

Medical Countermeasure MASS DISPENSING GUIDANCE

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This guidance was adapted from the MCM Base Guidance created by the Minnesota Department of Health

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Record of Revision1
Introduction 2
Steps to Request Medical Materiel in an MCM Incident Error! Bookmark not defined.3
Chart Notes on Medical Materiel Request Process 4
SNS Distribution Process Flow Chart
Chart Footnotes on Activation and Distribution Process 2
TRIBES AND LPHASInventory Management and Resupply Responsibilities
For Open PODs
For LDS coordinated by TRIBES AND LPHASs and serving only CLOSED PODSs: . Error! Bookmark not defined.
Staffing 4
POD Operations
General Client Policies5
Dispensing Functions
Other POD Operational Requirements11
Measuring Throughput During Exercises13
Information Use 11
Long-Term Dispensing Considerations12
Demobilization
Appendix A: Labeling Guide
Appendix A: Labeling GuideA-1
Appendix B: Suggested Best Practices for POD FlowB-1
Appendix C: Dispense AssistC-1
Appendix D: AcronymsD-1
Appendix E: Adverse Event ReportingE-1

Record of Revision

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Introduction

The purpose of this document is to provide necessary information and documents when planning for incidents that involved mass dispensing. This is not a response plan or template.

In the event of a naturally occurring outbreak, pandemic or a bioterrorist attack, a large population will be in need of life-saving prophylaxis. Local inventories of these medications will be insufficient to meet the needs of the incident. Fortunately, in such a scenario the state of Oregon may request additional supplies from the Strategic National Stockpile (SNS). The Assistant Secretary of Preparedness and Response's SNS is a repository of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency in which local supplies have been or may be depleted. Before 2018, the SNS was housed under the Center for Disease Control (CDC).

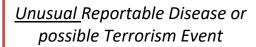
After Oregon requests SNS assets via the Governor, CDC ships the assets to a Receipt, Stage, Store (RSS) site run by the state. The state distributes the assets to Tribal and Local Public Health Authorities (LPHAs), which are then responsible for dispensing them to the public. The process of getting SNS assets out to the public is called medical countermeasure (MCM) distribution and dispensing (MCMDD). The SNS also contains other medical materiel, such as ventilators and personal protective equipment, which may be distributed to healthcare facilities directly by OHA in coordination with LPHA and healthcare coalitions. This will depend on the specific situation.

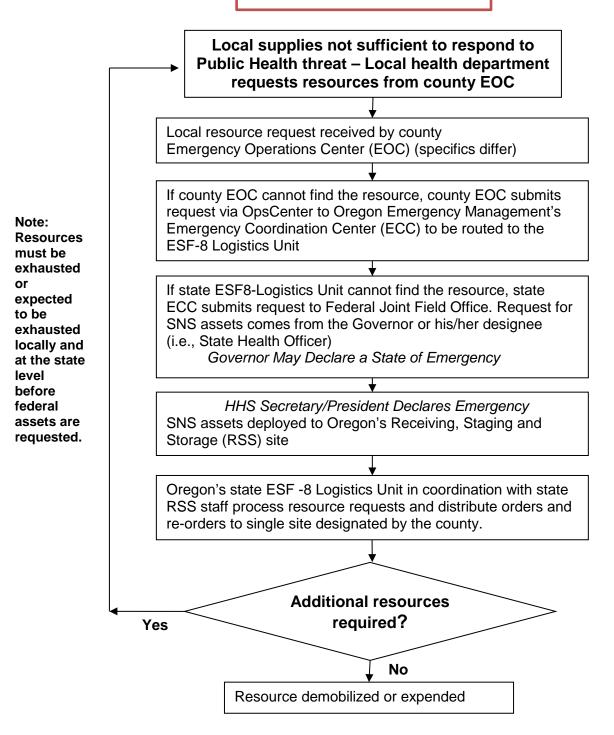
The public obtains SNS assets through Points of Dispensing (PODs). MCM dispensing occurs through two types of PODS: open PODs and closed PODs (CLOSED PODSs). Open PODs are run by TRIBES AND LPHAS. LPHAs and Tribes and serve any member of the public who comes in. Alternatively, CLOSED PODSs are run by specific organizations for their own constituents and, likely, their families. Examples of typical CLOSED PODS partners include large businesses, universities, healthcare facilities, and government agencies. CLOSED POD partnerships benefit TRIBES AND LPHAs by lessening the number of people coming into their open PODs and benefit the CLOSED POD organization by supporting continuity of operations during the emergency. CLOSED POD planning guidelines are available to TRIBES AND LPHAS from the State MCM Coordinator or PHEP/HPP Liaisons.

OHA has an agreement in place to ship SNS assets directly from the RSS to one site per LPHA/Tribe. This site, designated by the LPHA/Tribe is called a Local Distribution Site(LDS). From the LDS, each LPHA/Tribe will distribute to, or set up a pickup point for, open PODs and CLOSED PODs.

Many aspects of MCMDD operations will be the same no matter what the threat. These guidelines cover the processes and procedures that will take place in any mass dispensing scenario. Additional chapters addressing the unique requirements and considerations for specific pathogens and mass vaccination will be developed at a later date.

SNS Resource Ordering Process





Footnotes on Medical Materiel Request Process

- When initiating a request for MCM assets, the following information mustbe provided:
 - Description of situation.
 - Description of need.
 - Description of local efforts to fill request (to avoid duplication of effort).
- The request process and the information requirements are the same whether there has been a federal disaster declaration or not.

