

POINT OF DISPENSING (POD) STANDARDS

APRIL 2008

For the convenience of our state and local public health partners this document has been excerpted (with minor modifications) from the draft report entitled: *Recommended Infrastructure Standards for Mass Antibiotic Dispensing* C. Nelson, E. Chan, A. Chandra, et al., RAND Corporation.

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COORDINATING OFFICE FOR TERRORISM PREPAREDNESS AND EMERGENCY RESPONSE
DIVISION OF STRATEGIC NATIONAL STOCKPILE



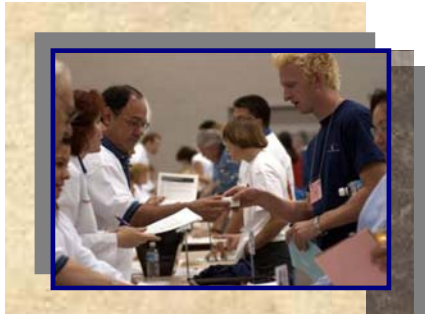
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PREFACE

THE MASS ANTIBIOTIC DISPENSING STANDARDS WERE DEVELOPED IN COLLABORATION WITH FEDERAL, STATE, AND LOCAL AGENCIES

The Rand Corporation, under contract to the U.S. Department of Health and Human Services (HHS), was directed to develop Point of Dispensing (POD) infrastructure standards in collaboration with HHS/Assistant Secretary for Preparedness and Response (HHS/ASPR), Centers for Disease Control and Prevention/Division of Strategic National Stockpile (CDC/DSNS), and state and local agencies that are current Cities Readiness Initiative (CRI) awardees. As such, CDC/DSNS collaborated closely in formulation and execution of the project, and HHS/ASPR was consulted on a regular basis. Federal, state, and local health officials were represented on an expert panel that was convened to provide guidance on the standards development process, and CRI sites were provided with an opportunity to comment on the draft standards. Detailed information on the development of the standards will be published in a public forum within the next six months.

THE STANDARDS ARE ALIGNED WITH THE CITIES READINESS INITIATIVE “48 HOUR” GOAL

CRI is organized around the planning scenario of an outdoor aerosolized anthrax attack. Anthrax is a particularly challenging scenario because, to be effective, prophylaxis must occur prior to the onset of symptoms. Based on available evidence, it was determined that providing oral antibiotics within 48 hours of exposure would be likely to prevent 95 percent or more anthrax cases.ⁱ Thus, CRI’s ultimate goal is that awarded MSAs are able to administer prophylaxis to their entire populations within 48 hours of the decision to do so.

Compliance with the following POD infrastructure standards help to build the capacity to meet the overall 48 hour CRI program goal. Throughout the report we distinguish *standards* for specific elements of POD infrastructure from the more general 48 hour *goal* of providing prophylaxis to the entire CRI MSA.

NUMBER AND LOCATION OF PODS

STANDARD		EXPLANATION	SUGGESTED DOCUMENTATION
1.1	The jurisdiction shall estimate the number of people who will likely come to PODs to pick up medication, along with their geographic distribution.	To ensure that the number of PODs is sufficient to provide initial prophylaxis within 48 hours, it is first necessary to develop an accurate estimate of the size of the population to be served via PODs. Thus, Standard 1.1 requires that CRI sites provide a systematic analysis of likely demand for PODs, including both (a) the <i>total number</i> of likely POD visitors and (b) their <i>geographic distribution</i> . The standard assumes that individual jurisdictions are in the best position to define the scope of the population for whom they will be responsible for administering prophylaxis.	Reference Appendix: A
1.2	The number of PODs shall be greater than or equal to (a) the number of persons needing to receive prophylaxis at PODs divided by (b) per POD throughput multiplied by 24 hours (48 hours minus 12 hours for initial CDC delivery to warehouse and 12 hours to get materiel from warehouse to PODs).	Standard 1.2 requires jurisdictions to combine the population analysis developed pursuant to Standard 1.1 with estimates of hourly POD throughput in order to ensure that the <i>supply</i> of PODs matches demand. Specifically, the following relationship among these four factors must hold: $\text{Number of PODs} \geq \frac{\text{Population visiting PODs in person}}{\text{Hourly per POD throughput} * 24 \text{ hours}}$ <p>The estimate of 24 hours for POD operations (in the denominator) is based on the CDC's assumption that it might take up to 12 hours for initial delivery of materiel from the DSNS and the Target Capabilities List's assumption that it might take up to 12 hours to get materiel from warehouses to PODs.</p>	Reference Appendix: B
1.3	All POD locations shall meet relevant SNS site guidelines and security criteria.	Standard 1.3 specifies that planned POD locations shall meet the basic site and infrastructure requirements in the DSNS guidance document, <i>Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness Version 10.02</i> .	Reference Appendix: C

INTERNAL POD OPERATIONS

STANDARD		EXPLANATION	SUGGESTED DOCUMENTATION
2.1	<p>Jurisdictions shall have at least one viable and exercised rapid dispensingⁱⁱ protocol that addresses the following minimal functions: (a) <u>directing</u> clients through the POD, (b) <u>deciding</u> which medication to dispense, (c) <u>dispensing</u> medication, and (d) <u>disseminating</u> information about the medication. Note that this standard does <u>not</u> mandate that these functions be provided by medically licensed personnel, and does <u>not</u> mandate that all of these functions be provided in-person or on-site at the POD.</p>	<p>Standard 2.1 defines the minimal functions that a POD must perform. Given that a wide variety of POD designs can produce the same throughput, the standard lists a set of <i>essential functions</i> but allows jurisdictions considerable flexibility in determining how to fulfill those functions. This includes the decision as to whether functions are to be provided in-person at the POD. The functions include: (a) messages that clearly communicate to clients POD location instructions and where to go if they are exhibiting symptoms; (b) a process for deciding which medications each client should receive; (c) mechanisms for handing over medications to clients; and (d) mechanisms for providing information about how to take the drug, and what to do and where to go if an adverse reaction is experienced.</p>	Reference Appendix: D
2.2	<p>Jurisdictions shall ensure that legal and liability barriers to rapid dispensing are identified, assessed, prioritized, and communicated to those with the authority to address such issues. Such issues include standards of care, licensing, documentation of care, civil liability for volunteers, compensation for health department staff, rules governing the switch between dispensing protocols, and appropriation of property needed for dispensing medications.</p>	<p>The POD protocols required to provide medication to an entire metropolitan area within 48 hours (e.g., relaxed screening and recordkeeping requirements, use of non-medically trained personnel) might conflict with routine legal strictures. Thus, Standard 2.2 requires that jurisdictions work with relevant state and local authorities to ensure that they have the legal authority to operate rapid dispensing PODs during a public health emergency. Note that the standard does not require CRI jurisdictions or other health departments to change laws – only to “identify, assess, prioritize, and communicate” such issues to those who do have the authority to change them.</p>	Reference Appendix: E

