health agency, for the entire state, which will ensure that the prescription label will be valid during any incident that occurs in the state.

Federal Medication Labeling Requirements

Federal regulations dictate information that must appear on prescription drug labels. Under federal law (Food Drug and Cosmetic Act Section 503(b)(2)(21 U.S.C. § 353(b)(2)),³² the label of a dispensed prescription drug must include the

- Name and address of dispenser;
- Medication serial number;
- Date of prescription or of its filling;
- Name of prescriber;
- Name of person for whom medication is prescribed, if stated on prescription; and
- Directions for medication use and cautionary statements, if contained in the prescription.

SNS-specific Drug Labels

CDC recognizes that meeting federal labeling requirements may be difficult in the midst of an emergency and is working to provide SNS products in packaging that includes as many of these federal requirements and other solutions as possible to help streamline dispensing. For example, for certain products in the SNS, some of the information required by federal law

³² The text of the Food, Drug and Cosmetic Act related to prescription drug labeling can be found at www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec353.htm.

will be pre-printed on the label of the unit-of-use bottles. In addition, SNS unit-of-use bottles include removable stickers with specific label information that can be placed in medical records or distribution logs with the recipient's name.

In addition, barcodes are included on bottles of certain MCMs in the SNS so that a dispensing site may scan unit-of-use bottles to facilitate tracking. The bottles will include a two-dimensional (2D) barcode containing the National Drug Code (NDC) and lot numbers of the drug and a second single-dimensional (1D) barcode containing the prescription number (Rx number) of the unit-of-use bottle (see Figures 8-6 and 8-7). Please note that 2D barcode readers can read 1D and 2D barcodes, but 1D barcode readers will only read a 1D barcode. Examples of possible unit-of-use bottle labels appear on the following pages of this chapter.

Label descriptions provided in this chapter apply to all ciprofloxacin, doxycycline, and amoxicillin shipped with an SNS 12-hour Push Package and from SNS managed inventory (MI).

The **front label** on a unit-of-use bottle (Figure 8-5) contains

- The name of the medication;
- Strength per tablet or capsule;
- The quantity of tablets or capsules in the bottle; and
- Usual dosage statement (e.g., Take one tablet every 12 hours).

The **left panel** of the label on a unit-of-use bottle (Figure 8-6) contains

- The name and address of manufacturer or re-packager;
- The product NDC number;
- A two-dimensional barcode that references the NDC and product lot number; and
- The recommended storage temperature.

The **right panel** of a unit-of-use bottle (Figure 8-7) contains the medication

- Lot number;
- Expiration date;
- Rx number (unique identifier);
- One-dimensional barcode (referencing the Rx number);
- Warning information (e.g., Keep out of reach of children); and
- Two perforated, removable tabs with identical information, including
 - The drug name;
 - Strength per tablet or capsule;
 - Quantity of tablets or capsule;
 - The expiration date;
 - NDC number;
 - Lot number; and
 - Unique prescription number (RX number).

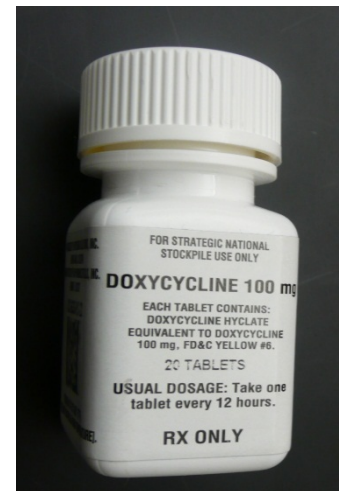


Figure 8-5: Front label



Figure 8-6: Left panel

One self-adhesive tab should be affixed to the recipient's information sheet. For tracking purposes, the second tab should be affixed to the client's record, which remains at the POD.

Note: All unit-of-use bottles of ciprofloxacin, amoxicillin, and doxycycline in SNS inventory will have identical information on both the removable stickers, ensuring that the pull-off labels may be used interchangeably.

Planners should note that state laws might impose additional requirements for labels on a dispensed drug that are not included on labels attached to SNS-supplied MCMs. Additional regulatory discretion, granted by the FDA under an Emergency Use Authorization (EUA), may allow states to dispense SNS assets without some of their usual required labeling elements. State planners should work with public health law professionals, pharmacists, and the medical officer to determine whether the state's current labeling requirements can be waived for MCMs used under an EUA.

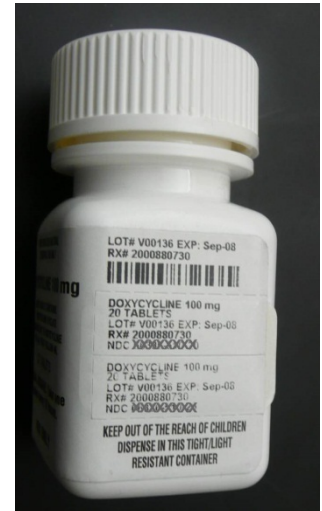


Figure 8-7: Right panel

Shelf Life Extension Program Labels

Some drugs in the SNS may be included in the Shelf Life Extension Program (SLEP). SLEP is a program run by the FDA and Department of Defense (DoD) designed to defer drug replacement costs for eligible date sensitive pharmaceutical products in federal stockpiles by extending their useful shelf life. As a participant in this program, DSNS ideally is responsible for relabeling product that undergoes SLEP testing to capture the approved adjusted shelf life. An SNS product that has gone through the SLEP may have an updated bottle label that clearly states the FDA-approved SLEP expiration extension date.

As previously mentioned, most 10-day unit-of-use bottles in an SNS 12-Hour Push Package and MI are pre-labeled with three sides of the bottle covered by labels. However, assets that have gone through SLEP and that have been relabeled will have an additional panel added to the label so that the FDA-extended expiration date is clearly stated (Figure 8-8).



Figure 8-8: SLEP label

The SNS holds over 4 billion dollars' worth of medical supplies that may be used during a public health emergency. Many of the products in the SNS that have gone through SLEP testing are waiting to be relabeled. The commercial capacity to relabel products to reflect extended expiration dates is very limited and the amount of SLEP-tested product in the SNS exceeds this market capacity. Additionally, since most products undergoing SLEP testing can receive 2 – 3 extensions on shelf life (in 12 – 18 month increments), testing cycles and relabeling cycles often do not align.

Therefore, depending on the scale of the response and quantity of product needed, CDC may deploy SNS product to the jurisdiction that does not reflect the most recent SLEP-

extended expiration date. CDC is currently developing a communications plan to further explain SLEP and help states address the questions that may arise when they receive product from the SNS that has gone through SLEP testing but has not been relabeled to reflect the most recently extended expiration date.

Information Dispensers Must Provide

In addition to standard drug labeling requirements found on SNS-supplied unit-of-use bottle labels, dispensers also must provide the following information:

- Date the medication was prescribed
- Name of prescribing physician or authority
- Name of person for whom medication is prescribed (i.e., dispensed)

Jurisdictions will need to compile and print this information and apply it either to the unit-of-use bottle or to the information sheet the MCM recipient receives. In addition, some drugs may require that additional labeling information be dispensed along with the drug in the form of medication guides or information sheets.

Note: Although all of these labeling requirements are currently part of legal dispensing of a drug product, if an EUA is granted, it is possible that no additional label information will be required. In addition, further changes may be forthcoming as new legislation is implemented, specifically the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA).

Creating POD Supplies and Equipment Lists

Planners must develop plans to acquire and provide the supplies and equipment needed at each POD. Planners can use site surveys to assist in identifying the supplies and equipment needs specific to each POD and developing site-specific equipment and supply lists. These lists should then be included in the written site-specific plans along with contacts for obtaining additional supplies as needed during POD operations.

Planning Considerations for POD Equipment and Supplies

Developing a plan to identify, store, and deploy the supplies and equipment for PODs will be critical for successful dispensing operations. The materials, equipment, and supplies needed will vary between PODs and the required supplies will vary depending on the types of PODs; for instance, a drive-thru POD will require more supplies for traffic control than a walk-thru POD. The facility manager may offer to supply some of the basic required supplies and equipment. If so, planners should be certain to include this in the written agreement. Planners should consider the following storage and deployment considerations when developing plans for POD supplies and equipment.

Identifying Supplies and Equipment

When determining POD supplies and equipment, planners should work with facility managers to determine supplies and equipment available on site that the facility will permit POD staff

to utilize. In addition, planners should discuss with facility management/owners any items POD staff are not permitted to use and clearly communicate this to POD staff. The written agreement between the jurisdiction and the facility should include the supplies and equipment that the facility will allot, if any, and how staff will gain access to these during POD operations. Once the written agreement is established, planners will need to consider what additional supplies and equipment staff will need to bring into the POD when setting up the facility.

It is important that POD supplies accurately reflect the needs of the specific POD. POD facilities will vary in size and physical characteristics, requiring varying quantities and/or types of supplies needed to support POD operations. For example, a POD located in a high school gymnasium that has 4,200 square feet of space might require fewer signs, tables, and chairs than a POD planned for a large conference center that has 50,000 square feet of space.

Planners often use annual influenza clinics to assess POD plans and these exercises can assist in determining the quantities of the supplies and equipment needed to run a longer or more intensive dispensing operation. Planners should use POD drills to validate the quantities specified on supplies and equipment lists to ensure they are adequate to support dispensing operations.

As mentioned, the type of dispensing operation also influences items included in the supplies and equipment list. Table 8.4, located at the end of this chapter, provides a possible list of POD supplies and equipment that planners can use to develop their own POD-specific lists.

Indoor PODs

For PODs located inside buildings, placement of the different stations will be dependent on the layout of the rooms and work space available within the facility and the number and type of signs used can be dictated by the availability of wall space or stanchions. More tables and chairs may be needed compared to a drive-thru POD. Congestion inside a closed space may place greater emphasis on staff identification tools, such as colored vests, and staff communication devices, such as hand-held radios to compensate for noise.

Drive-thru PODs

Because a drive-thru POD may use only the parking lot and not a building, plans should include more equipment for traffic control, such as traffic cones, in addition, clients may inadvertently leave items such as pens and clipboards in their cars as they drive through the dispensing process, so additional clipboards or pens may be required due to the increased possibility of these items being misplaced. In order to prepare for any weather conditions, the supply list for drive-thru PODs may include items such as rain ponchos for the POD staff and tents to help to keep people out of the weather. Additionally, portable toilets may be needed to accommodate staff and those waiting in line to receive MCMs.

Reproducing Information Forms and Medication Information Sheets

Planners will need to determine the best methods to print and distribute enough client information forms, agent fact sheets, and MCM information sheets for each POD, including

closed PODs, and alternate dispensing partners, such as those providing home delivery of MCMs.

Pre-printing all the forms and information sheets may be impractical because of the large storage space required and the possibility of changes to the information contained on the sheets. CDC suggests that planning jurisdictions hold a small pre-printed inventory or electronic master templates to support PODs until needed. It may be difficult to produce enough information sheets at the time of an emergency and some jurisdictions have made plans to have printing performed under contingency contracts with local printing and photocopy companies. In addition, planners can make arrangements to provide patient information forms online, which will encourage some people to fill in and print these before going to the POD, thus reducing the need to print as many forms. See the Promising Practice on page 28 of this chapter for information about electronic screening and client data collection tools developed by other planners.

Requirements for Fact Sheets

When MCMs are being dispensed under an EUA, it is likely that FDA will require specific approved medication fact sheets. For example, in the case of doxycycline provided under an EUA for anthrax, CDC has worked with FDA to develop a fact sheet and establish minimal information that it should include. FDA and CDC also developed a simple version of the FDA-approved fact sheet that includes all of the minimal requirements as set forth by the FDA. The simpler version of this fact sheet allows state and local planners to customize (add a logo, etc.) as long as they include the minimum elements. This fact sheet is available in English and several additional languages on the SNS Extranet site.³³ However, FDA advises state public health agencies to be aware that some changes could be made to the available fact sheets at the time of the incident. If this were the case, jurisdictions will need to use the newly updated sheets from that point forward. CDC will make every effort to get the updated fact sheets posted to a website for planners to download and use.

Storage Considerations

Planners should determine the storage needs of required supplies and equipment for PODs by establishing whether some or all of these items can be stored in one location (i.e., a warehouse). Alternatively, planners may determine that these items can be stored on site at the POD for easy access during an emergency. Whether POD supplies are stored at a centralized location or at POD sites, planners should ensure appropriate access to conduct scheduled inventory and maintenance of the items in storage.

Many communities have used systems such as pre-packaging supplies for quick deployment to the PODs, sometimes referred to as “POD in a Box” or “Go Kits.” Planners can color-code, number, or letter the pre-packaged containers of supplies and equipment according to the specific POD to which staff will transport them or specifics of each POD. Other communities have created “POD footprints,” which are kits containing the same contents for a typical

³³ <https://www.orau.gov/snsnet/EUA/languages.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

POD to support a certain number of people. If the POD will receive more people than one POD footprint can accommodate, the jurisdiction can send additional POD footprints to that location to accommodate the larger site.

Deployment Considerations

Deployment of supplies and equipment from storage to PODs is a major planning consideration. The written dispensing plan should include a plan for transporting the supplies to PODs. Staff should be aware of the plan in order to transport supplies and allow enough time to complete the POD set up prior the designated opening time. Plans should include the types of vehicles required to transport equipment and supplies, who is responsible for driving those vehicles, and who is responsible for deploying and ensuring delivery of supplies and equipment.

Most importantly, planners must take all these planning considerations into account to determine what works best for the jurisdiction and be certain that in the overall dispensing plan includes plans for supplies and equipment and the site-specific POD plans.

Activating Dispensing Operations

Whether dealing with a large- or small-scale incident, the jurisdictional dispensing plan should include steps the dispensing team will need to take to activate and begin dispensing operations. The dispensing lead will likely receive notification to activate the dispensing plan from the jurisdiction's emergency operations center or incident command. The dispensing lead will then need to activate the staff call-down list, which will include all of those responsible for organizing dispensing operations, including

- POD managers;
- Alternate dispensing partners;
- Medical personnel;
- Those responsible for moving supplies to PODs or other dispensing sites;
- Volunteers;
- Security personnel; and
- Any other partners involved in dispensing operations.

Staff and volunteers should know where to report or be informed of any changes to the activation plan during the call-down process. When staff and volunteers arrive at their designated duty stations, the process for checking identification and providing ID badges should be up and running (See **Chapter 11: Securing Assets, Personnel, and Operations** for further details on the identification and badging process). Once staff and volunteers have received their ID badges, they should be briefed on overall site operations and be provided with job action sheets and/or just-in-time training on their roles in the dispensing site.

Dispensing to Responders and Critical Infrastructure Staff

If the jurisdiction has a plan to provide prophylaxis to first responders, the dispensing location should be activated prior to other dispensing sites. Responders and other critical infrastructure staff (See the section on Responders and Critical Infrastructure Staff beginning on page 6 of this chapter for more information) could receive their MCMs prior to reporting to their duty locations or as they arrive at their duty locations, depending on the jurisdiction's plans.

Opening Dispensing Sites

Jurisdictions should make every effort to ensure that all dispensing locations open at the same time. Everyone living in the jurisdiction should have access to MCMs simultaneously to avoid the appearance that one area has better access to MCMs than another. Once the jurisdiction knows when MCMs will arrive, they should be able to estimate how long it will take them to activate and prepare all dispensing locations and alternate dispensing partners to receive and begin dispensing MCMs. By conducting POD drills and exercises they should have an estimate of the time it takes staff and volunteers to prepare POD locations and they can use these time estimates to inform the community of the time at which dispensing will begin. In addition, the jurisdiction should have a plan on how to communicate information on delayed POD openings, should they occur (See **Chapter 9: Public Information and Communication** for further information on developing messages for dispensing operations).

If using home delivery, planners should mobilize volunteers and provide them with MCMs and informational packets for delivery. The dispensing staff also should provide drivers/delivery personnel with instructions on their routes, how and where to pick up more MCMs, and how to communicate with dispensing lead or designated contact for that branch of dispensing operations.

Sustaining Dispensing Operations

Depending on the nature of the incident and the type of MCMs dispensed, the dispensing campaign could last for many days, weeks, or even months. For example, during a large-scale release of aerosolized anthrax, people who were exposed will need to take prophylactic oral antimicrobials for 60 days to prevent illness. Initially, CDC will provide 10-day unit-of-use MCMs for the jurisdiction to dispense to everyone in the community. Once epidemiological data is available, officials may be able to pinpoint the population that was most likely affected by the release and scale back dispensing operations, utilizing fewer dispensing sites to target those who will need to continue prophylaxis for the additional 50 days. Another long-term dispensing operation could occur during a pandemic influenza

PROMISING PRACTICE

Delaware Responder Caches

Planners from the Delaware's Department of Health and Social Services (DHSS) built up responder caches of 10-day supplies of antimicrobials for use during a large-scale emergency. DHSS purchased identical amber bags for the antibiotic caches and partnered with the state police and National Guard to store supplies for these responders in evidence lockers at their facilities. The pre-deployed assets are available to those responders as soon as an incident occurs, so they can receive medications for themselves and their family members and then deploy to their duty stations.

outbreak, which would result in waves of illness that recur over weeks or months, so a long-term dispensing program may be required to provide influenza vaccinations or antiviral medications.

Jurisdictions should develop plans that outline how they will scale back operations, allocate staff, and position dispensing sites should long-term dispensing operations be necessary. Planners also should remember that during an anthrax response in which 60 days of prophylactic MCMs are necessary for a designated population, other people may want to continue taking the MCMs and they should be provided with MCMs if they request them. In contrast, some people who can be identified as having been in the impacted area will decide not to continue taking the MCMs because of the side effects – nausea, diarrhea, vomiting – of oral antimicrobials. Therefore, staff should be prepared to answer questions about these side effects and why it is important for people to continue taking the MCMs. The jurisdiction should have information on how to ease side effects and provide messages that can assist people in continuing the course of prophylaxis. **Chapter 9: Public Information and Communication** provides further information on developing messages, methods, and materials to assist in dispensing campaigns.

During a long-term dispensing campaign, the jurisdiction may be able to utilize partnerships with commercial pharmacies or other retailers to provide MCMs; especially following a large-scale dispensing operation in which everyone received an initial 10-day course of MCMs, but may need to receive an additional 50-day supply of MCMs for a long-term course of prophylaxis. However, planners should determine whether dispensing partners, especially commercial pharmacies or other retailers, require an administration fee for providing federally supplied MCMs. If so, this should be clearly communicated with people who receive MCMs from those sources. Messages should be clear that the jurisdiction provides MCMs without charge, but the dispensing partner requires a small fee for handling them and, if possible, the jurisdiction should subsidize that fee for those who are not able to afford it, such as those living below the poverty level or on a fixed income.

Considerations for Vaccination Campaigns

During an incident that requires large-scale vaccination campaigns, such as a smallpox outbreak, dispensing operations will require additional considerations. For instance, many vaccinations must be stored in lower temperatures than other MCMs and will require refrigeration. Dispensing sites will need to have back-up refrigeration in case MCMs are not dispensed within the timeframe that CDC shipping containers can sustain the required storage temperature. In addition, a vaccination campaign will require more medical personnel to provide vaccines. Staff will need to be instructed on how to safely handle vaccines and ancillary supplies (e.g., needles, sharps containers, etc.). Following vaccination, people may need to be observed for a period of time (possibly 10 – 30 minutes) to ensure they do not have an adverse reaction to the vaccine. Therefore, vaccination dispensing sites will need a post-vaccination waiting area that is staffed with medical professionals or trained volunteers who can observe and recognize any adverse reactions.

Understanding How INDs and EUAs Affect Dispensing

Many of the MCMs in the SNS are approved for use in humans and have undergone rigorous testing as mandated by the U.S. Food and Drug Administration (FDA) to ensure their safety and efficacy in humans to treat certain diseases. However, some of the pharmaceuticals may not be approved for specific uses or have not previously been approved by the FDA. CDC stocks these pharmaceuticals in the SNS because case reports, in-vitro studies, small human trials, or animal data suggest they will be effective against a public health threat.

During public health emergencies, the FDA may permit the use of unapproved MCMs or approved drugs for unapproved uses, under an Investigational New Drug (IND) protocol or under an Emergency Use Authorization (EUA). Planners should be familiar with how INDs and EUAs can affect dispensing operations within the jurisdiction and work with public health law professionals to ensure their dispensing plans adhere to the regulatory requirements of the use of specific MCMs. Also, please note that further changes may be forthcoming as new legislation is implemented, specifically the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA).

Investigational New Drugs

The use of pharmaceuticals for purposes that have not been specifically approved by the FDA is referred to as off-label, or investigational, and those who receive them must be informed of and consent to using the medication in that manner. Off-label (i.e., investigational) use must comply with the FDA's Investigational New Drug (IND) protocol, which requires extensive informed consent. In addition, IND protocols require that those receiving the drugs must be monitored for adverse side effects.

During a large-scale public health emergency, the designated lead center/division or office at CDC (not DSNS) will obtain approval from the FDA to use specific IND protocols for the MCMs that are in the SNS, if required. Once FDA grants approval, the CDC lead will provide the consent forms that drug recipients must read and sign to give their informed consent.

Emergency Use Authorizations

HHS recognizes that the requirements of an IND protocol (informed consent, training on protocols, collection of safety and efficacy data) may not be practical during a rapidly progressing public health emergency. Because IND protocol requirements would limit the public health community's ability to respond to and contain emerging incidents, such as an anthrax or smallpox outbreak, federal agencies have worked together to devise ways in which life-saving MCMs can be dispensed during emergencies.

In July 2004, Congress passed the Project BioShield Act of 2004 (Public Law 108-276),³⁴ which amended Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21

³⁴ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108.pdf

U.S.C. § 360bbb-3)³⁵ and allows FDA to authorize the use of medical products during a declared emergency under a process referred to as an Emergency Use Authorization (EUA). An EUA allows the wide-scale use of unapproved, uncleared, or unlicensed MCMs in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

An EUA can be issued during a declared emergency involving a heightened risk of attack on the public or U.S. military forces. An example in which an EUA might be needed is in the use of ciprofloxacin as prophylaxis against plague. While ciprofloxacin is an FDA-approved antimicrobial, it has not previously been approved to specifically protect against plague.

For an EUA to be authorized, the HHS Secretary must first declare an emergency based on the determination of a domestic, military, or public health emergency as stated under Section 564(b)(1) of the FD&C Act. If an EUA is needed, a government entity (federal, state, or local), or a private entity (i.e., drug manufacturer), may request that FDA authorize an EUA. The requesting entity will work with the FDA to submit a protocol for use of the product in the intended emergency.

If the emergency request for product use meets the EUA eligibility criteria, the FDA Commissioner can authorize an emergency use of MCMs once he/she consults the National Institutes of Health (NIH) and CDC (to the extent feasible during an emergency). In this decision, the FDA Commissioner then determines that certain statutory criteria have been met, including that

- The agent specified in the HHS secretary's emergency declaration could cause serious or life-threatening disease or condition;
- It is reasonable to believe that the MCM being recommended for use may be effective in treating or preventing the emerging disease based on scientific evidence available;
- The known and potential benefits of the MCM outweigh the known and potential risks of the MCM if it is used to prevent or treat the defined, life-threatening disease or condition that is the subject of the declaration; and
- There is no adequate, approved, and available alternative to the MCM for treating or providing prophylaxis against the defined life-threatening disease or condition.³⁶

Once the EUA is authorized, states may then distribute/dispense the authorized MCMs according to the EUA conditions for the designated time of authorization. Based on the HHS declaration that justifies use of an MCM, EUAs can remain in effect for up to one year, unless the HHS emergency declaration is terminated or the EUA is revoked (e.g., if the criteria for issuing the authorization are no longer met or revocation is necessary in order to protect public health or safety). However, the emergency declaration and any associated EUAs can be renewed, if justified, after one year. FDA must publish notifications of any EUA, its

³⁵ www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm

³⁶ From the U.S. Food and Drug Administration (FDA) Emergency Use Authorization website, available at www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm269226.htm.

termination or revocation, and an explanation of why the authorization is being terminated or revoked in the Federal Register.³⁷

In preparation for an emergency that requires the use of assets from the SNS that are not FDA approved, or for the use of approved products for unapproved indications, CDC worked with FDA to develop pre-EUA protocols. This action will ensure that the review process required for these EUA protocols at the time of an incident is minimal.

Dispensing Under an EUA

Planners should note that when the jurisdiction dispenses MCMs under an EUA, the FDA EUA conditions for product use will likely mandate that healthcare providers and clients be informed of the risks, benefits, any alternative interventions, and be given the opportunity to accept or refuse use of the product. The authorization may also require collection and analysis of certain safety and efficacy data during the period of emergency use. For example, clients may need to be monitored for and report certain adverse drug reactions to the CDC or FDA.

Demobilizing Dispensing Operations

As the need to dispense to large numbers of people wanes, the jurisdiction will need to close down PODs. For large-scale incidents, this may require a graduated system for POD closures, so that a few sites stay open over the course of several days, weeks, or even months. The jurisdiction will need to provide the public with information on sites that remain open. In addition, staff will need to conduct inventory of MCMs at dispensing sites and arrange with the inventory control team and distribution team for pick up of any unused or damaged MCMs for return to the RSS or distribution to those dispensing sites that remain operational.

Demobilizing Staff and Volunteers

Demobilization plans should include plans for how to debrief staff and volunteers on operations and inform them of information that should remain confidential (e.g., RSS sites or distribution partners from the private sector). In addition, if long-term operations continue and some dispensing locations remain operational, the jurisdiction should plan for how to rotate staff and volunteers through those sites that remain open. Planners also should inform staff and volunteers on whether and how the jurisdiction will compensate them for their time and how to apply to receive compensation, if available.

Securing Client Information

Planners should be cognizant that the data collected on clients during dispensing is subject to privacy and security rules set down in Public Law 104 – 191: Health Insurance Portability

³⁷ From the U.S. Food and Drug Administration (FDA) Emergency Use Authorization website, available at URL www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm269226.htm.

and Accountability Act of 1996 (HIPAA).³⁸ Jurisdictions will need to secure information collected from clients at the POD in order to meet HIPAA standards for protecting the privacy of client's identifiable health information. In addition, the jurisdiction must secure any electronic health information collected on clients at dispensing sites according to national standards as set forth by HIPAA.

CDC recommends that client-level tracking be a function of a state, local, or regional jurisdiction to facilitate client notification should a drug recall occur from dispensed MCMs. Since drug recalls occur by lot number, knowing who received MCMs from the recalled lot will make it easier to issue recall information. Planners may find it helpful to organize any printed client information forms in groups according to the lot numbers of MCMs dispensed. This way, all those who received each lot number will already be filed together, making notification quicker. Jurisdictions should secure all client health information to protect the privacy of those who receive MCMs and planners should work with public health law professionals to determine the best way to save and secure this information, how long the jurisdiction must store the information, and how and whether the jurisdiction will destroy the information after a specified recordkeeping period.

Providing Follow-up Information

Besides specific follow-up information on the MCMs, people will want to know additional information, such as the number of casualties from the incident, how many people experienced reactions from the MCMs, and what to do if they have adverse reactions or lose their MCMs. Demobilization plans should include ways the jurisdiction can provide this information and any other important follow-up information for the incident, such as encouraging people to continue to take the MCMs. **Chapter 9: Public Information and Communication** provides further insights on how to reach people with important messages regarding the incident.

Medical Waste Management

Vaccination campaigns and certain other MCM dispensing campaigns will generate a great deal of medical waste, such as syringes and needles, intravenous administration supplies, soiled bandages, etc. The jurisdiction should arrange for pick up and handling of medical waste after such campaigns to ensure proper disposal of these items. The jurisdiction can work with local hospitals, medical clinics, and medical waste management companies to handle waste. It is important to note that jurisdictions should not dispose medical waste and biohazard materials in the general waste disposal system (e.g., landfills).

Return of Federal Assets

Planners should remember that MCMs will remain property of the state and will not need to be returned to CDC. However, it is important to note that MCMs distributed from federal

³⁸ Further information on HIPAA privacy and security rules is available from the Department of Health and Human Services (HHS) Health Insurance Portability and Accountability Act Health Information website. Available at www.hhs.gov/ocr/privacy/.

caches for an emergency may come with restrictions on use. For instance, if the state has SNS-supplied antimicrobials left in its holdings after receiving these in response to an anthrax attack, the state cannot dispense these SNS-supplied antimicrobials as treatments for other uses. Planners should work with CDC to determine how to properly store, maintain, and use federally supplied MCMs that remain in the state's possession after an incident.

State or local jurisdictions must return certain items, such as refrigerated shipping containers and ventilators, to CDC following an incident. Planners should work with CDC to determine how to return this property.

Facility Cleaning

Depending on the incident, facilities used for dispensing sites may require extensive cleaning during the demobilization phase of operations. Some POD facility owners or managers may agree to provide their own cleaning services for the facility after POD operations, but if the incident involved a contagious agent (e.g., smallpox or plague), a radioactive material or chemical agent, or intravenous administration of MCMs, the facility may require cleaning or decontamination by professional industrial cleaning crews. Written agreements with any facilities used for POD operations should include information on who is responsible for cleaning the facility after use and which agency is responsible for contracting and paying for industrial cleaning services if these are necessary.

Additional Resources

SNS Extranet

CDC offers resources on the **SNS Extranet** (available at <https://www.orau.gov/snsnet/default.htm>), a password protected internet site for state and local SNS planners. To obtain login information, planners should contact the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer. The SNS Extranet contains a variety of tools to assist in developing dispensing plans and specific URLs are included in the following sections.

At-risk Populations

CDC's **Public Health Workbook to Define, Locate, and Reach Special, Vulnerable, and At-risk Populations in an Emergency** provides a framework for developing a Community Outreach Information Network to assist with planning efforts. The workbook is available at www.bt.cdc.gov/workbook.

An **electronic toolkit** (eTool) is available as a companion guide to the *Public Health Workbook to Define, Locate, and Reach Special, Vulnerable, and At-risk Populations in an Emergency*. The eTool provides planners with a collection of customizable and fillable forms to capture the results of planning based on the original workbook. The new eTool is free and available at www.orau.gov/SNS/AtRiskTool/.

Mass Antibiotic Dispensing Broadcast Series

CDC produced a series of broadcasts on mass antibiotic dispensing that address a variety of topics related to dispensing, building volunteer registries, partnering with businesses, developing alternate dispensing plans, and streamlining POD operations. Planners can view the series on the CDC Learning Portal at www.cdc.gov/learning/by_media.html.

Mass Antibiotic Dispensing Courses

DSNS offers courses to assist planners in developing dispensing plans. Regional and local planners can contact their state SNS coordinator for information on training and training materials. State SNS coordinators should contact their DSLRL project officer for updated information and for scheduling training offered by DSNS. DSNS training includes the Mass Antibiotic Dispensing Course and Mass Antibiotic Dispensing Train-the-trainer Course. Additional information about SNS training opportunities is available on the SNS Extranet at <https://www.orau.gov/snsnet/conferences.htm#conferences>.

POD Planning

The key guidelines for establishing a dispensing site network are extensively discussed in ***Recommended Infrastructure Standards for Mass Antibiotic Dispensing***, commonly referred to as the POD Standards, published by the RAND Corporation. The POD Standards are available at URL www.rand.org/pubs/technical_reports/2008/RAND_TR553.pdf.

Closed POD recruitment tools, technical assistance, and the Community Partner Assessment Tool for closed PODs are available on the **SNS Extranet** at URL <https://www.orau.gov/snsnet/closedpod.htm>.

RealOpt is a modeling and optimization software tool for designing POD planning and operations. This software was developed by the Center for Operations Research in Medicine and HealthCare, School of Industrial and Systems Engineering, Georgia Institute of Technology. Public health professionals can request copies of this software by completing the form at <http://www2.isye.gatech.edu/medicalor/leaseSoft.php>.

Volunteer Recruitment and Management

The **Healthy People** website offers tips on how to engage potential partners. Available at URL www.healthypeople.gov/state/toolkit/partners.htm.

Resources to assist in recruitment and management of volunteers can be found on the **SNS Extranet** at URL <https://www.orau.gov/snsnet/volunteers.htm>.

Vaccine Planning

For more information on mass vaccination strategies, contact the National Center for Immunization and Respiratory Diseases at CDC and view CDC's **Smallpox Response Plan** at www.bt.cdc.gov/agent/smallpox/response-plan.

Security Planning

Recommended Infrastructure Standards for Mass Antibiotic Dispensing provides guidance to assist in implementing a comprehensive set of dispensing security measures. Available at www.rand.org/pubs/technical_reports/2008/RAND_TR553.pdf.

Legal Issues

The **Federal Employee Compensation Program** "Provides workers' compensation coverage to three million federal and postal workers around the world for employment-related injuries and occupational diseases. Benefits include wage replacement, payment for medical care, and where necessary, medical and vocational rehabilitation assistance in returning to work." From www.dol.gov/compliance/laws/comp-feca.htm#overview.

The **Federal Tort Claims Act** provides liability protection "to HRSA-supported health centers. Under the Act, health centers are considered Federal employees and are immune from lawsuits, with the Federal government acting as their primary insurer." More information is available at <http://bphc.hrsa.gov/ftca/about/index.html>.

National Vaccine Injury Compensation Program “was established to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines. The U. S. Court of Federal Claims decides who will be paid.” More information is available at www.hrsa.gov/vaccinecompensation/index.html.

Planners can find additional assistance from the **Network for Public Health Law**, which provides “insightful legal assistance, helpful resources and opportunities to build connections for local, tribal, state and federal officials; public health practitioners; attorneys; policy-makers; and advocates.” Information on the network is available at www.networkforphl.org.

Further information on the **Public Readiness and Emergency Preparedness (PREP) Act** (Public Law 109 – 148, December 2005) including links to the full PREP Act, amendments to the PREP Act, as well as current and past public health declarations are available at www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

Smallpox Vaccine Injury Compensation Program was created “to provide benefits and/or compensation to certain persons who have sustained injuries as a result of the administration of smallpox covered countermeasures (including the smallpox vaccine) or as a result of vaccinia contracted through accidental vaccinia inoculations.” More information is available from <https://www.federalregister.gov/articles/2003/08/27/03-21906/smallpox-vaccine-injury-compensation-program-smallpox-vaccinia-vaccine-injury-table>.

Emergency Use Authorization (EUA) Resources

Please note: Further changes may be forthcoming as new legislation becomes implemented that will impact EUAs, specifically PAHPRA .

The U.S. Food and Drug Administration (FDA) website provides EUA information at www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm and information on the Public Health Service Act at www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm.

Information on the Project BioShield Act of 2004 can be found on the HHS website at www.hhs.gov/aspr/bar/bioshield/index.html.