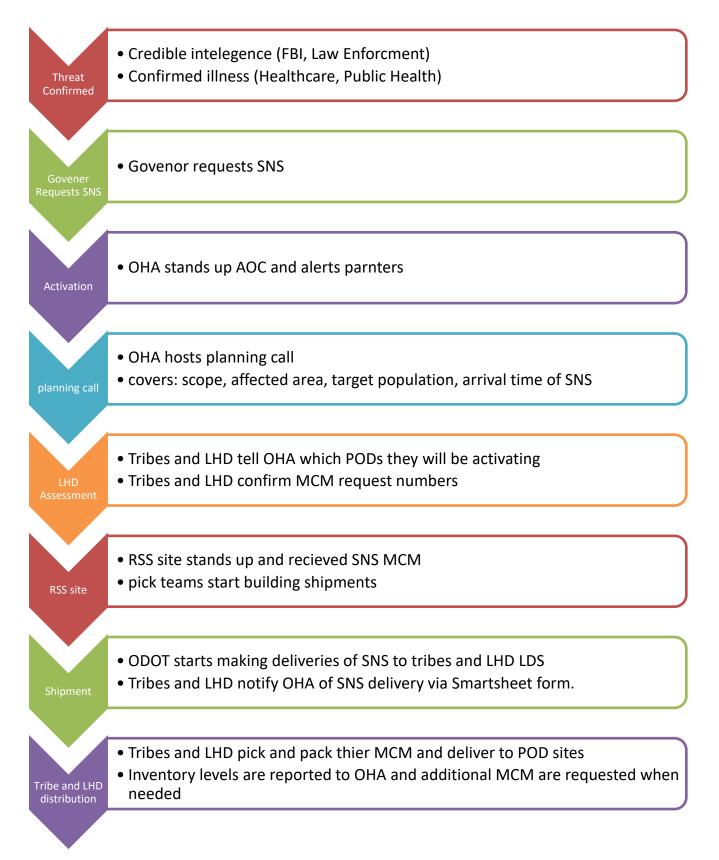


Chart Footnotes on Activation and Distribution Process

- Once a threat is confirmed, Oregon Health Authority (OHA) will notify affected Tribes and Local Public Health Authorities (LPHAs) by sending a Health Alert Notification (HAN) to their 24/7 contacts. This alert will include instructions for dialing into an initial planning teleconference.
- 2. On the initial planning teleconference, OHA will share information about the incident and approximate arrival time of SNS assets. OHA will defer to the local jurisdiction to identify an initial target population for prophylaxis based on information available about who may have been exposed. The local jurisdiction will provide approximate numbers based on the best available knowledge, but more specific information about who those affected people are and where they are from will likely not be known. When the incident deems it necessary, OHA will take the lead. Acute and Communicable Disease Prevention (ACDP), will work with locals to help develop the epidemiological investigation. The definition will likely change over time as more information about the incident becomes known.
- 3. Tribes and LPHAs will use the information they receive on the initial planning call to determine the number and location of PODs to open in their jurisdiction, including both open PODs and Closed PODSs, and email their decisions to OHA's Health Security, Preparedness and Response Program at php.DUTY-OFFICER@state.or.us and Public Health Preparedness Liaison.. Decision-making criteria may include:
 - o Proximity to affected site
 - o Proximity to public transportation
 - Accessibility to drivers (proximity to major roads, traffic concerns, parking availability)
 - o Proximity to location where affected population lives or is staying
 - Size of target population
 - o Option to use Closed PODs
 - o POD locations being opened by other jurisdictions
 - o Security concerns based on site and security staff available

Tribes and LPHAs are also responsible for verifying that all open PODs being activated have their correct facility addresses with OHA. If Closed PODs are used during the mass dispensing response, the location of the jurisdiction's Local Distribution Site (LDS) must also be submitted for awareness. Based on the information known about the incident and the PODs Tribes and LPHAs will be opening, OHA Incident Management Team (IMT) will determine how the first shipment of SNS assets will be divided up among the PODs and share this information with all LPHAs and Tribes.

4. Tribes and LPHAs may monitor their inventory levels continuously using any electronic or paper system they have in place. However, they must update -OHA's IMT Situation Unit periodically (see Inventory Management section on the next page) and request resupply through OpsCenter.

TRIBEs' AND LPHAs' Inventory Management and Resupply Responsibilities

For Open PODs

- 1. Mark shipments of assets as "received" in the Smartsheet Inventory Form when they reach the POD.
- 2. Monitor inventory levels and update POD inventory in The Smartsheet Inventory Form every 8 hours and immediately prior to resupply requests.
- Request resupply using the Smartsheet Inventory Form when inventory level reaches 30% of initial shipment and a need for more assets is anticipated.¹ Resupply may be requested earlier if the need is clear.

OHA strongly encourages a POD staff position dedicated to monitoring inventory levels. Local agencies may use an inventory system that works well for their jurisdiction to monitor inventory levels in real time.

Staffing

Staff and volunteers without a medical license – The majority of POD staff will be individuals who do not have any kind of medical license. An emergency authorization from the Oregon Board of Pharmacy will allow non-licensed staff and volunteers to dispense medicine during a public health emergency, provided they meet the following criteria:

- They are responding according to a Tribes and LPHAs or OHA plan, or an organization's Closed POD plan approved by respective LPHA or OHA; and
- They are staff or registered volunteers, activated by their organization.

The Public Readiness and Emergency Preparedness (PREP) Act also provides liability protection. See www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx for more information.

Staff and volunteers with a medical license – Doctors, nurses, and other medical professionals may serve in POD roles, though many of them may be needed by healthcare facilities overwhelmed with the public health emergency. It is recommended that if Tribes and LPHAs incorporate medical professionals into their POD staffing, that they be assigned to roles where their expertise is specifically useful.

The <u>Medical Practitioner</u> is the only POD staff required to have a license; however, not all PODs need a Medical Practitioner. Medical Practitioners are needed to prescribe medicines or provide additional guidance for clients for whom the available screening tools do not yield a choice of medication.(this is specifically to a non-vaccine POD)

- Tribes and LPHAs must ensure that each open POD has an Medical Practitioners available during hours of operation either in-person or by phone (Tribes and LPHAs may coordinate phone coverage by Medical Practitioners s of multiple POD sites, if needed).
- Closed PODs need to either have an Medical Practitioners available or have a plan to send patients requiring an Medical Practitioners consult to an open POD.
- Medical Practitioners s must be able to prescribe medicine in Oregon. People who can fill the role include Community Health Board Medical Consultants, medical professionals registered with MRC, or contracted professionals. Medical Practitioners s must be oriented to the appropriate prescribing protocol, any applicable emergency use authorizations from CDC, and how their role fits into the larger MCM dispensing process.

If the event deems it necessary, OHA will staff a provider hotline and additional clinical guidance for questions that medical providers may have regarding prescribing prophylaxis. The phone number(s) will be shared at the time of the event.