INTERNAL POD OPERATIONS

STANDARD		EXPLANATION	SUGGESTED DOCUMENTATION
2.3	Jurisdictions shall have viable and exercised procedures for selecting an appropriate dispensing protocol (e.g., medical model vs. rapid dispensing).	While the need to provide prophylaxis to an entire metropolitan area within 48 hours argues for streamlined, rapid dispensing protocols, changing circumstances might require more time, skill, and attention to be applied to each client. For instance, as jurisdictions move out of the initial 48 hour period further epidemiological investigation might suggest follow-up prophylaxis of only a limited portion of the population. This and other changes in the situation might necessitate a different balance between dispensing speed and screening accuracy. Thus, Standard 2.3 requires that jurisdictions have clear procedures for moving to and from streamlined prophylaxis operations.	Reference Appendix: F

POD STAFFING

STANDARD		EXPLANATION	SUGGESTED DOCUMENTATION
3.1	Jurisdictions shall estimate the number of individuals who are likely to visit each POD location and determine the required hourly throughput at each POD.	The first step in determining the staffing required for PODs is to determine the throughput that will be required at each POD. Thus, Standard 3.1 requires an estimate of the number of people who will likely come to <i>each</i> POD seeking prophylaxis. It should be noted that the standard does <i>not</i> require individuals to be assigned particular to PODs to pick up their medications; it only requires that jurisdictions' plans be based on <i>estimates</i> of the number of individuals <i>likely</i> to come to each POD.	Reference Appendix: G
3.2	Using a combination of exercises and/or computer models, jurisdictions shall determine and verify the number of staff required to administer prophylaxis to the population identified pursuant to Standard 1.1.	Standard 3.2 requires jurisdictions to estimate staffing requirements for each POD, given estimated throughput requirements (see Standard 3.1). Rather than mandating a particular staffing configuration, this standard adopts a "show me" approach, allowing jurisdictions to demonstrate that their POD designs and staffing configurations will produce the necessary throughput. Jurisdictions may use a combination of timed drills and computer simulation modeling software.	Reference Appendix: H
3.3	Jurisdictions shall recruit sufficient command staff, and provide plans for recruiting and training of spontaneous unaffiliated volunteers, in sufficient numbers to operate all the planned PODs in the jurisdiction at the levels of throughput required to meet the CRI timeline.	Standard 3.3 requires jurisdictions to identify and recruit the staff necessary to implement their mass prophylaxis plan, and enter them into a call-down roster.	Reference Appendix: I
3.4	Jurisdictions shall assess the availability of the command staff on their call-down rosters on a quarterly basis, via a no-notice call-down drill.	Standard 3.4 requires that jurisdictions demonstrate, via quarterly no-notice call-down drills, that they can promptly contact and assemble the required number of people to staff PODs within the first few hours of the decision to conduct mass prophylaxis operations.	Reference Appendix: J

POD SECURITY

Adequate security planning is essential to the safety of POD staff and clients, the sustainability of operations, and the safeguarding of countermeasures being dispensed. The main challenge in developing appropriate standards for POD security is to ensure that a comprehensive set of security measures are in place, while recognizing that state and local law enforcement agencies often have policies, procedures, and doctrine for performing many of these tasks. Thus, the proposed POD security standards favor flexible approaches over strict numerical thresholds.

STANDARD		EXPLANATION	SUGGESTED DOCUMENTATION
4.1	Site security assessments shall be conducted on every POD location in coordination with the agency (ies) responsible for security functions at the PODs.	Standard 4.1 requires site assessments for each facility, coordinated with the agency or agencies responsible for security functions at the PODs (which in most cases will be the local law enforcement agency).	Reference Appendix: K
4.2	The agency (ies) responsible for security functions at PODs shall be consulted on the security aspects of the overall mass prophylaxis plan.	Effective security planning requires consultation with the parties responsible for security at PODs (whether law enforcement or otherwise).	Reference Appendix: L
4.3	Law enforcement in the form of sworn uniformed officers shall maintain a physical presence at each POD location. This requirement may be waived with a written attestation from the parties responsible for POD security. The attestation shall include evidence that compliance with the standard as written is infeasible and that alternate measures designed to ensure adequate security are in place at each POD site.	Standard 4.3 requires physical presence of law enforcement at each POD. However, if this requirement is determined to be infeasible for some jurisdictions, alternate plans, developed by local law enforcement, are acceptable.	Reference Appendix: M

APPENDIX

APPENDIX A: STANDARD 1.1

Standard 1.1: The jurisdiction shall estimate the number of people who will likely come to PODs to pick up medication, along with their geographic distribution.

EXPLANATION

To ensure that the number of PODs is sufficient to provide initial prophylaxis within 48 hours, it is first necessary to develop an accurate estimate of the size of the population to be served via PODs. Furthermore, when considering the placement of PODs and the throughput required at each, jurisdictions need to characterize the geographic distribution of the population so that variations in population density among regions within the jurisdiction can be taken into account. The standard assumes individual jurisdictions are in the best position to estimate the population for whom they will be responsible for administering prophylaxis.

SUGGESTED DOCUMENTATION

Compliance with this standard requires documentation of the population characteristics shown in the *Sample Spreadsheet for Population Estimate* on page 11 (note that several of the estimates are optional and may not be applicable to all jurisdictions). These estimates should be provided for smaller geographic units – such as census tracts or ZIP codes – and then summed for the service region as a whole. Estimates should be reviewed annually and updated whenever new data are available (e.g., from the U.S. Census or from local metropolitan planning organizations).