Investigational New Drug (IND) Resources

Additional information about IND’s is available at the FDA website at www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm

Further information on legal issues surrounding a large-scale MCM dispensing operation can be found on the **SNS Extranet**. To obtain login information planners can contact the state SNS coordinator or DSLR project officer. Resources on the SNS Extranet include the following:

EUA Guidance including an online EUA course, information related to EUAs issued during the 2009 H1N1 influenza response, key message points for new EUAs, and other useful links. Available at URL <https://www.orau.gov/snsnet/guidance.htm#EUA>.

Public Readiness and Emergency Preparedness (PREP) Act in Brief is a short video that provides an overview of the protections offered under the PREP Act. Available at URL <https://www.orau.gov/snsnet/resources/videos/Prep-Act-Video.htm>

Mass Antibiotic Dispensing: Legal Ease is an archived version of a live television broadcast covering the PREP Act, EUAs, and CDC's pre-EUA submission. Available at URL <https://www.orau.gov/snsnet/conferences/MAD-Legal.htm>.

Mass Antibiotic Dispensing: Taking Care of Business is an archived version of a live television broadcast on partnering with businesses. This broadcast includes a discussion of some of the legal issues state and local planners face when partnering with businesses for closed PODs. Available at URL https://www.orau.gov/snsnet/av/MAD_TCB.htm.

Federal Labeling Requirements (video) is available at URL https://www.orau.gov/snsnet/resources/videos/DSNS_FederalLabelingVideo.htm.

Sample POD Supplies and Equipment Checklist

CDC compiled this sample equipment list for supplying and furnishing a POD from several established community lists. The supplies and equipment used during dispensing will vary widely depending on the POD set up and the way in which planners equip and supply PODs may require a different mix of supplies, furnishings, and equipment from other communities, but this list suggests a variety of materials that might be useful.

Table 8.4.1: Sample POD Supplies and Equipment List (Office)

Supplies	Equipment
<ul style="list-style-type: none"> • Badge neck straps • Badge strap clips • Badges, identity • Candy • Dry erase markers • Highlighters • Ink pens, black • Ink pens, red • Labels • Legal pads • Paper clips • Paper, colored • Paper, white copy • Permanent markers • Rubber bands • Scotch tape • Staples • Sticky notes 	<ul style="list-style-type: none"> • Calculators • Clipboards • Dry erase boards • Label makers • Pencil sharpeners • Portable copy machines • Scissors • Staplers

Table 8.4.2: Sample POD Supplies and Equipment List (Operational)

Supplies	Equipment
<ul style="list-style-type: none"> • Batteries • Biohazard bags • Broselow tapes (for determining approximate weights of infants) • Disposable cups • Distilled water • Duct tape • Face masks • Facial tissues • Gloves, latex • Gloves, nitrile • Hand sanitizer • Paper towels • Trash bags • Biohazard containers for sharps (e.g., needles) and non-sharps (e.g., gloves) • Bike flags • Blankets • Sign easels • Whistles (on lanyards) 	<ul style="list-style-type: none"> • Automated Electronic Defibrillators (AEDs) • Bullhorns • Chairs, folding • Coolers • Extension cords • Flashlights • Generators • Hand trucks • Lanterns • Measurement equipment for reconstituting medications • Mobile folding chair carts • Mobile folding table carts • Power strips • Radios • Radios, emergency-alert • Rain ponchos • Scales • Storage carts (wire or plastic) • Surge protectors • Tables • Tent poles • Tent weights • Tents • Thermometers • Trash cans with wheels • Vests • Waste Cans

Table 8.4.3: Sample POD Supplies and Equipment List (Traffic Control)

Supplies	Equipment
<ul style="list-style-type: none"> • Barrier tape 	<ul style="list-style-type: none"> • Traffic batons • Traffic cones

Table 8.4.4: Sample POD Supplies and Equipment List (Staff Identification)

Supplies	Equipment
<ul style="list-style-type: none"> • Supplies for making staff IDs 	<ul style="list-style-type: none"> • System to create staff IDs

Table 8.4.4: Sample POD Supplies and Equipment List (Signage)

Supplies	Equipment
<ul style="list-style-type: none">• Tape or Velcro to attach signs to walls• Easels and/or hangers to post signs• Posts, brackets, or easels for outdoor signs	<ul style="list-style-type: none">• POD Signage

Chapter 9: Public Information and Communication

Public information and communication (PIC) professionals serve an integral role in public health preparedness and response by informing, educating, and communicating with the public about health-related topics and emergencies.

When Strategic National Stockpile (SNS) assets are deployed, communities may face the added challenge of mobilizing the public to obtain medical countermeasures (MCMs) in a short period of time and to adhere to a medication regimen (e.g., up to 60 days for oral antimicrobial prophylaxis against anthrax). Similar challenges would accompany emergencies requiring mass vaccination, quarantine, movement restrictions, shelter-in-place, and mass evacuations. In each of these instances, the public must be informed, educated, and mobilized to do something in response to messages disseminated by public health professionals.

The Centers for Disease Control and Prevention (CDC) may deliver SNS assets within hours of the federal decision to deploy, but the time it takes to provide people with MCMs depends heavily on PIC planning and how quickly the public reacts to the messages provided. For that reason, it is important that planners develop MCM-specific information and integrate it into the all-hazards communication plan, which should include **messages, methods, and materials** specific to all of the dispensing modalities and combinations of dispensing modalities planned within the community.

A well written and well executed PIC plan can reduce public fear, decrease the possibility of wasted time and resources, curtail the demand for unneeded treatment, reduce alienation of the media, minimize confusion at dispensing sites, and lessen fear and mistrust of the government.

Identifying Public Information Personnel

For incidents or events that require mobilizing the public to perform specific actions, it is critical that PIC personnel are involved in the planning and response. As part of the planning process, planners should identify skilled communicators within the jurisdiction and maintain ongoing collaboration to ensure successful communication during an emergency.

Jurisdictions should identify the following personnel for planning and implementing PIC functions:

- Public information lead with training in health communications, public information and communication, or risk communications;
- Public information liaisons in each point of dispensing (POD);
- Joint information center (JIC) personnel; and
- Behavioral health workers.

Each of the personnel assigned to these roles (and their back-ups) should be trained on specific duties during an MCM response.

Public Information Lead

CDC strongly recommends that a communications professional receive this guidance and develop the PIC portion of the MCM distribution and dispensing (MCMDD) and all-hazards plans. The public information lead can assist in developing messages, methods, and materials specific to the public information needs before, during, and after an SNS deployment and any MCM dispensing campaign.

The collaboration between the SNS coordinator and public information lead is vital to ensuring the jurisdiction bases its PIC plan on the policies and procedures already outlined in the MCMDD plan. During an incident, the public information lead will likely serve as the state or local public information officer (PIO).

The PIC plan should outline a reliable method for communication among the public information lead, the SNS coordinator, and the public information staff in the PODs. In addition, the plan should name a back-up public information lead to allow for shift work or to fill in if the primary public information lead is not available.

Public Information Liaison at the POD

Because the PIO will likely be at the JIC or emergency operations center (EOC), CDC recommends identifying someone to serve as the public information liaison at each POD to coordinate information with the PIO, JIC, and the media at the POD. The person in this position does not necessarily need to be a trained communications specialist.

The PIC liaison will be responsible for coordinating with the PIO by receiving updated information from the JIC and ensuring that messages at the POD are consistent with the overall messages of the incident. In addition, the public information liaison can monitor frequently asked questions at the POD and inform the PIO of common concerns expressed by the public at the POD level. The public information liaison also can keep the PIO and JIC apprised of any vital information from the POD, such as throughput numbers.

In addition, the public information liaison should understand how to handle media at the POD, even if the jurisdiction's plan is simply to refer media inquiries back to the JIC. This liaison should be part of the command staff at the POD because a portion of this role includes managing media requests that come directly to the POD.

Based upon the established media policy, the role of the public information liaison may expand or contract depending upon the amount of media involvement allowed at the POD. Planners should designate an individual for the public information function or assign this function to the job-action sheet of another role at the POD.

Behavioral Health Personnel

Planners also should consider including behavioral health providers who can serve an important consulting role to the PIC campaign. Behavioral health professionals can help ensure that messages are emotionally balanced (deliver a sense of urgency without creating a panic) and persuasive. Behavioral health providers can monitor and evaluate the emotional needs of the affected jurisdictions and provide guidance on the development of future messages.

Joint Information Center Personnel

Personnel working in the JIC should have an understanding of SNS operations to better interact with field staff in the PODs and create useful messages for the public. Planners should consider providing basic pre-event or just-in-time training on SNS operations for the JIC staff.

Information Flow during an Incident

When PIC personnel are activated during an incident, communication channels should allow information to move freely between the EOC and PIO/PIC lead/JIC and the public information liaisons at the PODs. For example, the PIC lead can keep PODs informed of any policy changes that may come from the EOC. At the same time, the public information liaisons in the PODs can keep the PIC lead informed of such things as POD closures, delayed openings, or recurring questions from people arriving at the POD.



Developing a PIC Plan

The written PIC plan should integrate into the jurisdiction's overall all-hazards risk communications efforts. The PIC plan should outline the public information process and establish the **messages, methods, and materials** needed in an MCM response. The PIC plan should include

- **Messages** developed in advance;
- **Methods** of disseminating the messages; and
- **Materials** to deliver the messages for an MCM campaign.

Messages

Well-crafted messages are important during an emergency to help gain trust and encourage people to make the best choices regarding their health. Communication planners should prepare messages specifically tailored to each audience that might be addressed in an emergency and each medium used to reach them. Messages should be packaged and disseminated **before** an incident to provide information to the public, **during** an incident to direct people to and through PODs, and **after** an incident to provide people with follow-up information once they have left PODs. When developing messages, planners should consider possible questions, such as:

- What is happening?
- What should I do?
- Where do I go?
- Who should go?
- Is it safe to go to a POD?
- How do I get the medicine I need?
- How long will I have to take the medicines?
- Is there enough medicine?
- Is the medicine safe?
- Can my children take the medicine?
- How much does this cost?
- Can I get medicine for my pets?
- Where can I get more information?
- Will I have to go back to the POD?
- Why am I only getting ten days of medicine instead of 60 days?
- Will I need vaccination?

Pre-incident messages should condition the public to seek information from official sources and should begin to build credibility by informing the public that plans are in place to respond to a variety of public health emergencies. These messages should also attempt to define and familiarize people with public health terminology and threats prior to an emergency response. For example, polling conducted by the Harvard Opinion Research Program (HORP) in 2009 and 2010 indicated that approximately one-third of the U.S. population is unfamiliar with the term "inhalation anthrax." Furthermore, approximately one-third of those who say they are familiar with the term mistakenly believe that inhalation anthrax is contagious. This indicates a need for pre-incident educational messaging. Full results from these polls are available in the PIC section of the SNS Extranet.¹

During an incident, messages primarily will provide general information that empowers the public to make the best choices for their health. For example, messages may focus on getting people to go to the POD by providing information on why it is important and that the process at the POD is simple. For security reasons, planners will need to avoid releasing specific operational information about assets, sites (including POD sites and the receipt, stage, store [RSS] site), and the process for distributing assets. Instead, early messages should

¹ <https://www.orau.gov/snsnet/functions/PIC.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

focus on making people aware of the need to go to a POD to get medication, familiarizing people with possible health threats, and mobilizing them to take appropriate action. Most of the messages can be anticipated and cleared in advance as part of the planning process.

Some incidents or events may require specialized messages and the PIC plan should be flexible enough to adjust messages for a variety of emergencies. For example, in a radiological or nuclear incident, the messages should explain that

- Everyone does not need to go to a site (such as a POD) to be monitored for radioactive contamination, but all who want to be monitored will be accepted;
- Some people **will** need to be treated with MCMs; and
- Some people **will not** need be treated with MCMs.

Regardless of the circumstance, the content of the messages must be clear, consistent, coordinated, and shared with partners and stakeholders within and across jurisdictions. Planners will find it most efficient if messages are developed at the broadest level possible (state or region) and if they anticipate and encourage modification at the local level to address needs and challenges for the local community and vulnerable populations.

It is also important to develop messages that correctly and consistently use public health response terms, both from one instance to another within an agency and from one agency to another. For example, when it comes to MCMs, the terms “treatment” and “prophylaxis” have different meanings and should not be used interchangeably. In many cases, the term “medicine” could be used to replace both of those more technical terms and to make the message more understandable.

Ensuring that the messages are available and understandable to the entire community can be a challenge, but it is crucial that everyone, regardless of access to media or education and literacy level, is able to receive and understand these messages. Using plain, simple language that is generally free of jargon and technical terminology is the key to developing messages that most people will understand. When medical or technical terms cannot be avoided, planners should make every effort to define and explain the terms as simply as possible. The federal Plain Language website, www.plainlanguage.gov, has resources and guidelines on this topic.

Messages can and should be developed, tested, and approved before a public health emergency. Although messages may need to be updated as the event unfolds, research and past experience show that most questions and concerns from the public and other stakeholders can be anticipated. Recognizing that resources and time are limited, CDC and other public health organizations have produced fact sheets, frequently-asked-questions documents, and key messages on a variety of threats. Details of these are available in the resources section at the end of this chapter.

To further assist with identifying messages, refer to the HORP polling results, which offer insight into the public’s response to a possible scenario involving the release of anthrax in an unidentified location. The report on these polls is available in PIC section of the SNS Extranet.²

² <https://www.orau.gov/snsnet/functions/PIC.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

Methods

The use of multiple, pre-determined methods of disseminating messages to the public during an emergency will reduce the time it takes to reach the affected population and increase the availability of the message to the entire audience. In developing this section of the plan, communication planners should identify

- Methods to disseminate messages that get people to and through PODs;
- Alternate methods of dissemination in case of electrical outages and for populations who do not rely on mainstream media; and
- Media outlets.

The jurisdiction can accomplish the public mobilization required for a successful dispensing campaign with the help of radio, television, local-network broadcasting, the Internet, social media, hotlines, flyers/brochures, signs, and sound trucks. Each medium has advantages and limitations in speed of delivery, level of detail, sense of immediacy and importance, authority, and population saturation. Planners should determine the best methods for disseminating needed messages during each phase of the incident. Each medium also will have different planning considerations.

Planners should consider the media a partner in a response. Planners can engage media partners by inviting them to trainings and exercises. In doing so, planners can test the media policy and ensure that staff are comfortable with the protocol for handling media during a response.

Planners also should consider methods to communicate with those populations that might be harder to reach, sometimes referred to as vulnerable or at-risk populations, and consider the process to define, locate, and reach these populations. Planners may define these groups as those who cannot or will not

- **receive** the message;
- **understand** the message; and/or
- **act on** the message. (See Table 9.1)

Table 9.1: Hard-to-reach Populations Cannot or Will Not

receive the messages	understand the messages	act on the messages
Blind/visually impaired	People with low literacy levels	Illegal immigrants
Deaf/hearing impaired	People with language barriers	Isolated elderly
Physically disabled	Mentally disabled	People with religious restrictions
Tourists	Caretaker minors (minor children caring for siblings or others)	Tourists
Transient/migrant workers		Displaced residents
Isolated recreationalists		Geographically isolated persons
Isolated elderly		
Homeless people		

Additionally, planners should determine general characteristics that could make some people more vulnerable during an emergency and identify ways to reach them. For instance, some general characteristics might include

- Economic disadvantage;
- Language and literacy (limited English proficiency, low literacy in any language);
- Medical issues and disability (physical, mental, cognitive, sensory);
- Isolation (cultural, social, geographic); or
- Age (very young, very old, latchkey children).

The jurisdiction most likely will need specialized media to disseminate messages to and mobilize these populations. Some examples include translated broadcast and media materials, use of ethnic media; Reverse 911; AMBER alert or highway signs; ham radios; Meals On Wheels Association of America; bullhorns/loudspeakers; Women, Infants and Children (WIC) programs; senior centers; day care centers; or border control.

Another important way to reach vulnerable populations is through the use of community partnerships and trusted leaders. Planners should engage these partners early and often during the planning and response phases through a community outreach information network (COIN). For additional clarification on the process of building a COIN, refer to the *Public Health Workbook to Define, Locate, and Reach Special, Vulnerable, and At-risk Populations in an Emergency*.³

Planners should establish alternate communication channels that can reach vulnerable populations and channels they can use if a widespread power outage affects mainstream media and other communication channels. During an emergency, people may look to additional sources for information. For example, the 2009-2010 HORP polls showed that, after

³ www.bt.cdc.gov/workbook

seeking information from health departments and local news outlets, the public also would look to fire and police departments for information during an anthrax incident. Partnerships with other organizations will help disseminate messages across a wider segment of the population when traditional media is unavailable.

By identifying and engaging partners and stakeholders that can assist in disseminating the messages, planners can identify early in the process where roles, needs, and target audiences overlap. This will help planners and stakeholders develop a comprehensive, strategic plan for outreach that uses multiple organizations to reinforce coordinated key messages. Some of the partners may not be traditional public health partners.

In addition to traditional routes of information dissemination, people also may look to social media sites such as Facebook and Twitter. Because people will share information with one another through their own trusted networks, it will be important for PIC planners to disseminate information through these channels, as well. By monitoring social media during an incident, planners may be able to control rumors, reassure the public, and rapidly provide information on the public health emergency.

Regardless of the media used, planners should monitor all dissemination channels to ensure messages are being received appropriately. This creates a communications feedback loop that allows PIOs to coordinate a mass media announcement to clarify confusion or misinformation when questions or rumors about a certain topic arise.

Materials

During an emergency, the use of pre-developed, pre-approved materials and templates will assist in getting messages out quickly. When planners develop materials at the broadest level and then customize them to the specific locality and event, jurisdictions can better ensure that they disseminate consistent information among stakeholders.

PROMISING PRACTICE

Kentucky Outreach and Information Network

The Kentucky Outreach and Information Network (KOIN) helps the state communicate preparedness messages to trusted people and agencies in local communities, to informal and formal groups (the go-to people who are trusted sources of information on many topics), and to the media. Through the KOIN, official agencies will be prepared and so will trusted, local sources of information; the media; and those who provide services to special populations.

The goal of the KOIN is to ensure that communication channels are in place and KOIN members understand and perform their roles in notifying individuals in their appropriate channels. This network can be used in emergencies and disasters as well as to protect the health of Kentucky citizens in day-to-day situations for such needs as providing immunization clinics, diabetes education/screening, or flu shot distribution.

Another major advantage of the KOIN is its assistance during the planning process. For instance, Kentucky has developed a set of pictograms to use on POD signage. This POD signage was developed in collaboration with the agencies in the KOIN to ensure that their populations would be adequately represented. These pictograms are available at <http://chfs.ky.gov/dph/epi/preparedness/pictograms.htm>.

Further information on the KOIN is available at <http://healthalerts.ky.gov/koin/Pages/default.aspx>.

This section of the plan should include developed and approved materials that

- Explain the public health threat (e.g., category A agents, disease outbreak, radiation threat, etc.);
- Describe MCMs used for prophylaxis and treatment;
- Direct people to and through dispensing sites; and
- Provide information needed after people receive their initial course of the MCMs.

Planners should develop a kit of materials and templates in advance of an incident including template news releases, public service announcements (PSAs), web sites, and dispensing site signage. The plan should also describe how materials will be mass produced, where materials will be stored, and how printed materials will be distributed. Planners should save materials in hard copy and electronic formats so they can be located easily during an incident.

Planners also should consider plans for printing and distributing hard copy materials. The printing and distribution plan should answer the following questions:

- Will the materials be printed in advance? If so, where will they be stored?
- Is there an established printing contract that will support the 48-hour dispensing scenario?
- How will these materials be distributed to PODs or other locations where they will be needed?

If MCMs dispensed during the incident require an Emergency Use Authorization (EUA), the EUA likely will require the use of fact sheets containing information required by the U.S. Food and Drug Administration (FDA) as part of the EUA. Distributing or dispensing MCMs accompanied by fact sheets that do not contain the information required under an EUA would render these drugs unapproved and misbranded in violation of the law. Therefore, CDC and FDA have been working to develop, test, and translate pre-EUA versions of fact sheets for doxycycline and ciprofloxacin (for use in the case of mass prophylaxis for anthrax). It is possible some information on these fact sheets may change at the time of the incident and will need minor updates depending on the incident. Current versions of the pre-EUA fact sheets are available in the PIC section of the SNS Extranet.⁴

Implementing the PIC Plan

The jurisdiction should implement the PIC plan early in an incident. Personnel located in the JIC, PODs, closed PODs (e.g., businesses, government offices, colleges or universities that will set up PODs in their facilities for their staff and possibly the staff's family members), and other agencies will coordinate a public information campaign based on state and incident-specific plans and policies for dispensing. Messages, methods, and materials must provide pertinent, coordinated public information based on the combination and types of dispensing methods outlined in these plans.

⁴ <https://www.orau.gov/snsnet/functions/PIC.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

The POD, however, likely remains the cornerstone of the dispensing operation and the PIC plan should include messages, methods, and materials to encourage people go to the POD, assist people through the POD, and encourage people to follow-up with post-POD activities.

Pre-incident Preparedness

Preparedness campaigns can help the public become familiar with the actions they will take during an emergency. Terminology, such as the acronym POD, may be unfamiliar to the public and can cause further confusion during an emergency when people already are fearful.

Pre-incident campaigns should prepare the public for a response by defining unfamiliar terms and by encouraging people to seek information from specific, credible sources that the jurisdiction will update routinely during an emergency. In this phase, planners should work with any organizations that will be operating closed PODs to ensure that their messages are similar to those given at PODs for the general public and that the organization also is preparing its employees for such a response.

Providing this information to the public shows that public health is preparing for a response and will help maintain the public's confidence in actions taken during an incident. Planners should consider adding information about the SNS to existing preparedness materials and taking advantage of larger opportunities, such as National Preparedness Month, to support pre-incident messaging campaigns.

Communication planners also should work with security and other planning personnel to ensure that the materials developed for preparedness do not compromise the operations during an incident. For example, planners may be advised to avoid listing specific POD locations in advance of an incident since this could compromise POD security or the locations may change due to the circumstances of an emergency. In addition, communications planners should work with behavioral health professionals to craft messages that are appropriate for the incident and assist in encouraging people to make the best decisions for their health.

Getting People to the POD

For both closed and public PODs, getting the right people to the right place at the right time can be challenging. The messages must inform and mobilize people to take action. One of the main goals in this phase is to provide information to people so they can make the best choices to protect their health. Planners should develop specialized messages, methods, and materials to get the desired population to the dispensing site.

The 2009-2010 HORP polls identified five top reasons the public would not go to a POD. By considering the reasons people give for not going to a POD, planners can develop messages to counter these reasons before it is necessary to get people to the PODs. Table 9.2 shows the top five reasons identified in the HORP poll and the possible messages planners can use to address people's concerns. While the poll specifically focused on an anthrax scenario in which the jurisdiction would need to dispense MCMs within 48 hours of the federal decision to deploy, planners can extrapolate results for other types of public health emergencies as well.

Full results from the HORP polls are available on the public information and communication section of the SNS Extranet.⁵

Table 9.2: Results from Harvard Opinion Research Program (HORP) Polling on Public Concerns Related to Anthrax

Public Concern	Messages
Worried that officials will not be able to control crowds	Safety and security at PODs, possibly with video of orderly crowds
Worried about being exposed to anthrax, either from other people or from the environment	Reinforce message that anthrax is not spread from person to person and that the pills are effective in preventing disease if exposed
Worried that there would not be enough antibiotic pills	Reinforce message about ample supplies; federal supplies are being used
Would wait to get antibiotic pills until sure they were exposed to anthrax	Antimicrobials must be started as soon as possible to decrease the chance of serious disease or death; no time to wait for test results to determine whether or not people were exposed
Worried about the safety of the antibiotic pills, including side effects	The pills used are common antimicrobials and approved by FDA to prevent infections. Refer to FDA fact sheets about side effects*

*Messages of safety and efficacy will be particularly important if the countermeasure is dispensed under an EUA.

Jurisdictions will base many of the messages that encourage the public to get MCMs on the policies and procedures outlined in their SNS plans. Coordination between SNS planners and communicators will ensure dissemination of consistent, accurate information. Additional messages jurisdictions should release to direct people to PODs include:

- Going to the dispensing site is important;
- Taking this medicine is important;
- There is enough medication for everyone; and
- Go to the hospital (or alternate care facility) if you are sick (specify symptoms).

Information on wait times and off-peak times for PODs will need to be updated and provided to the public regularly. In the planning stages, planners should consider how the JIC will obtain pertinent information about each POD and disseminate that information to the public through mainstream media and other communication channels. Information gathering at the POD can be a function of the public information liaison. Table 9.3 provides some of the key communication objectives and sample messages for this.

⁵ <https://www.orau.gov/snsnet/functions/PIC.htm>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

Table 9.3: Communication Objectives and Messages

Communication Objective	What Is Needed	Messages
Reinforce public health information messages	Consistent messages about the evolving situation	<ul style="list-style-type: none"> • Express empathy at the beginning • Explain that an outbreak has occurred and who may have been exposed • Provide avenues for obtaining up-to-date, credible information, such as a hotline number or web address • Provide information on what people should do if they are sick
Let the public know that something is being done	Basic information about the overall response	<ul style="list-style-type: none"> • Provide information about the disease and symptoms • Provide information on what people should do if they are sick • Explain PODs and why they are important • Inform people that PODs will be opening soon • Explain that there may be multiple ways people can receive MCMs (explain alternate methods of dispensing) • Be prepared to answer questions about why certain populations (e.g., nursing home residents or incarcerated individuals) may get MCMs first • Reassure people that there will be ample supplies for all affected populations • Provide additional avenues for obtaining up-to-date, credible information, such as a hotline number or web address
Prepare the public to receive MCMs	Information about PODs and what to expect	<ul style="list-style-type: none"> • Reinforce public health messages about the disease and symptoms • Explain the importance of receiving MCMs • Provide instructions for vulnerable populations • Provide information about MCMs, side effects, and contraindications • Explain that people may get different types of medications • Explain how much medication people will receive and the rationale for that (e.g., in the case of anthrax, explain why people would receive an initial 10-day supply of prophylaxis instead of the full 60-day regimen) • Provide information about EUAs, if necessary • Explain that medication is not for pets • Reassure people that there are ample supplies of medication to discourage hoarding and illegal sales
Prepare the public to go to the POD		<ul style="list-style-type: none"> • Describe how to obtain forms prior to arrival at the POD

Communication Objective	What Is Needed	Messages
		<ul style="list-style-type: none"> • List POD locations and operational hours • Provide instructions on what to bring (e.g., filled-out forms [if available], list of medications and drug allergies, children's weights) and restrictions at the PODs (no pets, weapons) • Describe the head-of-household pick-up policy and minimum age for people to pick up medications • Describe what to expect at the POD – how long it will take, what information is needed, expected POD stations, and that staff will be there to help • Provide directions, traffic routes, and special considerations

Getting People through the POD

Good communication in the POD can increase the flow by reducing confusion, ensuring people are prepared, and answering questions before people ask them. Planners should develop communication strategies for the POD to

- Inform people about the MCMs and agent or disease outbreak;
- Tell people what to expect in the POD;
- Explain how to identify the staff;
- Inform people how to take the medication (including the importance of taking and continuing to take the medication);
- Explain why it is worth the wait;
- Explain that there will be enough medication for everyone; and
- Tell people how they can get their questions answered.

Communication in the POD can take several different forms, including posters, signs, videos, handouts, announcements over a loud speaker, and people answering questions. Each form of communication can serve different functions.

Well-designed and well-placed directional signage can be very useful in aiding people through the POD.

Directional signs should be in clear and simple language, use arrows or pictures, be big enough to be seen at a distance, and be posted in places that make them visible. For example, if signs hung on the front of a dispensing table might not be visible when people

PROMISING PRACTICE

Washington State POD Signs

The State of Washington developed standardized signs for use in PODs and vaccination clinics to ensure that each POD was easily able to provide the same information on the four simple steps in the POD: 1) fill out form; 2) show form 3) pick up medicine; and 4) turn in form and exit (see Figure 9-1). These simple steps also are a key message in a coordinated media campaign and work to ensure message consistency throughout the state. Keeping the information brief, making the font and the signs large and easy to read, and breaking the steps in the POD down into their simplest elements make this an effective PIC resource for PODs.

Washington State maintains a website where planners can download pdf versions or order printed versions of POD and medication site signage at <http://www.doh.wa.gov/phepr/toolkit>.

crowd around it. A better place to hang a sign might be above the table so that people can see it above the crowd.

Posters and handouts can educate and inform the public about the agent or medication dispensed. Informational posters can reinforce messages found on distributed fact sheets. The information should be consistent in all materials. When developing posters, planners should

- Provide information in chunks;
- Keep messages simple;
- Make the posters and font big; and
- Make the posters visually interesting.

Informational videos can educate the public but planners should use these in a way that will not affect the POD flow. In addition, planners should decide what language videos should use and ensure that people will be able to hear the video over ambient noise in the POD.

POD staff also can be a valuable source of information because they can explain the process and answer questions. Planners should ensure the public understands how to identify POD staff if they have questions, and staff should be trained to answer any questions they might be asked. If staff receives many questions about a particular subject, the public information liaison at the POD can create additional materials for the POD or can refer the question to the JIC to determine if the jurisdiction should issue a media release or other messaging.

As with any communication activity for the POD, planners should ensure they develop materials to accommodate vulnerable populations within the jurisdiction and include ways of handling both written and spoken language interpretation needed at the POD. Using U.S. Census data or other community resources will help planners better understand the specific language needs in the area of each POD. The jurisdiction also should obtain signed agreements for translation services before an event.

Planners should develop messages, methods, and materials for each function in the POD to help ensure consistent information and to train staff. Table 9.4 provides examples.

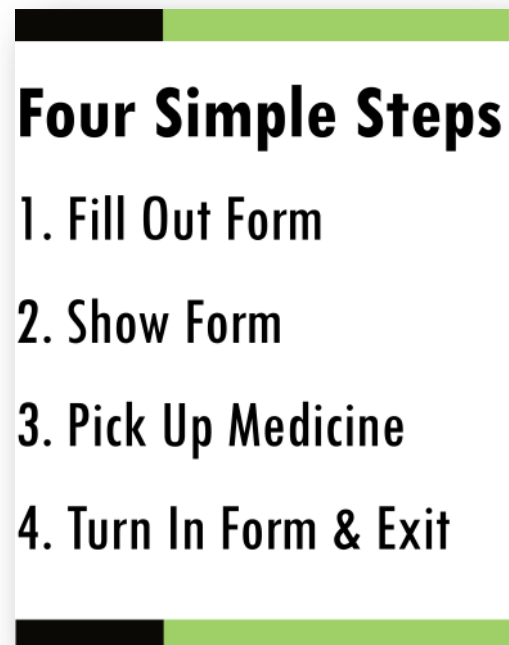


Figure 9-1: Washington State Four Simple Steps POD sign.

Table 9.4: Communication Objectives, Message Content, and Methods/Materials for Dissemination

Function	Communication objective	Message content	Method/Material
Security	<ul style="list-style-type: none"> Minimize security problems Reassure (regarding both safety of site and dangers to health at site) 	<ul style="list-style-type: none"> What (not) to bring Security/crowd control is provided Estimated wait time Medicine availability ("enough for everyone") 	<ul style="list-style-type: none"> Media Signage Personal/POD staff/spoken word
Traffic	<ul style="list-style-type: none"> Expedite getting people to PODs Increase access to MCMs 	<ul style="list-style-type: none"> Address of POD Special traffic routes or considerations Public transportation options 	<ul style="list-style-type: none"> Media Signage POD staff: verbal and pointing and providing directions
Parking	<ul style="list-style-type: none"> Facilitate parking Facilitate assistance for persons with special needs Get people to front doors of PODs 	<ul style="list-style-type: none"> Clear directions about where to park and how to get there Clear directions to front doors of PODs 	<ul style="list-style-type: none"> Signage Cones, barricades POD staff: verbal and pointing and providing directions
POD Entry/Triage	<ul style="list-style-type: none"> Facilitate screening at entry point Ensure symptomatic population goes to a treatment center Facilitate distribution of information and forms 	<ul style="list-style-type: none"> Symptoms and where to go if symptomatic Flow directions Vulnerable populations for additional assistance Instructions for filling out forms 	<ul style="list-style-type: none"> "Start Here" signage Informational posters POD staff: verbal and pointing and providing directions
Line Workers	<ul style="list-style-type: none"> Ensure form completeness Increase throughput Increase awareness of contraindications 	<ul style="list-style-type: none"> Instructions for filling out form Flow directions Information about MCMs, agent 	<ul style="list-style-type: none"> Signage Informational posters Examples of complete forms POD staff
Screening	<ul style="list-style-type: none"> Ensure form completeness Decision point: express vs. standard dispensing 	<ul style="list-style-type: none"> Flow directions Information about MCMs, agent 	<ul style="list-style-type: none"> Signage Informational posters Arrows
Dispensing	<ul style="list-style-type: none"> Give correct medication to the right person 	<ul style="list-style-type: none"> Information about MCMs, agent Adherence instructions 	<ul style="list-style-type: none"> Signage Arrows Informational posters Printed handouts

Function	Communication objective	Message content	Method/Material
Exit	<ul style="list-style-type: none"> • Ensure collection of forms • Ensure questions answered • Reinforce follow-up instructions 	<ul style="list-style-type: none"> • Reminder about form drop-off • Reminder about medication adherence 	<ul style="list-style-type: none"> • Signage • Informational posters • POD staff

After the POD

According to the 2009 HORP polls on the public's response to an anthrax release, 40% of those polled indicated they would not take the pills right away in an anthrax scenario. In the same poll, only 31% believed that the pills are safe to take and 30% felt the pills would be effective in preventing serious illness or death due to anthrax. Further information from the 2010 polls indicates that people who stated they will not start taking the pills right away did so for the following reasons: will wait until they see symptoms (73%); will only use the pills if they know for sure that they were in the location where the agent was released (65%); and will hold on to the pills for a second attack (42%). Based on this information, key messages in this phase should include information on

- The importance of taking the medication immediately, even if it is unclear exactly who has been exposed;
- Safety of the MCMs;
- Efficacy of the MCMs;
- How to take the medication (tablets and suspension);
- Special instructions for children's dosing;
- The importance of taking the full course of medication;
- Side effects or adverse effects of the medication;
- Whether or not people will need to return to a POD; and
- Where to go for additional information (e.g., hotline, web site, newspaper, radio/television station) or to ask questions, if needed.

Communications about medication adherence must be strategic. Messages should be repeated, should explain the need for and importance of the medication, and should include contacts for additional information (e.g., a telephone number staffed 24/7 that people can call for answers to questions regarding their prophylaxis and whether or not they should continue taking it). In an extended dispensing campaign, continued mass media announcements to take medication can keep people on their medications for the entire course.

