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/ng.pdf
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.

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](http://www.bt.cdc.gov/cri).
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) Act\(^ 7\) 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 constitute 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 counternmeasure 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/gethealthcare/conditions/countermeasurescomp/prepact.pdf](http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/prepact.pdf)

\(^8\) [www.gpo.gov/fdsys/pkg/FR-2008-10-06/content-detail.html](http://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), as enacted by the PREP Act (Pub. L. No. 109-148), 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](http://www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm)
10 [www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx](http://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.  

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.

---

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. 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. 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 [fema.gov/core-capabilities#PhysicalProtect](https://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](https://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm269226.htm)
caregivers in their planning efforts. According to the Pandemic and All-Hazards Preparedness Act (PAHPA),\textsuperscript{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. \textit{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,\textsuperscript{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 \textit{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 Installations\textsuperscript{17} 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 \textit{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

\textsuperscript{15} \url{www.phe.gov/preparedness/legal/pahpa/pages/default.aspx}
\textsuperscript{16} \url{http://emergency.cdc.gov/workbook}
\textsuperscript{17} \url{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>
<thead>
<tr>
<th>Threat</th>
<th>MCMs</th>
<th>Administration Route</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax</td>
<td>Antimicrobials (ciprofloxacin, doxycycline, amoxicillin) Post-exposure prophylaxis or treatment</td>
<td>Oral</td>
<td>Most antimicrobials will be used under an EUA or IND</td>
</tr>
<tr>
<td></td>
<td>Antimicrobials (ciprofloxacin, doxycycline, penicillin, clindamycin, rifampin, vancomycin, levofloxacin) Treatment</td>
<td>Intravenous (IV)</td>
<td>Most antimicrobials will be used under an EUA or IND</td>
</tr>
<tr>
<td></td>
<td>Anthrax immune globulin (AIG) Treatment for severe anthrax disease</td>
<td>Intravenous (IV)</td>
<td>Will be used under a pre-EUA</td>
</tr>
<tr>
<td></td>
<td>Raxibacumab (ABthrax) Treatment for severe anthrax disease and prophylaxis following exposure to B. anthracis</td>
<td>Intravenous (IV)</td>
<td>FDA approved</td>
</tr>
<tr>
<td></td>
<td>Anthrax vaccine adsorbed (AVA) Pre- and post-exposure prophylaxis</td>
<td>Subcutaneous (SC)</td>
<td>Will be used under an EUA or IND for post-exposure FDA approve for pre-event use</td>
</tr>
<tr>
<td>Plague</td>
<td>Antimicrobials (ciprofloxacin, doxycycline, gentamicin [IV only], levofloxacin [IV only])</td>
<td>Oral and Intravenous (IV)</td>
<td>Oral and IV ciprofloxacin, oral doxycycline, and IV gentamicin will be used under an EUA or IND; levofloxacin and doxycycline IV are FDA approved</td>
</tr>
<tr>
<td>Tularemia</td>