Decisions about who should be included in calculating the relevant population for the purposes of this standard will often vary by community. Thus, *Sample Spreadsheet for Population Estimate* suggests that jurisdictions begin with residential population and then make upward and downward adjustments, as appropriate. For instance, the number of people requiring prophylaxis at PODs may have to be adjusted upward to take into account daytime working population and tourists; depending on the jurisdiction or the specific area within the jurisdiction (consider, for example, downtown Manhattan), daytime worker and visitor populations may vastly exceed the nighttime residential population. Similarly, some jurisdictions might also expect to receive fleeing populations during an emergency.

Conversely, the number of people requiring prophylaxis at PODs may also be adjusted downward if “push” modalities – such as United States Postal Service (USPS) Postal Option – postal delivery to residences or direct delivery to institutions such as large companies, nursing homes, treatment centers, etc. – are employed to reduce the pressure on PODs. Many, although not all, CRI jurisdictions also allow for “head-of-household” dispensing, where one person is permitted to pick up medications for other members of his or her household. The standard allows jurisdictions to decrease the number of people who are anticipated to come in person to PODs according to any of these considerations.

APPENDIX A: STANDARD 1.1 (CONTINUED)

SAMPLE SPREADSHEET FOR POPULATION ESTIMATES

- Residential population:** At minimum, this represents the number of individuals who reside within each geographic unit of analysis. In addition, university students, persons living in patient care facilities, and others who maintain some sort of regular presence in the jurisdiction may need to be included.
- Worker population** (if applicable): This represents the number of employees who work in each geographic unit of analysis (the workers may reside elsewhere). It should be included if the jurisdiction plans to provide prophylaxis to people near their places of work.
- Visitor population** (if applicable): This represents the average number of tourists or other visitors who may be lodging within a geographic area on any given day. It should be included if significant numbers of out-of-town visitors might need to receive medication in PODs. It might be useful to provide estimates by seasons or time of year, as appropriate, given fluctuations in the tourist population.

Census Tract	Residential Population	Worker Population	Visitor Population	Adjusted Base Population	Population Served by Postal Delivery	Population Served by Other Push Strategies	Population Served by PODs	Expected to Visit PODs
Tract A								
Tract B								
etc.								
Tract X								
Tract Y								
etc.								
Total								

- Adjusted base population:** This is the total number of people within each geographic unit of analysis who need to receive prophylaxis, taking into consideration residential (1), worker (2), and visitor (3) population estimates.
- Population served via postal delivery** (if applicable): If a jurisdiction will be using the USPS Postal Option to supplement PODs, this column should list the number of individuals in each geographic unit of analysis who will receive regimens via postal delivery, and therefore will not need to receive medications at PODs during the first 48 hours
- Population served by other push strategies** (if applicable): This represents the number of people in each geographic area who will receive regimens via other push strategies (for instance, on-site delivery to large companies, military installations, prisons or nursing homes, or first responders given prophylaxis out of local caches) and therefore will not need to receive medications at PODs during the first 48 hours.
- Population served by PODs:** This represents the total expected number of people in each geographic unit of analysis who will receive their regimens from PODs. It is calculated by starting with the adjusted base population estimate (4) and then subtracting both the population to be served via postal delivery (5) and the population to be served via other push strategies (6).

APPENDIX A: STANDARD 1.1 (CONTINUED)

8. **Population expected to visit PODs (if applicable):** This represents an estimate of the number of people from each geographic unit of analysis who will come to a POD location in person. If the jurisdiction plans to follow a "head-of-household" dispensing procedure, where one individual can pick up multiple regimens for other members of the household, then this estimate should be substantially smaller than the number of individuals who will receive their regimens (directly or indirectly) from PODs. In this case, jurisdictions should develop an estimate of the average number of regimens to be picked up by each person who visits a POD (which might be related, for example, to the average household size within the region, a statistic that is available from US Census data). This estimate can in turn be used to approximate the number of individuals likely to visit a POD in person based on the total number of persons to be served.

APPENDIX B: STANDARD 1.2

The number of PODs shall be greater than or equal to (a) the number of persons needing to receive prophylaxis at PODs divided by (b) per POD throughput multiplied by 24 hours (48 hours minus 12 hours for initial CDC delivery to warehouse and 12 hours to get materiel from warehouse to PODs) (U.S. Department of Homeland Security, 2007, p. 469).

EXPLANATION

This standard requires *consistency* among four key elements of POD plans:

- **Number** of PODs in the mass prophylaxis plan.
- **Throughput** levels at the PODs, typically measured in terms of the number of persons per hour that the POD can serve.
- **Population** who will likely visit PODs in person to receive prophylaxis, as determined in Standard 1.1. Note again that jurisdictions will have little control over the size of their population, but they can reduce the number of people who will come to PODs by (a) allowing persons to pick up medications for others or (b) by directly delivering (“pushing”) medications to homes, businesses, or other segments of the population.
- **Timeframe** in which the prophylaxis campaign is to be carried out. The timeframe is based on the CRI goal of providing prophylaxis to the entire population within 48 hours of the decision to do so. However, up to 12 hours will be needed for the initial shipment of materiel from CDC to the state warehouse (CDC, 2006), and up to 12 hours more are needed to move materiel from the state warehouse to PODs (U.S. Department of Homeland Security, 2007, p. 469). During that transport time, the jurisdiction will have to simultaneously prepare PODs for operation. This leaves just 24 hours for dispensing medications.

Specifically, the following relationship among these four factors must hold.ⁱⁱⁱ

$$\text{Number of PODs} \geq \frac{\text{Population visiting PODs in person}}{\text{Hourly per POD throughput} * 24 \text{ hours}}$$

Thus, there are a variety of ways in which a jurisdiction’s mass prophylaxis plan can meet the requirement of administering medications to its population. Meeting a specific numerical standard on each of the three factors – number, throughput, and population – is not necessary. Rather, what is crucial is that the decisions regarding number, throughput, and population, all combine to produce an internally consistent plan, as expressed by the formula just shown.