Tribes and LPHAs must retain the names and contact information for all staff and volunteers who work in their PODs for the purposes of short and long-term tracking of exposures/injuries and any related health issues. OHA encourages Tribes and LPHAs to issue pre-deployment health surveys to all POD staff to serve as a baseline for post-deployment health assessments. These records will also be used to calculate costs of the event.

POD Operations

Many of the items below have detailed standard operating procedures (SOP) or just in time training (JITT) modules in the Oregon POD Field Operations Guide (POD FOG)

General Client Policies

- "Clients" are those who appear at a POD needing medication.
- Individuals may obtain medicines at any open POD in any Oregon jurisdiction and are not assigned to specific sites based on the jurisdiction of their work or residence.
- The "target population" is the definition of the population that OHA has deemed in need of
 prophylaxis. This definition may change over the course of an event as more information
 becomes known. POD staff shall share the current definition of the target population with
 clients, but they do not need to take extra steps to verify that clients meet the definition. It
 is up to individual clients to decide whether they are part of the target population and
 require medication.
- Public messaging will instruct symptomatic individuals to seek assistance at a designated healthcare facility, not a POD. This is especially important for pathogens that are transmissible person-to-person.
- Open PODs must serve everyone who comes, regardless of where they live or work. Identification and proof of address or citizenship are not required at open PODs and must not be requested by personnel. Minors must also be served even if they show up without a parent or guardian, though they must be served by the LPC.
- PODs must be prepared to accommodate those who fill out screening forms in advance using the Dispense Assist (found at www.dispenseassist.net) electronic screening tool and those who arrive at the POD needing to complete a form on site (see Appendix C for additional guidance on utilizing Dispense Assist).
- Assistance must be provided to clients who have difficulty filling out the screening form. However, if a client is unwilling or unable to provide complete name, address, and phone information, the POD may not deny them medication.
- Families who arrive at the site together should be kept together as much as possible through the process.
- Generally, a household representative can obtain up to ten regimens of medicine for family, friends, neighbors, etc. The POD manager may allow household representatives to obtain more than 10 regimens of medicine as long as a screening form is provided for each

individual. The purpose of the general limit of ten is to prevent line bottlenecks and largescale hoarding of medications, not to deny clients medications.

• Unaccompanied minors who appear able to understand and carry out the responsibility may serve as household representatives.

- Many medications in the SNS have had their expiration dates extended through the Food and Drug Administration (FDA) Shelf Life Extension Program (SLEP) but have not been relabeled. All medications received from the SNS have been determined to be effective through laboratory testing, regardless of the expiration date on the bottle. Some medications may only have a date of manufacture and no expiration date. POD staff must be trained to address concerns from clients about the expiration dates of their medications.
- Before leaving an open POD, all clients in the target population shall receive either:
 - a container of antibiotics;
 - o a letter of referral to get alternate medications.
- Clients cannot be charged for antibiotics from local, state, or federal caches or stockpiles, but under certain circumstances, some pharmacies may be able to charge an administration fee.
- If any clients experience any moderate to severe side effects related to the medications dispensed at the POD, these should be reported to MedWatch at <u>www.fda.gov/medwatch</u> or 1-800-FDA-1088 and the client should seek medical assistance from a healthcare provider. These phone numbers are included on the medication fact sheets given to clients. POD staff or healthcare providers noticing patterns of adverse events should contact their LHD. Tribes and LPHAs should closely watch all reported adverse events and relay them to OHA. (ref. Reporting Adverse Events Appendix E)

Dispensing Functions

There are lots of ways to organize a POD. We recommend using the functions below in your MCM dispensing operations at open PODs. Multiple functions may be co-located at the same station to increase efficiency or reduce staffing required. Tribes and LPHAs are encouraged to combine and organize the functions as necessary to increase their throughput. Additional supporting roles for POD staff (e.g. supply or inventory management) should be added as needed. For best practices on organizing these steps for the most efficient client flow, see Appendix B.

- <u>Triage</u> To triage is to identify people exhibiting symptoms of the disease in question.
 - i. For diseases that are not transmissible between people, such as anthrax, triage can be in the form of signage. POD signage can describe symptoms of the disease and encourage those people who have those symptoms to seek medical care.
 - *ii.* For diseases that are easily transmissible person-to-person in a public space, it is important that the POD not be a source of disease exposure. Public messaging will direct symptomatic individuals to healthcare facilities, not to PODs. Ill people who come to a POD with symptoms consistent with the public health emergency at hand shall be instructed by POD staff to leave and seek care at the nearest healthcare facility. *OHA, in situations that deem it necessary, will provide LPHAs and Tribes with a disease-specific protocol that will clearly indicate whether the disease is contagious and provide triage guidance.*
- <u>Greeting</u> Greeting is the first station at the POD. This station is used to direct clients to
 the appropriate next step in the POD. It can be used to assess, for example, whether a client
 is part of the target population, whether they can be directed to an expedited line, or if they
 have access or functional needs (see next page). Greeters must have a confident
 understanding of where to direct clients and should ideally have a calm or reassuring
 demeanor to help lessen fear and confusion clients may be experiencing. If you are using
 both paper and online screening, the Greeter can identify those people who need to
 complete a paper form.
- <u>Form Completion</u> Clients who did not complete an electronic screening tool in advance of their arrival at the POD will need a place to complete their screening forms. PODs may have computers and printers available to use the electronic screening tool and/or they may print paper screening forms to be filled out with pen. PODs may also choose to hand out forms to people in line so they can fill them out while they wait. Even PODs utilizing computers will need staff at the form completion station to assist clients who may have difficulty completing theform.
- <u>Form Review</u> POD staff should ensure that screening forms have been filled out correctly and direct clients to the appropriate next station. As noted on the previous page, if clients are unwilling or unable to complete the forms in their entirety, POD staff must let them proceed anyway, as long as the appropriate medication can be determined using the algorithm.

- <u>Screening</u> POD staff review the screening form to determine the correct medication for the client based on their answers to the screening form questions. This staff position applies only to paper screening forms, not ones generated using the electronic screeningtool.
- <u>Dosing</u> POD staff review the screening form to determine whether the client needs an adjusted dose of the medication or a specific formulation (ex. a liquid formulation or pill crushing instructions). This function is typically combined with Screening or Dispensing.
- <u>Dispensing</u> POD staff dispense medication(s) to clients based on the outcome of screening and dosing and label each bottle according to OHA instructions (see Appendix A). If a client presents a paper or printed screening form, the dispenser completes the lower portion and retains the form. Forms contain private information and should not be left out in the open

- a box behind the dispensing station could be a good method for retaining forms.

