

## **Legal and Policy Issue Considerations**

### **1. Legal Agreements**

#### **A. Open POD Memoranda of Understanding**

NMDOH requires a written Memorandum of Understanding (MOU) with each public or private facility (other than an NMDOH facility) that will serve as a POD site during a public health emergency.<sup>1</sup> NMDOH emergency preparedness specialists are responsible for facilitating MOUs between NMDOH and other state, local or tribal governmental entities who are willing to designate their owned facilities that will become part of the NMDOH POD site planning for mass distribution/administration of medical countermeasures. The MOUs will address various matters, including but not limited to:

- Immediate use at the onset of an emergency event
- Periodic access to the facility for inspection prior to an event
- 24-hour contact information for facility managers and key personnel
- Financial compensation (if any)
- Liability or compensation for damages
- Authority for use during exercises prior to an emergency event

POD sites will be required to meet the minimum access and safety standards set forth in the MOUs. POD planners should coordinate with the NMDOH SNS staff regarding site selection and be familiar with the MOU requirements and related documentation. The NMDOH POD MOU Template (General) is provided in the POD Toolkit (Document 1.5).

Special consideration will be given by NMDOH to New Mexico sovereign nations (i.e., tribes, pueblos and other sovereign governments) in reaching agreements for POD development that will recognize and respect their sovereignty, jurisdiction and relationships with the State of New Mexico. The NMDOH POD MOU Template (Tribal) for POD operations using tribal facilities is provided in the POD Toolkit (Document 1.8).

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<sup>1</sup> An exception exists with respect to point of distribution (POD) sites on tribal lands that are operated by the tribes, pueblos and other sovereign governments. The New Mexico Public Health Emergency Response Act (PHERA), § 12-10A-1, *et seq.* New Mexico Statutes Annotated (NMSA) (1978), authorizes the Secretary of Health to enter into memoranda of understanding (MOUs) with Indian pueblos or tribal entities within the State of New Mexico in order to effectuate the purposes, procedures and standards set forth in the Act. However, a sovereign government is not required to execute an MOU with NMDOH prior to receipt of SNS assets, and special consideration will be given by NMDOH to these sovereign nations such that their sovereignty, jurisdiction and relationships with the State of New Mexico are recognized and respected. NMDOH is willing to work amicably with sovereign governments to achieve POD development on tribal land that meets the federal criteria. NMDOH will also strive to work cooperatively and collaboratively with these sovereign nations toward achieving a joint mission of public health emergency preparedness and protecting the health, safety and welfare of the entire New Mexico population during a public health emergency.

## **B. Closed POD Memoranda of Understanding**

NMDOH will also be entering into POD MOUs with private entities who agree to facilitate “closed PODs” for distribution or administration of medical countermeasures to employees and their family/household members or other individuals as designated by such entities in the MOU. Special “closed POD” MOU templates have been developed for this purpose.

In the event that local planners encounter a private entity’s interest in or request to become a “closed POD” during a public health emergency, please contact NMDOH SNS staff to advise of that entity’s interest or request.

## **C. Mutual Aid Agreements**

Mutual aid agreements (MAAs) are generally entered into between political subdivisions (i.e., counties or municipalities), an Indian nation, tribe or pueblo, or other private entities that participate in an intrastate mutual aid system. For example, two public safety or fire departments in neighboring counties may have MAAs in place to govern a response where the demands for emergency services exceed either department’s capacity. MAAs may address:

- Payment or reimbursement for material resources and personnel time
- Workers’ compensation benefits and the entity responsible for providing such benefits
- Liability claims as a result of the provision of emergency services

POD planners are not likely to be subject to the terms and conditions of an MAA, but are encouraged to be familiar with their existence in local New Mexico communities.

## **2. Distribution of Medical Countermeasures**

### **A. Deciding which countermeasure is appropriate**

The NMDOH and the Secretary Health are responsible for the protection of the public’s health. Authority is vested in the Secretary of Health, pursuant to the New Mexico Public Health Act (PHA), § 24-1-1, *et seq.*, New Mexico Statutes Annotated (NMSA) (1978), and NMDOH regulations, Title 7 – Health, Chapter 4 – Disease Control (Epidemiology), Part 3 – Control of Disease and Conditions of Public Health Significance, New Mexico Administrative Code (NMAC), to among other things: (1) investigate, control and abate the causes of disease and other conditions of public health significance; (2) maintain and enforce rules for the control of communicable diseases and other conditions deemed to be dangerous to public health; and (3) to do all things necessary and to take such measures on the advice of the NMDOH medical officer as are deemed necessary and proper for the protection of the public health.