PIC Planning Resources

The **National Public Health Information Coalition (NPHIC)** is an independent organization of professionals working to improve the nation's health through better public health communications. Members of NPHIC are public health information officers for their states and communities, are familiar with CDC Public Health Emergency Preparedness (PHEP) cooperative agreement funding and are already developing materials for crisis and

emergency risk communications. NPHIC representatives can assist in developing SNS-specific public information materials. www.nphic.org

CDC partnered with NPHIC and the **Harvard Opinion Research Program (HORP)** to conduct a national poll about knowledge, attitudes, and beliefs about anthrax. Much of the information in this poll will be useful to PIOs in developing messages for this type of incident. This poll is available in the PIC section on the SNS Extranet or through the assigned CDC Division of State and Local Readiness (DSLRL) project officer.

The mission of the **Directors of Health Promotion and Education (DHPE)** is to strengthen, promote, and enhance the professional practice of health promotion and public health education nationally and within state health departments. DHPE can help planners identify health educators in their state health departments, find professionals who are familiar with at-risk populations in the community, and find individuals who can assist in developing SNS-specific public information materials. Visit the DHPE website at www.dhpe.org.

Model Emergency Response Communications Planning for Infectious Disease Outbreaks and Bioterrorist Events, second edition, published by DHPE, is an excellent reference for state and local public health and emergency-response officials. It provides a framework for public health officials to communicate with other health officials, emergency response organizations, the public, and media. The publication includes the latest information on infectious disease threats plus a CD-ROM of fact and work sheets for responding to bioterrorism hazards and other public health emergencies. The report is available online at www.dhpe.org/model.asp.

Communicating in the first hours: The Office of Public Affairs of the U.S. Department of Health and Human Services and CDC have developed messages and other resources for federal, state, local, and tribal public health officials to use during a response to an emergency. Provided here are messages that apply to all category A biological agents, as classified by the CDC, as well as messages about chemical and radiological events and suicide bombing. Available online at www.bt.cdc.gov/firsthours/index.asp.

The Department of Homeland Security's Office of State and Local Government Coordination and Preparedness funds the National Memorial Institute for the Prevention of Terrorism in Oklahoma City, Oklahoma, to develop and maintain the **Lessons Learned Information Sharing** website (www.LLIS.gov). LLIS is a secure, national online compendium of lessons learned and best practices designed to help emergency response providers and homeland security officials prevent, prepare for, respond to, and recover from acts of terrorism. LLIS access is restricted to verified emergency response providers and homeland security officials at the local, state, and federal levels. Its information resources have been conceived and developed by homeland security professionals for their peers and includes an extensive catalog of after-action reports from exercises and actual incidents as well as an updated list of homeland security exercises, events, and conferences. Available online at <https://www.llis.dhs.gov>.

The **National Association of County and City Health Officials (NACCHO)** has been funded by CDC to collect, develop, and disseminate resources that will help local public health agencies prepare to respond to an event like bioterrorism. NACCHO's Toolbox is an online

source for preparedness tools and resources developed by state and local public health agencies as well as SNS-related products from NACCHO and its partners. Available online at www.naccho.org/toolbox.

CDC's **Emergency Preparedness and Response** website at <http://emergency.cdc.gov> provides information (in English and Spanish) and fact sheets about bioterrorism agents, diseases and other threats. It also lists hotline phone numbers.

CDC has developed a variety of tools for **crisis and emergency risk communication**. Its training curricula can help novices and seasoned professionals alike hone their skills. Course offerings and resources are available at www.bt.cdc.gov/cerc.

The **Public Health Workbook to Define, Locate, and Reach Special, Vulnerable and At-risk Populations in an Emergency** is available to assist in planning for special/vulnerable populations. The workbook is available at www.bt.cdc.gov/workbook.

CDC health communication specialists are available for technical assistance. In addition, CDC offers a one-day workshop titled *Mass Antibiotic Dispensing: Public Information and Communication*. This workshop helps state and local communicators better understand their roles and responsibilities in the event of SNS deployment. This course focuses on the development of messages, methods, and materials for disseminating information to specific audiences. To learn more about the, planners should contact their assigned CDC DLSR project officer.

IS-702.a National Incident Management System (NIMS) Public Information Systems. The goal of this course is to facilitate NIMS compliance by providing planners with the basic information and tools that needed to apply NIMS public information systems and protocols during incident management. Online at: <http://emilms.fema.gov/IS702A/index.htm>.

IS-250 Emergency Support Function 15 (ESF 15) External Affairs: A New Approach to Emergency Communication and Information Distribution. The goal of this course is to provide basic training on the concept and practical application of the ESF 15 Standard Operating Procedures to all FEMA external affairs staff, regardless of duty station, as well as to staff in all other agency divisions and federal, tribal, state, local, private sector, military and Voluntary Organizations Active in Disaster (VOAD) partners. Online at: <http://training.fema.gov/EMIWeb/IS/IS250.asp>.

National Incident Management System (NIMS) Basic Guidance for Public Information Officers (PIOs) provides fundamental guidance for any person or group delegated PIO responsibilities during an incident or planned event when informing the public is necessary. Available for download at www.fema.gov/library/viewRecord.do?id=3095.

Terrorism and Other Public Health Emergencies: A Reference Guide for Media is a reference guide designed to be used in the field to quickly and clearly communicate terrorism and public health emergency messages to the public. Available online at www.phe.gov/emergency/communication/guides/field/pages/default.aspx.

Public Health Emergency Response: A Guide for Leaders and Responders is a guide on the public health response to emergencies that is specifically tailored for public officials (e.g., mayors, governors, county executives, emergency managers) and first responders (e.g., police, fire, EMS). Available online at www.phe.gov/emergency/communication/guides/leaders/Pages/default.aspx.

Emergency Risk Communication CDCynergy is an interactive course that gives participants essential knowledge and tools to navigate the harsh realities of communicating to the public, media, partners, and stakeholders during an intense public health emergency, including terrorism. Available online at www.cdc.gov/healthcommunication/CDCynergy/index.html.

Communicating in a Crisis: Risk Communications Guidelines for Public Officials is a brief, readable primer that describes basic skills and techniques for clear, effective crisis communications and information dissemination and provides some of the tools of the trade for media relations. It can help planners prepare for meeting the important responsibility of communicating with the public both directly and successfully during a crisis. Available online at www.riskcommunication.samhsa.gov/index.htm.

Effective Media Communication during Public Health Emergencies (World Health Organization [WHO]); Handbook, Field Guide, and Wall Chart
Handbook

The handbook describes a seven-step process to assist officials and others to communicate effectively through the media during emergencies.

Field Guide

The field guide is a shortened version of the handbook. It highlights the practical aspects of the seven-step approach.

Wall Chart

The chart shows the seven-step approach and provides easily recalled key information and advice. Available online at www.who.int/csr/resources/publications/WHO_CDS_2005_31/en/.

Chapter 10: Strategic and Tactical Communications

To support a coordinated medical countermeasure (MCM) response, planners should develop a communications plan (CP) that integrates into the jurisdictional tactical and strategic communications plans. The jurisdiction's CP should enable communication between all partner agencies and organizations, including government, private sector, and other partners involved in MCM operations at all levels. While previous versions of this guidance focused on counting pieces of communications equipment, the Centers for Disease Control and Prevention (CDC) now recommends that planners develop communications capabilities as elements of the jurisdiction's critical infrastructure. All state, local, tribal, and territorial (SLTT) agencies involved in an MCM response should develop a CP support annex, incorporate it into the overall emergency operations plan (EOP), and ensure that the CP remains within any existing SLTT or regional communications interoperability framework. Each jurisdiction should develop a CP that fits its needs and enables coordinated communication with neighboring jurisdictions, the next tier of communications, and any partner agencies and organizations.

Identifying Key Communications Partners

Strategic and tactical communications is a wide-ranging capability that challenges many SLTT jurisdictions. However, planners can partner with other agencies and communications professionals to incorporate the MCM response plan into any existing emergency, strategic, and tactical communications plans.

To assist in developing a comprehensive CP for the jurisdiction's MCM plan, planners can partner with state and local emergency management agencies for assistance in navigating the communications framework. In addition, planners should reach out to the lead agency for the statewide communications interoperability plan (SCIP) or the jurisdiction's tactical interoperability communications plan (TICP). All 50 states and the U.S. territories have developed SCIPs for improving communications interoperability, and 75 of the largest urban and metropolitan areas maintain polices for interoperable communications. According to the National Emergency Communications Plan, "TICPs present a region's plan for establishing and maintaining tactical interoperable communications, defined as the rapid provision of on-scene, incident-based, mission-critical voice communications among all first-responder agencies, in support of an incident command system as defined in the NIMS model."¹ Many

¹ From the National Emergency Communications Plan. Department of Homeland Security (2008). Available online at www.dhs.gov/xlibrary/assets/national_emergency_communications_plan.pdf

jurisdictions already have workgroups or committees that are charged with interoperable communications including the SCIP and TICP. Public health planners should seek to become a participating/voting member of these committees and approach the agency responsible for this communications plan to ensure that the health department is included in future revisions of the SCIP or TICP.

Understanding Communications Terminology

The complex lexicon of the communications community can serve as a stumbling block for public health planners trying to develop this capability and a subsequent CP. By familiarizing themselves with standard communications terminology and definitions from the National Incident Management System (NIMS)² and other federal guidance, planners will be better prepared to discuss the communication needs for an MCM response with partner agencies.

First, planners should become familiar with the basic types communications – strategic, tactical, and support – referenced in NIMS and other federal guidance documents. These terms refer to the flow of information and communication pathways rather than equipment or systems that transmit information.

- **Strategic communications** are the high-level directives, such as those related to prioritizing resources, assigning roles and responsibilities, and determining incident-specific courses of action. Strategic communications plans map out the chain of command as outlined in NIMS and the incident command system (ICS).³
- **Tactical communications** are the communications that occur between command and support elements and, as appropriate, cooperating agencies and organizations. Tactical communications plans (TCPs) outline who speaks to whom and how information is relayed during an emergency. For instance, in a large-scale public health emergency, the local SNS coordinator may receive directives (i.e., strategic communications) from the state SNS coordinator, state health official, or Cities Readiness Initiative (CRI) coordinator. In turn, the local SNS coordinator may communicate with dispensing site managers, hospitals, treatment centers, and local law enforcement. The tactical communications plan will assist responders with understanding how to relay and receive information during an incident.
- **Support communications** occur between agencies and organizations in support of strategic and tactical communications, such as communications among hospitals concerning resource ordering, dispatching, and tracking from logistics centers; or communications between public health departments and public works departments regarding traffic control around MCM dispensing sites.

When referring to communications equipment, systems, and planning, the following terms apply:

² www.fema.gov/pdf/emergency/nims/NIMS_core.pdf

³ www.fema.gov/emergency/nims/IncidentCommandSystem.shtm#item1

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- **Reliability** refers to the ability of a communications equipment, devices, or systems to function in any type of incident, regardless of cause, size, location, or complexity.
 - **Portability** refers to the ability of communications devices, equipment, technologies, protocols, and systems to be successfully and efficiently integrated, transported, and deployed when necessary. Portability includes the standardized assignment of radio channels across jurisdictions, which allows responders to participate in an incident outside their jurisdiction and still use equipment that is familiar to them.
 - **Scalability** refers to planning that can easily be adjusted for response to small- or large-scale incidents by allowing for an increasing or decreasing number of users as the incident evolves and changes.
 - **Resiliency** refers to the ability of communications systems to continue to perform even if the jurisdiction experiences damage to or loss of communication network infrastructure.
 - **Redundancy** provides for either duplication of identical services or the ability to communicate through diverse, alternate methods when standard capabilities suffer damage.

Planners can leverage **resiliency and redundancy** for a comprehensive and robust communications system. For example, if planners determined that the receipt, stage, store (RSS) facility will need ten phone lines, redundancy would dictate that 20 phone lines would be needed. However, by incorporating resiliency as well as redundancy, planners can use the ten existing phone lines and add other diverse communications systems, such as a mixture of cellular telephones, two-way radios, satellite phones, or other communications equipment.

The following terms from the National Emergency Communications Plan⁴ also are important for developing a comprehensive CP.

- **Operability** refers to the ability to establish and sustain communications in support of operations.
- **Interoperable communications** are those that occur within and across agencies and jurisdictions.
- **Continuity of communications** refers to the ability to maintain communications in the event of damage to or destruction of the primary infrastructure.

Assessing Communications Capabilities and Interoperability

The lead agency in an MCM response will need to ensure that the types of communications systems and equipment used are compatible with those used by other responders. The Department of Health and Human Services' (HHS') National Health Security Strategy (NHSS)⁵ provides a baseline standard for developing communications capabilities. NHSS recommends that jurisdictions have interoperable and resilient communications systems and "Obtain sufficient wireless communications equipment for routine internal and emergency

⁴ www.safecomprogram.gov/SiteCollectionDocuments/NationalEmergencyCommunicationsPlan_Aug08_v2.pdf

⁵ www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf

communication requirements; ensure that systems are interoperable (i.e., able to communicate seamlessly with other agencies), portable, meet standards, are resilient and redundant, and can be accessed by authorized users.”⁶

In order to develop an effective CP, planners may find it helpful to review federal guidance on communications planning, which can provide a clearer picture of the complex issues surrounding communications capabilities and interoperability requirements. In addition, planners should leverage any existing resources and work with members of the SCIP or TICP. With insights from federal guidance and the SCIP or TICP, planners can perform a communications capabilities and interoperability assessment. The interoperability assessment should identify the existing communications infrastructure and other organizations and agencies that could provide additional communication resources, if required. In addition, this assessment will allow public health planners to become familiar with the system’s capabilities and any challenges that may arise within the jurisdiction.

After conducting a communications capability and interoperability assessment, planners should conduct a needs assessment on communications equipment to determine what equipment is available, as well as where and how much equipment will be needed, while taking into account any pre-existing communications infrastructure. Planners should then identify all the possible locations, including but not limited to command and control centers, points of dispensing (PODs), distribution sites (if any), hospitals, alternate care facilities, and other locations that would need to be included in the communications network for a public health emergency.

As mentioned previously, planners should remember **redundancy and resilience** when determining the amount of communications equipment needed. When developing or adding to the communications infrastructure, planners also should consider whether a particular system or piece of equipment is interoperable, resilient, and redundant; the addition of a wireless component also could be beneficial. As part of the needs assessment, planners should remember that the goal in developing a resilient communications infrastructure is to develop the capability to maintain **continuity of communications** even if the primary communications infrastructure is damaged and that this can best be achieved by considering a diverse mixture of communications systems in the jurisdiction’s communications needs assessment.

Understanding Communications Systems

Communications systems consist of the equipment, services, and wired and wireless networks through which information is transmitted. When assessing the jurisdiction’s available communications systems, planners should ensure the chosen systems are appropriate to the abilities and skills of the intended users; that the systems are able to adapt to any new or added technology; and that the systems can be relied upon during any incident in which they might be used.

⁶ Department of Health and Human Services. National Health Security Strategy. (2009). Available from URL: www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf.

Communications systems are divided into three sub-components:

- **Communication platforms** include the equipment that provides the interface between individuals and the transmission media.
- **Communication services** are the methods in which communications platforms interact.
- **Transmission media** are the wired and wireless networks through which information is transmitted.

Communications Platforms

Communications platforms are the physical pieces of equipment that provide the interface between individuals and the transmission media. For example, the platform for a wired system could consist of a standard telephone or a computer connected to the Internet via a digital subscriber line (DSL) modem and the communication platform for a cable system could be voice over internet protocol (VoIP) phone system or a computer connected to the Internet via a cable modem. Communications platforms for wireless and satellite transmission media are comprised of a wide range of devices including cellular and satellite phones, air cards that allow wireless computer connections to the Internet, and a wide array of radios.⁷

Communications Services

Communications services are the methods in which communications platforms interact with individuals to provide information, transmit the information via a transmission media to another communications platform, which in turn delivers the information to the recipient. The CP plan should include a mixture of communications services including email, webmail, Internet, VoIP, facsimile (fax), file transfer, voice, and text messages. In addition to these communications services, every jurisdiction should consider including two additional emergency communications services in their communications toolbox: Government Emergency Telecommunications Service (GETS)⁸ and Wireless Priority Service (WPS).⁹ GETS and WPS do not provide actual communications capabilities, but instead are assistive communication services that provide the ability to place priority calls when networks are congested, as they may be during an MCM response. Because both GETS and WPS require pre-registration, planners should apply for these services during the development of the CP and include the required access information in the plan.

Government Emergency Telecommunications Service (GETS) provides the ability to place priority calls over the public switched telephone network (PSTN), i.e. landline telephones. GETS can be accessed from any wired phone and requires an access card and personal identification number (PIN) to use the service.

⁷ From the Department of Homeland Security. Communications Sector-Specific Plan: An Annex to the National Infrastructure Protection Plan. (2010). Available online at www.dhs.gov/xlibrary/assets/nipp-ssp-communications-2010.pdf.

⁸ <http://gets.ncs.gov>

⁹ <http://wps.ncs.gov>

Wireless Priority Service (WPS) is the equivalent of GETS for the cellular telephone network. WPS must be established on any cellular phone number that the jurisdiction intends to use for the service, which only can be accessed by dialing a specified access code prior to dialing the destination number.

In order to place a priority call from a cellular phone to a wired phone, WPS and GETS can be used together to ensure the call is a priority call end-to-end.

Wired Transmission Media

Wired transmission media consists primarily of the public switched telephone network (PSTN), but also includes the Internet and cable networks. The PSTN is the domestic communications network accessed by telephones, key telephone systems, private branch exchange (PBX) trunks, and data arrangements. The traditional PSTN remains the backbone of the communications infrastructure and includes landline telephone and the Internet.¹⁰ Figure 10-

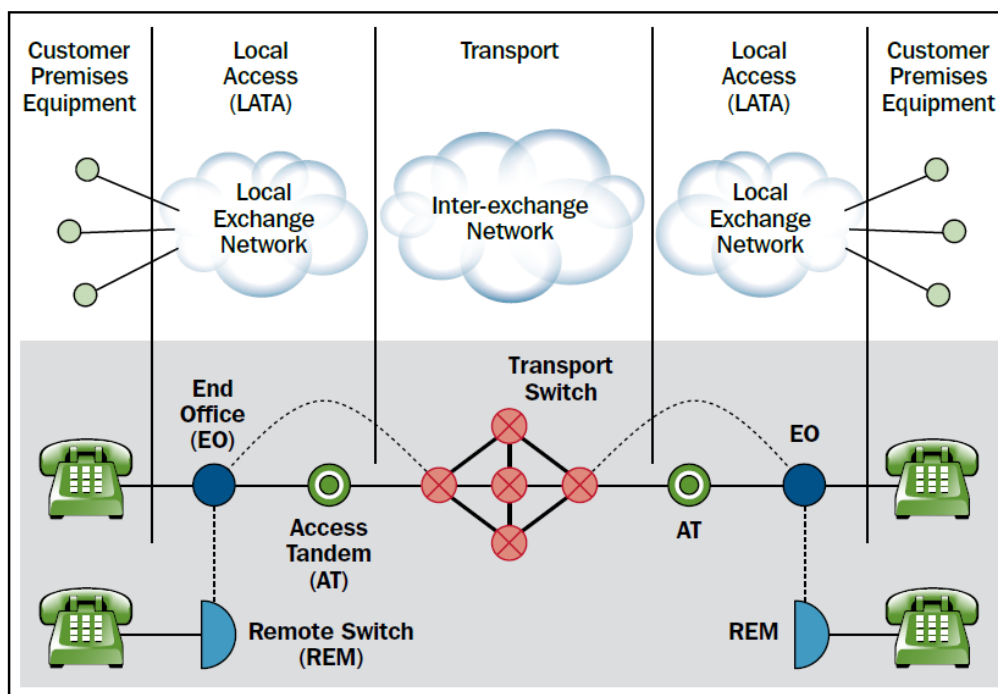


Figure 10-1: Wireline network architecture, from DHS' *Communications: Critical Infrastructure and Key Resources Sector-Specific Plan as input to the National Infrastructure Protection Plan*.

1 demonstrates the PSTN.

¹⁰ Department of Homeland Security. *Communications Sector-Specific Plan: An Annex to the National Infrastructure Protection Plan*. (2010). Available online at www.dhs.gov/xlibrary/assets/nipp-ssp-communications-2010.pdf.

The Internet

The internet is composed of a worldwide framework of networks and databases that use a common computer language to communicate information. Internet access occurs through a variety of communications platforms, including wired phone lines, DSL modems, and cable modems, among others.¹¹ Figure 10-2 shows the standard Internet framework.

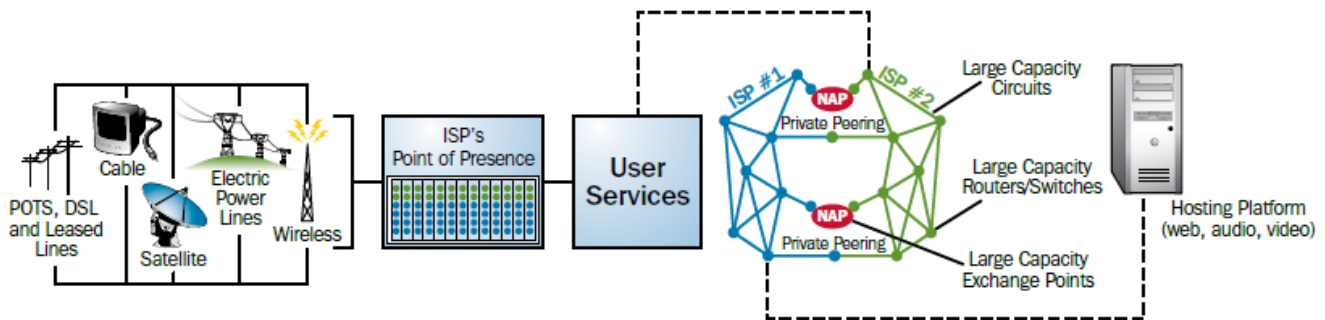


Figure 10-2: Internet architecture, from DHS' *Communications: Critical Infrastructure and Key Resources Sector-Specific Plan* as input to the *National Infrastructure Protection Plan*.

Cable Network

Cable is a wireline network through which television, high-speed Internet, and voice services can be accessed and interconnected with the PSTN through end offices. Information is transmitted in cable networks through both fiber and coaxial cable, which allows signals to be sent through multiple paths simultaneously.¹² Figure 10-3 depicts the cable network infrastructure.

¹¹ Department of Homeland Security. Communications Sector-Specific Plan: An Annex to the National Infrastructure Protection Plan. (2010). Available online at www.dhs.gov/xlibrary/assets/nipp-ssp-communications-2010.pdf.

¹² Department of Homeland Security. Communications Sector-Specific Plan: An Annex to the National Infrastructure Protection Plan. (2010). Available online at www.dhs.gov/xlibrary/assets/nipp-ssp-communications-2010.pdf.

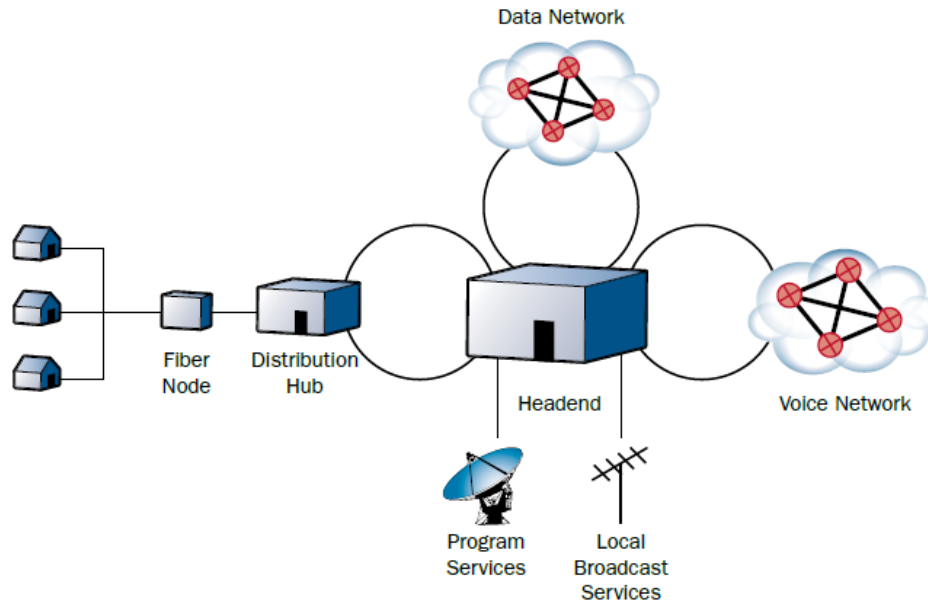


Figure 10-3: Cable network architecture, from DHS' *Communications: Critical Infrastructure and Key Resources Sector-Specific Plan* as input to the *National Infrastructure Protection Plan*.

Wireless Transmission Media

The main wireless category refers to telecommunication in which electromagnetic waves (rather than some form of wire) carry a signal over part or the entire communication path. Wireless transmission media "consists primarily of cellular telephones, pagers, personal communications services, high-frequency radio, unlicensed wireless, and other commercial and private radio services, including numerous law enforcement, public safety, and land mobile radio systems." ¹³ Figure 10-4 shows a basic cellular network.

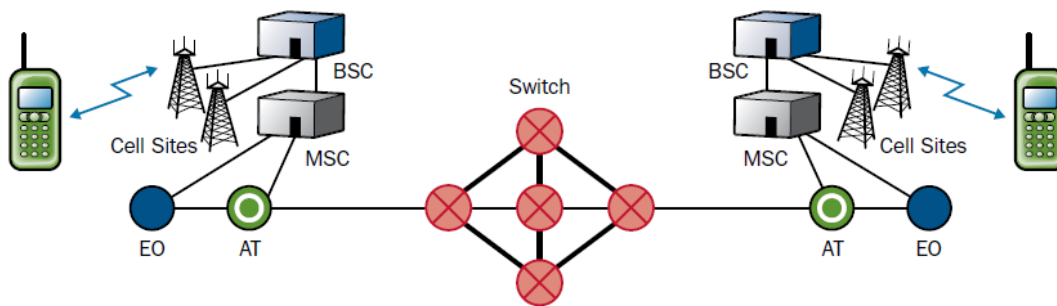


Figure 10-4: Wireless network architecture, from DHS' *Communications: Critical Infrastructure and Key Resources Sector-Specific Plan* as input to the *National Infrastructure Protection Plan*.

¹³ Department of Homeland Security. *Communications Sector-Specific Plan: An Annex to the National Infrastructure Protection Plan*. (2010). Available online at www.dhs.gov/xlibrary/assets/nipp-ssp-communications-2010.pdf.

Satellite is a special subcategory of wireless transmission media, in which audio, data, or video signals are transmitted via a space vehicle that was launched into orbit. Signals are transmitted to the satellite from antennas on earth, amplified, and sent back to earth for reception by other earth station antennas. Satellites are capable of linking two points, one point with many others, or multiple locations with other multiple locations. A satellite system uses a combination of terrestrial and space components to deliver various communications, Internet data, and video services.¹⁴ Figure 10-5 shows a typical satellite network.

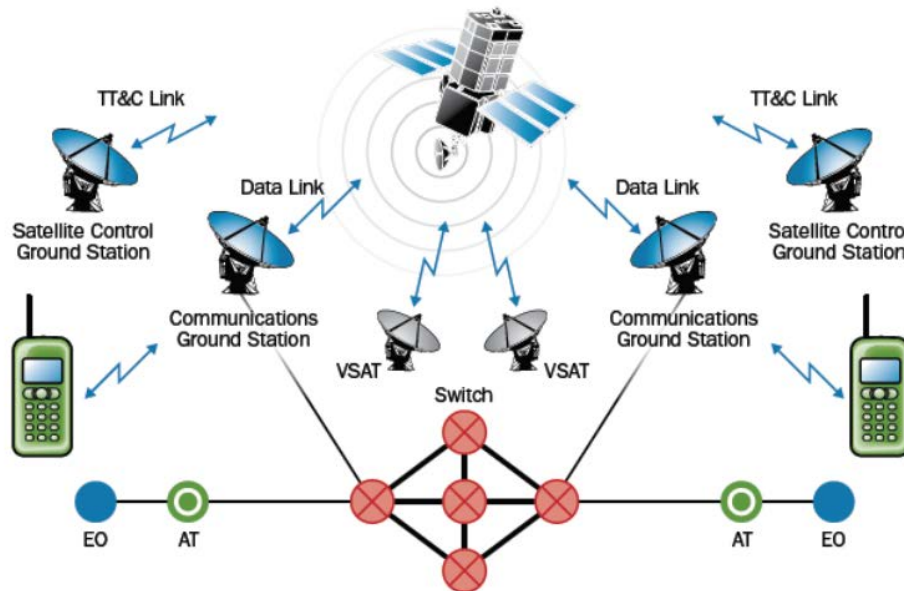


Figure 10-5: Satellite network architecture, from DHS' *Communications: Critical Infrastructure and Key Resources Sector-Specific Plan as input to the National Infrastructure Protection Plan*.

Building the Tactical and Strategic Communications Team

As previously mentioned, planners should contact members of the statewide communications interoperability committee or the jurisdiction's tactical interoperability communications committee and seek membership in these committees. In so doing, planners will be able to approach the agency responsible for the SCIP or TICP to ensure that the health department is included in future revisions of those plans.

In addition, all locations involved in an MCM response (e.g., EOC, RSS, PODs or other dispensing sites, hospitals, treatment centers, etc.) will need to be connected via the communications matrix. Each site should have a tactical communications point of contact

¹⁴ Department of Homeland Security. *Communications Sector-Specific Plan: An Annex to the National Infrastructure Protection Plan*. (2010). Available online at www.dhs.gov/xlibrary/assets/nipp-ssp-communications-2010.pdf.

(POC), such as the RSS or POD manager, who will receive directives from the jurisdiction's command center (e.g., EOC) and also will communicate with other sites in the communications matrix. The POC for a location or facility should be familiar with the POCs from locations to which they will need to communicate and know the communication pathways necessary to maintain strategic, tactical, and support communications. For example, the local SNS planner may provide directives to a POD manager as the POC (strategic communications), who in turn should know who to contact to place requests for additional MCMs (tactical communications), to request additional security support for the facility (support communications), or to report site-specific information (tactical communications). Figure 10-6, located on page 11 of this chapter, provides an example of strategic, tactical, and support communications pathways.

In addition, each site should identify one or more individuals to manage the communications platforms (i.e., equipment) at the site. These individuals will need to have knowledge of and experience with information technology (IT) and telecommunications and know how to build a resilient and redundant communications platform for the facility or location. This person should also be able to provide guidance on training and just-in-time training (JITT) to staff and volunteers on how to use the equipment and which redundant systems to use should the primary communications platforms become inoperable.

Developing the Communications Plan

The CP can be a stand alone plan, but should also serve as a support annex to the existing EOP as it supports all public health emergencies, including isolated or small-scale incidents or large-scale incidents that involve the jurisdiction's entire population.

Jurisdictions should develop the communications format and content in accordance with their SLTT interoperable communications committee or workgroup's governance, where one exists. For jurisdictions without a communications workgroup or committee, planners can refer to the Federal Emergency Management Agency (FEMA)'s Comprehensive Preparedness Guide (CPG) 101 – Developing and Maintaining Emergency Operations Plans Version 2.0¹⁵ and the CDC Public Health Preparedness Capabilities: National Standards for State and Local Planning.¹⁶ Capability 6: Information Sharing¹⁷ identifies planning activities and performance measures related to communications. In addition, the DHS National Emergency Communications Plan¹⁸ provides guidance on interoperable communications for both the state and local level.

As the jurisdiction develops its communications support annex, planners should ensure that the CP follows both NIMS and ICS and remember that communications functions are associated with ICS functions, not with individuals. Using NIMS and ICS as the basis for

¹⁵ www.fema.gov/pdf/about/divisions/npd/CPG_101_V2.pdf

¹⁶ www.cdc.gov/phpr/capabilities/index.htm

¹⁷ www.cdc.gov/phpr/capabilities/capability6.pdf

¹⁸ www.dhs.gov/xlibrary/assets/national_emergency_communications_plan.pdf

planning will ensure that both consistency and continuity will be maintained throughout the response.

Communications Matrix

The CP annex should include a communications matrix that identifies all the locations with which the jurisdiction has established communication pathways, including the EOC, PODs, RSS location(s), treatment centers or alternate care facilities, and private dispensing partners (such as businesses or universities). For each identified location, the matrix should identify communications equipment available and which ICS position is responsible for communicating with the department's operations center. In addition, each of the locations should identify data accessibility (Internet, email, etc.) since regular updates will be required in the form of situation reports and possibly inventory status. Figure 10-6 shows an example of strategic, tactical, and support communication pathways for a jurisdiction, while Table 10.1 demonstrates a basic communications matrix.

If possible, planners will find that having a uniform communications system across the jurisdiction will simplify the planning process, reduce equipment costs, and decrease required staff training. For example, if PODs use two-way, the best option is to use the same make and model of radio at all POD locations. Additionally, each dispensing location should use the same channel assignments, if possible, to maximize staff training.