The formula shown above presumes that each POD has essentially the same design and staffing, will serve approximately the same number of clients, and therefore will produce the roughly the same level of throughput. Some jurisdictions plan on employing PODs of different sizes. In some cases, larger PODs may be simply treated as multiples of small PODs: for example, a baseline small POD may have a throughput of 500 persons per hour, and thus a large 2000-person-per-hour POD may be considered equivalent to 4 small PODs.

APPENDIX B: STANDARD 1.2 (CONTINUED)

In cases where planned POD throughputs vary considerably and this simplification will not work, the jurisdiction should document this condition. A slightly more complicated form of the above formula, taking into account PODs of varying sizes and therefore throughputs, would be to add up the throughputs at each POD and make sure that total throughput is sufficient to administer prophylaxis to the entire population in 24 hours:

$$\sum_i \text{Hourly throughput at POD}_i \times 24 \geq \text{Population visiting PODs}$$

SUGGESTED DOCUMENTATION

Compliance with this standard would require the following documentation:

1. **Total number of PODs:** The jurisdiction shall specify the number of planned POD locations according to the mass prophylaxis plan.
2. **Throughput calculation:** The jurisdiction's mass prophylaxis plan shall demonstrate that the system of PODs satisfies the mathematical relationship shown earlier^{iv}:

$$\text{Number of PODs} \geq \frac{\text{Population visiting PODs in person}}{\text{Hourly per POD throughput} * 24 \text{ hours}}$$

Note that within this formula, the "greater than or equal to" relationship indicates that the jurisdiction must provide at least the minimum number of PODs necessary to serve the intended population within the CRI program goal of 48 hours within the decision to do so. Jurisdictions may want to include additional PODs in order to provide excess, or "buffer", capacity.

APPENDIX C: STANDARD 1.3

All POD locations shall meet relevant SNS site guidelines and security criteria.

EXPLANATION

Reference the facility requirements written into the DSNS guidance document, *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness Version 10.02*.

SUGGESTED DOCUMENTATION

Compliance with this standard would require the following documentation:

1. **List of all POD locations:** The jurisdiction shall provide a list of all POD locations. This should include both primary and backup POD sites. The listing for each location should include a name or description for the site (e.g., King High School) as well as a physical address (including street address, city, state, and ZIP code). If the site does not have a street address, a suitable alternative geographic reference (e.g., nearest intersection or latitude and longitude) should be specified.
2. **Certification that all sites meet appropriate physical characteristics:** The jurisdiction shall provide certification, in the form of a signature from a duly-authorized representative of the lead agency for mass prophylaxis, that all POD sites included in the list meet the physical requirements – such as accessibility, electricity, sufficient parking, sufficient floor space, climate control, and available restroom facilities – suggested within , *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness Version 10.02*, Chapter 12.
3. **Certification that all sites meet appropriate security guidelines:** On a regular basis the jurisdiction shall provide certification, in the form of a signature from a duly-authorized representative of the agency that will oversee security operations, that all POD sites meet the minimum security standards – such as the ability to secure and guard the medications and the ability to control POD entry and exit points (both are suggested within the *v.10.02 Guidance*, Chapter 12, and the Technical Assistance Review tool; see also standards 4.1, 4.2, and 4.3 on Security.)

APPENDIX D: STANDARD 2.1

Jurisdictions shall have at least one viable and exercised rapid dispensing^v protocol that addresses the following minimal functions: (a) **directing** clients through the POD, (b) **deciding** which medication to dispense, (c) **dispensing** medication, and (d) **disseminating** information about the medication. Note that this standard does **not** mandate that these functions be provided by medically licensed personnel, and does **not** mandate that all of these functions be provided in-person or on-site at the POD.

The functions are defined as follows:

- **Directing clients through the POD.** PODs must maintain adequate levels of throughput by ensuring that movement into, through, and out of the POD is rapid, smooth, and orderly. Thus, POD protocols should include measures that clearly communicate to clients when to go to a POD (versus going straight to a medical treatment facility), where to go within the POD^{vi}, and what to expect^{vii}. The standard allows jurisdictions to determine how best to provide this information. Some POD designs assign staff to perform “triage for symptoms” (from the Target Capabilities List), where individuals are screened just prior to entering the POD, so that symptomatic individuals can be directed to treatment facilities (U.S. Department of Homeland Security, 2007, p. 483). Given likely throughput demands and the likelihood of staff shortages, however, it is recommended that as much of this information as possible be provided by means of signs, call-banks, recordings, and public information campaigns (CDC, 2005).
- **Deciding which medication is appropriate.** A decision must be made about which medication each client will receive. In the Target Capabilities List, this is part of a step called “medical screening,” which is often conducted by licensed medical professionals, who review client screening documentation and available medical history to determine the proper course of treatment (U.S. Department of Homeland Security, 2007, p. 484). Given the likely throughput requirements and staffing constraints, drug decisions should be protocol-driven to the extent possible so that they can be made by individuals without medical training. Protocols must be approved by officials from the state medical licensing board or other relevant authority and must be consistent with state emergency medical practice laws, regulations, and other requirements (see Standard 2.2).
- **Dispensing the medication.** Medication must be handed over to clients. Note that the standard allows jurisdictions to determine whether to use head-of-household dispensing. Provisions for dispensing medication (including staffing and whether/how much information is collected of clients) must be consistent with state emergency medical laws (see Standard 2.2).
- **Disseminating information about medications.** Each person who receives medication must also be provided with information about how to take the drug, and what to do and where to go if an adverse reaction is experienced.^{viii} Some POD designs involve a group briefing given to clients by POD staff. Given likely throughput demands and the likelihood of staff shortages, however, it is recommended that as much of this information as possible be provided by modes such as signs, recordings, handouts, and public information campaigns (see CDC, 2005). POD plans should consider the language and reading skills of the population. POD materials should offer options (e.g., multiple languages, use of pictures) to address these needs.

EXPLANATION

POD protocols must be appropriate to the specific circumstances at hand, and that less elaborate dispensing protocols are not only appropriate, but are required for situations necessitating full-community prophylaxis in a short time period. A CRI scenario is at a far larger scale than most other public health emergencies.

APPENDIX D: STANDARD 2.1 (CONTINUED)

The need to streamline PODs would be especially acute in the aftermath of a covert bioterrorist attack, where awareness of the attack might come well into the 48-hour window for effective prophylaxis.