The New Mexico Public Health Emergency Response Act (PHERA), §12-10A-1, *et seq.*, NMSA (1978), also grants special powers and authority in the Secretary of Health to prepare for and to administer treatment (e.g. medications, vaccines, etc.) to the affected New Mexico population during a *governor-declared* public health emergency.

Decisions as to which countermeasures are appropriate for distribution to clients who come to a POD during a public health emergency are made by state public health officials in compliance with all applicable state and federal laws and regulations, after consideration of guidance and recommendations from the Centers for Disease Control and Prevention (CDC). Such decisions include what types of countermeasures will be distributed or administered to which individuals, in what dosages, and what, if any, prioritization will be implemented in the event of a limited supply or availability. These decisions are predicated upon evidence-based medicine and generally accepted standards of practice for effective treatment or prophylaxis for each specific disease, exposure to a biological or chemical agent, or other condition requiring public health intervention (e.g., pandemic influenza exposure or infection, anthrax inhalation, tularemia, etc.).

Special instructions (i.e., protocols) for each type of public health emergency and appropriate intervention will be utilized by authorized POD staff in conducting intake of POD clients and distribution of countermeasures. These instructions will be approved by the Secretary of Health or other designated “public health officials” (i.e., Chief Medical Officer or other state public health officials) for implementation at the time of a public health emergency.

## **B. Distributing countermeasures<sup>2</sup>**

The Secretary of Health and other “public health officials” designated by the Secretary are authorized under state public health and emergency response laws to administer treatment, including *distributing* or *administering* medical countermeasures for the affected population of New Mexico during a public health emergency.

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<sup>2</sup> In New Mexico, *dispense* refers to the implementation of a prescription, including preparation (e.g., compounding, labeling and repackaging from a bulk container) and delivery of a drug or device to a patient or patient’s agent in a suitable container appropriately labeled for subsequent administration to or use by a patient. Pharmacy Act, § 61-6-11.2.I., New Mexico Statutes Annotated (NMSA) (1978). *Administer* means the direct application of a drug directly to the body of a patient by injection, inhalation, ingestion or any other means as a result of an order of a licensed practitioner. § 61-11-2.A., NMSA (1978). *Distribute* means the delivery of a drug or device other than by administering or dispensing, and includes supplying one or more doses of a drug to a patient that has been prepackaged by a licensed pharmacist. § 61-6-7.1.C., NMSA (1978); § 61-11-2.J., NMSA (1978). Although the term “dispensing” has been used almost uniformly by federal and state emergency planners to refer to the “distribution” or “administration” of medical countermeasures from “Point of Dispensing” sites, the phrase “Point of Distribution” (POD) and the terms “distributing” or “administering” are used within this State of New Mexico Strategic National Stockpile Countermeasure and Distribution Plan to describe the physical delivery of countermeasures to POD clients.

Medical countermeasures will be distributed or administered to POD clients during a public health emergency in accordance with special instructions (i.e., protocols) developed by state public health officials. The decisions as to what countermeasures to distribute are predicated upon evidence-based medicine and generally accepted standards of practice for effective treatment or prophylaxis of each specific disease, exposure to a biological or chemical agent, or other condition requiring public health intervention (e.g., pandemic influenza exposure or infection, anthrax inhalation, tularemia, etc.). These instructions will be approved by the Secretary of Health or other designated “public health officials” (i.e., Chief Medical Officer or other state public health officials) for implementation at the time of a public health emergency.

The distribution or administration of countermeasures will be performed by POD staff in compliance with all applicable state public health laws and regulations, public health emergency response laws, and scope of practice laws and regulations, or pursuant to protocols approved by the Secretary of Health or other designated “public health officials” (i.e., NMDOH Chief Medical Officer or other state public health officials) for implementation at the time of a public health emergency. See, e.g., Secretary of Health *Protocols for Mass Distribution or Administration of Medical Countermeasures Under State of New Mexico Strategic National Stockpile Countermeasures and Distribution Plan* (hereinafter “Secretary’s Protocols”) in the POD Toolkit (Document 6.1), and Paragraphs 2. D. and 2. E. of this Appendix for further details.

