



**LEGAL ISSUES RELEVANT TO PRIVATE ENTITIES SERVING AS CLOSED POINTS OF DISPENSING (CLOSED PODS)  
IN EMERGENCIES**

**Issue Brief**

This memorandum analyzes key legal issues concerning the role of private entities as Closed Points of Dispensing (Closed PODs) during non-declared and declared emergencies<sup>1</sup> and public health emergencies.<sup>2</sup> Although this memorandum bases much of its guidance on Arizona law, other relevant federal and state laws are also cited.

A Closed POD is operated by a business or community organization that partners with a local health agency to dispense medication and medical supplies to a portion of the population during an emergency. Whether or not a state of emergency has been declared, a state may request supplies from the Strategic National Stockpile (SNS) to respond to a local or state-wide need. Upon receiving these supplies state authorities will typically distribute them to local agencies that will then determine how to distribute the supplies locally.<sup>3</sup> Local agencies may employ a Closed POD to distribute supplies directly to an organization's employees, members and their families, but not to the general population.

**Operation of a Closed POD implicates a series of potential legal issues including:**

- Impact of an official declaration of emergency, disaster or public health emergency
- Memorandum of Understanding (MOU) between a public health agency and an entity
- Ownership of medical supplies
- Medical personnel
- Authorization to dispense medications
- Emergency use authorizations
- Liability
- Workers' compensation
- Privacy (HIPAA Privacy Rule and State Privacy Law Compliance)
- Reporting and documentation requirements
- These issues are summarized below.

While this memorandum covers a number of legal issues relevant to private entities, it does not fully address tangentially related issues, such as labor laws or requirements issued by the Occupational Safety and Health Administration. Entities should continue to comply with these regulations as they are relevant to Closed PODs (or simply PODs as referred to below).



## **Impact of an Official Declaration of Emergency, Disaster or Public Health Emergency**

A formal declaration of a state of emergency or public health emergency is not required to request supplies from the SNS. Therefore, it may be possible for an entity to operate a POD even during a time of need that does not rise to the level of a declared emergency. However, a declared state of emergency or public health emergency from the state or federal government may trigger other legal provisions and protections, such as liability protections discussed below.<sup>4</sup>

## **Memorandum of Understanding (MOU) between a Public Health Agency and an Entity**

An MOU between a state or local public health agency and an entity operating a POD can help coordinate efficient emergency and public health emergency responses. An MOU may be either binding or non-binding based on the terms of the agreement and the intent of the parties. To the extent an MOU creates a contractual relationship,<sup>5</sup> the rights and obligations of the entity and the public health agency should be clearly specified. If an entity does not meet its obligations under a binding MOU, a court might order the entity to act as agreed or to pay damages, depending on the circumstances and whether the government, as a party to the MOU, is immune from private suits.<sup>6</sup>

## **Ownership of Medical Supplies**

Although an entity may obtain physical possession of SNS supplies while administering a POD, the entity does not “own” the supplies. All SNS medical supplies provided to the entity are the property of the SNS and the federal Department of Health and Human Services (DHHS).<sup>7</sup> DHHS transfers authority for SNS materials to local and state public health officials when those materials are delivered.<sup>8</sup> Upon receipt, the local health agency delivers SNS supplies to the population in accordance with the Cities Readiness Initiative or other emergency distribution plans. Supplies must be tracked and accounted for through distribution of the supplies at the entity. As custodian, the local public health agency has constructive possession of the supplies—meaning that the agency may have actual control even absent physical possession—and is authorized to distribute them according to its emergency distribution plan. Any unused supplies must be returned to the local public health agency, which will in turn deliver them to the SNS.<sup>9</sup>

Additionally, decisions regarding allocation of SNS supplies during an emergency are at the discretion of the local public health agency and should be done in accordance with a pre-established emergency plan and existing MOUs. During an emergency, the state, local or federal government may require reallocation of SNS supplies to priority groups (e.g., emergency response and medical personnel).<sup>10</sup>

## **Medical Personnel**

During the operation of a POD, a private entity may seek personnel to provide medical tests, screenings or examinations to manage the distribution of supplies. While there is no specific statute in Arizona that details whether these individuals must be licensed medical personnel to administer countermeasures at a POD during an emergency, a private entity operating a POD should follow ordinarily applicable rules regarding medical staffing. Generally, individuals providing medical care need to be properly licensed within the state to engage in the practice of medicine.<sup>11</sup> Similarly, hospitals and health care facilities are required to maintain entity licenses to provide medical care to patients. During an emergency, however, temporary waivers of licensure requirements and shifts in the standard of care may be approved by the governor to adequately address the state of emergency.<sup>12</sup> These and other measures may allow an entity to operate a POD with out-of-state medical personnel or unlicensed personnel (in some capacities) during a declared public health emergency.