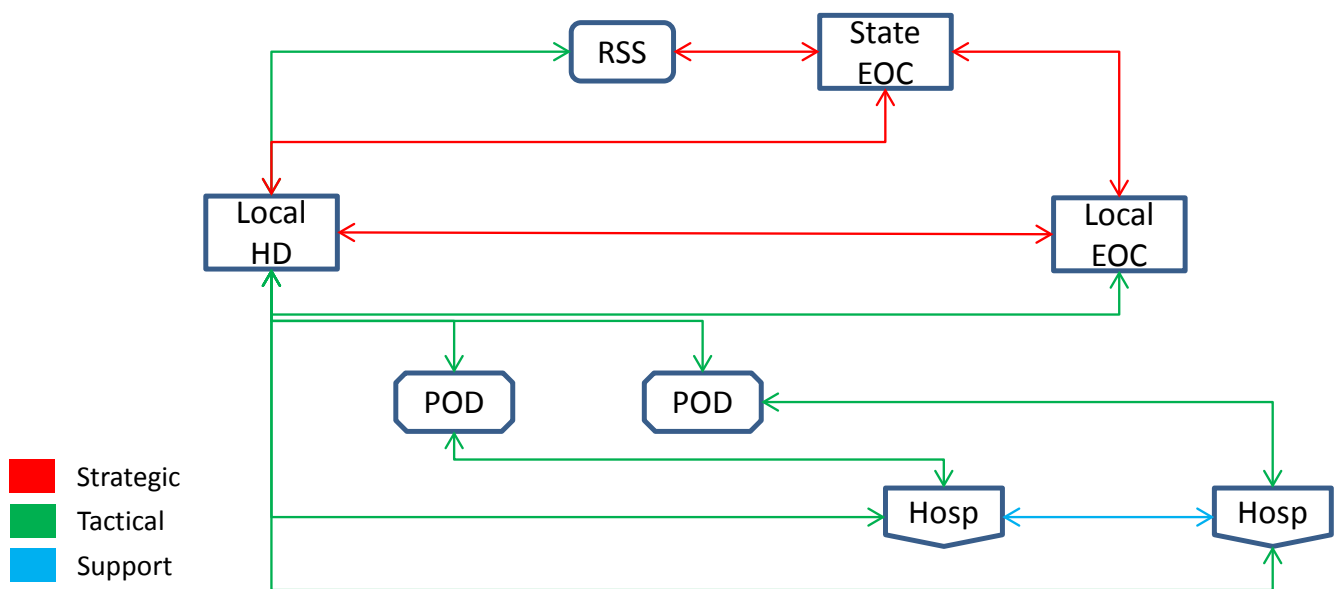


Figure 10-6: Example of a local jurisdiction's communications pathways

Table 10.1: Sample Communications Matrix

	POD 1	Channel	Telephone	FAX	Email	External Communications
1	POD Manager	Any	555-5551		PM@POD1.gov	7, 8, 9
2	Security	1	555-5552		SEC@POD1.gov	8
3	Finance	2	555-5553	555-5557	FIN@POD1.gov	
4	Logistics	3	555-5554		LOG@POD1.gov	8, 9
5	Operations	4	555-5555		OPS@POD1.gov	10
6	Planning	5	555-5556	555-5558	PLN@POD1.gov	
7	Health Dept	6	500-3000	500-3001	HD@LHD.gov	
8	Local EOC	N/A	500-3010	500-3011	EOC@EOC.gov	
9	RSS	N/A	430-989-1000	430-989-1001	RSS@HD.gov	
10	North Hospital	N/A	222-2000	222-2001	NHsp@Hosp.org	
	POD 2	Channel	Telephone	FAX	Email	External Communications
1	POD Manager	Any	455-5551		PM@POD2.gov	7, 8, 9
2	Security	1	455-5552		SEC@POD2.gov	8
3	Finance	2	455-5553	455-5557	FIN@POD2.gov	
4	Logistics	3	455-5554		LOG@POD2.gov	8, 9
5	Operations	4	455-5555		OPS@POD2.gov	10
6	Planning	5	455-5556	455-5558	PLN@POD2.gov	
7	Health Dept	6	500-3000	500-3001	HD@LHD.gov	
8	Local EOC	N/A	500-3010	500-3011	EOC@EOC.gov	
9	RSS	N/A	430-989-1000	430-989-1001	RSS@HD.gov	
10	South Hospital	N/A	244-2000	244-2001	SHsp@Hosp.org	

Call-down Lists

The jurisdiction’s CP should include call-down lists that provide the names of key communications personnel during an incident, including site POCs and IT and telecommunications professionals on the communications team. The call-down list should provide redundant methods of contacting the team during an incident. The jurisdiction should update these call-down lists at least quarterly. Planners may find it easier to update these lists if they are in a separate annex in the CP.

Training and Just-in-time Training

During the planning phase, planners should develop or acquire training material for each particular piece of communications equipment or system available to the health department during a response. In addition, each site should have regular training for staff and just-in-time training (JITT) materials for volunteers who may fill positions during an MCM response. In some cases, the staff may attend pre-existing training offered by other agencies within the jurisdiction, such as SLTT law enforcement or emergency management agencies or fire departments. These agencies may offer regularly scheduled training on specific equipment that MCM response staff seldom use but may rely on during an incident. For example, two-way radios may be part of the redundant communications for a location public health professionals will staff during an MCM response. However, they may seldom use

two-way radio devices during the course of their routine assignments. Local law enforcement or emergency management agencies may routinely use two-way radios and provide training on those devices for their staff. Public health professionals may be able to join professionals from these other agencies in that training. The added bonus is that they will be able to network with others on whom they may rely during an MCM response.

In addition to training and JITT for equipment, staff and volunteers should receive training or JITT, as appropriate, on the communication pathways required for their positions. For example, the JITT for a volunteer at the POD might tell them who the team lead is for their position and how they should contact that person (e.g., call on two-way radio, send a text message, or face-to-face) during their shift. POCs for each location should have a matrix and a list of contacts for tactical and support communications that will occur while they are on site.

The jurisdiction should document all training and JITT in the plan along with any after action reports from communications drills or exercises. See **Chapter 13: Training, Exercising, and Evaluating Plans** for further information.

Reviewing and Validating the Communications Plan

Once the jurisdiction completes its CP support, planners should seek a formal review by the jurisdiction's interoperability communications committee and agency or organization responsible for all communications within the jurisdiction. This will ensure the annex is consistent and follows interoperability governance. In addition, the communications team and members of the communications interoperability committee should review the CP, including the communication pathways and matrices, on a regular basis (at least annually) and correct any changes that occurred between reviews.

Resources

The following list of resources can assist in developing a comprehensive CP and includes many of the source documents used in preparing this chapter.

The **Communications and Information Management** component of the National Incident Management System (NIMS) provides guidance on establishing and maintaining common operating protocols and ensuring accessibility and interoperability of communications systems. It is available at

www.fema.gov/emergency/nims/CommunicationsInfoMngmnt.shtm.

The **Communications-Specific Tabletop Exercise Methodology** from the Department of Homeland Security (DHS) can assist planners to plan, design, and conduct communications-specific exercises that integrate with the emergency response community. Available at www.safecomprogram.gov/SiteCollectionDocuments/CommunicationsSpecificTabletopExerciseMethodology.pdf.

The Federal Emergency Management Agency (FEMA)'s **Comprehensive Preparedness Guide**

(CPG) 101, Version 2.0 provides guidance on overall plan development and is available at www.fema.gov/pdf/about/divisions/npd/CPG_101_V2.pdf.

DHS' **Improving Interoperability through Shared Channels** can assist planners in improving communications interoperability and determining solutions for communications issues. Planners can access this document online at www.safecomprogram.gov/library/Lists/Library/Attachments/246/Improving_Interoperability_through_Shared_Channels_Version%20_2.pdf.

The **National Emergency Communications Plan** from DHS helps to promote interoperable communications for SLTT jurisdictions. This plan is available at www.dhs.gov/xlibrary/assets/national_emergency_communications_plan.pdf.

The Department of Health and Human Services' (HHS') **National Health Security Strategy** (NHSS) provides a baseline standard for developing communications capabilities and is available at www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf.

DHS' **National Interoperability Field Operations Guide, Version 1.4** provides technical reference for emergency communications planning and for those responsible for equipment used in an MCM response. Available at www.dhs.gov/xlibrary/assets/nifog-v1-4-rotated-for-viewing.pdf.

Guide to Radio Communications Interoperability Strategies and Products, April 1, 2003 from National Law Enforcement and Corrections Technology Center describes interoperability strategies and characterizes products to implement those strategies. Available at www.safecomprogram.gov/library/Lists/Library/Attachments/215/Guide_to_Radio_Communications_Interoperability_Strategies.pdf.

The **Homeland Security Information Network** is an online portal for information sharing and collaboration between SLTT federal, private sector, and international partners engaged in the homeland security mission. Accessible from http://www.dhs.gov/files/programs/gc_1156888108137.shtm.

State/Region/Urban Area Tactical Interoperable Communications Plan Template is designed to provide a template on which planners can document interoperable communications governance structures, technology assets, and usage policies and procedures. Available from DHS at www.safecomprogram.gov/NR/rdonlyres/52953DB1-B8B4-4EF3-8806-8A83226A05AF/0/OECTICPTemplatev28609.doc.

Statewide Communications Interoperability Planning (SCIP) Methodology v2.0: A Collaborative Approach to Statewide Communications Interoperability Planning, from DHS provides step-by-step guidance for developing a locally-driven statewide strategic communications plan. Available at www.safecomprogram.gov/SiteCollectionDocuments/SCIPMethodologyv20FINAL.pdf.

Chapter 11: Securing Assets, Staff, and Operations

A comprehensive security plan is critical for ensuring the safety and security of medical countermeasure (MCM) operations, assets, and staff. A large-scale public health emergency will produce many casualties and people in the affected community will be concerned and fearful. The decision to deploy national assets will be newsworthy, which may make response operations a target for those who wish to do harm in the community or unwilling to wait for the planned dispensing of MCMs to protect or treat them and their families. Planners should work closely with state and local law enforcement officials to develop a comprehensive plan for securing assets, facilities, and personnel through all phases of medical countermeasure distribution and dispensing (MCMDD) planning and operations.

Leveraging Security Support for Public Health Emergencies

While developing security plans for MCMDD-related activities, jurisdictions should keep in mind that deployment of MCMs are not tied strictly to acts of bioterrorism, but are also used to support natural or technological disasters. Strategic National Stockpile (SNS) assets have played a key role in the federal government's response to numerous natural disasters, including hurricanes, earthquakes, and floods. The Centers for Disease Control and Prevention (CDC) regularly deploys various products from the SNS that are needed to care for a single patient. Consequently, it is important to note that security resources planned for in a biological emergency may not be available or deemed necessary during a natural disaster or other situation. Therefore, it is imperative that jurisdictions coordinate security resources to enable an appropriate response commensurate to the risk by developing scalable security plans that may require the allocation of scarce security resources during large-scale public health emergencies that involve the deployment of MCMs or a single officer to pick-up or escort a life saving medication to a local hospital.

The key function for planners in developing security plans is the outreach and coordination of the appropriate law enforcement or security personnel, since they routinely support Emergency Support Function 13 (ESF 13) – Public Safety and Security – of the National Response Framework (NRF). ESF 13 involves capabilities that support

incident management requirements including, but not limited to, force and critical infrastructure protection, security planning and technical assistance,

technology support, and general law enforcement assistance in both preincident and postincident situations. ESF #13 is activated in situations requiring extensive public safety and security and where State, tribal, and local government resources are overwhelmed or are inadequate, or for Federal-to-Federal support or in preincident or postincident situations that require protective solutions or capabilities unique to the Federal Government.¹

In addition, the federal government created numerous plans and legislation to assist in securing the nation's critical infrastructure, which the Department of Homeland Security (DHS) defines as "the assets, systems, and networks, whether physical or virtual, that are so vital to the United States that their incapacitation or destruction would have a debilitating effect on the nation."² Many federal agencies have coordinated in creating these critical infrastructure plans because

- Attacks on critical infrastructure could significantly disrupt the ability of the federal government and business to function, which could have additional far-reaching effects for the nation;
- A terrorist attack or natural disaster could produce large-scale casualties, property damage, and subsequent economic effects; and
- An attack in which any segment of the nation's critical infrastructure is used as a weapon of mass destruction could create overwhelming physical and psychological impacts in its wake.

The federal government has developed many resources to support security operations that may assist public health planners in understanding security needs and in partnering with law enforcement, emergency management, and other security partners.

Presidential Policy Directive 8 (PPD-8)

Presidential Policy Directive 8 (PPD-8) is designed to strengthen "the security and resilience of the United States through systematic preparation for the threats that pose the greatest risk to the security of the Nation, including acts of terrorism, cyber attacks, pandemics, and catastrophic natural disasters."³ The intent of PPD-8 is to promote action at the federal level, while facilitating a unified, national, capabilities-based approach to preparedness that involves private-sector partners, non-governmental organizations, and the general public. Under PPD-8, the president directed the development of a national preparedness goal, which identifies the core capabilities necessary for preparedness, and a national preparedness system, which will guide the activities essential to achieving the preparedness goal.

¹ From Emergency Support Function #13 – Public Safety and Security Annex to the National Response Framework (NRF); Federal Emergency Management Agency, (2008). Available at www.fema.gov/pdf/emergency/nrf/nrf-esf-13.pdf.

² From the Department of Homeland Security (DHS), www.dhs.gov/files/programs/gc_1189168948944.shtm

³ www.dhs.gov/xabout/laws/gc_1215444247124.shtm

Homeland Security Act of 2002 and Presidential Directive 7 (HSPD 7)

The Homeland Security Act of 2002⁴ provides the principal authority for the overall national security mission. This act charged DHS with developing a comprehensive national plan to secure critical infrastructure and recommend actions to protect key resources and critical infrastructure of the United States. Homeland Security Presidential Directive 7 (HSPD 7) established “a national policy for Federal departments and agencies to identify and prioritize critical infrastructure and to protect them from terrorist attacks.”⁵ The directive defines relevant terms and delivers 31 policy statements that define the directive and the roles partners from federal, state, and local agencies will play in carrying it out.

National Infrastructure Protection Plan (NIPP)

The National Infrastructure Protection Plan (NIPP)⁶ was developed by federal and private-sector partners and published by DHS in June 2006. NIPP was designed to provide a structure under which multiple security activities could be organized into a single national program. The healthcare and public health sector falls under the 18 designated critical infrastructure sectors of the NIPP as mandated by HSPD 7. “The overarching goal of the NIPP is to build a safer, more secure, and more resilient America by preventing, deterring, neutralizing, or mitigating the effects of a terrorist attack or natural disaster, and to strengthen national preparedness, response, and recovery in the event of an emergency.”⁷ DHS oversees management and implementation of NIPP.

Healthcare and Public Health Sector Critical Infrastructure Protection Program

The Department of Health and Human Services (HHS) Office of the Assistant Secretary of Preparedness and Response (ASPR)⁸ includes the Healthcare and Public Health Sector Critical Infrastructure Protection Program,⁹ which leads a unique partnership between the public and private sector for protecting healthcare and public health assets, services, and operations. NIPP provides the framework for this program.

ASPR also created the Healthcare and Public Health Sector-specific Plan,¹⁰ which establishes a relationship between the government and the private sector to promote the collaboration necessary to safeguard this healthcare and public health sector from natural or manmade disasters. The plan creates a pathway for this sector to “identify and prioritize its assets, assess

⁴ www.dhs.gov/xabout/laws/law_regulation_rule_0011.shtm

⁵ www.dhs.gov/xabout/laws/gc_1214597989952.shtm

⁶ www.dhs.gov/xlibrary/assets/NIPP_Plan.pdf

⁷ From DHS, www.dhs.gov/files/programs/editorial_0827.shtm

⁸ www.phe.gov/about/Pages/default.aspx

⁹ www.phe.gov/Preparedness/planning/cip/Pages/default.aspx

¹⁰ www.phe.gov/preparedness/planning/cip/Pages/default.aspx

risk, implement protective programs, and measure the effectiveness of its protective programs.”¹¹

The Role of Law Enforcement in Public Health Emergencies: Special Considerations for an All-hazards Approach

One key issue state and local public health officials face when reaching out to law enforcement professionals is a lack of understanding of how law enforcement would be involved in a large-scale public health emergency. To assist in the coordination of law enforcement and public health professionals, the U.S. Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Assistance developed *The Role of Law Enforcement in Public Health Emergencies: Special Considerations for an All-Hazards Approach*.¹² The DOJ developed this document to “help state and local law enforcement officials and policymakers understand communicable diseases (including terminology and methods of transmission) and the threat they pose to public health and safety. In addition, it outlines key concerns that law enforcement officials must address in preparation for a virus-caused pandemic and other public health emergencies and identifies issues that may arise in the department’s ‘all-hazards’ approach.”¹³ Public health planners can utilize this document to reach out to their jurisdictional law enforcement agencies for assistance in security planning.

National Preparedness Goal Core Capabilities

The National Preparedness Goal identifies 31 Core Capabilities¹⁴ as elements needed to for the nation to achieve the National Preparedness Goal, which is:

A secure and resilient nation with the capabilities required across the whole community to prevent, protect against, mitigate, respond to, and recover from the threats and hazards that pose the greatest risk.¹⁵

Several of the Core Capabilities apply to MCMDD security planning, including Screening, Search, and Detection,¹⁶ Access Control and Identity Verification,¹⁷ Physical Protective Measures,¹⁸ and Supply Chain Integrity and Security.¹⁹ These capabilities can assist jurisdictions in developing comprehensive security plans.

¹¹ www.phe.gov/Preparedness/planning/cip/Pages/ssp.aspx

¹² www.ojp.usdoj.gov/BJA/pdf/role_law_enforce.pdf

¹³ www.ojp.usdoj.gov/BJA/pdf/role_law_enforce.pdf

¹⁴ www.fema.gov/core-capabilities

¹⁵ From the Federal Emergency Management Agency *National Preparedness Goal* website. Available at URL www.fema.gov/national-preparedness-goal. (Accessed May 8, 2013)

¹⁶ www.fema.gov/core-capabilities#ScreenSearch

¹⁷ www.fema.gov/core-capabilities#Accesscontrol

¹⁸ www.fema.gov/core-capabilities#PhysicalProtect

¹⁹ www.fema.gov/core-capabilities#SupplyChain

Determining Security Needs

During an incident in which MCMs are deployed, these assets will need to be secured throughout the chain of custody, from the federal level all the way to the people who receive them. Planners will need to develop a detailed security plan that describes the actions required to protect

- Medical countermeasures and other medical assets;
- Various locations used to support an response;
- People that support response operations; and
- Distribution (i.e., transportation) infrastructure.

CDC strongly recommends that planners enlist law enforcement and security experts to assist in developing security plans. Additionally, planners should identify a security team leader to manage the security staff, available security resources, and security missions required to support MCM response activities, including the three critical functions of

- Receiving assets;
- Distributing assets; and
- Dispensing assets.

Once the assets are in state custody, the state is responsible for their effective safeguarding according to the written security plan. Planners should note that assets may be received in advance of Investigational New Drug (IND), emergency use authorization (EUA) or other utilization guidelines, in such cases staff from CDC's emergency operations center will alert SLTT staffs to any special quarantine or security requirements.

Security Missions and Tasks

Securing MCMDD operations is resource-intensive and will require detailed planning and coordination with numerous agencies at various levels of government, as well as within the local community. Security tasks surrounding a response can be divided into three categories:

- **Physical security** addresses measures to prevent or deter access to buildings and to protect property and assets against intruders.
- **Personnel protection** establishes security measures to ensure the safeguarding of staff involved in operations and people receiving MCMs.
- **Law enforcement** protocols and procedures for apprehending and/or arresting those in violation of the law who may attempt to disrupt the MCM operations.

These security tasks will require equal planning and varying staffing depending on specific missions within each task. In addition, planning for certain missions and tasks will require involvement from security partners long before an incident occurs. For example, security partners, especially local law enforcement, should conduct site visits to potential points of dispensing (PODs) and receipt, stage, store (RSS) facilities (see **Chapter 5: Receiving, Staging, and Storing Medical Countermeasures** for further information) to assist public health planners in determining the suitability of each site and developing site-specific security plans. Table 11.1 outlines some of the missions involved in each security task.

Depending on how the jurisdiction structures the overall response, it also may be necessary to plan for one or more of the following security tasks:

- Providing security for CDC response teams, such as the Stockpile Services Advance Group (SSAG), RSS Strike Team, or the Federal Medical Station Strike Team. These teams may need security support in the event of civil unrest or difficulty in maneuvering to their assigned location. Jurisdictions need to develop contingency plans to support these teams in the case that their deployment to the jurisdiction becomes necessary.
- Providing security at secondary storage and distribution sites (e.g. regional distribution site [RDS]), if these are used in the jurisdiction.

Table 11.1: Security Tasks and Missions

Physical Security	Personnel Security	Law Enforcement
<ul style="list-style-type: none"> • Securing the entry/meeting point for assets arriving in the state and escorting assets to RSS • Securing the RSS and RDS or secondary storage sites (if applicable) • Securing point of dispensing (POD) facilities and other dispensing sites (this includes providing security walk-throughs of potential sites to point out possible security threats) • Securing federal medical station (FMS) sites • Escorting distribution trucks carrying assets from RSS or secondary storage to PODs and other dispensing sites 	<ul style="list-style-type: none"> • Protecting deployed federal personnel • Protecting state and local responders and volunteers • Protecting people who come to PODs • Providing identification badges for personnel at operations locations (i.e., RSS, RDS, and POD sites) 	<ul style="list-style-type: none"> • Controlling traffic and crowds at points of dispensing (PODs) • Coordinating parking at PODs • Apprehending or subduing intruders or those who attempt to disrupt operations at the RSS, RDS, PODs or hospitals

CDC also recommends that jurisdictions incorporate the security of existing and/or ad hoc treatment centers (e.g., hospitals, clinics, and other medical facilities) and their staff into the security plan. Depending on the type of incident, symptomatic or injured people may self-refer to these locations. The crowds may become large and overwhelm the center’s staff and security resources. While public information and communication around incidents involving MCMs encourage people to go to hospitals or treatment facilities if they are ill and to go to dispensing sites (sometimes called points of dispensing [PODs]) if they do not have symptoms, people may still rush to treatment facilities seeking MCMs (See **Chapter 8: Dispensing Medical Countermeasures** for further information). Therefore, it is extremely important to include security personnel from hospitals, clinics, and other medical facilities in the planning for large-scale public health emergencies. Keeping these public/private security forces informed of the jurisdiction’s plans for such incidents will assist them in directing people who present to their facilities to the right locations to receive MCMs and information.

As with all aspects of planning, CDC recommends developing security plans that are scalable and appropriate to the level of response. Based on law enforcement agencies' collective risk assessment certain elements of the plan may not be deemed necessary. Many planners realized the need for a scalable security response during the deployment of federal assets to support the 2009 – 2010 H1N1 pandemic influenza response. During this response, antiviral medications and personal protective equipment were sent to jurisdictions on a pro rata basis, so the jurisdictions did not receive large shipments simultaneously, as might be the case when an SNS 12-hour Push Package is deployed. Since smaller jurisdictions might have received only one or two pallets of material at a time, they were not opening PODs for dispensing, and they did not implement large-scale distribution networks throughout the state, they could scale back the security requirements to meet the needs of the jurisdiction.

Forming the Security Team

CDC recommends establishing a security team comprised of law enforcement and security subject matter experts to develop and implement an operational, scalable security plan. In addition, planners should include the jurisdiction's emergency management agency in the planning process. Because of the complexity of operations that could be involved in a full-scale MCMDD response, it is doubtful that one law enforcement or security agency will be able to provide all of the resources required to support the jurisdiction. Consequently, CDC recommends that planners gain support from as many agencies as possible to ensure adequate security coverage. In addition, these partners will be able to provide varying perspectives on security, possibly pointing out weaknesses not seen by others. The size and specialties of the security team will depend on the number of organizations and resources available within the jurisdiction and the security team could be quite large.

At the state level, some law enforcement and security resources to consider adding to the security team may include

- State police;
- State fire marshal;
- State Defense Force;
- National Guard;
- Department of Corrections;
- Tribal police and fire marshal;
- Department of Natural Resources/Fish and Game; and
- Department of Probation.

At the local level, some law enforcement and security resources to consider adding to the security team may include

- County/parish/municipal sheriff's department;
- City/county police;
- City/county fire marshal;
- University/college security;
- Hospital security;
- School resource officers;
- Private security agencies;
- Probation services;

- Court security;
- Police auxiliary;
- Closed POD security personnel; and
- Volunteer security forces.

Because the pool of resources is large and an MCMDD response will have many moving parts, jurisdictional boundaries and authorities will be key considerations in the development of the security plan. Therefore, CDC highly recommends using law enforcement, emergency management, and security professionals to assist with developing the security plan to help planners understand the security challenges, develop ways to overcome those challenges, and ensure a coordinated security effort.

Additionally, many law enforcement and security organizations operate under existing command structures. Consequently, planners may find it simpler to assign a single organization or security force responsibility for a single site. For instance, the security team that already works at a warehouse facility selected as an RSS site might be assigned to continue their usual security efforts during an MCMDD response with additional guidance specific for RSS operations. Regardless of the arrangements, the written security plan for the jurisdiction must account for security in every possible location in which MCMs may be deployed and people may need to be protected.

Considerations for Working with Tribal Nations

Many planning jurisdictions may need to work with tribal law enforcement to develop security plans to support an MCMDD response on tribal lands. Planners who are working with tribal nations should be aware of the following information on tribal law enforcement from a 2006 report from the National Congress of American Indians:²⁰

- Police on tribal lands function within a complicated jurisdictional net, answer to multiple authorities, operate with limited resources, and patrol some of the most desolate territory, often without assistance from partner law enforcement agencies.
- There are only 2,380 Bureau of Indian Affairs and tribal uniformed officers available to serve an estimated 1.4 million American Indians covering over 56 million acres on tribal lands in the lower 48 states. In contrast, a total of at least 4,290 sworn officers would be needed on tribal land to provide the minimum level of coverage seen in most communities in the United States.
- On tribal lands, the ratio of police officers to citizens is only 1.3 officers per 1,000 citizens, compared to 2.9 officers per 1,000 citizens in non-Indian communities with populations under 10,000.
- Tribal law enforcement departments rarely have more than one officer on duty at any time and their officers often work without adequate backup.

Coordination Challenges

While all aspects of MCMDD planning have challenges, the following are some coordination challenges that planners may encounter when forming a security team:

²⁰ www.ncai.org/Law-Enforcement-and-Tribal-Cou.34.0.html

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- The lack of adequate manpower from a single law enforcement agency becomes more prominent as more local governments experience increasing budgetary constraints. Competing tasks with minimum staff to accomplish those tasks may make it difficult for an agency to support the security plan.
 - Policy or law may limit or restrict the aid provided by law enforcement or security agencies when crossing jurisdictional lines, which can be especially apparent when tribal organizations are involved.
 - The sovereignty of city and county governments and the lack of elected official buy-in can frustrate efforts to supplement small, local law enforcement agencies and may prevent some law enforcement agencies from making agreements to cover neighboring cities or counties.
 - Coordinating security support can be more difficult in states that lack a single state police agency. In those states, planners may need to recruit a law-enforcement-agency matrix in order to develop and staff security plans and operations. This will require planners to coordinate between multiple law enforcement agencies and security forces. If the jurisdiction can locate and recruit one person in law enforcement or security who can reach out and coordinate others, it will make the planning go more smoothly in these states.

Security Planning and Operations Lead

One of the most important aspects of the security plan is establishing a strong management structure to support security planning and operations. Such a structure begins with selecting a security support team leader. The ideal lead will have strong law enforcement credentials and credibility in the law enforcement and security communities within the jurisdiction. This credibility will go a long way in obtaining additional security resources through recruiting state, county, and city law enforcement officials and security experts and their agencies to the MCM security mission. The security lead at the local level should have contacts in neighboring jurisdictions and at the state level and to be able to coordinate smooth transition of security operations between jurisdictions.

Most law enforcement and security agencies will have competing priorities during an emergency, possibly with already limited resources, so it is important to consider having a security leader that is

- Aware of the challenges in assembling the security support team(s);
- Knowledgeable of the security tasks required to support response operations; and
- Can assist in communicating the importance of the MCMDD response to the leaders of the potential resource pools, obtain their buy-in, and ultimately obtain their support.

Determining Security Policies and Procedures

In collaboration with the security team, jurisdictions should develop specific policies for security partners at various MCMDD operations sites. Two specific areas of concern for jurisdictions are staff identification, which includes verifying identification and providing identity badges; and use of force, which has varying levels of physical force for control of unruly people and situations.

Planners should outline these policies with the security team lead to ensure that all security partners are aware of how to properly address these within MCMDD-related facilities. Once policies have been agreed upon, general policy guidelines should be included in the overall plan and site-specific policies should be included in those plans.

Identification Badges for Members of MCMDD Response Teams

Confirming the identities of everyone involved in MCMDD response activities is extremely important to ensure the integrity of operations and limit access to controlled and sensitive areas during response operations. Verifying identification and supplying identification badges will be a significant part of the security plan at some locations. Site-specific security teams may be large and consist of members from various agencies, so it will be important to have clear guidelines for verification and identification badges at each facility.

CDC recommends that site-specific security teams employ two identity measures for determining which personnel have access to facilities – a comprehensive access roster that serves as an approved list of all workers expected onsite and a photo identification (ID) badge for each worker.

Badging requirements will be jurisdiction-specific, and in many cases, site-specific. There are several approaches that jurisdictions and sites can take to providing ID badges: providing ID badges at the time of an incident, providing ID badges in advance of an incident, and utilizing existing ID badges. Each approach has pros and cons and the decision on which approach to use rests with the jurisdiction. The following information and guidance on these approaches will assist planners in determining the best approach to use for specific sites and throughout the jurisdiction. Table 11.2 lists the pros and cons of each approach to badging.

If the jurisdiction opts to produce either incident-specific ID badges or issue ID badges in advance of an incident, the security team lead should be involved in the design of the ID badge and the data required on the ID badge. This precaution is necessary to ensure that during an incident, those who report at the various sites are those who actually belong.

Issuing Incident-specific ID Badges

Some jurisdictions plan to issue incident-specific ID badges to everyone at the time of a response. In order to issue badges, the jurisdiction will need design the badge in advance and then develop a plan for issuing ID badges that includes

- Checking the identification of each person who arrives at a facility;
- Taking a photograph;
- Printing the ID badge; and
- Laminating the ID badge or placing it in a holder, such as a plastic sleeve that is hung from a lanyard or clipped onto clothing.

Providing incident-specific ID badges could be done by either having personnel report to their assigned location to receive ID badges or report to a central badging location. While on-site badging could prove faster than sending personnel and volunteers to a central location to receive ID badges, the cost of the badging operation could be prohibitive for some jurisdictions. By contrast, costs can be reduced by having only a few badging machines in one location, but this would require all staff and volunteers to report to a

location for badging prior to reporting to their duty locations, which could increase the time it takes to mobilize personnel.

If ID badges will be provided at each site during a response (i.e., RSS, each POD, etc.) then the jurisdiction will need to provide badging equipment (e.g., computer ID badge template, camera for providing photographs, etc.) to each site or ensure that existing badging equipment at the site is compatible with the jurisdiction's ID badge design. Plans also should include a way to provide necessary badging equipment to each site and detailed instructions on how to operate the equipment.

Jurisdictions that plan to issue ID badges from a central location should select a location other than the RSS site for those operations. Because of its critical role in response, the RSS location should remain confidential and as secure as possible.

Some jurisdictions plan to conduct MCMDD operations on government, military, or private property, onto which ID badges may be required for entry. In addition, these locations will likely raise their security levels during an incident, so it is best to conduct proper coordination for entry prior to an incident so access guidelines are clearly communicated prior to activating a response.

Issuing Identification Badges in Advance of an Incident

Some jurisdictions may plan to issue ID badges in advance of an incident. For areas planning this approach, the badging requirements are the same as for incident-specific badging, but some additional operational considerations must be addressed. For instance, the volunteer pool for emergency responses, as well as the staff of state and local agencies, is variable. People move from the jurisdiction, leave a response agency, become unable to participate, or simply lose interest. In addition, people may misplace their emergency response ID badges prior to an incident in which they are needed. Consequently, managing badging prior to an incident can be problematic. For jurisdictions using this approach to badging, plans should include procedures to

- Ensure ID badges are available to personnel at the time of an incident;
- Ensure ID badges remain with the person to whom they were issued;
- Ensure ID badges are not altered or copied by people who should not have access to facilities;
- Verify badge-holders' IDs as they arrive at their duty locations; and
- Provide rosters of reporting personnel at each facility during an incident.

Utilizing Existing Identification Badges

Jurisdictions may determine that personnel who report to specific locations may use their facility-specific ID badges during MCMDD operations. For instance, employees of a warehouse facility contracted for RSS operations may already have photo ID badges for the facility. The jurisdiction may determine that those staff can use their facility-issued ID badges during RSS operations provided they have been previously rostered and cleared for participation in RSS operations. In this approach, plans will need to include

- Rostered lists of which personnel can present with their own ID badges to each facility (e.g., warehouse workers at an RSS, public health employees, security personnel, etc.)

- How security personnel will determine which personnel arriving have appropriate badges;
- How security personnel at the facility will verify the identity of people arriving at a facility;
- How personnel or volunteers who arrive with no ID badges or inappropriate badges will be handled; and
- Ways in which non-rostered personnel can receive temporary ID badges to assist in facility operations.

Medical Credentials

CDC also recommends that jurisdictions collaborate with medical credentialing organizations, such as the state board of physicians or nurses, to obtain a list of possible medical personnel and verify the medical credentials of health professionals expected to support MCMDD operations. Under the Public Health Emergency Preparedness (PHEP) cooperative agreement, planners must comply with Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP) guidelines to coordinate recruiting of licensed medical volunteers. The ESAR-VHP will assist in identifying qualified and credentialed medical professionals. In addition, planners can work with the jurisdiction's Medical Reserve Corps (MRC) to recruit medical professionals with verified credentials. If possible, planners should include volunteer medical personnel in MCMDD training, drills, and exercises, which will give security partners an opportunity to train and exercise on verifying medical IDs and credentials.

Table 11.2: Pros and Cons of Badging Approaches

Approach	Pros	Cons
Incident-specific <ul style="list-style-type: none"> • On-site 	<ul style="list-style-type: none"> • Staff identities can be checked • Spontaneous volunteers can be accommodated • Staff can report directly to their duty locations 	<ul style="list-style-type: none"> • Increased cost to provide equipment at each location involved in the response • If existing facilities' badging equipment used, may not be compatible with ID badge design created by security support team • More staff need to be trained to operate badging equipment
<ul style="list-style-type: none"> • Designated badging locations 	<ul style="list-style-type: none"> • Staff identities checked • Spontaneous volunteers can be accommodated • Lower cost than providing badging equipment at each facility involved in response operations • Fewer staff require training on operating badging equipment 	<ul style="list-style-type: none"> • May slow down response since staff and volunteers will need to report to a badging location prior to reporting to their duty locations
Pre-incident	<ul style="list-style-type: none"> • Staff and volunteers will already have ID badges and can report directly to duty locations • Everyone will have the same ID badge, thus making verification at locations easier 	<ul style="list-style-type: none"> • ID badges could get lost before an incident • Staff and volunteer turnover will make it difficult to maintain control of ID badges • No control of who has access to ID badges, e.g. if volunteers leave the area or decide not to participate, badge could fall into the wrong hands • Does not negate the need to have badging processes in place at the time of incident
Existing ID Badges	<ul style="list-style-type: none"> • Staff will have ID badges already and be able to report directly to duty location • Great for access-sensitive areas, such as RSS or POD storage area, that may have magnetic card-key entry points 	<ul style="list-style-type: none"> • Will need to determine how to badge volunteers from the general public, if they are recruited to assist • Many different ID badges in an area will make verification of appropriate ID badges time-consuming • Security personnel will need to be aware of which ID badges are permitted at each site and in each area within a site

Use-of-force Policy for Law Enforcement

Planners sometimes are confused by the term “use of force.” According to the International Association of Chiefs of Police (IACP),

Police enforce social order through the legitimized use of force. Use of force describes the amount of effort required by police to compel compliance by an unwilling subject. The levels, or continuum, of force police use include basic verbal and physical restraint, less-lethal force and lethal force. Officers receive guidance from their individual agencies, but no universal set of rules governs when officers should use force and how much. The level of force an officer uses will vary based on the situation.²¹

The National Institute of Justice (NIJ) and the Bureau of Justice Statistics (BJS) prepared the report *Use of Force by Police: Overview of National and Local Data*,²² which looks at police use of force from several perspectives. The report provides an overview of compiled research on police use of force and provides planners with a resource for determining the best ways to address use of force as it relates to actions involved in MCM operations.