### **C. Setting priority groups for countermeasures**

During a public health emergency, medical countermeasures may be limited in supply or availability and there may not be an adequate amount for distribution or administration to all affected New Mexican residents and to all clients who come to a POD for receipt of medical countermeasures.

The NMDOH and the Secretary of Health are vested with authority under state public health laws and regulations to among other things: (1) investigate, control and abate the causes of disease and other conditions of public health significance; (2) maintain and enforce rules for the control of communicable diseases and other conditions deemed to be dangerous to public health; and (3) to do all things necessary and to take such measures on the advice of the NMDOH medical officer as are deemed necessary and proper for the protection of the public health. PHA § 24-1-3.C., M. and V., NMSA (1978); and § 7.4.3.9, NMAC. The New Mexico public health emergency response laws also authorize the Secretary of Health to “control, restrict and regulate the allocation, sale, dispensing or distribution of health care supplies” during a public health emergency that results in a statewide or regional shortage of such supplies during a *governor-declared* public health emergency. § 12-10A-6.B., NMSA (1978). “Health care supplies” include medications. §12-10A-2.D., NMSA (1978).

Decisions as to what prioritization of countermeasures, if any, will be necessary during a public health emergency are made by state public health officials in compliance with all applicable state and federal laws and regulations, after consideration of guidance and recommendations from the CDC. These decisions are predicated upon evidence-based medicine and generally accepted standards of practice for effective treatment or prophylaxis for each specific disease, exposure to a biological or chemical agent, or other condition requiring public health intervention (e.g., pandemic influenza exposure or infection, anthrax inhalation, tularemia, etc.) and for managing scarce medical resources during a public health emergency.

State public health officials will develop guidelines for any necessary prioritization of medical countermeasures that are appropriate for each public health emergency and related intervention, as well as the availability of such countermeasures. These guidelines will be utilized by POD staff in distributing or administering countermeasures to POD clients during a public health emergency.

#### **D. Prescriptive authority in New Mexico**

In New Mexico, several categories of health care professionals have or may have prescriptive authority that can be utilized for different types of treatment or different types of medications, including licensed physicians, dentists, veterinarians, psychologists, and licensed/registered pharmacist clinicians. Other health care providers with the appropriate levels of training, certifications and/or registrations may be able to prescribe medications for a patient either independently or under the appropriate and required supervision of a licensed physician (e.g., physician assistants, certified nurse practitioners, certified clinical nurse specialists, etc.). However, such prescriptive authority may be subject to many limitations and restrictions under state scopes of practice and prescriptive authority laws and regulations, as well as federal regulations for prescription drugs.

The New Mexico public health laws (PHA) and regulations provide authority in the NMDOH, through its Secretary, to among other things: (1) investigate, control and abate the causes of disease and other conditions of public health significance; (2) maintain and enforce rules for the control of communicable diseases and other conditions deemed to be dangerous to public health; and (3) to do all things necessary and to take such measures on the advice of the NMDOH medical officer as are deemed necessary and proper for the protection of the public health. PHA § 24-1-3.C., M. and V., NMSA (1978) and § 7.4.3.9, NMAC. The New Mexico public health emergency response laws (PHERA) also authorize the Secretary of Health to designate “public health officials,” including “qualified public individuals or groups” and “qualified private individuals or groups” to perform medical examinations, tests or administer treatment, including vaccination, in the event of a *governor-declared* public health emergency. § 12-10A-2.H. and §§ 12-10A-12. and 13., NMSA (1978).

Accordingly, the Secretary of Health or other designated “public health officials” (e.g., Chief Medical Officer or other state public health officials) will be the authorized “prescribers” for medical countermeasures that are appropriate for the affected population of New Mexico during a public health emergency, and will be the

“prescribers” listed on all required labeling and records of distribution or administration of countermeasures to POD clients during a public health emergency.