Tribes and LPHAs may acquire the hardware and software to scan QR codes off tablets and smartphones. If so equipped, when a client presents a form on a smartphone or tablet screen, the dispenser scans the QR code on the client's device and then scans the QR code for the medication dispensed. This QR code can be generated for each medication, dispenser, lot number, and POD location using the "Dispenser" tab/page at <u>www.dispenseassist.net</u>. These codes should be generated and printed as soon as the medications arrive at the LDS and the critical points of information like Lot Number are known. NOTE: at the time of publication, OHA does not have a large cache of scanners so if you want to use the smartphone function consider how you will obtain QR code scanners. Scanners are not required to use the web based Dispense Assist tool where client print out a paper voucher but they do make data gathering more simple.

In situations where you have limited staff or time, it is best to combine these three efforts into one Dispensing roll. Most of the tools in the POD FOG show this as a combined station.

<u>Medical Consult</u> – For some clients, the electronic screening form or screening algorithm
will yield an answer of "X" or "Consultation." This means that one of the Medical Consult
or Consultation team members, a medical provider if available, needs to determine the best
medication for the client. This station would ideally have a Medical Provider in person to
consult with these clients, but it could also be an area where POD staff assists clients in
contacting the Medical Provider by phone. It is possible to do this station without medical
personnel if the tools given to the team cover all situations.

Clients who go to this station will be dispensed medication if they are able to take them. it is a best practice to have a Dispensing staff assigned to this station so that the Medical Consult does not also have to dispense the medication.

 <u>Health Education</u> - All fact sheets included in the relevant prescribing protocol must be provided to clients before they exit the POD (medication-specific fact sheets only need to be provided to clients dispensed that medication for themselves or someone in their household). Fact sheets may be shared among household members to conserve resources. If resources allow, educators should be available to answer client questions after the dispensing station or near the POD exit (to minimize bottlenecks). Additional educational materials will be made available at the time of the event. Trusted sources of information will be the OHA website (<u>http://www.oregon.gov/oha</u>) and the CDC website (<u>https://www.cdc.gov</u>).

<u>Documentation</u> – Open POD and Closed PODs partners must keep records of medications dispensed to clients. Paper screening forms and printouts of online screening forms must be retained. For Tribes and LPHAs choosing to accept electronic forms presented on a phone or tablet screen, the QR code of the form must be scanned followed by the QR code for the medication dispensed. Open POD and Closed POD partners must maintain these records in accordance with their organizations' data retention policies. OHA does not require copies of these records. If no policy exists, OHA recommends retaining the records for at minimum 7 years (the statute of limitations for personal injury actions in Oregon).

Other POD Operational Requirements

- <u>Access and Functional Needs Support</u> Open PODs must have staff and resources assigned and accessible to assist clients with access and functional needs to move through the POD and receive their medications. This includes support for those who are visually impaired, hearing impaired, Limited English proficiency, non-English speaking, or who have a physical or mobility limitation. Measures may include use of plain language and/or pictures in signage, use of interpreters or multilingual staff, use of language lines, availability of wheelchairs, etc. Planning must also include how greeters who identify these needs coordinate their provision, for example by telephone or radio.
- <u>Signage</u> Signs are important to minimize confusion and increase efficiency. Each POD station must be labeled and directional signs may be needed as well. Signs should utilize images and pictograms to be as applicable to non-English and Limited English Proficiency speakers as possible. All signs must follow ADA and 508 rules and laws.
- <u>Security</u> Open PODs must have security plans that account for the security of the medications being dispensed and the staff and clients present at the site. Plans must include:
 - o Evacuation Procedures
 - Exterior security for location
 - o Interior security for location
 - o Scalability
 - o Security breach procedures
 - Security command/management plan

Other security considerations may include:

- A badging process to coordinate POD staff access, especially for volunteers.
- Credentialing for healthcare workers, if accepting spontaneous volunteers who have not been credentialed ahead of time.
- Extra staff safety considerations for drive-through PODs (ex. visible lane markings).
- <u>Inventory Management</u> Open PODs must track their inventory levels and promptly request resupply when needed. This process will likely be in coordination with but different from the agency's use of the Smartsheet Inventory form.
- <u>Staff Support</u> PODs must provide staff with food, bathroom, and break areas. Mechanisms must be in place to record and report any injuries sustained by staff during POD operations.
- <u>Monitoring for Adverse Events</u> Open POD staff shall be trained, for example through their Job Action Sheets, to watch for, recognize, and report any adverse events to medications that they witness at the POD site.
- <u>Media Management</u> Media are likely to show up at PODs during an emergency. OHA recommends that PODs plan for media staging and coordination of publicinformation.
- <u>Cold Chain Management</u> Antibiotics may be kept at room temperature, but since POD sites may also be used for vaccination, PODs must have cold chain management plans to keep any vaccine they receive at the appropriate refrigerated (or in the case of smallpox vaccine, frozen) temperature required by the manufacturer. These plans must include procedures for storing vaccine in an appropriate temperature range, monitoring temperatures periodically, and reporting deviations from temperature requirements. If appropriate refrigerators and freezers are not already available at the POD site, the POD

must have a plan to acquire these supplies for use during an emergency. More detail for vaccine storage requirements can be found in CDC's Vaccine Storage and Handling Toolkit: <u>https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMU</u>

Measuring Throughput During Exercises

- Measuring throughput is an important way to determine the efficiency of the POD flow and to identify opportunities for improvement.
- RealOpt is a good option for estimating throughput during the planning phase, but it is important to actually test throughput through exercises.
- While an overall measurement of throughput is useful (i.e. the moment a client arrives at the first POD station until the moment they depart the last POD station), measuring throughput at each station provides more detailed information about where slowdowns are occurring.
- Station throughput should be measured from the time a client arrives at the station to the time they leave. This is true regardless of whether a station only performs one POD function (for example, triage) or whether it combines POD functions (for example, combined screening and dosing).
- Times for at least 50 clients should be recorded for the throughput calculation to be accurate and meaningful.