Jurisdictions should discuss use of force policies with law enforcement and be clear on what actions may be appropriate at MCMDD operations sites, specifically at PODs. For example, if an unruly person is removed from the POD, at what point will they receive their MCMs? Will they be removed and provided MCMs in jail or sent home? Some jurisdictions feel people causing disruption should be taken away to a holding area or jail and then be given MCMs in order to avoid copycat disruptions. Planners should work with their law enforcement agencies and understand policies regarding use of force at facilities during large-scale incidents and then ensure that these policies are clearly communicated to all security personnel at each site.

Developing Site-specific Security Plans

All facilities face potential threats on a daily basis, whether from natural disasters, accidents, or intentional malicious acts. Threats can become even more possible during an emergency. Consequently, CDC recommends the security support team plan to use the risk management process to assess facilities that would be used during MCMDD operations and determine how best to lessen or mitigate potential threats. The risk management process is outlined in the *Whole Building Design Guide*²³ from the National Institute of Building Sciences and has been adapted and used by many federal agencies to assess facilities. According to the *Whole Building Design Guide*, the risk management process consists of three stages:

- **Threat Assessment** considers the full spectrum of threats from natural, criminal, terrorism, accidental sources, and others for the facility/location.
- **Vulnerability Assessment** considers the potential impact of loss from a successful attack as well as the vulnerability of the facility/location to an attack. Impact of loss is

²¹ <http://theiacp.org>

²² www.ncjrs.gov/pdffiles1/nij/176330-1.pdf

²³ www.wbdg.org/resources/riskanalysis.php?r=resist_hazards

the degree to which the mission of the agency is impaired by a successful attack from the given threat.

- **Risk Analysis** is a combination of the impact of loss rating and the vulnerability rating, which is used to evaluate the potential risk to the facility from a given threat.

Many law enforcement agencies, as well as state and local emergency management agencies can assist with the risk management process, since these organizations routinely have personnel trained in the process.

Protecting critical infrastructure and ensuring continuity of operations also will be essential to public health and safety and MCMDD operations. The jurisdiction's law enforcement professionals should assess the probability that adverse events or threats may follow a public health emergency or disastrous event and affect security operations. Follow-on incidents such as sabotage; a secondary terrorist attack; or secondary chemical, biological, nuclear, or radiological incident could affect MCMDD operations. In addition, conventional crimes such as theft, arson, assault, vandalism, and other criminal incidents could redirect security resources during an incident. By assessing the jurisdiction's critical infrastructure, especially those facilities and assets vital to MCMDD operations, the security team can develop plans to minimize the impact of conventional and follow-on incidents on MCMDD operations.

A standard part of any security risk assessment is to ask and answer the following questions:

- What asset or process am I protecting?
- What potential harm or threat could occur to that asset or process?
- Who or what could be harmed and to what degree?
- Do my existing security measures help mitigate these risks?
- If not, what measures should I plan to incorporate to reduce the risks?
- Where will I accept risk in this plan?

The jurisdiction's detailed, written security plan should specify the answers to these questions. By working through these questions, the security team will be able to conduct a thorough analysis of the potential threats to MCMDD operations and establish and incorporate security measures in the plan to mitigate threats to MCMDD operations. This process assists in determining gaps in the overall security planning. Because of resource constraints the jurisdiction may not be able to incorporate measures for every potential risk and will therefore have to determine which areas pose an accepted risk. When the jurisdiction identifies areas of accepted risk, planners can communicate these at all levels responsible for emergency preparedness and response within the jurisdiction.

Determining acceptable risk is another area where collaboration with other agencies will be key. In conducting a risk assessment, planners should work with security partners to determine which sites, areas, and assets need protection, such as

- Locations where RSS operations will occur;
- Treatment centers and PODs;
- MCMDD support personnel, vehicles, and equipment;
- MCM transport vehicles;
- Primary and alternate routes to key facilities, such as PODs;
- Federal Medical Station (FMS) locations; and
- Regional distribution sites (RDSes).

As planners collaborate with law enforcement and security professionals to identify the potential threats against critical MCMDD response locations and processes, they also should consider the risk of potential threats in and around the RSS sites, distribution facilities, and PODs, such as

- Railways;
- Petroleum pipelines;
- Facilities that store or produce hazardous materials; and
- Facilities that may themselves become a target of terrorist attacks.

POD-specific Law Enforcement Support

Managing a POD is one of the most challenging, yet vital, MCMDD response functions, and it is vital that the security plans address how to protect not only the physical location of PODs, but the people within, both staff and citizens. Providing sufficient security at PODs to help minimize unruly persons, manage chaotic flow, address traffic and parking issues, and mitigate threats to staff is essential to the overall success of POD operations. One challenge planners may encounter is determining how strict the POD security measures should be. The mission at the POD is to ensure that the maximum number of citizens in the affected area receive MCMs as soon as possible; so, the intent is to process people quickly or obtain maximum throughput. There must be a balance in the security measures established to ensure safety yet not inhibit maximum throughput. Because of this fine balance in planning, CDC recommends that planners involve the security support team early in the in the POD selection and planning processes.

The size, nature, and layout of PODs will vary and planners should work with law enforcement or security partners to establish a **separate, site-specific security operations plan for each POD**. Each POD security plan should include

- Potential risk areas (e.g., access points to the facility);
- Analysis of the surrounding area (e.g., providing adequate onsite or nearby parking near high-flow streets or freeways);
- Specific physical security measures and measures to effectively safeguard personnel at the POD;
- Security measures to mitigate risk (e.g., reducing the number of access points to the POD);
- POD layout (e.g., allowing a controlled flow of people through facility);
- Security and law enforcement support for segmented PODs, which could include rally points where the public gather for transport to the POD (see **Chapter 8: Dispensing Medical Countermeasures** for further information);
- Procedures for managing disorderly persons or crowds, traffic into and out of the facility, and parking;
- Traffic plans for each POD, including the mix of roads, streets, and highways at each location;
- Plans and procedures to ensure that access to the loading dock or drop-off site is clear of traffic, parked vehicles, and crowds;
- Number of security support team members needed per shift at each POD;
- Communications resources and plans for security team members; and
- The security management structure (chain of command) at each facility.

However, as the POD locations become known to the local community, traffic flow around the POD will likely increase and require crowd control, parking enforcement, and personnel protection. One major difference in opting for a segmented POD process (See **Chapter 8: Dispensing Medical Countermeasures** for a description of this process) is that the security plan must address how the jurisdictions will secure each additional remote-staging site, which will require conducting a risk assessment for each staging site and developing security measures to mitigate the risks identified. Additionally, it will be necessary to provide security escorts for vehicles transporting people between the remote staging site and the POD(s).

Security Prior to Federal Transfer of Assets

Assets may arrive in the state via trucks or aircraft, the latter of which will require transfer to the RSS via trucks. Timeliness in transporting these assets is essential, and the state should have well-developed security plans to avoid delays in receiving assets. Therefore, it is essential to designate a member of the security team to coordinate with the USMS senior inspectors prior to the arrival of assets. The jurisdiction's SNS coordinator will receive information from CDC on projected arrival times for assets. That coordinator should then inform the designated security team member of when and where transfer of the assets will occur. CDC recommends identifying this security team member during the planning phase and including their contact information in the security plan to ensure coordination and collaboration.

To ensure a smooth transfer of custody, the USMS will need to have a clear understanding of the jurisdiction's overall security plan and will need to know which agency is responsible for

- Meeting and escorting trucks moving SNS assets from the arrival airport or state line to the RSS facility;
- Escorting and safeguarding any deployed CDC personnel.

Security Following the Transfer of Assets

Under most plans, custody transfer of assets will occur at the RSS facility. The critical security tasks that the security plan should address for receipt of assets include

- Safeguarding the RSS facility, personnel, and assets once signed over;
- Safeguarding distribution vehicles for regional distribution sites RDSes and PODs while loading, offloading, and in transit; and
- Managing vehicle distribution routes.

Safeguarding the RSS/RDS Facility

RSS facility protection is essential to the effective receipt of assets during an incident. Compromising the location of this site could impair or even halt the flow of assets into the jurisdiction. The best way to protect the RSS site is to ensure that security measures are in place to keep its location confidential, allowing only authorized people to know its address. Utilizing the risk management process, the jurisdiction's security team can address the requirements for protecting the RSS facility, including

- Developing access control policies and procedures and maintaining access control at the facility during an incident;
- Requiring all personnel to enter and exit the facility through a single entrance;

- Posting guards or law enforcement officers at each entrance to the facility and establishing a mechanism to check the identification of each person attempting to enter the facility, e.g., checking ID badges, sign-in logs, and visitor escorts;
- Establishing multiple routes for vehicle entry and exit;
- Establishing a perimeter of 300 to 1,000 feet around the RSS facility within which only authorized distribution and emergency vehicles are permitted;
- Maintaining a well-lit facility exterior;
- Securing doors leading into or out of the facility by posting a guard at, locking, and/or installing alarms on each door;
- Safeguarding delivery and distribution trucks while they are staged and being offloaded or loaded;
- Establishing crowd-control procedures that restrain or remove disorderly persons who try to disrupt RSS operations;
- Developing an evacuation plan for the facility; and
 - Considering the need for
 - Roving security patrols,
 - Static guard posts,
 - Roadblocks,
 - Perimeter fences,
 - Physical barriers of various types,
 - Vehicle gates, and
 - Closed-circuit surveillance television.

Distribution System Protection

The distribution system within the MCMDD preparedness plan will ensure that the proper medical assets are transported via trucks or other vehicles from the RSS to RDSes (if used) and PODs, hospitals, or treatment facilities, as required. Designated distribution vehicles should have ready access to and from the RSS to ensure timely delivery. In addition, security plans should include the measures to safeguard vehicles or distribution routes, including checking driver ID.

During a large-scale incident, it is likely the jurisdiction will experience traffic congestion. CDC recommends that security plans incorporate measures to ensure unimpeded movement of distribution vehicles throughout the affected area and that these measures are coordinated with the proper law enforcement/security agencies. Jurisdictions might consider

- Coordinating law enforcement escort of distribution vehicles to and from PODs and treatment centers;
- Securing key road networks so that only MCMDD and other emergency vehicles can use them; and
- Using alternative transport methods to support distribution, such as air, railroads, subways, and waterways, where applicable.

Writing the Security Plan and Site-specific Plans

Once the security team has been identified and risk assessments of specific MCMDD operations sites have been conducted, the team should work together to develop the

overall MCMDD security plan. Most jurisdictions will find that they can incorporate MCMDD security plans into the overall emergency management all-hazards plan and that the only task that falls to the security team is to develop site-specific plans. Regardless of whether the security plan is embedded in other jurisdictional plans or not, there should be an overarching security plan that outlines the basic policies and procedures and assigns tasks to various law enforcement or security agencies. In addition, for every site involved in the MCMDD response, including RSS, RDS, POD, and FMS sites, the security team should develop a specific plan that outlines

- Potential risk areas (e.g., access points to the facility);
- Analysis of the surrounding area (e.g., providing adequate onsite or nearby parking near high-flow streets or freeways);
- Specific physical security measures and measures to effectively safeguard personnel at the site;
- Security measures to mitigate risk (e.g., reducing the number of access points to the facility);
- Staff identification and ID badging policies and procedures;
- Facility layout;
- Procedures for managing disorderly persons or crowds, traffic into and out of the facility, and parking;
- Number of security-support team members needed per shift;
- Call-down rosters for identified security personnel (primary and back-up);
- Just-in-time training or incident-specific orientation materials for security team members;
- Communications resources and plans for security team members; and
- The site-specific security lead and security management structure (chain of command) at each facility.

Each site-specific plan should be accessible to the security lead for that site, who in turn is responsible for mobilizing the identified security personnel during an incident and securing the facility for operations when notified that an MCMDD response is underway or being considered. This may include assisting in evacuating or shutting down operations of a facility before it converts to an MCMDD response facility. For instance, the site security team may need to clear students, teachers, and other personnel from a school that will be used as a POD and then secure the entrances, exits, and materials storage areas.

Mobilizing the Security Support Team

Once the security resources have been identified and the various security teams have been developed, an essential part of the security support planning process is to develop the procedures necessary to get the right security team(s) to the right location(s) in a timely manner to support response operations. This is especially important for those identified as the first shift of the site-specific security teams. The activation and mobilization timeline will most likely be event-driven, but planners can anticipate having to provide sufficient security staff to support 24/7 operations at the RSS, PODs, and other locations.

Because the security team will likely come from various agencies and institutions, establishing rapid activation procedures may be a significant challenge; but as stated previously, these

challenges can be minimized or even overcome by selecting a strong security team leader and maintaining constant dialogue with the other agencies involved in developing the MCMDD security plans. Regardless of the procedures established to activate and mobilize the security support team, CDC highly recommends the activation and mobilization process be documented in the plan, updated continually, and exercised periodically. A lack of clarity within the security support team about which agencies to call for a specific security duty (escort, RSS security, crowd control, etc.) and to which shift to assign them could have a significant negative impact on MCMDD response operations and put many lives at risk. Additionally, law enforcement activities and response actions should be part of the just-in-time training staff members receive at the RSS or PODs. This will allow all personnel to be familiar with the role of law enforcement during the operation.

Security teams should use an ICS-based reporting structure. The security lead at the state level most likely will be located in the state's EOC. The RSS security lead and distribution security lead would both report to the state security lead, as would jurisdictional security leads. Information regarding security issues, changes in policy, etc., can be conveyed up from the local jurisdictions to the state and vice versa. Figure 11-1 demonstrates how this structure may look. Note that the RSS security lead could report directly to the state security lead or to the security lead in the local jurisdiction in which the RSS is located.

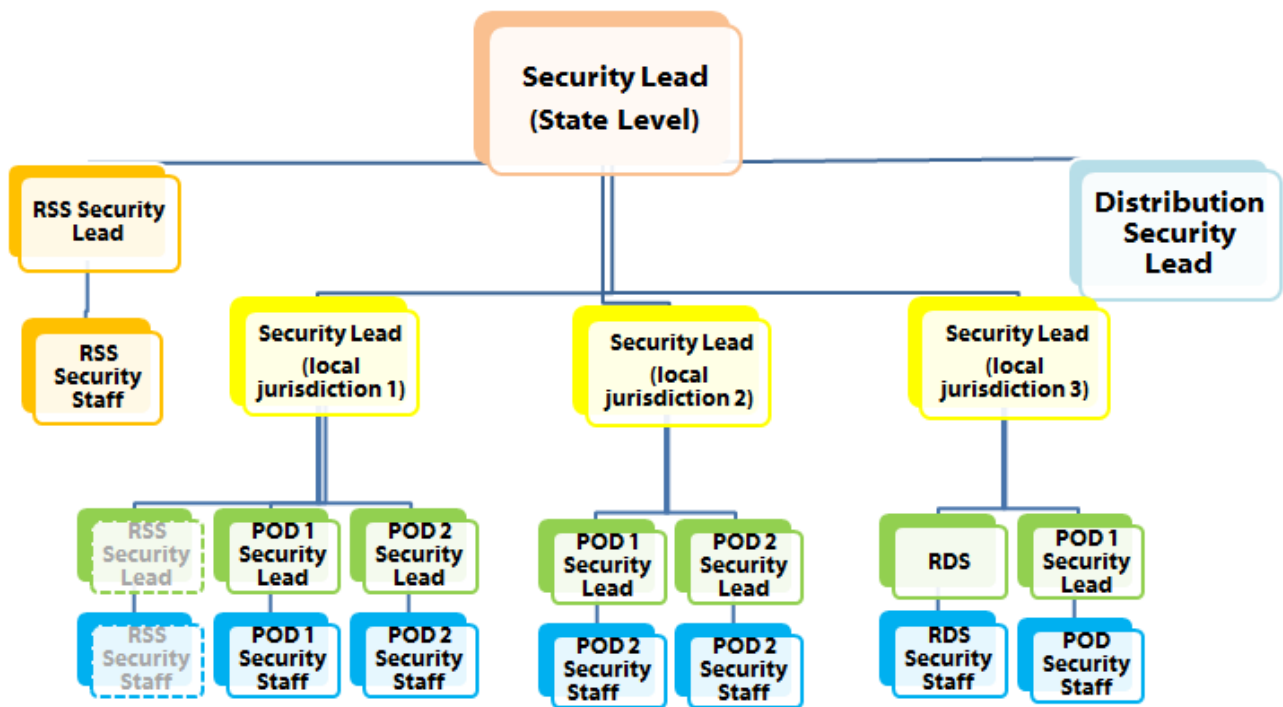


Figure 11-1: Possible reporting structure for security operations.

Chapter 12: Hospital and Treatment Center Coordination

A large-scale emergency or disaster can quickly overwhelm the resources of hospitals and treatment centers. During such incidents, normal supply chains may be interrupted or jurisdictions may not have the capacity to provide medical materials and supplies. In addition, should the jurisdiction need to provide medical countermeasures (MCMs) to hospitals and treatment centers, these facilities will require supplies of MCMs for their patients, staffs, and responders. Should hospitals and treatment centers be decimated or overwhelmed during an incident, the jurisdiction may need to set up alternate care facilities (ACFs) to take care of people who are injured and require supportive care and treatment. The jurisdiction's medical countermeasure distribution and dispensing (MCMDD) plan should include a plan to coordinate with and support the needs of hospitals, treatment centers, and ACFs during an incident.

Engaging Hospitals and Treatment Centers

The National Response Framework (NRF) guides national responses to all-hazards incidents and emphasizes a coordinated federal response requiring layers of mutually supporting capabilities. The NRF Emergency Support Function #8 – Public Health and Medical Services Annex (ESF #8) delegates responsibility to the Secretary of the Department of Health and Human Services (HHS) for response to incidents that require assistance to address medical needs during an incident that may include any or all of the following:

- Assessment of public health/medical needs
- Health surveillance
- Medical care personnel
- Health/medical/veterinary equipment and supplies
- Patient evacuation
- Patient care
- Safety and security of drugs, biologics, and medical devices
- Blood and blood products
- Food safety and security
- Agriculture safety and security
- All-hazard public health and medical consultation, technical assistance, and support
- Behavioral health care
- Public health and medical information
- Vector control

- Potable water/wastewater and solid waste disposal
- Mass fatality management, victim identification, and decontaminating remains
- Veterinary medical support

HHS' Office of the Assistance Secretary for Preparedness and Response (ASPR) plays a key role in ensuring healthcare preparedness through the Hospital Preparedness Program (HPP)¹ cooperative agreement, which provides funding and technical assistance to jurisdictions to prepare healthcare systems for disasters. HPP encourages hospitals and healthcare systems to partner with public health and other ESF #8 planners and responders. This partnership should enable hospitals and treatment centers to increase their capacity to respond to incidents that may result in mass casualties or a surge of people requiring medical care.

HPP provides a set of Healthcare Preparedness Capabilities² based on common Federal Emergency Management Agency (FEMA) preparedness methodologies and aligned with the Centers for Disease Control and Prevention (CDC)'s Public Health Preparedness Capabilities.³ Public health departments can link to healthcare systems through the jurisdiction's Healthcare Coalition, a multi-agency network of healthcare organizations and their partner agencies that collaborate for preparedness planning through the HPP. The Healthcare Coalition can assist public health planners in linking hospitals and treatment centers into the request process for medical supplies and coordination of facilities for medical surge capacity during a large-scale incident. Many of the partners from the jurisdiction's Healthcare Coalition are listed in Table 2.1 at the end of **Chapter 2: Developing a Medical Countermeasure Response Plan**.

Defining Treatment Centers and Alternate Care Facilities

While hospitals are the primary component of a healthcare delivery system, jurisdictions also may include many other healthcare providers, both as in-patient and out-patient facilities. In addition, should primary medical facilities become overwhelmed or incapacitated during an incident, patients may need to be treated in ad hoc facilities and jurisdictions should include plans for how communications will occur with these entities and how they will request medical supplies during an incident.

Treatment Centers

The jurisdiction's treatment centers could include free-standing clinics, skilled nursing facilities, renal dialysis centers, hospices, long-term care facilities, mental/behavioral health centers, urgent care centers, women's clinics, and other types of health delivery mechanisms. Treatment centers should be part of the jurisdiction's Healthcare Coalition and public health planners should include them in their request process to receive medical supplies from federal assets should it be required. Staff of the treatment centers should know the formal request process and whom to contact when they need additional medical supplies. In

¹ www.phe.gov/preparedness/planning/hpp/pages/default.aspx

² www.phe.gov/Preparedness/planning/hpp/reports/Documents/capabilities.pdf

³ www.cdc.gov/phpr/capabilities/index.htm

addition, staff from treatment centers can be called upon to assist in staffing ACFs or other facilities to assist with medical surge during a large-scale incident.

Alternate Care Facilities (ACFs)

During a large-scale incident, hospitals and treatment centers may be overwhelmed or become incapacitated. When this occurs, the jurisdiction may rely on alternate care facilities (ACFs), which are treatment centers set up to cover an overflow of patients from hospitals (medical surge) or to receive and treat those who are injured or ill as result of a large-scale incident. An ACF may be a site that is set up as an ad hoc hospital with Federal Medical Station (FMS) assets (see **Appendix A: Federal Medical Stations**) or sites set up with CHEMPACK (see **Appendix C: CHEMPACK**) or Diethylenetriamine pentaacetic acid (DTPA) (see **Appendix D: DTPA**) caches to treat victims of chemical or radiological contamination. While it is impossible to determine where an ACF might be needed, jurisdictions should be mindful of sites that could serve as ACFs during an incident. An ACF would need to have basic services, such as restrooms, electricity, and drinking water, but also may need to be large enough to house several hundred injured or ill patients. Such sites might be the same sites the jurisdiction has identified as possible points of dispensing (PODs) or emergency shelters. The jurisdiction is not required to document ACF sites in the MCMDD plan, but when the jurisdiction opens ACFs, these should be included in the request process and distribution network for MCMs and in the jurisdiction's strategic and tactical communications network. MCMDD planners should work with the jurisdiction's Healthcare Coalition to keep them informed of plans for requesting medical supplies, setting up ACFs, and communicating with the jurisdiction's emergency operations center during an incident.

Designating a Hospital and Treatment Center Coordinator

The jurisdiction should designate a hospital and treatment center coordinator (primary and back-up) to act as a liaison between the public health department and medical facilities within the jurisdiction. This person may be the jurisdiction's medical director, the Strategic National Stockpile (SNS) or Cities Readiness Initiative (CRI) coordinator, a public health nurse, or even a division or section of the public health department. The individual/s in this role must have a good working knowledge of the state's overall MCMDD response activities, a background in healthcare, familiarity with healthcare facilities within the jurisdiction, and the ability to foster and maintain relationships with healthcare facilities.

The hospital and treatment center coordinator should be involved in the jurisdiction's Healthcare Coalition and actively participate in planning with them on HPP's Healthcare Preparedness Capabilities. The hospital and treatment center coordinator can keep the Healthcare Coalition linked to the public health department and keep them involved in ESF #8 considerations of the jurisdiction's plans and annexes, including the MCMDD plan. The hospital and treatment center coordinator can serve as the health department's primary conduit to healthcare facilities and keep them apprised of plans related to emergency medical supplies, including MCMs. In addition, the hospital and treatment center coordinator will facilitate the request process and coordinate the distribution of medical supplies to hospitals and treatment centers, as well as identify sites and staffing pools for ACFs.

Developing the Hospital and Treatment Center Coordination Plan

Hospitals and treatment centers may have large requirements for a variety of medications, supplies, and medical equipment during an incident. Coordination must exist between incident command, the EOC, and the hospitals and treatment centers within the jurisdiction to procure emergency medical supplies as needed. Jurisdictions will need to develop a plan to coordinate with hospitals and treatment centers for requesting emergency medical supplies. In addition, public health planners will need to inform, train, and exercise with hospitals and treatment centers to assist them in understanding how all of the processes will work during an incident in which they may need additional emergency medical supplies from the local, state, or federal government. Public health planners should work with the jurisdiction's Healthcare Coalition to bring hospitals and treatment centers into the jurisdiction's communication, request, and distribution processes for emergency medical supplies. Hospitals and treatment centers need to have designated leads or operate under a hospital incident command system (HICS) and interact with the MCMDD operations team.

The Request Process

The jurisdiction should develop a defined process through which hospitals and treatment centers will request medical supplies should they face a shortage during a large-scale incident. The defined process should validate the hospital's or treatment center's request. In some cases, the jurisdiction may fill requests from hospitals and treatment centers with assets supplied from the federal level, including MCMs and medical supplies from the Strategic National Stockpile (SNS). Because of the need to track federal assets, the request process should include

- Who at the medical facility is designated to request emergency medical supplies;
- To whom the requestor directs their request (e.g., jurisdiction's EOC);
- The forms required for the facility to request emergency medical supplies;
- The approval process for requests for assistance; and
- Whom in the jurisdiction (e.g., hospital liaison, EOC, etc.) will contact the medical facility to inform them that their request has been approved, notify them that the supplies are being shipped, and provide an estimated delivery time for assets.

Designated Requestor

Each medical facility in the jurisdiction should inform the health department or ESF #8 lead of the person designated to place a request for emergency medical supplies. Ideally, the designated requestor will be a position rather than a name, such as the medical director or charge nurse on duty. By providing a designated position to serve as the requestor (rather than a specific name), the medical facility can ensure that the correct designator is identified regardless of staff turnover. In addition, the jurisdiction should train persons filling these positions and provide them with opportunities to participate in MCM exercises to assist them in understanding their roles during a response.

Request Forms and Processes

The jurisdiction should determine the best way for medical facilities to request emergency medical supplies during an incident. In some jurisdictions, this may be a simple phone call but other jurisdictions may determine that a formal process and forms are needed. The jurisdiction should develop any necessary forms medical facilities will use to request emergency medical supplies. These request forms should include basic information fields, such as

- Facility name;
- Facility address and phone number;
- Requestor name and title;
- Requestor phone number (preferably a cell phone or other direct line to the requestor or their designee);
- The title and contact information for the person who is designated to sign for controlled substances; and
- An inventory request list, which can simply be space in which the requestor can enter the items needed.

The hospital and treatment center coordinator should ensure that each hospital and treatment center is aware of the appropriate form to use, how that form should be forwarded (e.g., fax, electronically scanned, attached in an email, etc.), and to whom the form should be sent (e.g., fax number for the EOC or health department, email address, etc.). The form should also include contact information of the hospital and treatment center coordinator for the jurisdiction and emergency contact information (e.g., number for the jurisdiction's EOC) should the medical facility need to speak with someone regarding an urgent need.

Once the jurisdiction has determined a request process and developed a form, they should ensure that each hospital and treatment center has that information. Ideally, the jurisdiction will communicate the request process and forms through the jurisdiction's HPP Healthcare Coalition. In addition, the jurisdiction should train all hospital and treatment center partners on the request process and given an opportunity to ask questions and provide feedback on their experiences in using the process and forms. The jurisdiction also should include hospitals and treatment centers in MCM exercises to test the request process.

Chapter 4: Requesting SNS Assets provides further information on developing the jurisdiction's request process.

The Receipt Process

The jurisdiction should have a designated receipt process for medical supplies as part of the MCMDD response plan. The hospital and treatment center coordinator should ensure healthcare facilities are aware of the process for receiving emergency medical supplies. The jurisdiction may determine that healthcare facilities will use the same receipt process used by points of dispensing (PODs), which may include a designated signatory for receipt of medical assets and controlled substances.

Upon receipt, the hospital or treatment center should enter the medical supplies into their inventory management system. For medical assets that come from the federal level (e.g.,

SNS assets or other medical supplies), the healthcare facility will need to track this inventory carefully as they are not permitted to charge patients for these supplies.

Administration Fees

Emergency medical supplies provided by the federal government are free of charge to those who need them (e.g., patients). The hospital and treatment center coordinator will need to work closely with healthcare facilities to ensure that they use emergency medical supplies according to federal guidance. In some instances, a facility may need to charge a patient for administration, such as when the healthcare facility provides the syringe and needle and skilled nursing staff to administer a medication. However, if that medication came from the federal government (e.g., MCMs from the SNS) the facility cannot charge the patient the medication.

This can become increasingly problematic if the facility has a single charge for certain services. For instance, a facility's billing system may have a single charge for "intravenous (IV) administration" that includes all supplies (e.g., needle, IV tubing, 1,000 mL of 0.9% saline solution, healthcare provider time). However, if the facility runs low of medical supplies during a large-scale incident, they may receive federally supplied assets and they will not be able to use this billing charge if any of the supplies come from federal caches (e.g., the facility supplies the needle and IV tubing, but the 0.9% saline solution came from the SNS). Healthcare facilities may find it useful to keep all federally supplied assets in a separate storage area and clearly note these assets as federally supplied in their inventory management system (IMS) to ensure that they are not misallocated.

Administration Fees

Under federal guidance, healthcare facilities may be able to charge patients a fee for administering MCMs (e.g., for needles, syringes, or healthcare provider time), but they **cannot charge patients for any federally supplied medical assets or MCMs.**

Inventory Management

During an incident, hospitals and treatment centers must receive the proper resources in the quantities they need and in configurations they can manage. To account for all available MCMs in the healthcare system, each hospital and treatment center should have a system for tracking medical supplies from the time they are received at the facility until they are administered or dispensed to the people who need them. The facility's Inventory Management System (IMS) should be linked to the jurisdiction's IMS to assist planners in documenting the chain of custody of all assets used to respond to an emergency. This is especially important for providing a line of site for the jurisdiction on what supplies are available so they will know when they need to request additional medical supplies or reallocate supplies from one facility to another. In addition, the jurisdiction must recover certain SNS supplies, such as ventilators and refrigerated shipping containers, for return to the CDC. Tracking these items in the facilities' IMS will make it easier to locate recoverable items during demobilization of an incident response.

Chapter 6: Managing Medical Countermeasure Inventory provides further information on IMS.

The Written Plan

Once the jurisdiction has determined the request process and procedures for hospitals and treatment centers to coordinate with the public health department and ESF #8 partners, the jurisdiction should document this information in the MCMDD plan. The written plan should then include

- The process (perhaps in an algorithmic diagram) for hospitals and treatment centers to request emergency medical supplies;
- The forms used by hospitals and treatment centers to request emergency medical supplies;
- Any guidance hospitals and treatment centers may need for acquisition and use of federally supplied MCMs (including, pharmaceuticals, medical supplies, and medical equipment);
- A list of authorized requestors at hospitals and treatment centers and those authorized to sign for controlled substances;
- Training materials and exercise opportunities provided to hospitals and treatment centers on the request process;
- The jurisdiction's defined procedures for approval and allocation of requests for medical supplies;
- The specific delivery address at each facility (e.g., Building A, rear loading dock, helipad, south side, etc.) and alternate delivery sites;
- The designated communication pathways between hospitals, treatment centers, and ACFs and the jurisdiction's incident command or EOC; and
- The procedures and systems used to track inventory that the jurisdiction distributes to hospitals and treatment centers.

Chapter 7: Distributing Medical Countermeasures provides further information on developing the jurisdiction's distribution plans. **Chapter 10: Strategic and Tactical Communications** provides further information on developing communications pathways and systems.

Preparing for Medical Surge

During an incident, the jurisdiction may experience significant patient medical surge and the type of treatment required by the emergency or disaster can vary widely, depending on the type and scale of incident. Healthcare assets (including emergency rooms, operating rooms, intensive care units, surgical wards, isolation wards, diagnostic laboratories and equipment, and cardiac- and respiratory-assistance equipment) may be overwhelmed and the jurisdiction should develop strategies for managing these assets and the capabilities required to expand the existing healthcare system rapidly. Such strategies may include developing algorithms for triage and treatment and use of limited resources during an emergency response.

Working with healthcare facilities through the Healthcare Coalition, the jurisdiction should determine how to optimize hospital and treatment center floor space, staffing, and medical resources (drugs, bandages, whole blood, respirators, etc.) to support medical care during an emergency. In planning for the management of these resources, planners should work through the jurisdiction's Healthcare Coalition to determine the quantity and capabilities of

hospitals and treatment centers, their locations, and the estimated number and types of patients each can accommodate. The medical surge plan also should include how the jurisdiction will advise healthcare facilities on

- Deferring elective care;
- Discharging noncritical patients;
- Transferring noncritical patients from hospitals to step down facilities;
- Transferring noncritical patients from hospitals to ACFs; and
- Barring visitors who are not seeking treatment.

Public health will need to coordinate with hospitals and treatment centers to provide awareness of available assets within the jurisdiction and integration into the jurisdiction's plans for setting up and providing resources to ACFs, including plans for the types of patients that ACFs can accommodate. This coordination should assist to alleviate surge or enhance operations at affected healthcare organizations. Space and resource optimization, along with the stocking and staffing of ACFs during an emergency, will require significant planning and coordination by every agency and institution involved.

While documentation in the MCMDD plan is not required, medical surge plans should identify the types of facilities within the jurisdiction that would make suitable ACFs and how the jurisdiction may obtain access to those facilities if they are needed to serve as ACFs. The jurisdiction should develop an anticipated inventory list that includes cots and/or beds, wheelchairs and stretchers, IV poles, respiratory care services and equipment, and all the other types of medical supplies required in an ACF by those who may be ill or injured. Public health, emergency management, and the Healthcare Coalition should work closely to determine the best sites for ACFs, from where initial equipment and supplies may come, and how those supplies would be transported to an ACF. In addition to the identification of potential ACFs and medical equipment supplies, planning partners should identify personnel for staffing ACFs, including

- Medical staff to attend to patients;
- Security forces to maintain order and control traffic;
- Laborers to move large amounts of resources and supplies; and
- Volunteers to collect information from, organize, and inform patients seeking treatment.

Coordinating the Response with Hospitals and Treatment Centers

At the time of a large-scale response, coordination will be needed among the existing hospitals and treatment centers to accommodate the direction or redirection of patients to the most suitable facility; requesting medical supplies; allocating, reallocating, and distributing emergency medical supplies; identifying and directing staffing needs; managing medical supply inventory levels; and setting up ACFs.

Communication Pathways

The hospital and treatment center coordinator will need to maintain communication with hospitals, treatment centers, and ACFs (if activated); communicate their needs with the jurisdiction's MCMDD lead and its functional teams; and field requests of emergency medical

supplies. Hospitals, treatment centers, and ACFs should be linked to the incident command center or EOC through the jurisdiction's designated communication pathways and systems. The hospital and treatment center coordinator may need to provide the MCMDD lead with a periodic case-count of medical supplies inventory and available assets. In addition, the MCMDD may need to know any epidemiological, intelligence, or other information from hospitals, treatment centers, and ACFs to support decision-making.

The jurisdiction's hospital and treatment center coordinator should work with the strategic and tactical communication lead to ensure all hospitals and treatment centers have all the required communication pathways (phone numbers, radio frequencies, e-mail addresses, etc.) needed to maintain contact during the response. When the jurisdiction activates ACFs, the MCMDD strategic and tactical communication lead will need to maintain current information on the availability of phone, fax, radio, cell phone, e-mail, and paper forms at all ACFs.