<td>Antimicrobials (ciprofloxacin, doxycycline, gentamicin [IV only]) Post-exposure prophylaxis or treatment</td>
<td>Oral and Intravenous (IV)</td>
<td>Oral doxycycline and oral and IV ciprofloxacin and IV gentamicin will be used under an EUA or IND</td>
</tr>
<tr>
<td>Threat</td>
<td>MCMs</td>
<td>Administration Route</td>
<td>Other Information</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Smallpox</td>
<td>Vaccine (ACAM2000, Aventis Pasteur-WetVax, Modified Vaccinia Ankara [MVA])</td>
<td>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.</td>
<td>Aventis Pasteur-WetVax and MVA will be used under an EUA or IND ACAM2000 is FDA approved</td>
</tr>
<tr>
<td></td>
<td>Post-exposure prophylaxis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tecovirimat</td>
<td>Oral</td>
<td>Will be used under an EUA or IND</td>
</tr>
<tr>
<td></td>
<td>Treatment of disease symptoms and adverse reactions to smallpox vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaccinia immune globulin (VIG), cidofovir, and</td>
<td>VIG and cidofovir are administered via intravenous (IV)</td>
<td>Cidofovir will be used under an IND or EUA</td>
</tr>
<tr>
<td></td>
<td>Treatment of adverse reactions to vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Botulism</td>
<td>Antitoxins (Heptavalent &amp; A Botulinum Antitoxin)</td>
<td>Intravenous (IV)</td>
<td>Botulinum A Antitoxin will be used under an IND or EUA; Heptavalent botulism antitoxin is FDA approved</td>
</tr>
<tr>
<td>Chemical</td>
<td>CHEMPACK – atropine, pralidoxime, diazepam, atropens, and Mark 1 kits/DuoDotes</td>
<td>Intramuscular (IM) or intravenous (IV)</td>
<td>All drugs are FDA approved; Mark 1 kits and DuoDotes are not approved for use in children</td>
</tr>
<tr>
<td>Radiation</td>
<td>Calcium (Ca)- and zinc (Zn)- Diethylenetriamine pentaacetic acid (DTPA)</td>
<td>Intravenous (IV)</td>
<td>FDA approved</td>
</tr>
<tr>
<td></td>
<td>Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prussian blue</td>
<td>Oral</td>
<td>FDA approved</td>
</tr>
<tr>
<td>Threat</td>
<td>MCMs</td>
<td>Administration Route</td>
<td>Other Information</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------</td>
<td>-----------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Antiemetics</td>
<td>Oral</td>
<td>FDA approved</td>
</tr>
<tr>
<td></td>
<td>Neupogen® (filgrastim) Treatment</td>
<td>Subcutaneous (SC)</td>
<td>Will be used under an IND or EUA</td>
</tr>
<tr>
<td></td>
<td>Antimicrobials for secondary infections</td>
<td>Intravenous (IV)</td>
<td></td>
</tr>
<tr>
<td>Burn/Blast</td>
<td>Medical/surgical supplies</td>
<td>Various</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IV fluids</td>
<td>Intravenous (IV)</td>
<td></td>
</tr>
<tr>
<td>Influenza (Pandemic)</td>
<td>Antiviral drugs (oseltamivir, zanamivir) Treatment</td>
<td>Oral, Inhaled</td>
<td>FDA approved</td>
</tr>
<tr>
<td></td>
<td>Personal protective equipment (PPE) (gloves, N-95 respirators, surgical masks, gowns, face shields)</td>
<td></td>
<td>N-95 respirators require fit testing to ensure proper use</td>
</tr>
<tr>
<td></td>
<td>Antimicrobials for secondary infections</td>
<td>Intravenous (IV)</td>
<td></td>
</tr>
<tr>
<td>Natural Disasters</td>
<td>Medical/surgical supplies and equipment</td>
<td>Various</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IV fluids</td>
<td>Intravenous (IV)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Federal Medical Stations</td>
<td></td>
<td>Beds and medical equipment to support non-acute care, special needs care, or quarantine operations (See Appendix A: Federal Medical Stations for more information)</td>
</tr>
</tbody>
</table>