Given the likelihood of staff shortages, persons without formal medical training or licensure could be used to perform most POD functions, including most client interview/screening and dispensing. However, members suggested that in such cases, non-medical personnel should be supervised by medically trained and/or licensed personnel.

Many important POD functions can happen outside of the formal POD boundaries. For instance, information campaigns could be used to instruct the public to recognize some of the most important contraindications for antibiotics (e.g., pregnancy), thus reducing the need for on-site screening and triage at the POD sites. Similarly, effective pre-POD communication about POD flow and procedures could help increase throughput and reduce the need for security.

The Postal Option that is currently being considered as justification for a minimal POD design. If this option were to be used, all screening and triage would occur through public information campaigns (e.g., media messages, fliers distributed with the medication).

SUGGESTED DOCUMENTATION

- Copies of relevant plans and materials
- Training materials and schedules
- After action reports demonstrating that they have exercised the POD design
- Corrective action plans documenting process improvements made in response to exercises

APPENDIX D: STANDARD 2.1 (CONTINUED)

DOCUMENTATION FOR STANDARD 2.1

Directing	<ul style="list-style-type: none">▪ Copies of relevant signage from PODs▪ Public messages▪ Floor plans for PODs▪ Protocols for dealing with ill, upset clients, those refusing medication, those with contraindications, unaccompanied minors, non-English speakers▪ Job action sheets▪ Training materials▪ Training logs
Deciding	<ul style="list-style-type: none">▪ Protocols for guiding decisions about which medications to dispense▪ Protocol/guidance on number of regimens that may be dispensed to each clients▪ Job action sheets▪ Training materials▪ Training logs
Dispensing	<ul style="list-style-type: none">▪ Job action sheets▪ Training materials▪ Training logs
Disseminating	<ul style="list-style-type: none">▪ Copies of relevant signage from PODs▪ Public messages (e.g., handouts) including drug and reaction information

APPENDIX E: STANDARD 2.2

Jurisdictions shall have at least one viable and exercised rapid dispensing protocol that addresses the following minimal functions: (a) directing clients through the POD, (b) deciding which medication to dispense, (c) dispensing medication, and (d) disseminating information about the medication. Note that this standard does not mandate that these functions be provided by medically licensed personnel, and does not mandate that all of these functions be provided in-person or on-site at the POD.

EXPLANATION

In discussing the need for this standard, some panelists pointed to the Swine Flu event (Mello, 2005; Neustadt and Fineberg, 1983) and other historical examples as evidence that “eventually people will sue each other” over adverse reactions to medication, workers compensation claims, and other conflicts. This identifies to the need to develop a prior consensus about how decision makers will make tradeoffs between speed and accuracy while engaging in rapid dispensing. Several panelists pointed to the Model State Health Emergency Powers Act (MSHEP) as a useful tool in standardizing legal frameworks across the nation (Center for Law and the Public’s Health, 2001; Gostin et al., 2002). However, panelists believed that a standard on legal frameworks was also required.

SUGGESTED DOCUMENTATION

Provide citations to relevant sections of law or other policy documents that address the items in the *Checklist of Legal Issues Related to POD Operations* below^{ix}. This should be accompanied by a discussion of how each addresses the relevant checklist item. All of the items in the checklist must be addressed.

CHECKLIST OF LEGAL ISSUES RELATED TO POD OPERATIONS

✓	Standard of care can be temporarily relaxed if necessary to reduce total processing time and increase POD throughput
✓	Documentation of care standards can be temporarily relaxed to increase POD throughput
✓	Licensing requirements can be temporarily waived to allow non-medically trained personnel to carry out essential POD functions
✓	Scope of practice requirements can be temporarily relaxed in order to provide more flexibility in the use of available medically-trained personnel
✓	Labeling requirements can be temporarily relaxed or waived support efforts to reduce processing times
✓	Liability can be temporarily waived or reassigned to reduce barriers to use of volunteer staff and organizational entities working under the direction of and coordination with health officials
✓	Workers Compensation requirements can be changed temporarily to reduce barriers to full and effective use of medical and non-medical government staff and volunteers
✓	Property and facilities can be appropriated where needed to support dispensing operations
✓	Health authorities can compel treatment and isolation and quarantine of individuals where necessary to protect public health ^x
✓	Laws are clear about who has the authority to waive requirements, under what conditions, and for what period of time
✓	Responsible officials can temporarily waive other laws, regulations, and other requirements that might create barriers to mass prophylaxis operations

APPENDIX E: STANDARD 2.2 (CONTINUED)

To the extent possible, these efforts should build on existing laws, regulations, and other provisions. Multiple avenues may exist for addressing each item in the table, including (but not limited to):

- Public Readiness and Emergency Preparedness Act
- Volunteer protection statutes (Hodge, Pepe & Henning, 2007)
- Sovereign immunity doctrine
- Good Samaritan statutes
- Emergency response laws
- Mutual aid laws
- Memoranda of understanding (Hodge, Pepe & Henning, 2007)

Note that each of the issues raised above is relevant to public health emergency preparedness generally – not just to POD planning – and that efforts to address them should be part of a holistic approach to modernizing public health and other emergency preparedness laws.

APPENDIX F: STANDARD 2.3

Jurisdictions shall have viable and exercised procedures for selecting an appropriate dispensing protocol (e.g., medical model vs. rapid dispensing).

EXPLANATION

PODs designed to respond to a CRI-like scenario are part of a broader spectrum of POD designs and protocols. While the need to provide prophylaxis to an entire metropolitan area within 48 hours argues for streamlined, rapid dispensing modalities, changing circumstances might require more time, skill, and attention to be applied to each client. For instance, as jurisdictions move out of the initial 48 hour period further epidemiological investigation might suggest follow-up prophylaxis of only a limited portion of the population. This and other changes in the situation might necessitate a different balance between dispensing speed and screening accuracy. Thus, mass prophylaxis plans must include a clear statement of triggers/conditions under which rapid dispensing should be activated.

SUGGESTED DOCUMENTATION

- A copy of relevant sections of mass prophylaxis plans, including references to relevant laws and authorities who must be consulted in selecting a protocol.
- An after action report that demonstrates that the triggering procedures have been used in an exercise or a real event.