### **E. Who can distribute or administer medical countermeasures in New Mexico?**

The New Mexico public health laws (PHA) and regulations provide authority in the NMDOH, through its Secretary, to among other things: (1) investigate, control and abate the causes of disease and other conditions of public health significance; (2) maintain and enforce rules for the control of communicable diseases and other conditions deemed to be dangerous to public health; and (3) to do all things necessary and to take such measures on the advice of the NMDOH medical officer as are deemed necessary and proper for the protection of the public health. PHA § 24-1-3.C., M. and V., NMSA (1978) and § 7.4.3.9, NMAC.

The New Mexico public health emergency response laws (PHERA) grant special powers and authority in the NMDOH Secretary of Health to prepare for and administer treatment to the affected population of New Mexico during a *governor-declared* public health emergency, and also authorize the Secretary of Health to designate “public health officials,” including “qualified public individuals or groups” and “qualified private individuals or groups” to perform medical examinations, tests or administer treatment, including the *distribution* or *administration* of medical countermeasures (e.g., medications or vaccines) during a declared public health emergency. § 12-10A-2.H. and §§ 12-10A-12. and 13., NMSA (1978).

In the absence of special NMDOH protocols designating other “public health officials” or “qualified persons” who can distribute or administer countermeasures to POD clients during a public health emergency, the following categories of health care providers are authorized to distribute and/or administer medications and vaccines *within the limitations of state licensing and scope of practice laws and regulations*: (1) licensed physicians and physician assistants; (2) licensed pharmacists, pharmacist interns and pharmacist technicians; (3) licensed registered nurses and practical nurses (administer but do not generally distribute); (4) certified nurse practitioners and clinical nurse specialists; (6) emergency medical services (EMS) personnel; and (7) medical students, interns, residents and fellows.

Certain scopes of practice requirements and limitations have been modified for emergency circumstances by currently existing regulations. The supervision and delegation requirements for licensed physician assistants do not apply to medical tasks performed during a “major disaster” (defined as a disaster declared by the federal emergency management agency or FEMA). § 16.10.15.19.A., NMAC. A physician assistant may provide medical services and perform tasks permitted in their normal scope of practice while under the supervision of ***any physician who is also performing volunteer work*** during the disaster or ***without the supervision of a physician if one is not available***. § 16.10.15.19.B., NMAC.

In addition, during an “emergency” or “disaster” (terms not defined in the regulation), the State EMS Medical Director or NMDOH Chief Medical Officer may temporarily

authorize EMS personnel to administer pharmaceuticals or tests, including the administration of immunizations, vaccines, biologicals, and testing not generally included within their scopes of practice. §§ 7.27.2.14.I(4) (EMT – Basic); 7.27.2.14.J(2)(g)(iv) (EMT – Intermediate); and 7.27.2.14.K(5)(d) (EMT – Paramedic), NMAC. The expansion of the scopes of practice of other licensed health care professionals may be authorized by the Secretary of Health during a public health emergency.

It is anticipated that there will be an inadequate number of licensed health care professionals to distribute and administer medical countermeasures during a public health emergency. Because of these difficult circumstances, the Secretary of Health and NMDOH Chief Medical Officer have approved Protocols that will apply whenever there is a need for mass distribution or administration of medical countermeasures under the State SNS Plan and from activated POD sites in response to a public health emergency as determined by the Secretary of Health. Specifically, Section 5. Paragraph A. (3) of the Secretary's Protocols provides for the use of non-licensed health care professionals or lay volunteers in the following manner:

(3) A volunteer shall be approved as a credentialed volunteer in NM-MRCServes or otherwise approved and authorized by the Department in its discretion prior to the performance of any assigned task. Such volunteer assignments are at the sole discretion of the Department and may include but are not limited to the following:

(a) *Administration of Medical Countermeasures* - The Department may approve and authorize individuals already licensed or otherwise authorized by law to *administer* medical countermeasures (e.g., vaccines) to serve as volunteers. This may include New Mexico licensed health care providers or medically trained individuals with licenses from other jurisdictions. [Footnote 4 omitted.]

(b) *Distribution of Medical Countermeasures* - The Department may approve and authorize non-licensed individuals with medical training or lay volunteers (with no medical training) to *distribute* medical countermeasures under the supervision of a DOH staff person with medical training (e.g., POD medical officer or other medically trained POD staff). During a public health emergency, such volunteers shall be permitted to distribute appropriate medical countermeasures in accordance with Department approved and authorized medical protocols specific to that public health emergency. ***This Protocol expands the authority to distribute medications during a public health emergency to individuals not otherwise permitted by law to do so.*** See **Section 1. Paragraph E.** and **Footnotes 2 and 3** of these Protocols for further explanation.