* 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, 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

---

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. 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. In addition, the FDA provides pill crushing instructions 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 Adolescents 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](http://www.cdc.gov/nchs/data/nhanes/growthcharts/set1/all.pdf)
20 [https://www.orau.gov/snsnet/default.htm](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 (DSLRA) project officer.
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) to assist...
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. 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]).

**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.

---


25 [http://emergency.cdc.gov/snaps](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 healthcare 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)
- Adequate bathrooms, water, and electricity
- Compatibility with Americans with Disabilities Act (ADA) 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

---


27 [www.ada.gov](http://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 Los 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](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);
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 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 should also 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](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 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

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). Among the many advantages to this volunteer registry system is the ability to 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 COIN 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) 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;

---


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](http://www.fema.gov/about/stafact.shtm).
• 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**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reduced need for resources compared to segmented PODs</td>
<td>• Requires additional parking at the POD site</td>
</tr>
<tr>
<td>• All dispensing operations presented in a single location</td>
<td>• Requires additional emergency medical services (EMS) so that EMS units can be available at each POD</td>
</tr>
<tr>
<td>• May permit clients to walk, bicycle, or take other transportation methods to the dispensing site</td>
<td>• 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</td>
</tr>
</tbody>
</table>
**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.*
Table 8.3: Advantages and Disadvantages of Segmented PODs

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Regulated flow of clients through POD because people arrive in regulated groups</td>
<td>• 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)</td>
</tr>
<tr>
<td>• Reduced bottlenecks in the POD due to regulated flow of people arriving</td>
<td>• Requires exceptionally large parking area and traffic management plan for the staging area for multiple POD segmentation</td>
</tr>
<tr>
<td>• Reduced parking and traffic congestion concerns at the POD</td>
<td>• Contagious clients may be interacting at staging area before triaged and sent to treatment centers</td>
</tr>
<tr>
<td>• Improved security at the POD because of controlled access</td>
<td>• Requires additional staff and resources, such as vehicles, drivers, fuel, and maintenance for transportation vehicles</td>
</tr>
<tr>
<td>• Symptomatic people are kept out of the POD and transported directly to treatment centers</td>
<td>• Requires additional planning and written agreements with transportation services</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
</tr>
<tr>
<td></td>
<td>• May not keep clients from traveling directly to POD sites and skipping the staging area</td>
</tr>
</tbody>
</table>
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)), 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

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).
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.

**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).

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 workspace 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. 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](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 (DSLR) 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 by 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.
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

U.S.C. § 360bbb–3) 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.

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


termination or revocation, and an explanation of why the authorization is being terminated or revoked in the Federal Register.\textsuperscript{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**

Plans 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

and Accountability Act of 1996 (HIPAA). 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 administrations 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 (DSLR) 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 DSLR 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**


**Closed POD** recruitment tools, technical assistance, and the Community Partner Assessment Tool for closed PODs are available on the [SNS Extranet](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](http://www2.isye.gatech.edu/medicalor/leaseSoft.php).

**Volunteer Recruitment and Management**


Resources to assist in recruitment and management of volunteers can be found on the [SNS Extranet](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](https://www.bt.cdc.gov/agent/smallpox/response-plan)

**Security Planning**


**Legal Issues**

The [Federal Employee Compensation Program](https://www.dol.gov/compliance/laws/comp-feca.htm#overview) “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](http://www.dol.gov/compliance/laws/comp-feca.htm#overview).

The [Federal Tort Claims Act](http://bphc.hrsa.gov/ftca/about/index.html) 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](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](http://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](http://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](http://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](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](http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm) and information on the Public Health Service Act at [www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm](http://www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm).


**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](http://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.


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.

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 setup 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)

<table>
<thead>
<tr>
<th>Supplies</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Badge neck straps</td>
<td>Calculators</td>
</tr>
<tr>
<td>Badge strap clips</td>
<td>Clipboards</td>
</tr>
<tr>
<td>Badges, identity</td>
<td>Dry erase boards</td>
</tr>
<tr>
<td>Candy</td>
<td>Label makers</td>
</tr>
<tr>
<td>Dry erase markers</td>
<td>Pencil sharpeners</td>
</tr>
<tr>
<td>Highlighters</td>
<td>Portable copy machines</td>
</tr>
<tr>
<td>Ink pens, black</td>
<td>Scissors</td>
</tr>
<tr>
<td>Ink pens, red</td>
<td>Staples</td>
</tr>
<tr>
<td>Labels</td>
<td></td>
</tr>
<tr>
<td>Legal pads</td>
<td></td>
</tr>
<tr>
<td>Paper clips</td>
<td></td>
</tr>
<tr>
<td>Paper, colored</td>
<td></td>
</tr>
<tr>
<td>Paper, white copy</td>
<td></td>
</tr>
<tr>
<td>Permanent markers</td>
<td></td>
</tr>
<tr>
<td>Rubber bands</td>
<td></td>
</tr>
<tr>
<td>Scotch tape</td>
<td></td>
</tr>
<tr>
<td>Staples</td>
<td></td>
</tr>
<tr>
<td>Sticky notes</td>
<td></td>
</tr>
</tbody>
</table>
### Table 8.4.2: Sample POD Supplies and Equipment List (Operational)