APPENDIX G: STANDARD 3.1

Jurisdictions shall estimate the number of individuals who are likely to visit each POD location and determine the required hourly throughput at each POD.

If jurisdictions do not calculate the expected number of individuals who will visit each POD and adjust their staffing plans accordingly, then PODs in dense areas subject to above-average demand are likely to be overwhelmed during actual operations, while PODs in sparse areas with lower than average demand may have more staff than needed.

This standard requires a POD-by-POD assessment of expected demand, and thus, of throughput required. The first part of the analysis required by this standard, estimating the number of people likely to visit each POD, builds upon the analysis required in Standard 1.1, which called for an estimate of the number of persons likely to visit PODs, broken out by geographic region. That standard requires jurisdictions to determine the population they are responsible for and allows them to adjust the population estimate to account for push strategies, head of household dispensing, and the postal option.

It should be noted that the standard does *not* require individuals to be assigned to PODs, only that plans are based on *estimates* of the number of individuals *likely* to come to each POD. Furthermore, in a real emergency, there will likely be surges in the arrivals that will be difficult to predict, depending on when the public receives instructions, how they comply, when they choose to come to the POD, etc. Though not required by this standard, jurisdictions are encouraged to plan for more than just the minimum required throughput as calculated above.

SUGGESTED DOCUMENTATION

1. **POD assignment plan, if applicable:** Jurisdictions shall document whether groups of people will be directed to specific POD locations (for example, based on their residential ZIP code) or whether individuals will be allowed to choose the most convenient POD location (typically the closest). If residents are to be assigned to specific POD locations, the jurisdiction should append a plan that specifies the assignment rules. Once again, the standard does not require assignment of individuals to PODs.
2. **Demand estimate, by POD:** The jurisdiction shall provide an estimate of the number of people who will likely go to each POD, listed by POD. The result should also be totaled for all PODs, and this total should correspond to the total number of people in the jurisdiction who will be coming to PODs. Note that the number of individuals who will likely come to PODs will depend in part on whether or not the jurisdiction plans to use a "head-of-household" (multiple-regimen) dispensing.
3. **Required throughput, by POD:** The jurisdiction shall determine the required throughput for each POD, listed by POD. This shall be done for each POD. Required throughput is determined by taking the number of people who will go to each POD as determined above, and dividing it by 24 hours. (The estimate of 24 hours comes from the 48 hour CRI goal, minus 12 hours from CDC to warehouse, minus 12 hours for transport from warehouse to PODs. Jurisdictions may use different estimates for these transportation times.)

Example: If assignments are based on ZIP codes, the assignment plan could be presented as follows:

<u>POD Location</u>	<u>ZIP Code</u>	<u>Population</u>	<u>Required Hourly Throughput</u>
Location #1	A, B, C	12,000	500 per hour
Location #2	D, E, F	18,000	750 per hour
etc.			

APPENDIX H: STANDARD 3.2

Using a combination of exercises and/or computer models, jurisdictions shall determine and verify the number of staff required to administer prophylaxis to the population identified pursuant to Standard 1.1.

OPTIONS FOR MEETING THE STANDARD

Offering two options allows jurisdictions to choose a method that corresponds to their level of comfort with computer modeling, and with their ability to conduct POD drills. It also gives jurisdictions the flexibility to demonstrate their ability to perform prophylaxis using whatever staffing configuration they have designed.

The options are:

1. **Drill.** Ideally, jurisdictions should conduct a POD drill to demonstrate that the required throughput can be achieved with the planned POD design, process steps, protocols, and staffing level that would be used in the CRI scenario. If the protocol calls for “head of household” pickup, then the drill should accordingly assume the persons coming to the POD for prophylaxis are picking up prophylaxis for their respective family members. A challenge often faced in using drills to estimate the throughput of a POD is the lack of sufficient volunteers to serve as the persons receiving prophylaxis. Jurisdictions should attempt to recruit enough people so that some crowding may be observed at the POD. If a POD is able to enlist only small numbers of people to receive prophylaxis, drill controllers may wish to group them together and send them through all at once, so that, at least for a brief period, the POD will be busy and a throughput number can be estimated during that busy period^{xi}.
2. **Model.** If a jurisdiction has not performed a dispensing drill, or was not able to generate reliable throughput estimates from a drill that was performed,^{xii} an alternative method for estimating the staff required to attain a desired level of throughput would be to use a computer model. Possible computer models include:
 - BERM (Weill/Cornell Medical College) (Weill, 2005)
 - Clinic Generator (University of Maryland) (ISR, 2008)
 - RealOPT (Georgia Institute of Technology) (ISYE, 2006)

Using a computer model requires jurisdictions to input the design of their POD: listing out the process steps that each person going through the POD goes through (e.g., forms, screening, dispensing), the number of staff at each step, and the average *processing time* for a person at each of the process steps in the POD. The processing time for a step is the amount of time it takes for a station to serve a person who comes to it, not counting the time the person spends waiting in line. The computer model then uses this information, along with information about the rate at which people arrive at the POD, to calculate estimates of the average throughput, length of the lines at the POD, and time spent waiting in line. **With time study data:** Preferably jurisdictions should input process time parameters for each of the process steps based on experience with time studies conducted at drills. Jurisdictions should have evaluators posted at each step of the POD, and record the time it takes for a station at that step to serve each person, from start to finish, but not counting the time spent waiting in line. To ensure a good sample of the process time at each step, evaluators should take as many observations as possible and from several different stations of that process step. From these observations, the jurisdiction can calculate the mean (and if possible, standard deviation) of the time needed to serve each person at each step in the POD process, and enter those as inputs in the computer model. **Without time study data:** If jurisdictions lack time study information, they may use their best estimates, or use the default values for processing times that are built into the computer models.