Demobilizing Response Activities

During the demobilization of MCMDD operations, the hospital and treatment center coordinator should request inventory levels of federally supplied assets from all healthcare entities that received assets during the response. The jurisdiction's MCMDD response plan should include plans for how the jurisdiction will handle unused assets from federal caches, such as the SNS.

Planners should remember that once the state designee signs for SNS assets, the emergency medical supplies and MCMs remain property of the state. The state's plan for how to handle unused medical supplies and pharmaceuticals after an incident should include plans to determine inventory levels of federally supplied assets and how these should be handled following the incident. As mentioned, the state must return some items, such as ventilators and refrigerated shipping containers for vaccines, to CDC. Planners should work with their CDC contacts to determine how to properly store, maintain, and use federally supplied MCMs that remain in the state's possession after an incident.

However, it is important to note that MCMs distributed from the federal government for an emergency may come with restrictions on use. For instance, if the state receives antimicrobials from the SNS as prophylaxis in response to an anthrax attack, any SNS MCMs left in the state's holdings after the incident cannot be dispensed as treatments for other uses because those MCMs were deployed under an emergency use authorization (EUA).

Chapter 8: Dispensing Medical Countermeasures provides further information on EUAs and demobilizing MCMDD operations. Planners should work with CDC to determine how to return and properly use assets following an incident.

Resources

Grant support for state and local readiness planning related to public health emergencies can be found at www.grants.gov.

National Health Security Strategy

www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf

Public Health Preparedness Capabilities: National Standards for State and Local Planning

provides guidance for planning for mass care and developing medical surge capacity at www.cdc.gov/phpr/capabilities/DSLRCapabilities_July.pdf.

Staffing Resources

The **Medical Reserve Corps (MRC)** are community-based volunteer medical and public health professionals, such as physicians, nurses, pharmacists, dentists, veterinarians, and epidemiologists, who donate their time and expertise to prepare for and respond to emergencies and supplement existing emergency and public health resources. More information is available at www.medicalreservecorps.gov/HomePage.

Emergency Systems for Advance Registration of Volunteer Health Professionals (ESAR-VHP)

www.phe.gov/esarvhp

Triage and Shelter Resources

HHS and the American Red Cross provide an **Initial Intake and Assessment Tool** for use at shelters, www.acf.hhs.gov/ohsepr/snp/docs/disaster_shelter_initial_intake_tool.pdf.

CDC **Field Triage Decision Scheme** www.cdc.gov/fieldtriage/pdf/triage%20scheme-a.pdf

CDC **Shelter Assessment Tool** www.emergency.cdc.gov/shelterassessment/pdf/shelter-tool-form.pdf

Agency for Healthcare Research Quality

HHS' Agency for Healthcare Research Quality provides resources for disaster preparedness including mass care and sheltering at www.ahrq.gov.

Mass Medical Care with Scarce Resources: A Community Planning Guide

www.ahrq.gov/research/mce

Pediatric Terrorism and Disaster Preparedness

<http://archive.ahrq.gov/research/pedprep/pedchap1.htm>

National Hospital Available Beds for Emergencies and Disasters (HAvBED) System

<http://archive.ahrq.gov/prep/havbed>

Hospital Preparedness Program

HHS/ASPR's **Hospital Preparedness Program** provides leadership and funding through grants and cooperative agreements to assist jurisdictions to improve surge capacity and enhance community and hospital preparedness for public health emergencies at www.phe.gov/preparedness/planning/hpp, which also includes several resources for hospital and treatment center coordination and preparedness.

Hospital Preparedness Program Guidance FY10

www.phe.gov/preparedness/planning/hpp/Documents/fy10_hpp_guidance.pdf

Medical Surge Capacity and Capability: A Management System for Integrating Medical and Health Resources During Large-Scale Emergencies

www.phe.gov/preparedness/planning/mscc/handbook/pages/default.aspx

Medical Surge Capacity and Capability: The Healthcare Coalition in Emergency Response and Recovery

www.phe.gov/Preparedness/planning/mscc/healthcarecoalition/Pages/default.aspx

Chapter 13: Training, Exercising, and Evaluating Plans

Once the jurisdiction has developed all the components of its medical countermeasure distribution and dispensing (MCMDD) plan, it will be vital to train everyone on the MCMDD plan and determine whether the plan's components will function during an incident response. In order to ensure that everyone will know their roles and the required actions during MCMDD operations, the jurisdiction will need to develop a multi-year training, exercise, and evaluation (TEE) plan that supports the MCMDD planning effort; incorporates agencies, organizations, and individuals into TEE activities; and works on an incremental approach to training and exercising. Continuous testing and evaluation will ensure that everyone involved in MCMDD response is ready to achieve the goals of receiving, distributing, and dispensing MCMs during an incident.

Understanding Training, Exercise, and Evaluation Programs

In 2002, the National Strategy for Homeland Security directed the Department of Homeland Security (DHS) to establish a national exercise program. One of the objectives of this program is to maintain and expand existing collaborative management processes, support systems and integrate multi-year scheduling of major training and exercise activities at the national, state, and local levels. The Homeland Security Exercise and Evaluation Program (HSEEP)¹ recommends an incremental approach to exercises – beginning with discussion-based and working up to operation-based – that includes an overarching planning and training component. Figure 13-1 from HSEEP demonstrates this building block approach.

An effective TEE program uses a combination of exercise types coupled with training activities to accomplish specific objectives and goals. Although each exercise type can be executed as a single activity, HSEEP encourages multi-year plans to gradually build capabilities by employing a building-block approach of linked training and exercise activities that increase in complexity and intensity. As part of a broader preparedness cycle, developing an effective MCMDD TEE plan involves development of multi-year plans that complement the full range of the jurisdiction's preparedness efforts.

¹ https://hseep.dhs.gov/pages/1001_HSEEP7.aspx

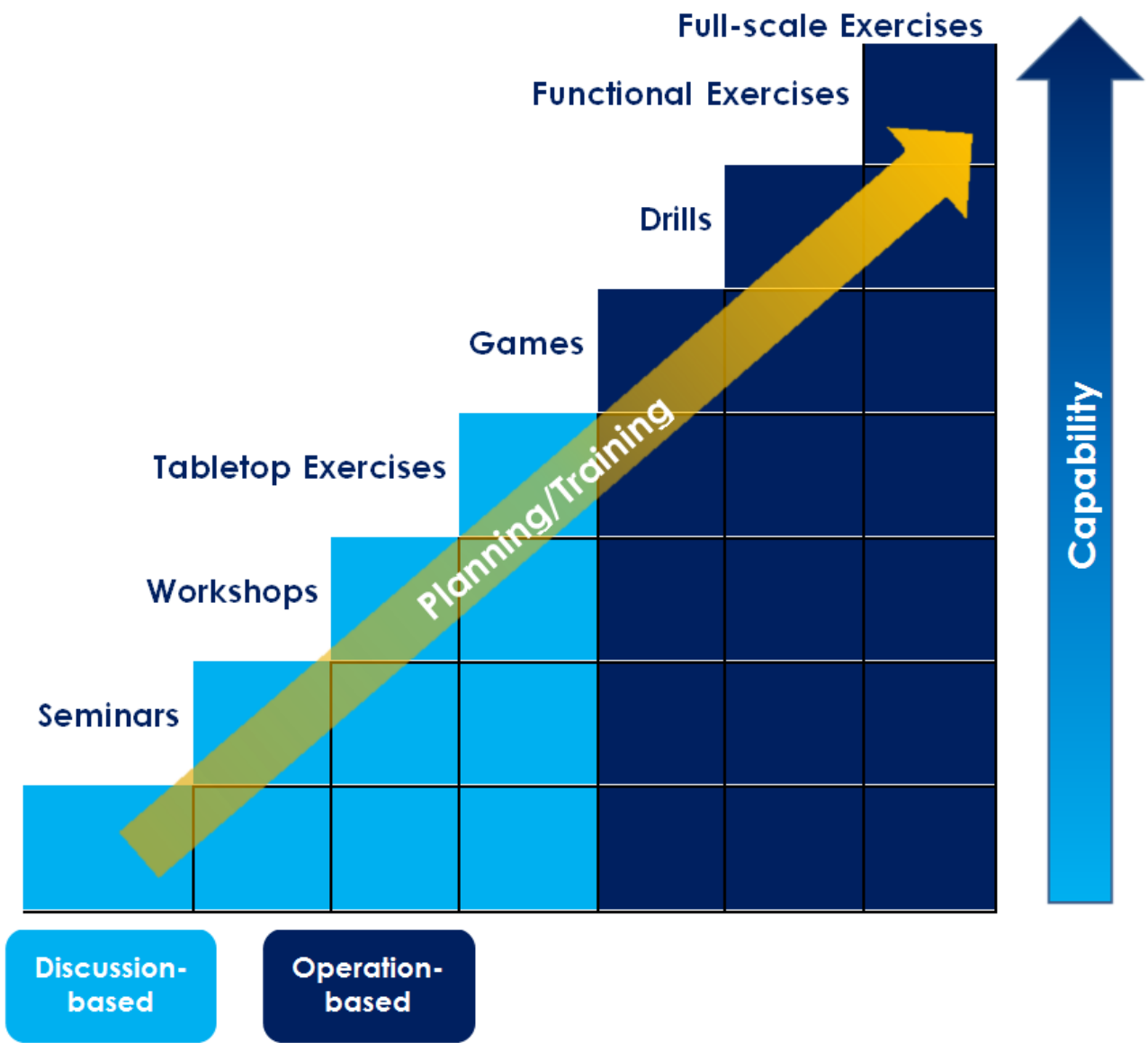


Figure 13-1: Building-block approach to training and exercise programs based on HSEEP.

Essentially, the jurisdiction should develop a logical, sequential, written TEE plan that

- Outlines initial and annual refresher training for those involved in MCMDD operations;
- Exercises the plan and people’s abilities to perform their roles in MCMDD operations; and
- Provides guidelines for evaluating drills and exercises to determine gaps in planning and assists in developing corrective action plans to fill those gaps.

In addition, the jurisdiction should have a multi-year TEE calendar that outlines when it offers TEE activities and opportunities, who should attend each activity, and how participants sign up to attend. The overall TEE plan also should include exercise evaluation plans that explain how the jurisdiction will document after action reports (AARs) and the plan for addressing those AARs.

Building the Training, Exercise, and Evaluation Team

In order to develop the multi-year TEE plan and calendar, HSEEP² recommends that jurisdictions conduct an annual training and exercise plan workshop (T&EPW). The T&EPW brings together all partner agencies to develop, review, and/or update the jurisdiction’s multi-year training and exercise plan. During the T&EPW, partner agencies can determine how the jurisdiction will execute its multi-year TEE plan during that year. The jurisdiction can use the T&EPW and the multi-year TEE plan to determine strategic goals and priorities, develop the goals and priorities into specific TEE activities, coordinate TEE activities, and address any scheduling conflicts between partner agencies’ TEE activities. In addition, the jurisdiction should integrate the TEE plan for MCMDD into its overall TEE plan. Multi-agency training and exercising will provide increased collaboration, as well as consolidate the multiple exercise requirements mandated by various organizations and funding streams. Communicating with the planners from each agency’s internal TEE program may present opportunities to capitalize on other’s expertise and may incorporate agency-required objectives, such as Public Health Emergency Preparedness (PHEP) cooperative agreement requirements, into planned or future events.

Many of the partner agencies listed in **Table 2.1 in Chapter 2: Developing the Medical Countermeasure Response Plan** can participate in the T&EPW and offer functions that will enhance the TEE plan. Ideally, the jurisdiction will have a lead agency for overall emergency management and jurisdiction-wide exercise scheduling, design, and implementation that will schedule and host the annual T&EPW.

The jurisdiction should identify one person or agency to lead MCMDD TEE planning and execution. Depending on the size of the jurisdiction, that person or agency might be the state or local health department, the Strategic National Stockpile (SNS) or Cities Readiness Initiative (CRI) coordinator, the emergency management agency, or another agency. In addition, the jurisdiction should identify a person, agency, or organization to head up each of the three components, i.e., training lead, exercise lead, and evaluation lead. In a small

² <https://hseep.dhs.gov/support/Volumel.pdf>

jurisdiction, one person may serve as the lead for all functions, but many jurisdictions will find it best to identify partner agencies to assist in these functions.

Depending on the level of the organization within a jurisdiction, a lead agency should be responsible for maintaining the multi-year TEE plan and calendar. The lead will be part of the T&EPW and work with partner agencies and organizations on the scheduling, design, and implementation of TEE plans.

Building the Training Program

The comprehensive MCMDD training program will require training people on the MCMDD plan, the functional areas of the plan, and their individual roles. The SNS coordinator or a training specialist who is involved in MCMDD operations may oversee the MCMDD training plan. In addition, the MCMDD training lead may delegate training on functional areas of MCMDD operations and individual roles to others who specialize in those areas.

Assess Training Needs

The jurisdiction will need to assess its training needs and MCMDD functional roles on a regular basis. Needs may be identified based on the staff's expertise or as a result of previous responses, training, or exercises. The jurisdiction can incorporate short- and long-term training goals into the multi-year TEE plan.

Additionally, the jurisdiction can request that new team members review any written plans that are relevant to their job duties. This could include public health emergency response plans, MCMDD plans, descriptions of essential functions, hospital preparedness program (HPP) plans, the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), state legislation and/or local ordinances and regulations, and any other relevant planning documentation. Through reviewing relevant written plans and documentation, new team members can gain an understanding of how the jurisdiction's plans work together or separately, which can help them develop their knowledge of the program.

In addition, the training lead should work with the SNS coordinator to develop a comprehensive MCMDD training plan that includes

- An orientation and training plan and a list of minimum course requirements for new MCMDD team members, employees, and staff members;
- A list of required coursework for each position in the MCMDD planning and response team;
- A timeframe for completing coursework and refresher training;
- Tiered levels of training (e.g., Tier I needs minimal training while Tier V needs more comprehensive training);
- Plans for annual refresher courses; and
- Cross training for inside and outside of public health and the jurisdiction.

Conduct Training

A comprehensive training program should build from the top down, providing an overview of the mission (e.g., providing MCMs to everyone in the community), working through functional areas of the mission (e.g., receipt, stage, store [RSS] or dispensing operations), and moving down into the individual roles.

A comprehensive training program may include any or all of the following:

- Orientation – overview of an MCMDD response
- Functional areas – specific pieces of the response, e.g., RSS or dispensing operations
- Skills/tasks – specific tasks within the functional area, e.g., picking inventory in an RSS or greeting clients at a point of dispensing (POD)
- IT/computer/equipment – training on use of tools required for tasks, e.g., two-way radios for communications, electronic inventory management systems, or pallet jacks for moving pallets of material in an RSS
- Individual roles within each functional area, e.g., greeter in the POD or forklift driver in an RSS
- Just-in-time training (JIT) plan for providing on-site training to spontaneous volunteers or refresher training for staff. JIT should include
 - Overview of operations;
 - Specific functions within the operation;
 - Reporting structure for various roles;
 - Specific roles in the functional area;
 - Steps for doing the role; and
 - Job action sheets that include key information.

MCMDD Orientation

An orientation on MCMDD operations is the broadest level of training in the jurisdiction and should be offered to everyone who needs to be aware of or could be involved in such a response, including

- Elected and appointed leaders;
- Emergency planners;
- Members of the incident command structure or command and control;
- Essential emergency response personnel, including first responders and personnel from the medical infrastructure (hospitals, health clinics, and professional associations);
- Other jurisdictional partners involved in key positions of executing the MCMDD plan (e.g., commercial distributors assisting in the distribution function, commercial warehouse partners assisting in RSS operations, or closed POD partners); and
- Public-information and/or health education specialists.

The MCMDD program orientation should provide participants with the broadest view of MCMDD operations and include briefings on

- Overall MCMDD operations;
- How the jurisdiction's MCMDD plan fits into the broader all-hazards or bioterrorism response plan;
- Why and when the community might require MCMs;
- How the jurisdiction will request, receive, distribute, and dispense MCMs;

- The types of MCMs, equipment, and technical assistance the jurisdiction might request; and
- How dispensing sites are planned and operated.

Functional-area Training

Functional-area training should orient functional MCMDD groups on their roles within MCMDD operations (e.g., RSS, distributing, or dispensing). Functional-area training should begin with an emphasis on the goal of the functional area (e.g., goal of RSS operations is to receive, inventory, and ship MCMs) and provide trainees with the process, flow, and expectations for the functional area. Once a functional group understands its role, training should bring all groups together so that they can understand how their functional areas work together.

Functional-area training should ensure that all team members understand

- The goal of their functional area;
- How their functional area supports overall MCMDD operations;
- Overall operations of their functional area (e.g., dispensing MCMs to the general public or distributing shipments of MCMs to dispensing sites)
- Timeframes for completing the tasks associated with their functional area (e.g., dispensing sites might need to provide MCMs to everyone in the community within 48-hours or the RSS might need to be open and operational within 6 hours of the jurisdiction's notification that MCMs will arrive);
- Where they will report during an MCMDD activation; and
- Any safety or security measures associated with the functional area (e.g., required safety devices in the RSS or security measures at a dispensing site).

Once individuals understand their functional area, they should receive training on their specific roles within the functional area and any associated tasks.

Task-specific Training

Task-specific training ensures that personnel understand their tasks and roles in a functional team. For many individuals (such as warehouse workers, transportation dispatchers, truck drivers, inventory managers, and pharmacists), their tasks in MCMDD operations will be the same as those they routinely perform. For others (such as volunteers or those whose MCMDD roles differ from their daily occupations), their tasks will be new to them and they will need specific training to assist them in performing their tasks. Everyone who is part of an area's MCMDD response will need to understand

- How their function integrates into the overall MCMDD operational plan;
- What their role is in the functional area;
- Their assigned tasks and how to perform them;
- What identification to bring when reporting for duty;
- How they will be notified to activate;
- Where and when to report for duty; and
- To whom they should report when they are activated.

In addition to providing task-specific training, the jurisdiction should ensure that personnel and volunteers know how to utilize any equipment, computer software, or IT tools needed to perform their tasks during a response.

IT, System, Equipment Training

Training for specific IT or computer systems or equipment should be part of regular trainings for functional areas. For instance, those who will be responsible for inventory management at the RSS should receive routine training on using the jurisdiction's inventory management system or the POD manager should receive training on how to use the jurisdiction's designated communications system for contacting the dispensing lead. The specific training will vary depending on the system or equipment used, however some basic elements will include

- An orientation on the equipment;
- Whom the user should contact if the equipment/system breaks;
- Where to pick up equipment, if necessary, when they respond; and
- How to operate the equipment or system.

This type of training should be offered for all IT, systems, and equipment the jurisdiction will use during a response, which may include

- Communications devices and systems;
- Client information forms at the POD;
- Pallet jacks and forklifts for RSS staff; and
- Computer software.

Just-in-time Training (JITT)

Information from the functional area operations/overview, task-specific, and equipment training should be captured in just-in-time training (JITT) materials for use during an activation. Because training and exercising of functional areas may occur during broad timeframes, MCMDD responders will need a refresher on their particular roles and a reorientation to the functional area in which they will participate during the response. In addition, volunteers and any new team members who respond during MCMDD operations will need information on how they can assist in the response. Key points of all training should be captured for quick refreshers for existing team members or orientation for volunteers. JITT should provide MCMDD response staff and volunteers with

- A brief overview of MCMDD operations;
- A brief overview of the role of their particular functional area in the overall MCMDD response;
- An orientation on the work location, facilities, equipment, and leadership;
- A safety and security brief that is specific to their functional area and the facility in which they are working;
- Information on how to use any required equipment, forms, or paperwork;
- Information on their specific role during the response;
- Information on how long their shift will last; and
- A job action sheet with key points for their particular role at the facility.

It is important to note that JITT should be an orientation session in which responders can ask questions and get important information. While a job action sheet is part of JITT, it cannot substitute for an overview of operations, even a very brief one.

Job Action Sheets

Job action sheets should capture and maintain important information for performing specific roles within a functional area. Job action sheets should be a quick reference for staff and volunteers and they should reiterate information responders receive in JITT, but not replace JITT. For example, the job action sheet for someone who will greet clients at the POD may include

- Incident-specific information,
- Information on the MCMs dispensed at the facility,
- Brief answers for any possible frequently asked questions clients may have,
- Information on how to direct clients from the entrance to the next step in the POD, and
- The name/position of the person the greeter should contact if they have questions or concerns during their shift in the POD.

Written Training Plan

The jurisdiction's written training plan should include information on tiered training levels and required coursework; the plans for MCMDD overview, functional-area, task-specific, IT/computer/equipment, and just-in-time training; plus any job action sheets for specific functional tasks. The jurisdiction should include the written training plan in its multi-year TEE plan and the training lead should track when training is offered, who attends, and who completes or needs to complete all required training for their response tier.

Building the Exercise Program

While training will bring the organizational staff and supporting partner agencies to a baseline level, the exercise program will test participant's abilities and understanding of their roles in MCMDD operations. The HSEEP methodology provides jurisdictions with guidance on developing a continuous exercise cycle of planning, exercising, and evaluating plans (see figure 13 -2). A progressive and integrated exercise program moves an organization towards better emergency preparedness by periodically assessing components of the plan, improving interagency coordination and collaboration, clarifying roles and responsibilities, enhancing individual performance, validating response and communication



Figure 13-2: HSEEP cycle of exercise planning and evaluation, from the Department of Homeland Security at https://hseep.dhs.gov/pages/1001_HSEEP7.aspx.

systems, and confirming resource availability. Each jurisdiction should develop a comprehensive exercise program designed to evaluate and improve operational readiness; determine areas for improvement; and identify gaps in knowledge, training, and resources. As the jurisdiction builds the knowledge base and expertise of its staff and responders, it will move from simple discussion-based exercises designed to familiarize everyone with MCMDD plans through more complex operations-based exercises designed to test their abilities to operationalize those plans.

Discussion-based Exercises

Jurisdictions can use discussion-based exercises, including seminars, workshops, tabletop exercises (TTXs), and games, as a starting point for building the exercise program. These types of exercises focus on existing plans, policies, interagency/inter-jurisdictional agreements, and procedures. Discussion-based exercises provide the opportunity for everyone involved in MCMDD response to become familiar with current or expected capabilities. Discussion-based exercises typically utilize a facilitator and/or presenter to lead the discussion and keep participants on track toward meeting exercise objectives.

Seminars provide participants with an overview of plans, policies, procedures, and protocols. Seminars are typically presenter-led informal discussions that walk participants through a description of events.

Workshops offer participants an opportunity to interact and work towards achieving a goal. Workshops focus on a specific issue with a clearly defined outcome or goal.

Tabletop Exercises (TTXs) should assess the validity of plans, policies, procedures, and protocols. TTXs provide participants with an opportunity to engage in group problem solving and are an effective method for developing interagency coordination and information sharing. For TTXs, personnel who will respond during an incident come together in an informal setting to discuss the actions they or their agencies would take during a specific hypothetical scenario. TTXs allow participants' the opportunity to clarify their understanding of concepts, identify strengths and weaknesses in their plans, and determine any changes that might be required in their planning.

Basic TTXs are facilitator-led activities that describe a scenario (e.g., large-scale disease outbreak) and allow participants to address problems based on their knowledge and skills. Participants discuss the problems as a group and the facilitator assists them in developing a summary of their resolutions. In advanced TTXs, the moderator or exercise controller also delivers pre-scripted messages during discussions that alter the original scenario. Participants discuss the issues raised by the simulated problems by applying appropriate plans and procedures.

Games simulate operations that participants would take during an actual situation. They often involve two or more teams; use rules, data, and procedures to depict a real-world incident; and allow participants to explore decision-making processes that affect the outcome of events in the game. Games can be computer-generated simulations or facilitator-led activities.

Operation-based Exercises

Jurisdictions can use operation-based exercises, such as drills, functional exercises, and full-scale exercises, to validate plans, policies, agreements, and procedures. Operation-based exercises provide the jurisdiction with an opportunity to clarify roles and responsibilities, identify gaps in resources, and improve individual and team performance. These exercises are characterized by actual reaction to simulated situations and information; response to emergency conditions; and mobilization of equipment, resources, and personnel, usually over an extended period of time.

Drills allow an agency or organization to validate a specific operation or function (e.g., dispensing in a POD or RSS operations). Drills can be used to provide training on new equipment, develop or validate new policies or procedures, or practice and maintain current skills. Drills give participants an opportunity to practice any skills they have in a controlled environment and to receive feedback on their performance.

Functional exercises provide the opportunity for agencies within the jurisdiction to validate and evaluate their capabilities in one or more functions (e.g., RSS, inventory management, and distribution functions). Functional exercises use a scripted scenario and incident updates to drive activity and simulate the operations in a function by introducing realistic problems for participants to work through.

Full-scale exercises (FSEs) provide the opportunity for multiple agencies, jurisdictions, and organizations to exercise together to test all the functional areas of the MCMDD plan. FSEs allow participants to experience MCMDD operations through a scripted exercise scenario in real time, with problems inserted by the exercise designer. The idea behind FSEs is to create a stressful, time-constrained environment that closely mirrors actual operations.

MCMDD-related Drills

The jurisdiction can conduct drills that apply to various capabilities, a wide range of agencies, and a variety of MCMDD functions. Drills generally test one functional area of an MCMDD response and may be run as stand-alone assessments or be combined with other planned exercises. Drills provide an opportunity to test important operational capabilities without imposing heavy burdens on the jurisdiction. Small-scale drills also are less likely to overwhelm the jurisdiction's MCMDD operational improvement efforts, thus increasing the likelihood that the assessments will be useful for internal as well as external accountability purposes.

Call-down: The staff call-down drill tests the validity of jurisdictions' emergency personnel lists and their ability to contact staff in a timely manner. This drill also estimates the percentage of staff who could report for duty within a designated timeframe.

Site Activation: The site activation drill tests jurisdictions' ability to quickly contact operators/owners of sites that would house critical facilities (e.g., RSS warehouses, PODs, EOCs) and determine how quickly the sites could be made ready for emergency operations. Site activation is a crosscutting capability, applicable to multiple functions in an MCMDD response, such as dispensing (POD), warehousing (RSS) and command centers (EOC).

Facility Set-up: The goal of a set-up drill is to test the amount of time it takes to completely set up a facility with the material, layout, and supplies necessary to perform a given MCMDD function. Facility setup is applicable to a wide variety of MCMDD functions, including dispensing (POD), warehousing (RSS), and command and control (EOC) among others. Proper setup is an important precondition of a rapid and effective response.

Pick List Generation: The pick list generation drill is designed to assess jurisdictions' proficiency in generating pick lists for distribution of MCMs from the RSS. These lists translate command-level decisions about allocation of MCMs among dispensing sites into detailed guidance about the specific quantities of MCMs distributed to each site.

Dispensing throughput: This drill assesses the speed and accuracy with which local jurisdictions can dispense MCMs in a POD setting. The purpose is to measure dispensing throughput, as well as collect data on client flow time and processing times at each step.

Exercise Design, Development, and Execution

The T&EPW and the exercise lead should work together to design, develop, and execute exercises by identifying capabilities, tasks, and objectives for the exercise and determining a scenario through which participants will work. Exercise planners should begin with the desired end-state in mind in order to focus the exercise and evaluation process on the capabilities of greatest interest. While exercises in the jurisdiction may not be specifically focused on MCMDD operations, several relevant MCMDD functions cross over into other emergency response activities and activating those areas during other all-hazards exercises may offer an opportunity for staff to participate in additional drills and exercises.

Exercise Capabilities and Tasks

Capabilities, tasks, and objectives are the foundation of any exercise and should be used to drive the exercise design and development. The goal of exercise evaluation is to validate that plans are operational through the performance of identified capabilities and tasks. The exercise planning team should determine which capabilities they wish to evaluate and identify specific tasks associated with each capability. These tasks form the basis for actions participants should perform during the exercise in order to validate the capability. The exercise planning team can select capabilities and tasks to formulate exercise objectives that reflect the jurisdiction's specific needs, environment, plans, and procedures.

Exercise Objectives

Planners should establish specific objectives for each exercise, whether discussion- or function-based. Objectives will define the context for scenario development, assist planners in developing exercise evaluation criteria, and align participants' actions by focusing their responses on exercise priorities and goals. HSEEP advocates the use of SMART objectives, which are those that are

- Simple,
- Measurable,
- Achievable,
- Realistic, and

- Task-oriented.

Exercise planners should limit the number of exercise objectives to enable timely execution and to facilitate design of a realistic scenario.

Exercise Scenarios

The exercise scenario is the storyline that prompts participants' actions during an exercise. Once exercise planners have determined the capabilities, tasks, and objectives for an exercise, they should select a type of threat/hazard (e.g., biological, chemical, explosive, natural disaster) that will realistically stress participants' or agencies' resources and serve as the basis of the exercise. Once planners have defined the hazard, they should determine the venue (i.e., facility or site) in which exercise play will take place. The venue should be appropriate for the selected hazard and provide participants with a realistic, exercise-based simulation of the hazard. For instance, the jurisdiction could stage a POD exercise at an actual, pre-identified POD site or an RSS exercise could take place at the jurisdiction's designated RSS facility.

Developing the Evaluation Program

The jurisdiction should design an exercise evaluation program that validates strengths and identifies opportunities to advance its response capabilities. HSEEP *Volume III: Exercise Evaluation and Improvement Planning*³ outlines the exercise evaluation process in four steps

1. Plan and organize the evaluation
2. Observe the exercise and collect data
3. Analyze data
4. Develop the draft after action report/improvement plan (AAR/IP)

The exercise planning committee should develop an evaluation plan (EvalPlan) that describes what the jurisdiction will evaluate, what criteria it will use to measure performance, and how it will collect data. For operational exercises, planners can use the HSEEP Exercise Evaluation Guide (EEG)⁴ to identify existing EEGs, e.g., "1283 Mass Prophylaxis Ops Based EEG Template." The HSEEP website also offers the EEG Builder,⁵ a tool for developing standardized evaluation instruments. In addition, the DHS' Lessons-Learned and Information Sharing (LLIS) website⁶ provides useful EEGs. The criteria and process will vary between discussion- and operation-based exercises, but planners can improve the evaluation process by conducting a briefing between the exercise controller and the exercise evaluators prior to the exercise and developing a comprehensive EvalPlan for evaluators to follow when collecting data during exercise play.

³ <https://hseep.dhs.gov/support/Volumelll.pdf>

⁴ <https://hseep.dhs.gov/eegb/standalone.aspx>

⁵ <https://hseep.dhs.gov/eegb/standalone.aspx>

⁶ <https://www.llis.dhs.gov/index.do>

Exercise Data Collection

The type of data collected will vary depending on the type of exercise. Evaluators might note observations on the EEG or collect data on specific actions, such as throughput data collected as part of a time-motion study for a POD exercise. Planners also should consult exercise participants to see where roadblocks or lack of appropriate training may have hindered completion of tasks. Exercise facilitators should conduct an informal discussion, known as a hot wash, with participants and evaluators as soon as possible after the exercise. During the hot wash, the exercise facilitator should collect group comments and provide participants with feedback forms on which they can comment on their experiences during the exercise. In addition, the exercise planners can hold a formal meeting with exercise evaluators, facilitators, and controllers to debrief on their observations and recommendations for improvements.

Data Evaluation

The exercise planning team should review and analyze data collected from the hot wash, debrief, participant feedback forms, and EEGs, and compare exercise results with the jurisdiction's plans and the intended outcome of the exercise. The team should use this data to develop the AAR/IP, which will vary in detail depending on the type and scope of the exercise. The AAR/IP and exercise data become part of the process for developing the corrective action plan (CAP). The draft AAR should be sent to the members of the exercise planning committee and any participating agency representatives.

Improvement Planning

Improvement planning is the process by which planners develop definitive corrective actions based on the observations and recommendations recorded in the AAR. Within 30 days of the exercise, the planning committee and participating agency representatives should meet to discuss the draft AAR/IP. During this meeting, the exercise planning committee and others can correct inaccuracies in the AAR/IP, determine which agency is responsible for corrective actions, offer alternative corrective actions, develop timelines for completing corrective actions, and validate the final AAR/IP. The T&EPW can assist in prioritizing and tracking corrective actions to completion as part of a continuous corrective action program. The corrective actions recommended may include such items as conducting training for all or part of an agency or jurisdiction, purchasing equipment, developing additional planning documents or operational guides, or refining procedures to insure clarity.

Corrective Action Plan (CAP)

The corrective action plan (CAP) is a tool that can assist the jurisdiction in developing a thorough, continuous training and exercise planning process. The CAP provides a single site in which to accumulate corrective actions from many exercises and incidents and enables consistent tracking of corrective actions to completion. The TEE program manager should review the CAP periodically to track the progress of corrective action items, send reminders to action item owners, develop planning or training products, and plan the purchase of equipment and supplies identified for procurement. In addition, the CAP provides a definitive

site to collect objective exercise data that can inform exercise planning and facilitate updating the multi-year training and exercise plan.

The TEE lead should transfer corrective actions listed on each exercise AAR/IP to the agency/jurisdiction CAP but each organization also should track these. A CAP can simply be a loose collection of corrective actions copied from the agency/jurisdiction’s exercises into a single document or it can be entered into a calendar to help track due dates for corrective actions. A simple spreadsheet or database used as the CAP allows viewers to search recurrent or related issues that might not be apparent in other formats. The CAP also can incorporate fields for “key phrases” or “codes” that enable “sorting” the corrective actions into related groupings. Figure 13-3 provides a sample CAP with key phrase fields.

Exercise	Date	Key Phrase 1	Key Phrase 2	Recommended /Observed Problem	Corrective Action Plan	Primary Responsibility/ POC	Start Date	Completion Date
Jun EOC Refresher	Jun-12	Tactical Communications	EOC	Increase awareness and knowledge of redundant tactical communications systems				
Jun EOC Refresher	Jun-12	Procedures	EOC	Develop SOPs for all EOC sections and units				
Jun EOC Refresher	Jun-12	Training	EOC	Review ICS structure for EOC				
Jun EOC Refresher	Jun-12	Training	EOC	Plan specific training for EOC sections				
Jun EOC Refresher	Jun-12	Plans	EOC	Develop tactical communications plans that emphasize redundant systems				

Figure 13-3: Sample corrective action plan with “key phrase” fields.

As corrective actions are completed, the T&EPW can tailor subsequent exercise evaluations to re-evaluate the skill, task, or function and validate whether the corrective action was successful. Completed corrective actions that fail to yield the expected result should be closely scrutinized to ensure quality improvement of the agency’s or jurisdiction’s process. The CAP system will help the jurisdiction track improvement for established benchmarks or goals. The jurisdiction should see a consistent trend of progress toward implementation of the improvement actions listed in the AAR/IP. Once participating organizations have had time to implement post-exercise corrective actions, a new cycle of exercise activities can begin to test and improve further capabilities.