## **Authorization to Dispense Medications**

Usually, only a pharmacist or supervised intern may dispense prescription medications,<sup>13</sup> though other registered medical practitioners, such as licensed physicians, doctors of osteopathy, physician assistants and registered nurses, may dispense medications for conditions they are treating.<sup>14</sup> Additionally, state- or county-run public health centers may



dispense medications at no cost without a written prescription if the facility meets requirements for storage, labeling, safety and record-keeping.<sup>15</sup> Limitations on the persons who are able to distribute prescription medications may require an entity to employ (or contract with) a licensed professional to distribute SNS medical supplies. However, in a declared emergency, temporary waivers of licensing requirements<sup>16</sup> (as noted above) may allow an entity to operate a POD without traditionally licensed professionals in some instances.

## **Emergency Use Authorizations**

Drugs or medicines that have not yet been approved by the federal Food and Drug Administration (FDA) cannot generally be distributed to the public. However, during a federally declared public health emergency,<sup>17</sup> the federal government may temporarily authorize entities such as PODs to dispense drugs that have not yet received final approval by issuing an Emergency Use Authorization (EUA).<sup>18</sup> The Secretary of DHHS is authorized to approve the use of a product that is either not yet approved, or is not approved for the proposed use.<sup>19</sup> Once the EUA is in effect, POD personnel may legally dispense unapproved, temporarily authorized drugs.

## **Liability**

While administering a POD, an entity may be exposed to additional liability risks stemming from injuries resulting from an employee or volunteer's actions during administration of the POD or adverse reactions to medications distributed through the POD. Volunteers or employees may face similar liability risks. Despite these risks, liability protections within state and federal law may protect volunteers, employees and entities. Generally, during a non-declared emergency an entity may assume (or take responsibility for) the liability of employees or volunteers.<sup>20</sup> During a federally declared emergency, the Public Readiness and Emergency Preparedness (PREP) Act offers some legal protections for entities. The PREP Act allows the Secretary of DHHS to extend liability protection to entities and individuals for injuries resulting from the distribution of "covered countermeasures" (e.g., flu vaccines, antiviral medications) during a declared emergency. This protection would allow an entity to distribute medications, which have been deemed covered countermeasures, without risk of civil liability for adverse drug reactions. Additional liability protections at the federal, state and local levels may also apply depending on the state of emergency declared in a given jurisdiction.

## **Workers' Compensation**

An entity may be responsible for workers' compensation injuries sustained by an employee while administering a POD. For purposes of workers' compensation, an "employee" is any person in the service of an employer subject to the state's workers' compensation laws.<sup>21</sup> Therefore, employees injured while administering the POD would be eligible for workers' compensation benefits as if they were working in any other capacity for the employer.<sup>22</sup> In some circumstances a volunteer or an independent contractor may be deemed an "employee" for purposes of workers' compensation. For example, a volunteer who has an interest in the completion of the work may be deemed a "gratuitous employee" and may be entitled to workers' compensation benefits if injured.<sup>23</sup>

## **Privacy (HIPAA Privacy Rule and State Privacy Law Compliance)**

Personal information obtained in the process of administering a POD may be subject to federal and state information privacy laws. Generally, medical records are privileged and confidential. Entity personnel should only disclose identifiable information as allowed pursuant to federal or state law.<sup>24</sup> An entity operating a POD may be subject to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which applies to covered entities or business associates who electronically retain or transmit individually identifiable health information.<sup>25</sup> Under the HIPAA Privacy Rule, all identifiable health information retained or transmitted by a covered entity or business associate is "protected health information."<sup>26</sup> Subject to potential limited waivers or exceptions in declared emergencies, the Privacy Rule (and other similar state or local laws) requires entities to disclose only the minimum information necessary to accomplish the purpose of the disclosure, which will often be dictated by state reporting statutes.<sup>27</sup>