POD flow can be structured in different ways. Below is an example of how throughput would be measured in a POD that combines screening and dosing

Station	Time IN:	Time OUT:
Triage	Initial Contact with Client	Leave Station
Form Completion	Given Form or Seated at Computer	Leave Station
Form Review	Review Started	Review Completed/Leave Station
Screening/Dosing	Arrive at Station	After Screening/Leave Station
Dispensing	After Screening/Before Administration	After Administration/Leave Station
Overall	Initial Contact with Client at Triage	Leave Dispensing Station

Example:

Information Use

- Tribes and LPHAs are responsible for the data created through open POD operations (i.e. the completed forms and the medications dispensed). They must keep this data according to their own agency's data retention policies and schedules. Closed PODs partners are responsible for keeping their own data according to their own organization's data retention policies and schedules. Should the need arise, Tribes/LPHAs may request Closed PODs share that data.
- OHA will not collect screening forms or screening form data. Dispense Assist does not retain any data.

Long-Term Dispensing Considerations

- In some mass dispensing scenarios, medications will be distributed and dispensed in two waves: an initial smaller supply followed by a larger resupply. For example, in an anthrax scenario, PODs would initially dispense a 10-day supply of antibiotics. After those operations are completed, there would be a follow-up response in which they dispense a 50-day supply to affected individuals.
- The same POD locations do not necessarily have to be used for the initial dispensing operations and the follow-up dispensing operations. POD hours may also be adjusted.
- Additional information may be acquired that would allow OHA to further narrow down the exposed population, meaning that follow-up dispensing operations may serve fewer people.
- A long-term response may require mutual aid to ensure adequate staffing.

Demobilization

- During demobilization, certain medical assets must be returned to CDC:
 - o CDC-issued coolers and containers.
 - Any medications requested back by CDC (depending on quantity and demand).
 - o All durable medical equipment (ventilators)

OHA may also request the return of pallets sourced by the RSS, in order to use them for CDC return shipments.

- OHA will coordinate the return shipment of CDC assets from the RSS. In general, demobilized assets will be returned to the RSS by the Tribe/LPHA that received them, whether direct ship or pick-up.
- Tribes and LPHAs shall retain names and contact information of all staff and volunteers who served as part of the response for responder safety and health tracking.

Appendix A: Labeling Guide

- The labeling of prescription medications is a legal requirement of FDA and the Oregon Board of Pharmacy.
- During an emergency, some elements of labeling that are typically required will be legally suspended. However, all of the antibiotics dispensed for anthrax will require some amount of additional labeling.
- SNS assets must be labeled at PODs with the following additional information:
 - o Patient name,
 - o Medication dosage,
 - Medication frequency, and
 - Date medication is dispensed.

If a household representative is picking up medications for multiple people, each medication must be individually labeled for the appropriate person. If someone refuses to provide their name, enter "Name Refused" in the line for the patient's name.

- POD dispensing staff are required to document prescription information.
 - For printed forms, this means peeling a label from the bottle and affixing it onto the dispensing form in the designated space and signing where required. (This label comes on the bottle and is not printed by the POD)
 - For electronic forms, this means scanning the QR code on the screening form followed by the QR code for the medication dispensed. These QR codes are made by the LHD using the tool available on the dispenser tab on the <u>www.dispenseasssist.net</u> website. More info can be found in Appendix C.

Example: Website

Output

	DISPENSE ASSIST			
VOUCHERS FOR:	Pharmaceu	itical Medication	Voucher Input Screen	
 <u>Anthrax</u> <u>Influenza</u> 	Medication B	ar Codes Entry		
Plague	Medication Type:			
Tularemia	Clinic Site:			
	Administrator:			
	Manufacturer:			
Additional Languages:	Lot #:			
Languages.	Expiration Date:	mm / dd / yyyy		
 Español 	NDC #:			
	Next		Clear	



Example of how to label a bottle:

1. Single regimen for doxycycline and ciprofloxacin – please note "blank side" of the container:



2. Illustration of application of label (note that label avoids covering pre-printed information):



3. Medication with Complete Patient Label:



4. Peeling label from bottle to affix to paper form for documentation:



Appendix B: Suggested Best Practices for POD Flow

The most efficient method for moving clients through the required steps described above may vary. Tribes and LPHAs and Closed PODS partners have some flexibility in determining how clients flow through their PODs.

When considering POD flow, it is important to also consider how designated expedited lanes can move some clients through the POD faster, increasing overall throughput, as well as how different functions may be combined or reordered for maximum efficiency. Triggers and mechanisms for increasing throughput when bottlenecks form are suggested options to incorporate into POD flow planning. POD staff are trained and empowered to take action if they observe a correctable bottleneck occurring.

Two possible models are described below (for a non-contagious disease, so the triage step is eliminated). Tribes and LPHAs are encouraged to explore alternative models that they believe will increase efficiency.

Option 1: Expediting Clients Based on Electronic Screening Form Completion

- **Step 1:** Clients arrive at the greeting station. Populations with access and functional needs are assessed and clients are connected with support as needed. Clients with completed electronic screening forms are routed directly to a Dispensing Station (step 5).
- **Step 2:** Clients without forms complete their forms with support as needed.
- **Step 3:** POD staff person checks to ensure forms are completed and directs the client to a line for screening, or to medical consult if needed.
- **Step 4:** Screeners/Medical Practitioner review client form to determine correct medication and dose.
- **Step 5:** All clients go to dispensing station to receive their medications.
- **Step 6:** Clients reach the Education Station where they receive informational handouts and can have their questions answered.

Option 2: Expediting Clients Based on Ability to Get Either Doxy or Cipro

- **Step 1:** Clients arrive at the greeting station. Populations with access and functional needs are assessed and clients are connected with support as needed. Examples of some options:
 - **limited sight** pair with a guide/reader/writer to help move through the POD
 - **limited mobility** guide to a single stop station or provide a wheelchair
- **Step 2:** Clients complete screening forms (those who brought completed, screening forms with them proceed to Step 3).
- **Step 3:** All clients present screening forms to a line monitor. Line monitor directs those who can receive either Doxy or Cipro at the usual adult dose to a dispensing station to receive their medications. Everyone else is directed to the medical Practitioner station to receive their medications or referral.
- Step 4: Clients pass by Education Station where they receive informational handouts

and can have their questions answered.