APPENDIX H: STANDARD 3.2 (CONTINUED)

NOTE: Many computer models estimate only the “contact” staff required, i.e., the number of staff engaged in activities where they interact directly with the person receiving prophylaxis, such as distributing forms, performing interviews, or dispensing prophylaxis. Some models omit the support staff (e.g., translators, runners, guides, inventory managers), supervisors, and command staff required. **Consequently, jurisdictions may have to separately estimate the number these additional staff required if the computer model does not already estimate them.**

SUGGESTED DOCUMENTATION

1. **Table of PODs.** Jurisdictions shall construct a table listing all the PODs in the mass prophylaxis plan. For *each* POD, sites shall document:
 - POD name or identifier
 - Demand estimate: Number of people who will visit this POD
 - Required throughput: as calculated in Standard 3.1.
 - Staff required to operate one shift of this POD and the estimated throughput
 - Method by which the staff estimate was generated (exercise date or model name)
 - Number of shifts of distinct staff (this is the number of shifts per day, assuming staff will return for another shift on subsequent days)
 - Total number of staff required to operate this POD through entire mass prophylaxis campaign
2. **Total number of staff required for entire jurisdiction:** the sum of the estimated staff required for each POD, totaled for all the PODs in the jurisdiction’s mass prophylaxis plan.

ADDITIONAL DOCUMENTATION SPECIFIC TO METHOD CHOSEN:

For Option 1, Drill:

- POD flow plan
- When the drill was performed
- How many staff were used, listed by role and/or station
- Total number of clients processed during drill
- Total length of time of drill
- If a specific measurement period is used to estimate throughput, then also document
 - Number of clients processed during measurement period
 - Length of measurement period

APPENDIX H: STANDARD 3.2 (CONTINUED)

For Option 2, Model:

- POD flow plan
- Throughput desired
- Estimated processing time per step and the basis for this estimation
- Computer model used
- Staff required, listed by role and/or station

PLANNING FOR “BUFFER” STAFF

Results from either computer models or drills will tend to underestimate the number of staff required at PODs in an actual emergency^{xiii}. This suggests that jurisdictions should increase their estimates of the number of staff that would be required^{xiv}.

APPENDIX I: STANDARD 3.3

Jurisdictions shall recruit sufficient core staff, and provide plans for recruiting and training of spontaneous unaffiliated volunteers, in sufficient numbers to operate all the planned PODs in the jurisdiction at the levels of throughput required to meet the CRI timeline.

EXPLANATION

Ideally, jurisdictions would have all the persons they need for PODs recruited on a call down list ready at a moment's notice. This would help ensure that POD staff could be called, assembled, trained, and able to set up the PODs by the time material arrives from the CDC through the state and local warehouse and distribution network. (We estimate this would be somewhere between 12 and 24 hours.)

Command staff are defined as the command staff for each POD, who are pre-recruited, trained staff and/or volunteers.

SUGGESTED DOCUMENTATION

Jurisdictions would provide for inspection a call down roster containing names and contact information of POD managers, staff, and volunteers. Jurisdictions intending to draw upon municipal workers for disaster service may present those rosters as part of demonstrating compliance. Jurisdictions should ensure, however, that these other employees will not be required to perform critical functions in their normal jobs. Jurisdictions are encouraged to provide copies of agreements with volunteer and community-based organizations that will assist in POD operations.

Appendix J: Standard 3.4

Jurisdictions shall assess the availability of the command staff on their call-down rosters on a quarterly basis, via a no-notice call-down drill.

EXPLANATION

Any delay in assembling staff and setting up PODs will delay dispensing operations, putting a greater burden on PODs to administer prophylaxis to the entire population in the remaining portion the 48 hour time window (previously estimated as 36 hours).

The call-down drill serves several purposes: Running the drill verifies the accuracy of the names and contact information for the staff on the jurisdiction's list. The drill also tests the ability of the jurisdiction to call POD staff in a timely manner when needed. Finally, it gives an estimate of the percentage of staff that would not be available on a given day. Jurisdictions should use this information to estimate how many backup staff they would need to recruit.

The recommended standard requires jurisdictions to conduct quarterly call-down drills as a means to periodically review the contact information and willingness to serve on the part of POD staff. The requirement for a quarterly test is based upon CDC/DSNS's Technical Assistance Review tool.

The no-notice requirement is intended to gauge the availability of POD staff to report on any random day without prior warning. Drills would be conducted *without* prior notice, but to avoid placing undue burden on call-down list members, staff would *not* be required to physically assemble for duty. In the drills, jurisdictions would record whether each staff member is reachable, and whether staff members report that they would have been able to report for duty had the call been for a real emergency.

As described above in Standard 3.3, regarding the number of staff that must be recruited, some jurisdictions do not intend to pre-recruit the entire staff necessary to operate all the PODs in the mass prophylaxis plan. Some jurisdictions intend to rely on aid from other agencies, or activation of their municipal employees for emergency duties, or recruiting spontaneous volunteers on a just-in-time basis. We thus present two alternative standards on the pool of staff to be called in a call-down drill, consistent with the alternatives presented in Standard 3.3.

SUGGESTED DOCUMENTATION

Jurisdictions should perform call-down drills quarterly and document the results of the drill, including:

1. Number of staff on call-down list
2. Call down method (manual? automated? calling tree?)
3. Percent confirmed reached
4. Percent reporting that they would be available to report for duty, had this been a real emergency call-down
5. Time necessary to perform call-down
6. Time necessary to receive acknowledgements from those called

APPENDIX K: Standard 4.1

Site security assessments shall be conducted on every POD location in coordination with the agency(ies) responsible for security functions at the PODs.

EXPLANATION

The standard requires site assessments to be coordinated, at a minimum, with the health department and the agency or agencies responsible for security functions at the PODs (which in most cases will be the local law enforcement agency). The standard allows jurisdictions flexibility in delegating responsibilities for planning in a manner that matches the resource availability and interagency relationships in the jurisdiction.

SUGGESTED DOCUMENTATION

Site security assessments should be conducted using methods consistent with the guidelines included in the SNS Planning Guidance.

In order to demonstrate compliance with the standard, jurisdictions should provide:

- **Documentation of the members of the team(s)** assigned to conduct site security assessments
- **Description of the site security survey methodology** used
- **Copies of site security assessments** (including data) conducted on all selected POD locations
- **Documentation of review of POD security assessments** by the CRI or SNS coordinator and lead security official

Appendix L: Standard 4.2

The agency(ies) responsible for security functions at PODs shall be consulted on the security aspects of the overall mass prophylaxis plan.

EXPLANATION

Parties responsible for security at PODs (whether law enforcement or otherwise) should be consulted on the location(s) of the PODs and development all security aspects of the plan.