(c) *Non-Medical Tasks* - The Department may also approve and authorize non-licensed individuals with medical training or lay

volunteers to perform other non-medical tasks, such as directing POD clients to various POD stations, handing out information sheets, completing or filing forms or records, or any other tasks assigned by DOH staff.

See Secretary's Protocols in the POD Toolkit (Document 6.1), Section 5.

### **3. Use of volunteers for distribution of countermeasures**

#### **A. NM-MRCServes and the provision of medical countermeasures**

NMDOH maintains a registry, called NM-MRCServes, of volunteer health care professionals whose licenses and credentials are verified in advance of a public health emergency. The NM-MRCServes categories of volunteers who may be available to distribute or administer medical countermeasures include physicians, physician assistants, nurses, pharmacists, EMS personnel and other licensed health care providers. NM-MRCServes also registers other volunteers with no licenses or specialized health care training (referred to as "lay volunteers").

Generally, volunteers who are registered in NM-MRCServes may only distribute or administer medical countermeasures during a public health emergency to the extent permitted by state licensing and scope of practice laws, unless otherwise authorized by the Secretary of Health at the time of a public health emergency. See, e.g., Secretary's Protocols in the POD Toolkit (Document 6.1), and Paragraph 2. E. of this Appendix.

NMDOH planners should consult regularly with NM-MRCServes on the status of the registry and the availability of volunteers who can distribute or administer medical countermeasures in their communities. Planners should also develop and implement strategies to address identified gaps in staffing for planned PODs and outreach efforts.

#### **B. Other non-NM-MRCServes registered volunteers, including "spontaneous volunteers"**

NMDOH will utilize volunteers registered in NM-MRCServes and approved under its credentialing process before other non-NM-MRCServes registered volunteers to support the mass distribution or administration of medical countermeasures from activated POD sites during a public health emergency.

The selection, approval and use of non-NM-MRCServes registered volunteers (including "spontaneous volunteers" who come to a POD offering assistance) to support POD operations must be in accordance with NMDOH protocols and procedures governing volunteer qualifications, training, management and acceptance/termination. See Secretary's Protocols in POD Toolkit (Document 6.1), Section 5; *Volunteer Application for Mass Distribution/Administration of Medical Countermeasures During a Public Health Emergency* (Volunteer Application) (Document 3.1); and *Volunteer Agreement for Mass Distribution/Administration of*



*Medical Countermeasures During a Public Health Emergency* (Volunteer Agreement) (Document 3.2) in the POD Toolkit.

A Health Insurance Portability and Accountability Act of 1996 (HIPAA) Volunteer Training for Mass Distribution of Medical Countermeasures has also been developed pursuant to the Secretary's Protocols and is included in the POD Toolkit (Document 3.3). Other related documents may be developed for future inclusion in the POD Toolkit.

#### **4. Accommodations and considerations for groups and individuals with special planning needs.**

##### **A. At risk populations**

See **Appendix C - Accommodations and Considerations for At Risk Populations** for general guidance on planning to reach at risk populations.

##### **B. Incapacitated adults and unaccompanied minors**

The NMDOH and the Secretary Health are vested with authority under the state public health laws and regulations to among other things: (1) investigate, control and abate the causes of disease and other conditions of public health significance; (2) maintain and enforce rules for the control of communicable diseases and other conditions deemed to be dangerous to public health; and (3) to do all things necessary and to take such measures on the advice of the NMDOH medical officer as are deemed necessary and proper for the protection of the public health. PHA § 24-1-3.C., M. and V., NMSA (1978) and § 7.4.3.9, NMAC. Moreover, one significant purpose and goal of state public health laws is to provide access to appropriate care, if needed, for an indefinite number of infected, exposed or endangered persons in the event of a *governor-declared* public health emergency. PHERA § 12-10A-2.C., NMSA (1978).

It is expected that some adults who present to a POD site for receipt of medical countermeasures during a public health emergency may lack the capacity to consent to medical care and may not be accompanied by his/her legal guardian or surrogate decision maker. In addition, unaccompanied minors who lack the legal ability to consent to medical care may also come to POD sites seeking medical countermeasures.