## Reporting and Documentation Requirements

Medical information obtained during the administration of a POD may also be subject to state reporting and documentation laws regarding communicable diseases. While there is no specific statute in Arizona addressing reporting requirements for information about communicable diseases gathered during the administration of PODs, state law requires generally any person who becomes aware of the existence of a reportable communicable disease to file a report with the health department.<sup>28</sup> Communicable disease reports would need to be made to the local health agency (often the county health department) within 24 hours of receiving the information.<sup>29</sup> The report must include information about the patient (e.g., name, address, date of birth, etc.) and the disease (e.g., name of the disease, date of onset, etc.).<sup>30</sup>

### SUPPORTERS



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<sup>1</sup> “‘State of Emergency’ means the duly proclaimed existence of conditions of disaster or of extreme peril to the safety of persons or property within the state caused by air pollution, fire, flood or floodwater, storm, epidemic, riot, earthquake or other causes, except those resulting in a state of war emergency . . . .” A.R.S. § 26-301(15).

<sup>2</sup> A public health emergency is a declared state of emergency “in which there is an occurrence or imminent threat of an illness or health condition caused by bioterrorism, an epidemic or pandemic disease or a highly fatal infectious agent or biological toxin and that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability.” A.R.S. § 36-787(A).

<sup>3</sup> OFFICE OF PUB. HEALTH PREPAREDNESS AND RESPONSE, CTRS. FOR DISEASE CONTROL AND PREVENTION, STRATEGIC NATIONAL STOCKPILE (SNS), <http://emergency.cdc.gov/stockpile/>.

<sup>4</sup> A.R.S. § 36-790(B).

<sup>5</sup> See, e.g., New Mexico Dep’t of Health, New Mexico Medical Countermeasures POD Administrative Toolkit, “Closed POD MOU Template,” available at [http://nmhealth.org/hem/sns/PodToolkit\\_001.shtml](http://nmhealth.org/hem/sns/PodToolkit_001.shtml).

<sup>6</sup> See, e.g., Alden v. Maine, 527 U.S. 706 (1999).

<sup>7</sup> A.R.S. § 36-790(B).

<sup>8</sup> OFFICE OF PUB. HEALTH PREPAREDNESS AND RESPONSE, CTRS. FOR DISEASE CONTROL AND PREVENTION, STRATEGIC NATIONAL STOCKPILE (SNS), <http://emergency.cdc.gov/stockpile/>.

<sup>9</sup> NAT’L ASSOC. OF COUNTY AND CITY HEALTH OFFICIALS, STRATEGIC NATIONAL STOCKPILE (SNS): A REFERENCE FOR LOCAL PLANNERS, available at [http://www.naccho.org/toolbox/toolbox/NACCHO\\_SNSGuide\\_FNL.pdf](http://www.naccho.org/toolbox/toolbox/NACCHO_SNSGuide_FNL.pdf)

<sup>10</sup> A.R.S. § 36-787(B)

<sup>11</sup> A.R.S. § 32-1422.

<sup>12</sup> A.R.S. §§ 36-787(7); 36-422.

<sup>13</sup> A.R.S. § 32-1961(A).

<sup>14</sup> A.R.S. §§ 32-1921; 32-2532; 32-1901(48).

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<sup>15</sup> A.R.S. § 32-1921(D).

<sup>16</sup> A.R.S. § 36-787(A)(6).

<sup>17</sup> 21 U.S.C.A. § 360bbb-3(a)(4)(b).

<sup>18</sup> 21 U.S.C.A. § 360bbb-3(a)(1).

<sup>19</sup> 21 U.S.C.A. § 360bbb-3(a)(2)(a-b).

<sup>20</sup> If the entity operating the POD is a non-profit organization, volunteers may be protected under the Federal Protection Act, or the state volunteer protection law. However, this law offers limited protections. 42 U.S.C.A §14503(a); A.R.S. 12-982 (The federal and state laws provide liability protections to volunteers acting within the scope of their duties when providing services for a non-profit or governmental entity. At the state level protection is also extended to volunteers working within a hospital).

<sup>21</sup> A.R.S. § 23-901(6)(b).

<sup>22</sup> A.R.S. § 23-1021.

<sup>23</sup> *Bond v. Cartwright Little League, Inc.*, 112 Ariz. 9, 14–15 (Ariz. 1975)

<sup>24</sup> A.R.S. § 12-2292(A).

<sup>25</sup> 45 C.F.R. §§ 160.102 and 160.103.

<sup>26</sup> *Id.*

<sup>27</sup> 45 C.F.R. §§ 164.502(b) and 164.514 (d).

<sup>28</sup> A.R.S. § 36-621 .

<sup>29</sup> ARIZ. ADMIN. CODE § R9-6-202 (2008).

<sup>30</sup> *Id.*