Line Management: General Best Practices

- People will accept a long line if they keep moving; moving in periodic surges is less acceptable. Even inching along is better than standing still for long periods.
- When possible, use a single line to feed multiple stations so that it keeps moving and there is no perception that one is in the wrong (slower) line.
- If there are two lines that move at different speeds (i.e. expedited dispensing vs. regular), avoid having them visible to each other. Manage lines to ensure that the longest line is always at the point where medicine is handed out.
- If lines are extremely long, natural visual barriers may reduce the psychological impact of seeing that very long line.
- Line comfort is important heat/air-conditioning, benches, shade, water, etc. should be provided when possible. It is not acceptable to have people queueing outside during extreme or inclement weather.
- People need distractions—visual, auditory or tasks. Keep them busy with things to watch or read. If wait times are longer than a few minutes, consider providing a simple distraction for young children in line (coloring pages, books, etc.).
- Use the line to hand out clipboards and the screening form or use signage to direct them to the Dispense Assist app (if you have scanner capability in your pod)
- Move your patent educators to roving the line to engage and answer questions while clients wait.
- Set expectations for how long the wait will be and be conservative it is better for the wait time to be shorter than expected than to be longer. Use ushers to provide updates on wait time and other information related to the event. Provide other options if available (i.e. going to a different POD).
- Give people instructions while in line so they move quickly when they reach the end of the line. Tell them exactly what to do giving them a choice for what to do when they reach the end of the line slows them down.
- At the point that lines diverge, it is important to keep families together. If lines are based on different levels of need, families should be directed through the line appropriate to the most complex case among them.

Additional tips for maintaining calm at a POD are available on the Assistant Secretary for Preparedness and Response (ASPR) website:

http://www.phe.gov/Preparedness/planning/abc/Documents/calm-pod.pdf.

Appendix C: Dispense Assist (DA)

Overview

- DA is an electronic screening tool that determines which antibiotic(s) a client may safely be dispensed during an MCM incident based on their answers to a small number of health-related questions. It works on computers and on mobile devices. For most clients, this form will take fewer than 5 minutes to complete. DA also works for influenza by determining if a client may safely be vaccinated.
- DA uses the same screening algorithm as OHA's Anthrax post exposure algorithm. Because the risk of human error is reduced with DA, its use is recommended over the use of paper screening forms whenever possible.
- DA indicates all antibiotics a client may be safely dispensed. If multiple antibiotics are listed on the printout, the dispenser may determine which medication to dispense based on available supply and any guidance from the POD manager or CDC/OHA. While both doxycycline and ciprofloxacin are equally effective against anthrax, doxycycline has fewer side effects, if there is a sufficiently great supply. If all other factors are equal it is good to listen to the patent who may say they have a preference due to a sensitivity to one mediation or another that would not have removed it as an option using DA.
- DA is available at: www.DispenseAssist.net.
- The DA application does not save any client data. First Responders or other organizations wishing to prescreen may aggregate completed screening forms (paper, PDF, or Excel spreadsheet) in accordance with their own agency's data policies. Care should be taken to ensure anyone with a change in medical status (for example, a new pregnancy) is rescreened.

DA can be completed by clients before they arrive at the POD.

- Public messaging from OHA and LPHAs will encourage POD clients to complete electronic screening forms before they arrive at a POD.
- PODs may consider expediting clients that arrive with their screening forms already completed.
- Clients may come to the POD with their screening forms completed on mobile devices. At this time, PODs may only accept screening forms on mobile devices if they have QR code scanning capability (see "Record-Keeping") below. Otherwise, the client will have to fill out a paper form or print an electronic form at the POD to obtain a paperrecord.

PODs can allow clients to complete DA at the POD.

 PODs are strongly encouraged to set up computers or tablets and printers to allow POD clients to complete and print the electronic screening form on site. Using DA instead of paper screening forms reduces the number of screening staff needed, reduces human error, and increase efficiency. PODs should still plan to have staff to assist clients in using the computers to fill out the forms.

Record-keeping is important.

- PODs are responsible for retaining records of which medication has been dispensed to each client. For Dispense Assist, there are two options, and PODs may use either:
 - Saving paper records: the labels for the dispensed medication can be affixed to the paper printout of the screening form and the form can be retained.
 - Scanning QR codes: If they have access to QR code scanners, PODs may maintain records electronically using QR codes. The Medication QR code generator (<u>http://www.dispenseassist.net/dispensers.html</u>) can be used to create a QR code for each medication dispensed. POD staff would first scan the QR code on a client's screening form (either printed or shown on a device screen) and then scan the Medication QR code for the medication dispensed to link them in an Excel spreadsheet. NOTE: this option requires the use of QR codes scanners.

Language you can use to add DA to your plans:

Overview: Dispense Assist (DA) is an online screening tool developed and maintained by Johnson County, Kansas for use by any jurisdiction. DA can be used to speed up the throughput time, increase ease of Point of Dispensing (POD) process and reduced the screening errors within a POD. Dispense Assist can be used for three Category A agents: Anthrax, Plague and Tularemia as well as Seasonal Influenza.

The public access DA prior to arriving at a POD.

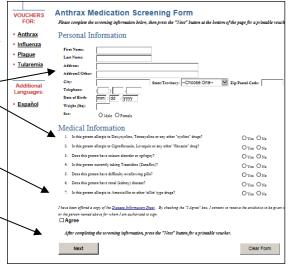
How it is used:

Accessed via computer at <u>www.dispenseassist.net</u>

- 1) Internet Explorer (IE) works the best for this website
- 2) Through your IE settings enable pop-ups.

Once in DA, there are 4 steps:

- Choose correct event: anthrax, plague, tularemia or Influenza
- Fill out the online screening form with demographic information and screening questions. Questions are the same as those asked on the paper forms in PODs.
- Download the Disease Information Sheet (link at the bottom of the form page) and Check the "Agree" box
- 4) Click the "Next" button to get the voucher that indicates which medication you can take and go ` to a POD. Printed Voucher which will say "Bring this voucher with you" at the top must be taken to the POD.



Accessed via App (Droid or IOs)

1) Download the App from the appropriate app store by searching for "Dispense Assist" the App was developed by Johnson County.