In these situations, there will be inadequate time for POD staff to obtain consent from the legal guardian or surrogate decision maker of an incapacitated adult, or from the parent or guardian of an unaccompanied minor or one standing *in loco parentis* for that minor (i.e., relating to, or acting as a temporary guardian or caretaker, taking on all or some of the responsibilities of a parent to the minor).

Because of these difficult circumstances, the Secretary of Health and NMDOH Chief Medical Officer have approved and signed Protocols that will apply whenever there is a need for mass distribution or administration of medical countermeasures under

the State SNS Plan and from activated POD sites in response to a public health emergency as determined by the Secretary of Health. Specifically, Section 4, Paragraph C. of the Secretary's Protocols provides that:

When an incapacitated adult (unaccompanied by a legal guardian or surrogate decision maker) or unaccompanied minor present to a POD site for receipt of medical countermeasures in response to a public health emergency as determined by the Secretary of Health, consent for the receipt or administration of such medical countermeasures will be implied,<sup>3</sup> and POD staff will not be required to obtain the express consent of the legal guardian or surrogate decision maker of such incapacitated adult, or of the parent, guardian or one standing *in loco parentis* of such minor before distributing or administering medical countermeasures to these individuals.

See Secretary's Protocols in POD Toolkit (Document 6.1), Section 4.

**C. Multiple versus individual regimens: pickup by family/ household representative for other family/household members**

Distribution of multiple medication regimens to individuals who present to a POD site would provide a means for distributing medical countermeasures to a greater number of individuals, some of whom may not be able to come to the POD site (e.g., due to physical inability, lack of transportation, need to care for other family/household members, etc.). This distribution method would also result in fewer individuals coming to the POD sites to receive medical countermeasures, thus resulting in improved throughput of POD clients.

Because of these circumstances, the Secretary of Health and NMDOH Chief Medical Officer have approved Protocols that will apply whenever there is a need for mass distribution or administration of medical countermeasures under the State SNS Plan and from activated POD sites in response to a public health emergency as determined by the Secretary of Health. Specifically, Section 3., Paragraphs B., C. and D. of the Secretary's Protocols permit the distribution or administration of multiple regimens of countermeasures to a household representative and states as follows:

B. A family/household representative is a person 18 years of age or older who has been designated by a group of family/household members who wish to be considered one household for the purposes of receiving medical countermeasures.

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<sup>3</sup> "Implied consent" in this context is warranted based upon the assumption that, given the nature of the public health emergency and the need for rapid and efficient mass distribution or administration of medical countermeasures to the New Mexico population, the reasonably prudent individual with the legal authority to consent on behalf of either the incapacitated adult or the unaccompanied minor would consent to the distribution or administration of the appropriate medical countermeasures to these individuals.

C. A family/household representative is eligible to receive multiple regimens of the appropriate medical countermeasures after he/she provides the required information for each family/household member for whom medication is requested, and has signed the *New Mexico Department of Health Intake Screening and Consent Form* for each such household member.

D. A family/household representative WILL be required to provide specific information (e.g., age, weight, known allergies, medical conditions, current medications, etc.) as to each family/household member for whom medication is requested. An identification card or some other form of identification (e.g., utility bill or tax return form) WILL be requested, but if the family/household representative is not able to produce identification, he/she WILL NOT be turned away from the POD site and multiple regimens of the appropriate medical countermeasures WILL be provided for each family/household member for whom complete information has been provided and on whose behalf the family/household representative has signed a consent form.

See Secretary's Protocols in POD Toolkit (Document 6.1), Section 3.

## **5. Other Issues**

### **A. Application of state and federal confidentiality, privacy and security laws and regulations under emergency circumstances.**

#### **i. POD staff compliance with confidentiality statutes and regulations.**

New Mexico public health laws provide privacy protection for the identity of clients and their health information. The "files and records of the department giving identifying information about individuals who have received or are receiving from the department treatment, diagnostic services or preventive care for diseases, disabilities or physical injuries, are confidential and are not open to inspection except where permitted by rule by the department." § 24-1-20(A) NMSA (1978).