SUGGESTED DOCUMENTATION

Security aspects of the POD plan extend beyond providing public safety and facility security around the POD. Jurisdictions should provide documentation addressing each of the points listed below to indicate review (and/or approval) of the POD plan from all parties responsible for any aspect of security at any facility selected as a POD location:

- **POD selection and operations.** It is prudent to incorporate security into the process of selecting PODs and establishing the operational plans. The security perspective can facilitate selection of PODs that will be easier to manage. The security perspective can also provide suggestions on the process of moving people through the POD in ways to minimize risk to POD staff and materials.
- **Communication efforts regarding POD operations.** Communication with the public is an integral part of effective security because clear and instructive communications can help to ensure that citizens and POD staff make decisions during an emergency that are in the best interest of themselves and others. As such, security planning should be coordinated with the POD communications plan. A comprehensive communications plan should address the following three topics: (1) enabling interoperable communication systems; (2) providing guidance to POD staff on where to report and what to do before, during and immediately after the POD operations; and (3) providing information to the community about how to get to a POD, what to do once at a POD, what to expect in taking prophylaxis, and what to expect after receiving prophylaxis. If these topics are not adequately addressed, the potential exists for the community to lose confidence in the POD mission and subsequently for security around PODs to deteriorate.
- **Plans for providing transportation to and from PODs.** Transporting people to and from the POD may require closure of roads, increased security around mass transportation, or special provisions for parking. Transportation may be required both for POD staff and clients. In some jurisdictions this may require participation of local law enforcement. In all cases, it is important to capture the perspective of security to ensure the feasibility of the transportation plans.

Because of public safety resources available for planning and interagency agreements may vary across jurisdictions, consultation with security experts need not be limited to local law enforcement if the lead party for security is private facility security, state law enforcement, or another organization.

Appendix M: Standard 4.3

Law enforcement in the form of sworn uniformed officers shall maintain a physical presence at each POD location. This requirement may be waived with a written attestation from the parties responsible for POD security. The attestation shall include evidence that compliance with the standard as written is infeasible and that alternate measures designed to ensure adequate security are in place at each POD site.

EXPLANATION

The survey of current security practices adopted by CRI sites indicates that many of the security tasks required at a POD facility can be provided by trained volunteers, private security, or other personnel besides sworn law enforcement officers. However, experts believe that there is a need for some level of sworn law enforcement presence at each facility because some tasks cannot be delegated. While the standard is not prescriptive of which tasks must be performed by sworn law enforcement, the most obvious tasks that cannot be delegated are arrest authority and command and control of security at a facility to enable escalation of security capability or the ability to exercise arrest authority, if required. Use of non-sworn law enforcement officers for other tasks will depend on local laws and requirements regarding delegation of security authorities for specific tasks. For example, in some communities, only sworn law enforcement agencies can enforce street closures. The minimum number of sworn law enforcement agents and whether these officers must be dedicated to specific PODs, will depend on standard operating procedures used by local law enforcement agencies and special provisions to these procedures that are arranged in advance to accommodate the demands of anthrax and other scenarios.

SUGGESTED DOCUMENTATION

Jurisdictions must provide a signed letter from presiding law enforcement with the jurisdictional responsibility of the POD area.

NOTES

ⁱ See Wilkening, 2006; Wein, Craft, and Kaplan, 2003.

ⁱⁱ “Rapid dispensing POD” is the term used in the Technical Assistance Review (TAR) tool.

ⁱⁱⁱ The formula is taken from CDC (2006).

^{iv} For brevity, the simpler version of the formula is shown here. The more complicated form previously described may also be used as appropriate.

^v “Rapid dispensing POD” is the term used in the Technical Assistance Review (TAR) tool.

^{vi} The issue of which POD to visit is part of public information and communication and therefore falls outside the purview of POD infrastructure standards.

^{vii} For some POD designs, this will involve direction to an “express” or “special needs” line. However, the standard does not require that PODs use express vs. special needs lines.

^{viii} The monitoring of adverse effects is one of the capabilities in the Target Capabilities List (U.S. Department of Homeland Security, 2007, p. 485).

^{ix} Note that the items in Table 2 include the legal elements in CDC/DSNS’s state Technical Assistance Review tool (TAR). Also see the discussion in ARHQ (2005) and Hodge, Raymond, Pepe, and Henning (2007).

^x Readers should note, however, that there is considerable controversy about this point. See, e.g., Annas, Parmet & Mariner (2008).

^{xi} One reviewer suggested that this tactic of intentionally bunching up persons going through the POD should be standard practice for exercises, as a way of testing the ability of a POD to respond to surges or arrivals.

^{xii} For instance, jurisdictions might have trouble recruiting enough test clients to adequately stress the POD during a drill or exercise. [this point is made in the main text. Could delete it]

^{xiii} Computer models can miss factors that would be important in a real-world emergency: they assume that staff know their jobs and do not tire, that persons receiving prophylaxis do not get lost within a POD, etc. Users of computer models can compensate by adjusting the parameters to incorporate these factors. Furthermore, obtaining estimates of parameters even under ideal situations can be challenging. Nonetheless, computer models provide valuable guidance, particularly if one performs multiple runs under varying assumptions allow planners to see how staffing and throughput estimates can change.

Drills and exercises capture more of these real-world factors, but even they are performed in shorter duration and under more ideal circumstances than will actually occur. Volunteers receiving prophylaxis in drills are typically healthy adults, and even if they are told to play roles, they may not truly represent the range of ages and abilities of the people who actually visit a POD should a CRI scenario occur. Staff performance in an actual emergency will also differ since over the course of a shift, staff may become more efficient with as they perform their tasks, but then slow down as they fatigue. In a real situation, staff would need breaks, and staff may not even show up. Consequently, more staff would be needed to serve as relief or backups. (See also Spitzer, et al, 2007)

^{xiv} Furthermore, as noted in the discussion of Standard 3.1, the estimate of the required throughput is based on the assumption that people will come to the POD at a constant, even rate over the course of the POD’s operation. In reality, there will likely be surges in the arrivals that will depend on behavioral factors that will be difficult to predict. These surges will cause lines to form at or outside the POD despite efforts to size and staff PODs according to the estimated throughput required.