Multi-year Training and Exercise Calendar

The state should keep a calendar of planned exercises in which MCMDD planners and responders may participate. The multi-year training and exercise calendar outlines all of the jurisdiction's exercise and training opportunities and provides a single location to view any training and exercise opportunities occurring in the jurisdiction. Figure 13-4 provides a sample jurisdictional multi-year training and exercise calendar. The multi-year training and exercise calendar should include

- Exercise or training name or topic (e.g., MCMDD overview webinar, Crystal River reactor meltdown exercise, or Palma County POD drill);
- Exercise or training dates;
- Point of contact and their contact information, which could be an agency, organization and/or individual involved in developing or hosting the exercise;
- Scope, which represents the level of the exercise participants from government or private sector involved exercise play, including local, regional, state, international, federal, private sector, intrastate, and nongovernmental/volunteer organization;
- Which capabilities will be exercised;
- Any previous related exercises and dates (e.g., a previous drill related to the listed exercise or the first phase of a multi-phase exercise);
- Which Public Health Emergency Preparedness (PHEP) cooperative agreement or Healthcare Preparedness Program (HPP) requirements the exercise fulfills;
- The exercise sponsor (e.g., state emergency management agency, local hospital, etc.);
- The exercise objectives based on the target capabilities and associated tasks; and
- Any planning meetings for the exercise and the dates those will take place, which can include any or all of the following, depending on the level of the exercise:
 - Initial planning meeting
 - Concepts and objective development meeting
 - Master scenario meeting
 - Mid-term planning meeting
 - Final planning meeting
 - After action conference

Jurisdiction Agency Division Unit Name	Jurisdiction Training and Exercise Calendar Year 2 2013 - 2014											
	1 st Quarter			2 nd Quarter			3 rd Quarter			4 th Quarter		
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
State EM		EOC Planning committee		EOC Refresher Training		MCM Disp. TTX	Inter-operable Comms Drill	T&EPW	Plague FSE		EOC emergency notification seminar	
County	Communities Prepared and Aware Campaign	ICS 400						ICS 400	Plague FSE			MCM Disp Drill
CRI MSA			Call down drill		Volunteer Recruitment				Plague FSE			
State/Local PH Dept.			MCM RSS drill						Plague FSE		Webinar	Unknown agent TTX
PH Labs		Webinar		Training	Webinar			Webinar	Plague FSE	LRN Cert		
Epi			Multistate outbreak investigation seminar	Training			Annual epi workgroup meeting		Plague FSE		Webinar	
PHEP		Call-down drill			Call-down drill	MCM Disp TTX	Inter-operable Comms Drill	Call-down drill	Plague FSE		Call-down drill	
University Hospital			Webinar				Med Surge Drill		Plague FSE		Webinar	
CERT/MRC							FMS Training		Plague FSE		Webinar	
State University	Communities Prepared and Aware Campaign	Health fair	Volunteer Recruitment						Plague FSE			MCM Disp Drill

Priority 1 – Community Preparedness	
Priority 2 – Medical Surge Capacity	
Priority 3 – Communications	
Priority 4 – Emergency Ops Coord	
PHEP Capability 12 – PH Lab Testing	
PHEP Capability 7 – Mass care	
PHEP Capability 9 MCMDD	
Year 2014 Grant Requirement	

Figure 13-4: Sample multi-year training, exercise, and evaluation calendar

Example

State Multi-year Training and Exercise Plan

The state develops a multi-year training and exercise schedule that calls for a full-scale exercise (FSE) to validate their capability to conduct MCMDD operations. After the state SNS coordinator develops the MCMDD plan, the state's training and exercise planning workgroup (T&EPW) meets in January 2010 and works with the TEE lead to schedule a series of MCMDD-related exercises, leading up to an FSE. The first exercise, in March 2010, is a seminar delivered to senior officials from the governor's office, cabinet members, department heads, and local community leaders from designated dispensing sites. The seminar provides an overview of MCMDD operations and how all the functional areas work together. In June 2010, the TEE lead conducts a tabletop exercise (TTX) with key players in the MCMDD plan. The TEE lead then provides the SNS coordinator with the exercise After Action Report/Improvement Plan (AAR/IP). The SNS coordinator then refines the MCMDD plans based on the AAR/IP and in September, the training lead provides key agencies instruction on the updated plans. Using the updated plans, various agencies with specific MCMDD functions then perform a series of drills between October and December 2010. The SNS coordinator then takes the AAR/IP from those drills and refines the plan further. In January 2011, the T&EPW meets again and plans for a state-wide MCMDD FSE in August 2011 that incorporates participants from all levels of government and includes

- Activation of state, regional, and local emergency operations centers (EOCs);
- Delivery of MCMs to the receipt, stage, store (RSS) site;
- Distribution of MCMs to dispensing sites (PODs, alternate dispensing partners, closed PODs, and treatment centers); and
- Dispensing to recipients, who would then be processed and tracked by healthcare personnel.

At each step in the process, the SNS coordinator, TEE lead, and partner agencies and organizations incorporate and share lessons learned through AARs and IPs that are catalogued in each of their corrective action plans (CAPs) as well as the overall state CAP.

Benchmarks for Drills and Exercises

Preparedness drills and exercises underscore how much progress the United States has made in a short time, particularly, with how the nation moves emergency MCMs into many communities simultaneously. The PHEP cooperative agreement includes requirements mandated by the Pandemic and All Hazards Preparedness Act (PAHPA) of 2006. PHEP cooperative agreement requirements for drills and exercises differ slightly from one budget period to the next. Jurisdictions should refer to the CDC PHEP website⁷ for current CDC PHEP cooperative agreement requirements.

Coordinate Exercise Resources

The jurisdiction's T&EPW may include representatives from the entire spectrum of an exercise program's stakeholders, such as law enforcement, public health and medical community,

⁷ www.bt.cdc.gov/cdcpreparedness/coopagreement/index.asp

and emergency management. The various agencies and organizations involved in the T&EPW may receive funds from a number of different programs (federal, state, local, or private sector), which all have associated exercise requirements. For instance, the Chemical Stockpile Emergency Preparedness Program (CSEPP) and Radiological Emergency Preparedness (REP) program have exercise requirements that are mandated by public law, various U.S. Army regulations, and/or Nuclear Regulatory Commission (NRC) regulations. Jurisdictions can maximize their efforts by coordinating the organizations' (e.g., law enforcement, health departments, citizen groups, transit agencies, power plants) exercises in order to meet requirements from various funding streams. By developing a coordinated and integrated exercise program, organizations and agencies can avoid duplicating efforts and reduce the burden of conducting multiple exercises. In addition, the National Preparedness Goal identifies expanded regional collaboration as a national priority and each jurisdiction should strive to include neighboring jurisdictions in their T&EPWs to create multi-functional, multi-disciplinary exercises that involve cooperation of numerous jurisdictions. All PHEP awardees should submit state public health exercise schedules, which CDC will use to create a national calendar of public health exercises on the CDC DSLR secure channel of the LLIS.gov system and NEXS.

By planning a comprehensive jurisdiction-wide program, all partner agencies may be able to meet their TEE needs through a single coordinated schedule. In addition, jurisdictions can partner with neighboring jurisdictions to jointly exercise their response plans and determine gaps between jurisdictional plans. While planning a full-scale MCMDD exercise may be impractical, partnering with other agencies to participate in their exercises can be useful in testing some of the vital MCMDD functions. For example, if the emergency management agency holds an earthquake exercise, while not specifically focused on MCMDD operations, the jurisdiction could test some MCMDD functions, such as public information and communications, strategic and tactical communications, or distribution.

Resources

Public Health Emergency Exercise Toolkit: Planning, Designing, Conducting, and Evaluating Local Public Health Emergency Exercises from the Columbia University School of Nursing includes templates, checklists, and forms to assist with every stage of the exercise process. Available online at <http://www.nycepce.org/Documents/PHEmergencyExerciseToolkit.pdf>.

Homeland Security Exercise and Evaluation Program (HSEEP)

HSEEP Toolkit is an interactive, on-line system for exercise scheduling, design, development, conduct, evaluation, and improvement and corrective action planning https://hseep.dhs.gov/pages/1001_Toolk.aspx.

Training and Exercise Planning Workshop Handbook

[https://hseep.dhs.gov/support/TEPW_Users_Handbook_\(V30\).pdf](https://hseep.dhs.gov/support/TEPW_Users_Handbook_(V30).pdf).

HSEEP Exercise Evaluation Guides (EEGs) can assist jurisdictions with their exercise evaluation programs by providing evaluators with consistent standards and guidelines for observation, data collection and analysis, and report writing. Using the EEGs, jurisdictions can develop

stronger and more consistent After Action Report/Improvement Plans (AAR/IPs). EEGs provide exercise evaluators with a manageable tool for collecting data during an exercise and formatting it for use in the AAR/IP. Available online at <https://hseep.dhs.gov/eegb/standalone.aspx>.

Federal Emergency Management Agency (FEMA)

The **FEMA National Preparedness** provides further information on preparedness at www.fema.gov/prepared.

FEMA offers an **online catalog of coursework** at www.training.fema.gov.

Lessons Learned and Information Sharing (LLIS) is a Department of Homeland Security/Federal Emergency Management Agency program that serves as the national, online network of lessons learned, best practices, and innovative ideas for the emergency management and homeland security communities. LLIS is available online at <https://www.llis.dhs.gov/index.do>.

Incident Command System (*online and classroom*)

- Incident Command System (ICS) 100 Training: Provides training on and resources for personnel who require a basic understanding of the Incident Command System (ICS).
- Incident Command System (ICS) 200 Training: Provides training on and resources for personnel who are likely to assume a supervisory position within the Incident Command System (ICS). The primary target audiences are response personnel at the supervisory level.
- Incident Command System (ICS) 300 Training: Intermediate ICS for Expanding Incidents. Target audiences are those personnel involved in the incident in a command role.
- Incident Command System (ICS) 400 Training: Advanced ICS Command and General Staff—Complex Incidents. Individuals involved in supervising several staff and may be in a command position.

National Response Framework (NRF) Training

- Introduction to the National Incident Management System (NIMS) (IS-700): Provides training on and resources for the National Incident Management System (NIMS). NIMS provide a consistent nationwide template to enable all government, private sector, and nongovernmental organizations to work together during domestic incidents.
- Introduction to National Response Plan (NRP) (IS-800): Provides training on and resources for the National Response Plan (NRP). The NRP specifies how the resources of the Federal Government will work in concert with State, local, and tribal governments and the private sector to respond to Incidents of National Significance. The NRP is predicated on the National Incident Management System, or NIMS. Together the NRP and the NIMS provide a nationwide framework for working cooperatively to prevent or respond to threats and incidents regardless of cause, size, or complexity
- HSEEP overviews or actual completion of training, as appropriate (classroom)

Available online at

http://training.fema.gov/EMIWeb/IS/ICSResource/ICSResCntr_Training.htm

National Association of County and City Health Officials (NACCHO)

Preparedness Toolbox www.naccho.org/toolbox.

CDC-designed Simulation Drills

CDC designed a series of drills that simulate real-life MCMDD operations and incorporate scenarios and decisions that may occur during an MCMDD response. These simulation drills can be used by the jurisdiction to generate observations, lessons learned, and areas for improvement.

The **Decision-Making Tool** is a paper-and-pencil tool that focuses on the quality of decision-making processes, including developing situational awareness, planning specific actions, and using process controls. This tool requires deliberation among two or more individuals and is best played in groups.

The **RSS-POD Supply Chain Management Game** is made up of five modules to test distribution and resource allocation during an MCMDD response. The first three modules can be played with individuals or in a group and allow players to practice managing inventory and distribution under a variety of scenarios, including those in which the player has

- No information available about inventory levels at the PODs;
- Known inventory levels from the PODs; or
- A mathematical algorithm to help make distribution decisions.

Modules 4 and 5 of the **RSS-POD Supply Chain Management Game** focus on testing resource allocation during MCMDD operations. Unlike Modules 1-3, these modules are best played in small groups of two – five individuals. The group plays the role of the jurisdiction's POD manager in order to address

- Which PODs to open during staffing shortages; and
- How to allocate and dispense inventory when shipment delays cause a temporary inventory shortage.

CDC Courses

Preparedness – Office of Public Health Preparedness and Response

www.bt.cdc.gov/cdcpreparedness

Public Health Training Network www.2a.cdc.gov/phtn

Association of State and Territorial Health Officials

Preparedness Programs www.astho.org/programs/preparedness

Planners should develop the habit of regularly checking information sharing websites, such as the Department of Homeland Security's Lessons Learned Information Sharing (LLIS) and the National Association of County and City Health Officials "Tool Box," to increase their

knowledge and gain insight into the practice of the CAP. Most of the sites referenced require a simple registration process before users are allowed to conduct key word searches or post information, but the time saved can easily be worth the effort. More often than not, corrective actions that seem daunting, if not insurmountable, have been encountered elsewhere. Rather than “re-inventing the wheel,” planners are well advised to first invest time researching how others have applied creative problem solving solutions.

CDC Training and Exercise Support

CDC has devoted considerable time and effort to developing training material and technical assistance staff. Local and regional planners should contact their state SNS planners to learn about the material that the state or CDC can make available. A state planner should contact his or her state’s CDC project officer (located in the Division of State and Local Readiness [DSLRL]) to learn about the latest training and exercise material.

CDC Training

CDC’s Division of Strategic National Stockpile (DSNS) offers a variety of training tools to assist planners in their training efforts. Such tools include videos, hands-on training material, and classroom instruction. Regional and local planners can contact their state SNS Coordinator for information on training and training materials. State SNS coordinators should contact their DSLR project officer for updated information and scheduling of new training material and efforts developed by DSNS. Training offered by the DSNS includes:

- SNS Preparedness Course
- Mass Antibiotic Dispensing Course
- Mass Antibiotic Dispensing Train-the-trainer course
- Receive, Store, Stage (RSS) Course
- Public Information and Communication Course

Information on these courses and other training resources is available on the SNS Extranet site at <https://www.orau.gov/snsnet/conferences.htm#DSNSTraining>. The SNS Extranet is password protected. Planners should contact their state SNS coordinator or CDC DSLR project officer to obtain the login information.

Accessing Training Tools

Many SNS-related training resources are available on the SNS Extranet at <https://www.orau.gov/snsnet/>. If jurisdictions determine that an existing SNS course meets their training needs, they should take the following steps to coordinate the training:

- If the request comes from any jurisdiction lower than state, the requestor must contact the state’s SNS coordinator.
- The state coordinator will determine if a request for SNS courses is warranted. A current list of SNS training can be found on the SNS extranet at <https://www.orau.gov/snsnet> under the conferences and training tab.
- State coordinators desiring SNS training activities should contact the DSLR project officer to start the request process.

- Frequently, coordinators ask for a portion of time to have a state instructor cover state-specific topics. DSNS course managers are always able to arrange course agendas to give coordinators the necessary time.
- Once a course is completed, DSNS managers may provide a confidential trip report to the DSLR project officer and the state coordinator.

Protocol for Requesting Training and Exercise Support

1. State, local, territorial, and tribal (SLTT) entities may request training and exercise assistance through their assigned DSLR project officer. SLTT partners cannot make requests for training or exercise assistance directly to members of the DSNS Training and Exercise Teams.
2. External training could range from providing assistance in creating training products or requesting a formal division-sponsored course.
3. SLTT requestors will use the DSNS Exercise Request form for requesting exercise support and submit it to their assigned DSLR project officer.
4. Within two weeks of a written request, a conference call will be scheduled to discuss request with state (DSNS exercise team, DSLR project officer, and SLTT representative). DSNS representatives will provide confirmation of DSNS support through an email to SLTT representative.
5. Regular exercise communication between the Exercise Team, DSLR project officer, and SLTT representative will be necessary for exercise development.

Appendix A: Federal Medical Stations

During a large-scale natural or man-made disaster, casualties and displaced individuals could quickly overwhelm local and state medical response resources. If hospitals and treatment facilities are decimated due to an incident or incapacitated due to a surge in the number of people in need of shelter and treatment beds, the Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) can deploy Federal Medical Stations (FMS) to augment treatment beds in the community. FMS is a flexible, scalable asset designed to provide beds and medical equipment to support non-acute care, special needs care, or quarantine operations anywhere in the United States and is intended to supplement local healthcare infrastructure in mass casualty incidents as well as actual or potential public health threats.

Developing the Federal Medical Station Concept

The HHS' Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) (now ASPR) and the Centers for Disease Control and Prevention (CDC)'s Division of Strategic National Stockpile (DSNS) developed the FMS concept to be a federally-managed and deployable medical care capability to address public health needs during an emergency. Authority for development of this asset comes from the National Response Framework (NRF) and Emergency Support Function #8: Public Health and Medical Services Support (ESF-8).¹

During development of the FMS concept HHS estimated a potential significant deficit in treatment bed capacity at state and local levels in the aftermath of a catastrophic event. These estimates found that the federal capabilities provided by the National Disaster Medical System (NDMS), the Department of Defense (DoD), and the Veterans Administration (VA) did not adequately address the potential requirements for a mass casualty event.

Under the direction of HHS, CDC partnered with the VA's National Acquisition Center to assist with acquiring and maintaining FMS material. In 2004, HHS recognized the need for expertise in acquiring, storing, staging, and deploying critical medical supplies in addition to working with state and local authorities to prepare to receive such assets. At that time, HHS assigned CDC as the lead federal partner for developing the FMS concept into a prototype. HHS/ASPR reviewed and approved the types and quantities of the various items contained in FMS modules, sets, and kits, but CDC gained responsibility for managing and deploying FMS assets. Since the initial development of the FMS concept, CDC has deployed FMS modules in

¹ www.phe.gov/Preparedness/support/medicalresponse/Pages/default.aspx

support of national crises, including Hurricanes Katrina, Rita, Dean, Gustav, Ike, Isaac, and Sandy, as well as for the widespread flooding in the state of North Dakota in 2009 and 2010. CDC has deployed more than 14,000 beds to these types of incidents.

Understanding the Federal Medical Station Concept

The FMS concept offers a deployable federal asset that provides three capabilities:

- A shelter for displaced special needs persons with chronic diseases, limited mobility, or other impairments that make them unqualified for general population shelters;
- A program and material to relieve a surge in hospital bed requirements following a disaster; and
- Material to support a quarantine station operation.

FMS is designed to be installed quickly in available buildings that can accommodate the required beds. It can also be adapted to help meet a range of mass medical care needs following a disaster. The FMS is

- Scalable to meet the needs of a specific incident;
- Transportable by air, sea, or ground for maximum geographic distribution;
- Quickly integrated into an available structure;
- Designed to accommodate all age populations; and
- Expendable.

Jurisdictions can adapt an FMS to help meet a range of mass medical care needs that might emerge in a disaster. For example, in the aftermath of Hurricane Katrina in September of 2005, Louisiana officials used FMS units deployed by CDC to provide a more advanced level of medical care. Various public and private entities from nearby communities and other states co-located their mobile medical services with the FMS to create a medical facility on the campus of Louisiana State University in Baton Rouge. With the aid of these mobile medical services, this facility was able to offer clinical laboratory, radiological diagnostic, intensive care, and surgical services in a building that usually served as a student recreational facility.

FMS Contents

Each FMS consists of 250 beds and an initial three-day supply of pharmaceuticals, medical equipment, and medical-surgical and general supplies in three core modules:

- The **Pharmacy** module consists of medications and pharmacy supplies required to support the 250 patients for three days. The formulary includes pharmaceuticals that require refrigeration and must be locked in a secured area with limited access by staff.
- The **Base Support** module includes 250 beds, 200 of which are general use beds (cots) and 50 of which are enhanced care beds that allow adjustments to head and foot elevation. In addition, this module includes 25 pediatric/toddler cots, 24 portable cribs, and a bariatric kit for the morbidly obese that provides 5 electric beds and other medical equipment and supplies capable of supporting care for patients up to 600 pounds. This module also contains general and emergency medical supplies,

equipment, housekeeping items, nursing station supplies, and personal protective items (e.g., gloves, gowns, masks, etc.).

- The **Base Treatment** module includes medical supplies and equipment for special needs and other non-acute care. If necessary, the community can request augmentation kits, including latrine kits and electrical distribution kits, which provide additional capability in extremely austere environments.

Overall, there are approximately 700 line items in an FMS set, including the pharmacy items.

It is important to note that when a jurisdiction requests an FMS, it will arrive as a 250-bed set. If the jurisdiction needs fewer than 250 beds, the extra beds can be left in their packing containers. However, each FMS contains medical-surgical and pharmacy supplies to support 250 beds and planners should work with CDC to determine how to store and use any extra supplies. In addition, due to the limited initial supply levels, planners should determine how they will request re-supply as soon as possible following the initial request for an FMS.

Planning Considerations

Although the FMS provides critical capabilities during an emergency, it also has several limitations including

- Absence of dedicated transportation support that forces this resource to compete with other government agencies during an emergency response in order to acquire appropriate and timely commercial transportation resources;
- No deployable shelter capability means this resource is completely dependent upon a pre-selected facility that meets specific operational requirements;
- Deploys with only an estimated three days of supplies and equipment and once it is established, FMS support and clinical staff must immediately begin planning for re-supply of critical items and needed medical supplies and equipment;
- Complete dependence on the host agency (federal, state, or local) for service support, including staffing, power, water and food sources, and waste removal capabilities;
- Provides supplies and equipment for sheltered individuals only so that clinical and support staff will require additional housing support provided by the host entity; and
- No acute care capability. However, HHS ASPR may deploy a NDMS Strike team to provide emergency medical care for a deployed FMS. This team will bring their own personnel, equipment, and transportation. The jurisdiction will need to be support this team with housing, food, and water.

Preparing for FMS Arrival and Sustainment

When requested by a jurisdiction, an FMS may go to a staging site selected by HHS ASPR or directly to the site selected for its set-up and operation. Planners should work with their HHS regional emergency coordinators (RECs) to identify possible facilities in cities and regional areas well in advance of a disaster. Written agreements with facilities and firms could greatly ease an FMS staging and improve its ability to effectively function during an emergency. Aside from developing contingency agreements in advance of an incident, planners may need to revisit possible FMS sites periodically to make certain that changes in corporate

ownership and/or personnel have not compromised prior understandings or changed designated contact personnel or information.

Selecting FMS Sites

CDC recommends that planners look to existing structures for use as FMS sites. Possible FMS sites include National Guard armories, gymnasiums, civic sports centers, schools, large hotel ballrooms, convention centers, warehouses, and community centers. Planners should consider that National Guard armories and schools generally are publicly owned structures, which can make access easier and can rapidly ramp up operations during an emergency. However, convention centers and warehouses may provide more open floor space. For quarantine purposes, an FMS can be established in an airport building or similar location to properly isolate and care for people who require observation and monitoring for symptoms of an outbreak.

Planners should consider the following specifications when identifying possible facilities to use as an FMS site:

- Sufficient size; a 250-bed FMS will require approximately 40,000 square feet of enclosed space
- Close proximity to a supporting hospital to allow for transfer of patients and sharing of resources, such as laboratories and diagnostic capabilities
- Sufficient existing communications links and electrical capacity
- Adequate parking and loading docks that can facilitate 53-foot tractor trailers
- Adequate staging area for parking or maneuvering tractor trailers
- Sufficient material handling equipment (MHE) such as forklifts, pallet jacks, and licensed operators to assist in offloading and staging FMS materials
- Back-up generator capability
- Separate rooms for functional areas (e.g., pharmaceutical storage, storage of supplies, etc.) with a large open floor space for patient care
- On-site refrigeration
- Bathrooms with shower capabilities for patients and staff
- Adequate security and/or capacity to be adequately secured by law enforcement
- Secure storage area for pharmaceuticals
- Climate control equipment
- Communications and information technology (IT) support; an ideal site will have wireless internet capacity with no interference or signal shielding affecting connectivity

Ancillary Support Services

In addition to functional support, an FMS will require the ancillary support services listed below:

- Perimeter security
- Waste removal, including biomedical waste disposal
- Electrical power source and distribution
- Potable water and ice
- On-site patient transportation and other support services
- Emergency transportation services

-
- Accommodations for up to 200 staff/personnel
 - Food service for staff and patients, including special diets
 - Access to ground and air evacuation
 - Access to medical oxygen vendor to refill oxygen tanks
 - Laundry services
 - Mortuary support
 - Accommodations for pets and service animals
 - Approximately 12 –15 support staff to assist with set-up and tear-down of the FMS; additional volunteers (ancillary and professional medical staff) may be required to assist with patient care

Building Size Considerations

The jurisdiction should identify a building large enough to provide shelter and care for at least 250 patients, which will require approximately 40,000 square feet. The facility design will likely determine the exact allocation of space to FMS functional areas. However, if the jurisdiction needs fewer than 250 beds, planners can plan on approximately 15,000 square feet per 50 beds. Functional layout, patient flow, access, and security are primary considerations when selecting potential sites and these considerations can have a significant impact on required space.

Packaging and Shipment

An FMS consists of approximately 185 Tri-Wall containers, which are large corrugated cardboard shipping containers with plastic lids and bases. An FMS can be transported by air or sea, but is most commonly shipped by ground transportation consisting of four trucks – three 53-foot tractor trailers and one refrigerated tractor trailer for pharmaceuticals, which may be smaller than a 53-foot tractor trailer. Shipment by air may require more than one cargo aircraft and will need to be loaded onto tractor trailers at the arrival airport for transport to the designated set-up location. At seaports, once containers are removed from the ship, ground transportation will be needed to move to the FMS to the set-up site.

Technical Assistance for FMS Set-up

CDC may send an **FMS Strike Team** with the FMS to provide technical assistance to the jurisdiction and the U.S. Public Health Service Rapid Deployment Force or HHS Logistics Response Assistance Team (LRAT) responsible for the set-up and operation of an FMS. The strike team will consist of a leader and two or three technical specialists to provide subject matter expertise on set-up, material and pharmaceutical resupply processes, and recovery of FMS assets. The actual mobilization timeframe will be coordinated between the jurisdiction and HHS prior to deployment.

Site Layout

FMS layout space is based on providing specific areas for general patient beds, handicapped accessible beds, and support areas. The various functional support area dimensions are relatively constant in each configuration while the patient bed space, nurses' station space, and the space for supporting staff will increase with increases in the number of beds beyond 250. When a large open floor space is used for the FMS site, it is best to arrange support, storage, and supply receiving areas around the periphery and near the entrances

or exits. The flow pattern inside the FMS should allow rapid access to every area with a minimum of cross-traffic through the patient areas. Figure A-1 depicts the required space for the patient bed areas and support staff areas.

Specific building design and characteristics will ultimately drive the FMS configuration; however, the following provides a list functional support areas and their approximate dimensions:

Administration and Admission Area: 1,610 square feet (35 x 46 feet)

Waiting Area: 840 square feet (25 x 33.5 feet)

House Support: 770 square feet (35 x 22 feet)

Medical Support: 1,610 square feet (35 x 46 feet)

Pharmacy Area: 280 square feet (35 x 8 feet)

Treatment Area: 1,680 square feet (35 x 48 feet)

Holding Area: 1,435 square feet (35 x 41 feet)

Staff Rest Area: 600 square feet (30 x 20 feet)

Walkways and Patient Bed Areas: When possible, the patient bed area should be centrally located to all functional areas within the FMS and allow at least two feet of clear floor space between the “heads” of the beds. Side-by-side spacing between beds should be approximately four feet. The bed spacing should not restrict routine patient care activities and there should be complete access to the patient and enough circulation space to allow movement of staff.

When setting up pediatric beds and cribs, planners should make accommodations for parents to be close to their children; so adult beds should be positioned in the same area. For safety and security, children or pediatric patients should not be placed near exits or on the periphery.

According to Americans with Disabilities Act² guidelines, a minimum of 10% of beds and patient facilities should be set up for those with disabilities. This requires a minimum space clearance between beds of 36 inches to accommodate a standard wheelchair or people with guide dogs.

The 2, 4, 6, 8 Rule for Bed Spacing

One easy way to consider bed spacing requirements is to use the 2, 4, 6, 8 rule:

2 feet for heads

4 feet between beds

6-foot aisles

8 feet (minimum) between bariatric beds

² www.accessboard.gov/adaag/html/adaag.htm

For setting up a bariatric unit, planners should be aware that FMS bariatric beds accommodate people up to 600 pounds. Often, people who are morbidly obese cannot move around by themselves and must be transported on large stretchers or in bariatric wheel chairs. Spacing between the bariatric beds needs to be at least 8 –10 feet to accommodate these stretchers and wheelchairs, as well as the bariatric lift if it is needed to move the patients from the beds to stretchers or wheelchairs.

Common Area: 1,152 square feet (36 x 32 feet). While there is no requirement for a recreational area for patients, CDC recommends that an FMS have a place for the ambulatory patients, family members, and medical escorts to watch television, play games, or read that is away from the busy floor of an open FMS site.

Biomedical Waste and Morgue Area: approximately 500 square feet (20 x 25 feet)

- Biomedical: 396 square feet (18 x 22 feet)
- Morgue: 100 square feet (8 x 12.5 feet)

Housekeeping Area: 45 square feet (15 x 3 feet)

Pallet Storage Area: 2,718 square feet (in aisles along edges of FMS)

- See Figure A-1 for examples
- For planning purposes, planners can use the following dimensions:
 - Aisle at “top” of station: 448 square feet (8 x 56 feet)
 - Large aisle on “left” side of station: 1,490 square feet (149 x 10 feet)
 - Aisle on “right” side of station: 780 square feet (6 x 130 feet)

General factors to consider:

- Tri-wall shipping containers and pallets (approximately 185 per 250-bed FMS) can be stacked or disassembled to maximize space for other areas. Planners also can use these large containers as physical barriers around the perimeter of the FMS or functional areas and as storage space for unused supplies and equipment.
- Patient walkways and aisles between patient bed sections must be a minimum of 8 feet wide to allow unencumbered maneuvering of mobility-impaired persons, wheelchairs, and stretchers.
- If required due to elevation changes in the facility, wheelchair ramps should have 12 inches of run for every inch of rise to facilitate easy maneuvering by transport personnel.
- Re-usable packing materials that arrive in the FMS containers should be stored for use in returning items to CDC.

Staffing the FMS

An FMS requires human resources to set it up, provide patient care, and to support it over the span of its operations. The immediate need will be acquiring enough personnel to assist the with site set-up. Planners should be aware that staffing the FMS with medical personnel is the responsibility of the requesting jurisdiction. However, HHS may deploy NDMS or U.S. Public Health Service personnel to assist in providing patient care depending on the incident. In

some instances, the Veterans' Administration also can provide FMS staffing. In general, an FMS will require the following staff:

- Physicians
- Physician Assistants
- Nurses
- Pharmacist
- Laboratory personnel
- Support staff (LPNs, nurses aids)

Staff ID Badges, Credentials, and Identification

Staff and volunteers should know where to report or be informed of any changes to the activation plan during the call-down process. When staff and volunteers arrive at the FMS, the process for checking identification, credentials (for medical personnel), and providing ID badges should be operational (See **Chapter 11: Securing Assets, Personnel, and Operations** for further details on the identification and badging process). Once staff and volunteers have received their ID badges, they should be briefed on overall site operations and be provided with job action sheets, just-in-time training on their roles, and information on the chain of command in the FMS site.

Staff and Volunteer Compensation

Planners should be aware that during a Robert T. Stafford Disaster Relief and Emergency Assistance Act (Public Law 93-288)³ declaration, staff compensation may be available through the federal government. It will be important that staff and volunteers who assist in FMS operations maintain records of the time spent at the facility so they can be compensated once the FMS demobilized. However, in many cases professionals and non-professionals alike will volunteer their time as a goodwill gesture.

³ Information on the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Public Law 93-288) is available from URL www.fema.gov/about/stafact.shtm.

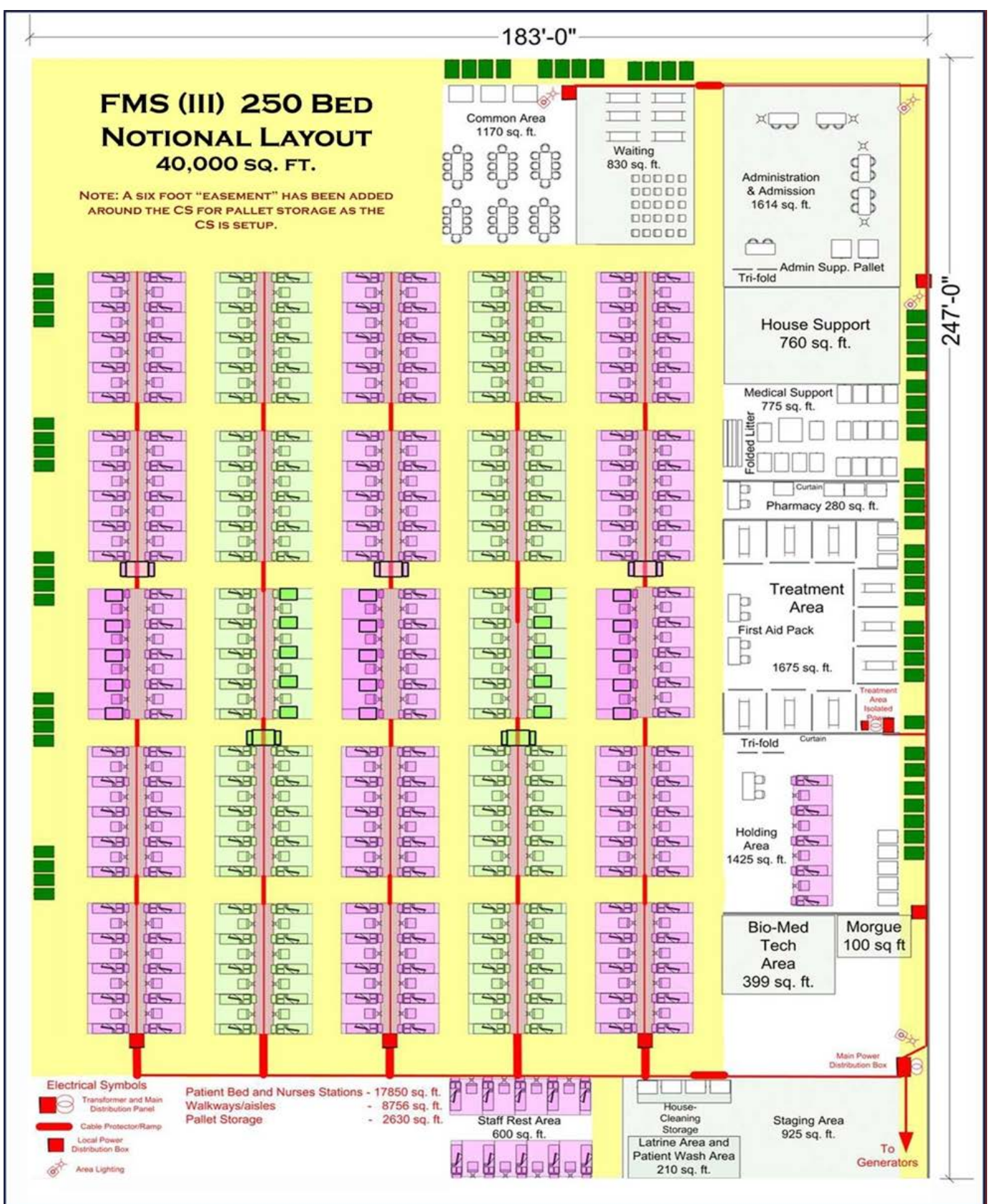


Figure A-1: FMS layout. Note: this image depicts an FMS that includes the optional latrine and electrical support kits.