- 2) When using the App:
 - a. Each person can fill out, and save, vouchers for all of their family members.
 - b. If the person has a way to print from their phone it is better to arrive at a POD with a paper copy.
 - c. Ensure that your phone has adequate power, you bring a charging cord or back up power supply to make it through the POD.
 - d. If you are unable to print, you may have to fill out a paper form at the POD but DA is a great way to keep track of the answers to the screening questions for each of your family members.

Key Public Information Dispense Assist (DA) Use Talking Points:

- 1) Use of Dispense Assist will improve your experience at a POD by making it faster and easier
- 2) To use Dispenseassist.net

Anthrax Medication

Please complete the screening informa

Personal Information

nm / dd / jyy

Online O'Penne
 Online O'Penne
 Online O'Penne
 I. Is this person allergis to Deccyceli
 I. Is this person allergis to Deccyceli
 Dess this person allergis to Chronology
 I. Is this person allergis to Chronology
 Dess this person three difficulty via
 Dess this person allergis to allergis
 To be person allergis to the chronology
 There been offered a copy of the Decement for
 the physical material body for them allows

First Name:

Last Name:

Date of Birth:

Weight (lbs Sex:

Agree

After completing the screening info

Address: Address2/Others

City:

OUCHERS

Anthrax

Influenza

Plague

Tularemia

Additional Languages

Español

- a. Internet Explorer works best
- b. You must enable pop-ups when you open IE
 - i. Under Tools turn off the pop-up blocker

	C Dispense Assist -	Internet Explore	er provided by Washington County
	📀 🕞 🗢 🩋 http	ps://dispens \mathcal{P}	💌 🔒 😏 🥔 Dispense Assist 🛛 🗙 🏠 🄅
	File Edit View	Favorites Tools	; Help
	Delete browsing history InPrivate Browsing	Ctrl+Shift+Del Ctrl+Shift+P	y Meetings - Zoom 🥨 On-TRAC - Home 🕼 LA MCM EX 👋
	Turn on Tracking Protection ActiveX Filtering Fix connection problems Reopen last browsing session Add site to Start menu		rax Medication Screening Forr^ omplete the screening information below, then press the "Next" onal Information
	View downloads	Ctrl+J	
Turn off Pop-up Blocker Pop-up Blocker settings	Pop-up Blocker SmartScreen Filter Manage add-ons	•	Name:
	Compatibility View settings		2551
	Subscribe to this feed Feed discovery Windows Update	÷	ss2/Other: State/Territory:C >

(miles)

3) You must bring the voucher to a POD. First fill out the online form. Then click the "Next" button at the bottom of that page to get your voucher

4) Vouchers will have "C", "D", "C/D" "X" in the upper left-hand corner

This voucher permits the individual named below Pint BRING THIS VOUCHER WI Degrese Assist Post Exposure Prophylaxis Voucher Medication: Either Ciprofloxacin or Dos Pints Name: Donner DoB: Address 2: 1234 Weight: Address 2: 1234 Sec: City, 5120: portland, OR 97213		This voucher permits the in BRING THIS V Dispense Assist Post Exposure Prophylaxis ion: <u>Ciprofloxacin</u>
Health History Information 1. Is this person allergic to Ciprofloxatin or any other "eyclin" 2. Is this person allergic to Ciprofloxatin or any other "discatin" drug? 3. Is this person have seizure disorder or epilepsy? 4. Does this person have seizure disorder or epilepsy? 5. Is this person taking Trainatine (Zanaflew etc)? 6. Does this person have difficulty swallowing pills? 7. Is this person less than 18 years old? 8. Does this person have Renal (Kidney) disease? 9. Does this person have an allergy to amovicillen?	NG NG NG NG NG NG MG	This voucher permits the BRING THIS V Dispense Assist Post Exposure Prophyla cation: Doxycycline
I, the undersigned, certify that all of the above information is correct to the la authorize the recipient of this document to share this information with public and federal level for purposes of ensuring medication efficacy and safety. I Notice of Information Practices. Client Signature: Date <u>Point of Dispensing Use Only:</u> Medication Provided: Doxycycline Ciprofloxacin Place Lot # Sticker Here Dispensing Site Name: Dispensing Site Name:	health entities at the le	5 bring it w will be aske to receive m instructions

5) If your voucher has and "X" please bring it with you to a point of dispensing. You ill be asked to fill out a new form but may be able preceive medication and will receive further astructions

Using a Scanner with Dispense Assist (DA):

What you need:

- 1. From <u>www.dispenseassist.net</u> (Dispensers Tab):
 - a. Bar Code (QR) for the medication you are dispensing using the Bar Code Creation tool
 - b. Data Collection spreadsheet for capturing all client and medicine dispense data
- 2. Other Resources:
 - a. Computer
 - b. QR code scanner





Setup:

- 1. Create a Bar Code for the specific medication you have on hand using the Bar Code creator on Dispense Assist. Info you will need:
 - a. Vaccine/Medication Type
 - b. Clinic Site (could be county PH)
 - c. Administrator (could be lead person)
 - d. Manufacturer
 - e. Lot #
 - f. Expiration Date
- 2. Download and open the correct Data Collection Spreadsheet. Recommend saving to desktop for easy retrieval.
- 3. Plug in QR Code scanner

Pharmaceutical Vaccine Voucher Input Screen		
Vaccine Bar	Codes Entry	
Vaccine Type:		
Clinic Site:		
Administrator:		
Manufacturer:		
Lot #:		
Expiration Date:	mm / ldd / yyyy	
Next	Clear	

Operating/Process:

When the client comes to the dispensing/vaccination station they should have a form that has a D,C, or D/C (for dispensing antibiotics) or an "I" for flu vaccination.

eparate Values

Т

BRING THIS VOLCHER WITH YOU

Tabaha DOB Age San

- Use the computer mouse to activate (click in) the first empty data cell in column A (row 4 for first scan) of the Data Collection Spreadsheet
- 2. Scan the QR code on the Dispense Assist Voucher. Data will show in the spreadsheet (see note below)
- 3. Scan the QR code on the appropriate medication or location for vaccines.

appropriate vaccination



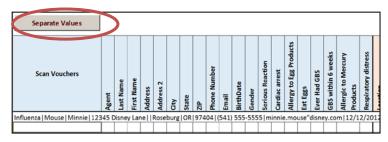
C D E F G H I J K L M N O P Q R

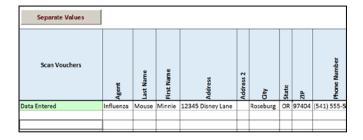
Dispense Assist Vaccine Data Collection

- 4. Press Enter on your keyboard
- 5. Repeat from step 2 for each new client.