<table>
<thead>
<tr>
<th>Supplies</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batteries</td>
<td>Automated Electronic Defibrillators (AEDs)</td>
</tr>
<tr>
<td>Biohazard bags</td>
<td>Bullhorns</td>
</tr>
<tr>
<td>Broselow tapes (for determining approximate weights of infants)</td>
<td>Chairs, folding</td>
</tr>
<tr>
<td>Disposable cups</td>
<td>Coolers</td>
</tr>
<tr>
<td>Distilled water</td>
<td>Extension cords</td>
</tr>
<tr>
<td>Duct tape</td>
<td>Flashlights</td>
</tr>
<tr>
<td>Face masks</td>
<td>Generators</td>
</tr>
<tr>
<td>Facial tissues</td>
<td>Hand trucks</td>
</tr>
<tr>
<td>Gloves, latex</td>
<td>Lanterns</td>
</tr>
<tr>
<td>Gloves, nitrile</td>
<td>Measurement equipment for reconstituting medications</td>
</tr>
<tr>
<td>Hand sanitizer</td>
<td>Mobile folding chair carts</td>
</tr>
<tr>
<td>Paper towels</td>
<td>Mobile folding table carts</td>
</tr>
<tr>
<td>Trash bags</td>
<td>Power strips</td>
</tr>
<tr>
<td>Biohazard containers for sharps (e.g., needles) and non-sharps (e.g., gloves)</td>
<td>Radios</td>
</tr>
<tr>
<td>Bike flags</td>
<td>Radios, emergency-alert</td>
</tr>
<tr>
<td>Blankets</td>
<td>Rain ponchos</td>
</tr>
<tr>
<td>Sign easels</td>
<td>Scales</td>
</tr>
<tr>
<td>Whistles (on lanyards)</td>
<td>Storage carts (wire or plastic)</td>
</tr>
<tr>
<td></td>
<td>Surge protectors</td>
</tr>
<tr>
<td></td>
<td>Tables</td>
</tr>
<tr>
<td></td>
<td>Tent poles</td>
</tr>
<tr>
<td></td>
<td>Tent weights</td>
</tr>
<tr>
<td></td>
<td>Tents</td>
</tr>
<tr>
<td></td>
<td>Thermometers</td>
</tr>
<tr>
<td></td>
<td>Trash cans with wheels</td>
</tr>
<tr>
<td></td>
<td>Vests</td>
</tr>
<tr>
<td></td>
<td>Waste Cans</td>
</tr>
</tbody>
</table>

### Table 8.4.3: Sample POD Supplies and Equipment List (Traffic Control)

<table>
<thead>
<tr>
<th>Supplies</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier tape</td>
<td>Traffic batons</td>
</tr>
<tr>
<td></td>
<td>Traffic cones</td>
</tr>
</tbody>
</table>

### Table 8.4.4: Sample POD Supplies and Equipment List (Staff Identification)

<table>
<thead>
<tr>
<th>Supplies</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplies for making staff IDs</td>
<td>System to create staff IDs</td>
</tr>
<tr>
<td><strong>Supplies</strong></td>
<td><strong>Equipment</strong></td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>• Tape or Velcro to attach signs to</td>
<td>• POD Signage</td>
</tr>
<tr>
<td>walls</td>
<td></td>
</tr>
<tr>
<td>• Easels and/or hangers to post</td>
<td></td>
</tr>
<tr>
<td>signs</td>
<td></td>
</tr>
<tr>
<td>• Posts, brackets, or easels for</td>
<td></td>
</tr>
<tr>
<td>outdoor signs</td>
<td></td>
</tr>
</tbody>
</table>