Demobilizing the FMS

Once the incident has been mitigated and patients at the FMS are released, the FMS site will need to be demobilized and cleaned and certain FMS items will need to be returned to CDC. The jurisdiction is responsible for providing a 10 – 15 person team to help demobilize the FMS site. In addition, the jurisdiction is responsible for cleaning the facility. The FMS Strike Team and/or the HHS Logistics Response Assistance Team (LRAT) members on site are responsible for packing and returning FMS items, but the jurisdiction is responsible for recruiting the personnel to perform necessary tasks.

Returning Items to CDC

In general, pharmaceuticals and medical supplies sent to the jurisdiction in an FMS become the property of the jurisdiction once the site is demobilized. The jurisdiction is responsible for storing and utilizing or destroying any pharmaceuticals in accordance with standard pharmacy practices. Certain durable items should be packed into the Tri-Wall containers for return to CDC. In general, FMS recoverable items include the following list of items:

- Beds – all types
- Continuous Positive Airway Pressure (CPAP) devices
- AED, defibrillator
- Crash cart
- Aspirators/portable suction devices
- Pulse oximeters
- Braslow bag
- Oxygen tanks/cylinders
- Oxygen regulators
- Wheelchairs
- Backboards (Adult/child)
- Stretchers
- Patient lifts and slings
- Walkers
- IV Poles
- Thermometer, electronic
- Chairs, folding
- Tables, folding
- Lamps, gooseneck
- Electrical Distribution system (all components)
- Sinks
- Un-opened boxes of supplies
- Refrigeration freezers
- Pallet jacks
- Dollies, handtruck
- Bariatric Equipment, including
- Beds
- Mattresses
- Stretchers
- Walkers
- Lifts
- Bedside commode

Cleaning, Decontamination, and Medical Waste Disposal

The facility used for an FMS will require extensive cleaning and biomedical or other decontamination by a professional industrial cleaning crew. Written agreements with any facilities used for an FMS should include information on which agency in the jurisdiction is responsible for contracting and paying for industrial cleaning services. In addition, the jurisdiction will need to contract for biomedical waste removal and disposal. All materials soiled with human body fluids (i.e., blood, urine, excrement, pus, etc.) must be placed in red biohazard bags. Biomedical waste and sharps containers (i.e., red plastic bins used for the disposal of needles) also must be properly disposed of, which often requires incineration. Area hospitals may agree to facilitate medical waste disposal for the FMS and are a good resource to look to when planning for an FMS.

Appendix B: Ventilators

The Strategic National Stockpile (SNS) contains a limited number of mechanical ventilators for use during a public health emergency. The request and distribution strategies for SNS ventilators consider multiple factors, including the size and scope of the incident (e.g., localized anthrax response vs. nationwide event such as pandemic influenza), the need for ventilators at the local level, and the number of personnel available to support ventilator use. For nationwide outbreaks, such as a pandemic influenza incident, additional ventilator allocation strategies may be considered (e.g., allocation based on population). During an emergency, the Centers for Disease Control and Prevention (CDC) will deploy ventilators directly to states, recover ventilators after the incident is resolved, and coordinate recovery and return of ventilators. After decontamination and maintenance checks, equipment will be returned to the SNS inventory to SNS inventory.

Using SNS Ventilators

Mechanical ventilators included in the SNS are able to provide continuous respiratory support for adult and pediatric patients with respiratory insufficiencies. Planners should note that ventilators are medical devices and as such require trained personnel to operate and monitor them. Trained personnel also should be prepared to address equipment malfunctions and circumstances in which equipment fails or power is lost for extended periods. An alternative method of ventilation (e.g., manual pulmonary resuscitator [MPR] bag) should be available for all patients dependent on a ventilator and trained personnel should be fully familiar with emergency ventilation procedures.

Requesting SNS Ventilators

The request process for ventilators follows the process outlined in **Chapter 4: Requesting Strategic National Stockpile Assets** and planners should consider the type of triggers the jurisdiction will use for requesting SNS ventilators.

The SNS contains three brands of ventilators:

- Covidien (Puritan Bennett) – LP10
- CareFusion – LTV® 1200
- Impact Instrumentation – UNI-VENT Eagle 754

When a jurisdiction requests ventilators, CDC will deploy these assets based on the size and scope of the incident and availability of ventilators. CDC may not be able to honor requests for specific ventilator brands. In addition, during a large-scale incident, ventilators may be allocated by population and not deployed based on state requests.

To assist in training and preparing personnel for using SNS ventilators, manuals and instructional videos are available on the SNS Extranet.¹ The SNS Extranet also includes training materials from Project XTREME,² created by a team of respiratory care specialists from Denver Health Medical Center and designed to help cross train health professionals for mass casualty respiratory needs.

In addition to the SNS Extranet, the same ventilator training is available on the American Association for Respiratory Care (AARC) web site, www.aarc.org/resources/sns_vent_training. This particular link on the AARC website is open to anyone needing pre-event or just-in-time SNS ventilator training (no password needed). Jurisdictions may download any of the information on the AARC SNS ventilator web site and use it to develop personalized training, including train-the-trainer modules, within hospitals or other medical treatment facilities.

Returning SNS Ventilators

Once the incident is resolved and the jurisdiction no longer needs the devices, the state should conduct an inventory of SNS recoverable assets. Personnel at the medical treatment facility that utilized the ventilators will be responsible for properly disposing of used ancillary items (such as patient circuits, bacterial filters, etc.) and cleaning ventilators according to their infection control policy. Following cleaning, staff should place ventilators, battery packs, oxygen and air hoses, AC adaptors, manuals, and videos back in the shipping cases for return to CDC. The state should contact the Division of Strategic National Stockpile (DSNS) Team Room; DSNS logistics personnel will coordinate return shipping of recoverable items.

¹ <https://www.orau.gov/snsnet/about.htm#formulary>. The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC Division of State and Local Readiness (DSLRL) project officer.

² <https://www.orau.gov/snsnet/resources/videos/ProjectXTREMEVideo.htm> The SNS Extranet is password protected. Login information is available from the state SNS coordinator or CDC DSLR project officer.

Appendix C: CHEMPACK

During an incident involving the release of chemical nerve agents, victims will need to be treated immediately with medical countermeasures (MCMs) to reduce their injuries. Because of the immediate need for these MCMs during a nerve agent incident, the Centers for Disease Control and Prevention (CDC) determined that it could not deliver Strategic National Stockpile (SNS) assets rapidly enough to affected areas to treat those injured. CDC tasked the Division of Strategic National Stockpile (DSNS) to develop CHEMPACK, a program for the forward placement of chemical nerve agent antidote caches. CHEMPACK caches are fielded in 62 project areas within the continental United States, Alaska, Caribbean Islands, Hawaii, and freely associated states. Each of the over 1,340 approved CHEMPACK storage sites is a voluntary participant in the program and has met the storage requirements through the Public Health Emergency Preparedness (PHEP) cooperative agreement¹ funding or through their own operating budgets.

Understanding the CHEMPACK Formulary

The CHEMPACK program procures and provides project areas with caches of chemical nerve agent antidotes (Mark 1 kits/DuoDote, atropine, pralidoxime, and diazepam), which are placed in centralized locations to assist first responders to quickly administer life-saving antidotes. Because diazepam is a schedule IV controlled substance, all CHEMPACK containers are U.S. Drug Enforcement Agency (DEA)-approved for secure storage of controlled substances. CHEMPACK cargo containers are designed of aluminum and Lexan® with wheels to facilitate mobility of deployment during a response. Each container holds antidotes both as auto-injectors (e.g., specially designed prefilled syringes that are ready for use) and vials. CHEMPACK containers are fielded in two formularies – emergency medical services and hospital – both of which contain the same products, but the quantities of each product included are adjusted to address their intended uses.

Emergency medical services (EMS) caches hold treatment for 454 people, contain more



Figure C-1: CHEMPACK cargo container.

¹ www.cdc.gov/phpr/coopagreement.htm

auto-injectors than vials, and are designed for deployment with first responders.

Hospital (HOS) caches hold treatment for 1,000 people, contain more multi-dose vials than auto-injectors, and are designed for use in a hospital or clinical setting.

CDC retains ownership of the CHEMPACK assets but gives custody of the nerve agent antidotes to jurisdictions upon receipt. Through automated monitoring devices placed with each cache of material, CDC is able to ensure that storage conditions of CHEMPACK material comply with the prescribed criteria.

Cache Site Survey, Fielding, and Sustainment

CHEMPACK containers must be stored in secure, environmentally controlled storage areas with phone connectivity. DSNS logisticians evaluate proposed storage sites for compliance with program requirements prior to fielding or relocating containers. CDC maintenance technicians establish connectivity and alarm functionality once containers are in place and then continue to monitor temperature and security of containers remotely on a 24-hour basis. **CHEMPACK containers may not be opened** unless the contents are needed during a chemical nerve agent emergency.

Members of the CHEMPACK program continuously conduct sustainment operations to rotate stock and perform preventive maintenance on the containers and monitoring devices fielded across the nation. The sustainment of each jurisdiction is scheduled independently, based on the expiration date of product, availability of fresh product, and the scheduling needs of the jurisdiction's staff. As long as the antidotes are maintained under federal control and stored under proper conditions, CDC is able to request multiple extensions of product shelf life through U.S. Food and Drug Administration/Department of Defense Shelf Life Extension Program (SLEP). SLEP allows stability testing of federally held MCMs to extend the manufacturer's expiration date listed on a product. In addition, should the jurisdiction need to relocate the CHEMPACK containers for any reason, members of the CHEMPACK program will support movement of containers within host sites and between facilities in the jurisdiction.

Storage Requirements

The site at which CHEMPACK containers are kept should meet storage and security requirements for controlled substances. DEA regulates the storage and transfer of controlled substances in accordance with 21 Code of Federal Regulations (CFR).² DEA registers individuals and organizations, such as hospital pharmacies, to handle specific classes of controlled substances by issuing them a distributor's license. Members of such organizations are known as agents. Because of the special security requirements of controlled substances, jurisdictions should

- Leave CHEMPACK assets in the specialized containers provided;
- Select a CHEMPACK location (e.g., pharmacy, hospital, trauma center, law enforcement facility, or wholesale drug distributor) that meets DEA standards for controlled substances; and

² www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

- Use local law enforcement to provide security for transporting CHEMPACKs when they are needed.

Licensees and agents (referred to here as “registrants”)³ who transfer controlled substances must ensure that those who receive the drugs have the proper DEA authorization to receive them. They also must keep a detailed chain-of-custody record of all transfers. The person who receives controlled substances is required to initiate a request to transfer the material using a DEA Form 222. Each jurisdiction participating in the CHEMPACK program should register as a distributor with DEA in order to provide a legal conduit for the shipment of controlled substances during an emergency.

The controlled-substance laws of the jurisdiction may be more stringent than the 21CFR,⁴ under which the requirement for DEA Form 222 falls. Planners need to work with public health legal advisors in the jurisdiction to review these specific laws and ensure compliance. If state laws are more restrictive, public health law professionals can assist SNS planners in determining the effects of these laws on the ability to respond and propose solutions to the state Board of Pharmacy.

For detailed information about federal controlled-substance regulations see DEA’s Diversion Control Program.⁵

Planning for CHEMPACK

Each jurisdiction in which a CHEMPACK is fielded must

- Designate a lead agency and a primary and secondary point of contact (POC) to work with CDC/DSNS staff;
- Identify and maintain secure and climate controlled storage sites that best support their emergency response plans;
- Identify a DEA registrant to accept custody of CHEMPACK assets;
- Sign the memorandum of agreement to partner with CDC in the CHEMPACK program; and
- Integrate CHEMPACK assets into their all-hazards response plans.

The POCs are responsible for developing CHEMPACK plans, scheduling sustainment with the cache storage sites, and communicating and coordinating with CDC CHEMPACK program staff. CHEMPACK plans should include a mechanism for accessing and transporting CHEMPACK containers when they are needed.



Figure C-2: CHEMPACK deployed by emergency personnel.

³ www.deadiversion.usdoj.gov/drugreg/reg_apps/index.html

⁴ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1305

⁵ www.deadiversion.usdoj.gov

Resources

CDC maintains a **CHEMPACK SharePoint** site for jurisdictions in which CHEMPACK containers are fielded. Planners can request access to SharePoint by going to the website <http://www.orau.gov/chempack>, clicking on the "Request Access" button, and following the prompts to request a user name and password.

Appendix D: Management of Forward Deployed DTPA

Internal contamination with radioactive materials can result in exposure to life-threatening doses of ionizing radiation. Removing radioactive material from the body is the best way to reduce such radiation exposure. Diethylenetriamine pentaacetic acid (DTPA) is a medical countermeasure (MCM) currently approved by the U.S. Food and Drug Administration (FDA) to treat suspected or known internal contamination with specific radioactive materials (americium, curium, or plutonium). In a continued effort to minimize the effects of potential threats, the Department of Health and Human Services (HHS) acquired 450,000 doses of DTPA and the Centers for Disease Control and Prevention (CDC) developed a program to pre-position DTPA in project areas. In 2009, CDC offered project areas a **one-time** opportunity to obtain a cache of DTPA to mitigate possible health effects of suspected or known internal contamination to americium, curium, or plutonium resulting from a radiological incident.

Understanding Radiological Threats

As part of national planning, the Department of Homeland Security developed a list of potential threats to the United States.¹ One possible way in which terrorists could create fear and injure people is through the use of a radiological dispersal device (RDD), sometimes referred to as a dirty bomb. National Planning Scenario 11: Radiological Attack describes the threat from an RDD incident. An RDD would consist of a conventional explosive device laced with radioactive material. When the device is detonated, the radioactive material would be dispersed, thus causing radioactive contamination of people and the environment. During such an incident, people can remove radioactive material from the outside of their bodies by removing contaminated clothing and washing their skin and hair. However, during an RDD incident, people could be internally contaminated with radioactive material through inhalation, absorption through skin wounds, or accidental ingestion. Radioactive material inside the body can cause health effects from exposure to dangerous levels of ionizing radiation when the radioactive material is absorbed into internal organs. However, some radioactive materials can be removed from the body by DTPA, a chelating agent that binds to certain radioactive materials (plutonium, americium, and curium), which are then excreted from the body.

¹ See the list of National Planning Scenarios in **Chapter 1: Concept of Medical Countermeasure Operations**.

Caching DTPA in Project Areas

In 2009, CDC provided project areas with an opportunity to receive a one-time cache of DTPA. Project areas that took advantage of this deployment are responsible for maintaining the cache and CDC will not replace the DTPA product once it has expired. Project areas holding DTPA must develop a DTPA response plan annex that builds on existing emergency response and MCM distribution and dispensing plans. The DTPA annex should include plans detailing where and how DTPA is stored and how the jurisdiction will transport DTPA to sites where it may be needed. Once received, DTPA became the property of the project area and CDC does not manage the product as it does with CHEMPACK; therefore, DTPA response annexes must include plans for recovery or recycling of unused product after expiration (currently 2014 – 2015). Planners should ensure that DTPA annexes include plans to dispose of containers and unused contents in accordance with federal, state, and local requirements. Project areas should review and revise this annex annually for as long as they maintain DTPA.

Using DTPA as a Chelating Agent

DTPA comes in two forms: calcium (Ca-DTPA) and zinc (Zn-DTPA). Both forms work by chelating plutonium, americium, and curium, which are then excreted from the body in the urine. Chelating agents work best when given shortly after internal contamination with radioactive materials.

When given within the first day after internal contamination has occurred, Ca-DTPA is approximately 10 times more effective than Zn-DTPA at chelating plutonium, americium, and curium. After 24 hours have passed, Ca-DTPA and Zn-DTPA are equally effective in chelating these radioactive materials. After 24 hours, plutonium, americium, and curium are harder to chelate; however, DTPA can still be effective at removing these radioactive materials from the body several days or even weeks after a person has been internally contaminated.

Resources

Additional planning and training resources related to DTPA are available from the following sources:

CDC Radiation Emergencies website includes information for public health and medical professionals as well as the general public at www.bt.cdc.gov/radiation/training.asp. DTPA administration guidelines are available at <http://emergency.cdc.gov/radiation/dtpa.asp>.

The **FDA Center for Drug Evaluation and Research (CDER)** provides information on the use of Ca- and Zn-DTPA for treatment of internal contamination with radioactive materials at www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm130311.htm.

Appendix E: Cold Chain Management

Cold chain management is the temperature controlled shipment and storage of certain medical countermeasures (MCMs), particularly pharmaceuticals and vaccines. These MCMs must be transported and stored at temperatures below typical ambient temperatures. Some of these MCMs must be kept within a temperature range of 35° – 46° Fahrenheit (2° – 8° Celsius) to maintain their efficacy according to Title 21 Code of Federal Regulations, Part 211 (21CFR211),¹ which pertains to the current good manufacturing practices (cGMP) for pharmaceuticals. During certain instances, the Centers for Disease Control and Prevention (CDC) may direct the Division of Strategic National Stockpile (DSNS) to deploy MCMs that require cold chain management. CDC will ship these MCMs in specialized containers that can maintain appropriated temperature ranges for a specified period of time, but jurisdictions should have plans for maintaining MCM efficacy while handling, storing, tracking, and transporting of these MCMs.

Receiving Cold Chain Products

When CDC ships items that require refrigeration, such as vaccines (smallpox vaccine or anthrax adsorbed vaccine) or other biologic products requiring cold chain management, CDC uses cold chain packing protocols and specialized shipping containers to ensure that the items remain at the proper temperature throughout the packing and shipment processes. These items will be shipped in either an active (electric/battery back-up refrigeration) shipping container, such as a Vaxi-Cool™, or a passive (certified insulated) shipping container, such as an Endurotherm™, both of which can maintain temperatures for prescribed periods of time without electricity or the need for additional refrigeration. These units have digital data temperature monitoring systems that record temperatures in the package so that users can verify that the product has been maintained in the prescribed temperature range during shipment. Once the jurisdiction receives these MCMs from the Strategic National Stockpile (SNS), it is responsible for maintaining them at the appropriate temperature to maintain efficacy. In addition, the jurisdiction is responsible for returning refrigeration units used to ship cold chain products, along with their batteries and power cords, to CDC.

Jurisdictions should have plans for receiving and handling SNS products requiring cold chain management. These plans should outline how receipt, stage, store (RSS) facilities and

¹ www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

dispensing sites will store material requiring cold chain management if the jurisdiction does not dispense the product within the timeframe for which shipping containers can sustain the required storage temperature. This plan should ensure that the product is kept at the prescribed temperature until it is administered or disposed of and should include processes and procedures for monitoring and logging the temperature of the storage containers in which the product is kept over time.

Because CDC will sign assets over to the state at the time they are delivered, the RSS facility should have the capacity to receive these assets. When the cold chain materials arrive, RSS staff should plug in refrigeration units (e.g., Vaxi-Cool™) and leave specialized foam shipping containers, such as the Endurotherm™, closed and sealed. Product should remain in its shipping container until it is moved to a vaccination site and ready for use or transferred into an appropriate refrigeration unit (**Note:** an Endurotherm™ will maintain temperature for up to 72 hours). Jurisdictions can partner with area medical facilities or pharmaceutical warehouses to request appropriate refrigerated storage space and then make a plan for transporting materials under cold chain management in a manner that maintains the temperature. For short shipments, passive packing containers (i.e., polystyrene packing containers) may be enough to maintain materials at the appropriate temperature. The jurisdiction should have the necessary supplies to ship vaccines or other biological products, including polystyrene packing containers; ice, dry ice, and/or gel packs; and a temperature monitoring process.

Temperature Monitoring

CDC's interim vaccine storage and handling guidelines² recommend the use of a digital thermometer with a biosafe glycol-encased or similar temperature buffered probe in all refrigeration and cooling devices in which vaccines are stored. The thermometer also should be able to provide and store data monitoring information set at programmable intervals in an active display that allows for reading temperatures without opening the door of the refrigeration unit or cooler in which cold chain items are stored.

According to the CDC guidelines, the best thermometer will have a detachable probe and facilitate downloading temperature data without removing the probe from the storage unit. The digital data logging thermometer probe should be able to remain in place and not be disturbed during data reading and recording, which will simplify use and minimize temperature variability by opening the containers. The digital data logger also should have

- A Hi/Lo alarm for out-of-range temperatures;
- A reading of current temperature, as well as minimum and maximum temperatures;
- A reset button;
- Low battery indicator;
- Accuracy of +/- 1° F (0.5° C);
- Memory storage of at least 4,000 readings (i.e., device will not write over old data and stops recording when memory is full); and
- User programmable logging interval or reading rate (e.g., 12-hour intervals).

² www.cdc.gov/vaccines/recs/storage/interim-storage-handling.pdf

Continuous temperature monitoring allows more accurate and comprehensive monitoring of temperature variations and diminishes the need for opening the unit door while conducting routine monitoring.

Also, CDC recommends jurisdictions read and document storage unit temperatures twice daily and that minimum/maximum temperatures be checked and documented once per day, preferably in the morning. Reviewing the minimum/maximum temperatures helps to ensure that temperature excursions will be identified more quickly and corrections made that can prevent vaccine loss. All locations in which cold chain materials will be held or dispensed (including the RSS facility, dispensing sites, and hospitals or treatment centers) must maintain the product in its temperature range prior to use and follow the jurisdiction's temperature monitoring procedures.

Temperature Excursions

The jurisdiction should develop a plan to document and act on temperature excursions. When an out-of-range temperature reading (i.e., temperature excursion) is discovered, the jurisdiction should take immediate action to determine the cause and whether the cold chain materials have been compromised.

CDC's *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*³ provides information on maintaining vaccines, including safe handling and storage. In case of a temperature excursion, the ACIP recommends transferring the vaccine to a designated alternate emergency storage site if a temperature problem cannot be resolved immediately. For instance, materials stored in a unit that goes out of the temperature range can be quarantined, removed from the storage unit if the unit is broken, and placed in an alternate site with the product clearly marked "do not use." If the storage unit is operable after the temperature excursion is discovered (e.g., plugging in the refrigeration unit brings it back into proper temperature range), the product should be clearly marked "do not use" and kept in the unit until the jurisdiction can determine the product's efficacy.

After the temperature excursion is discovered, the jurisdiction should contact the manufacturer or state health department to determine if the vaccine can still be used. Depending on the type of vaccine, brief changes to temperatures outside of the recommended range may or may not affect the vaccine efficacy if it will be used promptly. Depending on how long the temperature excursion lasted and when the vaccine may be used it may still be viable.

Anthrax Vaccine Guidelines

DSNS will ship anthrax vaccine in insulated shipping containers (e.g., an Endotherm™, which can maintain temperature for 72 hours) or in temperature controlled trucks. The "clock" on an Endotherm™ starts as soon as DSNS staff packs and seals the box. Once an Endotherm™ is opened, the temperature has been compromised and the vaccine can no longer be

³ www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm

stored inside. At this point, the vaccine either must be immediately used or appropriately stored to maintain cold chain management.

In some cases, DSNS will ship anthrax vaccine in a temperature-controlled truck and product will be on pallets. As a result of the limited time temperature can be maintained when shipping anthrax vaccine, it is important that states have cold chain management available to immediately transfer all SNS vaccine upon state receipt and not rely on federally owned shipping containers or trucks for their cold chain management plans.

DSNS does not currently have guidelines on how long a temperature-controlled truck can be held at the state, so jurisdictions should have a plan for receiving and storing these vaccines once they receive them. Trucks will have the capacity to be plugged into electrical outlets or run the refrigeration unit from the truck's engine to maintain their temperatures, but the state should have a plan to unload and store the vaccine as soon as possible. The sooner states can unload trucks, the faster they can return to CDC warehouses to pick up and ship more vaccine to the states.

Additional Resources

CDC's Vaccine Storage and Handling website includes CDC's Interim Storage and Handling Guidance (2012), Vaccine Storage and Handling Guide (2011), and the Vaccine Storage and Handling Toolkit, which includes checklists, common errors, tips, temperature logs, maintaining cold chain during transport, emergency procedures for protecting vaccine inventories, impact of power outage on vaccine storage, and a video. Available online at www.cdc.gov/vaccines/recs/storage/default.htm.

The **Immunization Action Coalition** is a 501(c)(3) non-profit organization and a source for child, teen, and adult immunization information for health professionals and their patients. Available online at www.immunize.org. The IAC also has **storage and handling** recommendations at www.immunize.org/clinic/storage-handling.asp.

CDC's publication, **General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)** also provides information on www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm.

CDC's **Smallpox Response Plan and Guidelines** outline the public health strategies that would guide the public health response to a smallpox emergency and many of jurisdictional public health activities that would occur during a smallpox outbreak. Available online at www.bt.cdc.gov/agent/smallpox/response-plan.

Acronyms and Abbreviations

The following list contains acronyms and abbreviations found throughout *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness, Version 11*.

A

AAR	After action report
AAR/IP	After action report/improvement plan
ABthrax	Raxibacumab – treatment for severe anthrax disease
ACFs	Alternate care facilities
ADA	Americans with Disabilities Act
AI/AN	American Indian and Alaska Native
AIG	Anthrax immune globulin – treatment for severe anthrax disease
ARF	Action request form
Anthrax	Aerosolized <i>Bacillus anthracis</i>
ART	Action request form
ASPR	Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services (HHS)
ASTHO	Association of State and Territorial Health Officials
AVA	Anthrax vaccine adsorbed

B

BARDA	Biomedical Advance Research and Development Authority, HHS, ASPR
BERM	Bioterrorism and Epidemic Outbreak Response Model
BJS	Bureau of Justice Statistics, Department of Justice (DOJ)
BP	Budget period
BT	Bioterrorism

C

CAP	Corrective action plan
CBRNE	Chemical, biological, radiological, nuclear, and explosive
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CERC	Crisis and emergency risk communications
CERT	Community emergency response team
CFR	Code of federal regulations
cGMP	Current good manufacturing practices
CIO	Center, institute, or office (at CDC)
CIT	Countermeasure Inventory Tracking dashboard, CDC's Countermeasure Tracking System (CTS) component
COIN	Community Outreach and Information Network
COOP	Continuity of Operation Plan
CP	Communications Plan
CP	Communications Portal, CDC's CTS component
cPAT	Community Partner Assessment Tool, Los Angeles County Department of Public Health & Naval Postgraduate School

CPG 101	Comprehensive Preparedness Guide 101, Version 2.0
CRBNE	Chemical, radiological, biological, nuclear, and explosive
CRA	Countermeasure and Response Administration (CRA) system, CDC's CTS component
CRI	Cities Readiness Initiative
CSEPP	Chemical Stockpile Emergency Preparedness Program, Department of Homeland Security (DHS), Federal Emergency Management Agency (FEMA)
CTS	Countermeasure Tracking Systems, CDC

D

DEA	U.S. Drug Enforcement Administration, Department of Justice (DOJ)
DHHS	United States Department of Health and Human Services
DHPE	Directors of Health Promotion and Education
DHS	Department of Homeland Security
DoD	Department of Defense
DOH	Department of Health
DOJ	Department of Justice
DOT	Department of Transportation
DSL	Digital subscriber line
DSLRL	Division of State and Local Readiness, CDC
DSNS	Division of Strategic National Stockpile, CDC
DTPA	Diethylenetriamine pentaacetic acid

E

EEG	Exercise Evaluation Guide, DHS, FEMA, Homeland Security Exercise and Evaluation Program (HSEEP)
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EIS	Epidemic Intelligence Service, CDC
EMAC	Emergency management assistance compact
EMI	Emergency Management Institute, Federal Emergency Management Agency (FEMA) online training institute available at visit http://training.fema.gov/IS/NIMS.asp .
EMS	Emergency medical services
EO	Executive Order
EOC	Emergency operations center
EOP	Emergency operations plan
ESAR-VHP	Emergency System for Advance Registration of Volunteer Health Professionals
ESF	Emergency support function
ESF 8	Emergency Support Function 8 – Public Health and Medical Services Annex
ESF 13	Emergency Support Function 13 – Public Safety and Security
ESF 15	Emergency Support Function 15 – External Affairs
EUA	Emergency use authorization
EvalPlan	Evaluation Plan
F	
Fax	Facsimile
FDA	U.S. Food and Drug Administration, HHS
FD&C Act	Federal Food, Drug, and Cosmetic Act, 21 U.S. Code of Federal Regulations
FEMA	Federal Emergency Management Agency, DHS
FMS	Federal medical station
FMS ST	FMS Strike Team, CDC
FSE	Full-scale exercise

G

GETS	Government Emergency Telecommunications Service
GIS	Geographic information system
GPS	Global positioning system

H

HAN	Health Alert Network
HAvBED	National Hospital Available Beds for Emergencies and Disasters System
HICS	Hospital incident command system
HIPAA	Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191)
HHS	U.S. Department of Health and Human Services
HOH	Head-of-household
HORP	Harvard Opinion Research Program
HOS	Hospital caches, CHEMPACK
HPP	Hospital Preparedness Program, HHS, ASPR
HSC	Homeland Security Council
HSEEP	Homeland Security Exercise and Evaluation Program, DHS, FEMA
HSPD	Homeland Security Presidential Directive
HSPD 7	Homeland Security Presidential Directive 7 – a national policy for Federal departments and agencies to identify and prioritize critical infrastructure and to protect them from terrorist attacks

I

IACP	International Association of Chiefs of Police
IAG	Interagency agreement
IAP	Incident action plan

IC	Incident command
ICS	Incident command system
ID	Identification
IHS	Indian Health Service, HHS
IIS	Immunization information systems
IM	Intramuscular, i.e., into a muscle
IMATS	Inventory Management and Tracking System
IMS	Inventory management system
IMT	Inventory management team
IND	Investigational New Drug
IRCT	Incident response coordination team
IT	Information technology
IV	Intravenous (as in medication administration route, tubing, or needles)

J

JAS	Job action sheet
JFO	Joint field office
JIC	Joint information center
JIS	Joint information system
JITT	Just-in-time training

L

LEA	Law enforcement agency
LLIS	Lessons Learned Information Sharing (LLIS.gov); national network of lessons learned and best practices for emergency response providers.
LNO	Liaison officer

LTAR Local technical assistance review

M

MA Mission assignment

MAA Mutual aid agreement

MAD Mass antibiotic dispensing

MCM Medical countermeasure

MCMDD Medical countermeasure distribution and dispensing

MHE Material handling equipment

MI Managed inventory

MMRS Metropolitan Medical Response System

MOA Memorandum of agreement

MOU Memorandum of understanding

MRC Medical Reserve Corps

MSA Metropolitan statistical area

N

NACCHO National Association of County and City Health Officials

NAPH Name, age, patient history (patient intake form)

NCIRD National Center for Immunization and Respiratory Diseases, CDC

NDC National Drug Code

NDMS National Disaster Medical System

NGO Nongovernmental organization

NHSS National Health Security Strategy

NIH National Institutes of Health

NIJ	National Institute of Justice
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NPHIC	National Public Health Information Coalition
NRC	Nuclear Regulatory Commission
NRF	National Response Framework
NSSE	National special security event

O

OpDiv	Operating division
OPHPR	Office of Public Health Preparedness and Response, CDC
OSELS	Office of Surveillance, Epidemiology and Laboratory Services, CDC

P

PA	Project Area
PAHPA	Pandemic and All Hazards Preparedness Act
PAHPRA	Pandemic and All Hazards Preparedness Reauthorization Act
PBX	Private branch exchange
PCR	Perishable Cargo Regulations, International Air Transportation Association
PEP	Post-exposure prophylaxis
PHE	Public health emergency
PHMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEO	Public health emergency officer
PH EOC	Public health emergency operations center
PHEP	Public Health Emergency Preparedness cooperative agreement

PIC	Public information and communications
PIN	Personal identification number
PIO	Public information officer
POC	Point of contact
POD	Point of dispensing
PPB	Program Preparedness Branch, CDC, DSNS
PPD	Presidential Policy Directive
PPD-8	Presidential Policy Directive 8 – designed to strengthen “the security and resilience of the United States through systematic preparation for the threats that pose the greatest risk to the security of the Nation, including acts of terrorism, cyber attacks, pandemics, and catastrophic natural disasters.”
PPE	Personal protective equipment
PREP Act	Public Readiness and Emergency Preparedness Act, Public Law 109-148, December 2005
PSA	Public service announcement
PSC	Program services consultant, CDC
PSTN	Public switched telephone network
PVS	Pre-event Vaccination System
Q	
QC	Quality control
R	
RACES	Radio Amateur Civil Emergency Services
RDD	Radiological dispersal device
RDS	Regional distribution site
REC	Regional emergency coordinator, HHS

REP	Radiological Emergency Preparedness
RFI	Request for information
RITS	RSS Inventory Tracking System, CDC
RRCC	Regional response coordination center, FEMA
RSS	Receive), stage, store (warehouse)

S

SAMS	Secure Access Management Systems
SC	Subcutaneous, i.e., under the skin
SCIP	Statewide communications interoperability plan
SEOC	State emergency operations center
SLEP	Shelf-life extension program
SLTT	State, local, tribal, and territorial
SME	Subject matter expert
SNAPS	Snapshots of state population data, CDC website of population data, http://emergency.cdc.gov/snaps
SNS	Strategic national stockpile
SOC	Secretary's Operations Center, HHS, ASPR
SSAG	Stockpile services advance group, CDC
Stafford Act	Robert T. Stafford Disaster Relief and Emergency Assistance Act

T

T&EPW	Training and exercise plan workshop
TA	Technical assistance
TAR	Technical assistance review
TCP	Tactical communications plan

TEE	Training, exercise, and evaluation
TICP	Tactical interoperability communications plan
TP	Total population
TTX	Tabletop exercise

U

UC	Unified command
USPHS	U.S. Public Health Service, HHS
URL	Uniform resource locator
UTL	Universal task list

V

V11	<i>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets, A Guide for Preparedness, Version 11</i>
VA	U.S. Department of Veterans Affairs
VIG	Vaccinia immune globulin
VOAD	Voluntary Organizations Active in Disaster
VoIP	Voice over internet protocol

W

WHO	World Health Organization
WMD	Weapons of mass destruction
WPS	Wireless Priority Service