NOTE: Data first entered into the spreadsheet will look messy.

To improve the look of the data Click the "Separate Values" button. After that all the data will scan in in a visually appealing manner.





Appendix D: Acronyms

Acronym	Meaning
CDC	Centers for Disease Control and Prevention
Closed PODs	Closed Point of Dispensing
DOC	Department Operations Center
FDA	U.S. Food and Drug Administration
IMATS	CDC Inventory Management and Tracking System
LDN	Local Distribution Node
МСМ	Medical Countermeasure Dispensing
ОНА	Oregon Health Authority
MRC	Medical Reserve Corps
POD	Point of Dispensing
RSS	Receipt, Stage, Store Site
SLEP	Shelf Life Extension Program
SNS	Strategic National Stockpile

Appendix E: Adverse event reporting

PURPOSE

These guidelines have been established to identify the roles and responsibilities of the Local Public Health Authorities (LPHA) and Tribes as they pertain to adverse events reporting related to mass dispensing operations.

SCOPE

This document defines adverse drug reactions; identifies roles, responsibilities, and authorities as they related to adverse events reporting; and establish procedures for the health authority to maintain situational awareness of adverse event incidents.

BACKGROUND

During certain public health emergencies, the need for LPHAs/Tribes to engage in mass dispensing of medical countermeasures may be necessary. During these incidents health authorities may be required to dispense large quantities of medication to the general public, and due to the time sensitivity of the situation, do so without the ability to provide thorough clinical consultation to each and every citizen that the Point of Dispensing (POD) serves. Due to this fact, it is necessary for federal, state, and local public health officials, as well has healthcare providers, to establish protocols to track and act upon any adverse reactions that may result from mass dispensing operations. While it is important all adverse reactions are reported to federal authorities, it is also necessary for state and LPHAs/Tribes to be aware of significant numbers of adverse reactions following mass dispensing operations. The Oregon Health Authority (OHA) and the LPHA/Tribe must maintain awareness of the situation so that it may be reported to the Centers for Disease Control and Prevention (CDC) and any necessary corrective actions regarding medication that has been dispensed may be carried out.

Definition of Adverse Event: Adverse reactions are different from common drug side effects. The American Food and Drug Administration (FDA) defines a serious adverse event as one when the patient outcome is one of the following:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability Significant, persistent, or permanent change, impairment, damage or disruption in the body's function/structure, physical activities or quality of life
- Congenital anomaly
- Requires intervention to prevent permanent impairment or damage

ROLES AND RESPONSIBILITIES

Health Care Providers:

 Report all adverse reactions (except for vaccines) to the FDA at: <u>https://www.accessdata.fda.gov/scripts/medwatch/</u>

- Vaccine adverse reactions are reportable to: <u>https://vaers.hhs.gov/esub/step1</u>
- If unusual numbers of adverse reactions are being reported, notify the LPHA/Tribe and OHA

U.S. Department of Health and Human Services and Food and Drug Administration

• Compile reports of adverse reactions and follow up with providers, manufacturers, and individuals having reactions

Oregon Health Authority

- At the time of the incident, educate private providers and hospital emergency departments about how to report adverse reactions to OHA and the FDA
- Regularly contact the FDA requesting significant adverse reaction reports during an incident
- Coordinate with field staff and LPHAs/Tribes regarding any follow up needed for reported adverse drug reactions
- Report to the CDC regarding significant adverse reactions to any medications used in a mass dispensing campaign

Local Public Health Authority:

- Distribute medication information sheets to consumers along with the medication during mass dispensing operations
- Educate the public on the difference between side effects and adverse reactions
- Educate the public during mass dispensing operations on adverse reactions. Individuals serviced by the POD should be informed to:
 - Take all medication as directed
 - Call local health care provider for bothersome side effects
 - Report to their health care provider, clinic, or hospital emergency department if any serious adverse reactions result from medication given to them
 - Call 911 for life threatening reactions
- If notified of an adverse event, maintain communication with OHA field epidemiologist and participate in any conference calls or briefings necessary to monitor the situation
- Vaccine adverse reactions are reportable to: <u>https://vaers.hhs.gov/esub/step1</u>
- Assist in epidemiological investigation of adverse event as necessary

ADVE	ERSE DRUG REACTIONS: PATIENT INFORMATION
What is it?	 Adverse drug reactions are different from common drug side effects.
	 Adverse drug reactions are harmful effects that occur after medical treatment. The treatment could include the use of a drug, vaccine, or other medical supplies.
	 Adverse drug reactions are rare and most of them are minor, but some can be dangerous for the health of an individual.
	 The American Food and Drug Administration (FDA) defines a serious adverse drug reaction as one where the patient may need immediate medical treatment. The person may be hospitalized, be disabled due to the treatment, or require immediate help to prevent major health issues.
	• Side effects that are listed on your patient information sheet are <u>not</u> considered adverse drug reactions.
Who do I contact?	 If you feel you are experiencing an adverse drug reaction from the treatment, please contact your local healthcare provider. If you do not have a provider, you may report the adverse drug reaction to the Local Health Authority/Tribe at XXX-XXXX.
	 You may report the adverse drug reaction directly to the Food and Drug Administration (FDA). Completion of the on-line voluntary reporting form can be found at: <u>https://www.accessdata.fda.gov/scripts/medwatch/</u>
	 Or you can contact the FDA directly at 1-888-INFO-FDA (463- 6332).
	 If you have any further questions or are not sure about whether or not you are experiencing an adverse drug reaction, please contact your local health care provider.
Where can I find	Agency Website
more	Local Public Health Authority/Tribe (insert URL)
information?	Oregon Health Authority (OHA) <u>www.oregon.gov/oha</u>
	Centers for Disease Control and Prevention (CDC) <u>www.cdc.gov</u>