Additionally, "[a]ll health information that relates to and identifies specific individuals as patients is strictly confidential and shall not be a matter of public record or accessible to the public." § 14-6-1(A) NMSA (1978). There are currently no exceptions to the above statutes for application during a public health emergency.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HIPAA "Privacy Rule" regulations protect an individual's "individually identifiable health information" from use or disclosure by "covered entities" subject to HIPAA. The Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) establishes certain requirements for being compatible with the security and privacy regulations of the HIPAA Privacy Rule, further protecting the security and privacy of health information.

A “covered entity” subject to HIPAA and its entire workforce (including its employees and volunteers) must meet certain standards for controlling the use and disclosure of “protected health information” (PHI). NMDOH and its business associates who encounter (e.g., access to or disclosure of) PHI in the performance of services on behalf of NMDOH are subject to HIPAA.

Under HIPAA, covered entities may not use or disclose PHI except “as necessary” to provide treatment, to seek payment for health care services, for health care operations, or with a valid written authorization from the individual who is the subject of the PHI or that individual’s personal representative. Beyond these permitted uses and disclosures, there are certain limited exceptions permitting the use or disclosure of PHI without the written authorization of the patient (e.g., disclosures to a public health authority for public health activities, disclosures to notify a person who is at risk of contracting or spreading a disease or condition as necessary to carry out public health interventions or to prevent or control the spread of the disease, disclosures otherwise required by law, etc.). Other exceptions and limitations may apply depending upon the circumstances.

To date, there have been no general alterations or modifications to the HIPAA Privacy Rule regulations that specifically apply to public health emergencies or emergency preparedness activities. However, guidance was provided by United States Department of Health and Human Services (HHS) following Hurricane Katrina in 2005 which stressed that covered entities may share PHI in the following ways:

- (1) as necessary, to provide treatment (or seek payment for treatment);
- (2) as necessary to the police, the press, or the public at large to the extent necessary identify, locate and notify family members, guardians or anyone else responsible for the care, location, general condition or death of an individual, *even without an individual’s permission if it cannot be obtained due to incapacitation or non-availability and the health care provider believes it is in the individual’s best interest*;
- (3) with disaster relief organizations (i.e. American Red Cross) on the basis of their legal authority or charter to assist in disaster relief efforts, even without obtaining an individual’s permission if doing so would interfere with the organizations ability to respond to the emergency;
- (4) with anyone as necessary *to prevent or lessen a serious and imminent threat to the health and safety of an individual or the public -- consistent with all applicable laws and the provider’s standards of ethical conduct*; and
- (5) to provide information from a directory of patients maintained by the facility to those who call or ask about individuals (i.e. whether

individual is at the facility, the location in the facility and their general condition).

Hence, the HIPAA Privacy Rule and HITECH Act regulations are not suspended or waived during a public health emergency. However, in the event of a federally declared major disaster or emergency by the President of the United States or the Secretary of the Department of Health and Human Services (Secretary of HHS), the Secretary of HHS may waive sanctions and penalties arising from noncompliance with HIPAA or other federal regulations (referred to as “Section 1135 Waivers”). For example, the Secretary of HHS may waive sanctions and penalties against a covered entity that does not comply with the following requirements and provisions of the HIPAA Privacy Rule: (1) to obtain an individual’s agreement to speak with family members or friends involved in the individual’s care; (2) to honor a request to opt out of a facility’s directory; (3) to distribute a notice of privacy practices; (4) the individual’s right to request privacy restrictions; and (5) the individual’s right to request confidential communications.

Even if the sanctions and penalties arising from noncompliance with HIPAA Privacy Rule requirements or provisions are waived, ***such waivers are only applicable where the health care providers acted in good faith, but were unable to comply with one or more of these requirements, and in the absence of a determination of any fraud or abuse.***

The NMDOH and its workforce, including its employees, volunteers and business associates, are all subject to the HIPAA privacy regulations. Local planners and staff, including volunteers, will receive NMDOH required HIPAA training and are strongly encouraged to make a good faith effort to comply with these federal regulations for the protection of the confidentiality, privacy and security of health information of POD clients.

## ii. DOH *Notice of Privacy Practices*

The federal HIPAA regulations require that the NMDOH *Notice of Privacy Practices* must be distributed to all DOH clients when DOH is acting as a health care provider. Hence, all POD clients must receive a copy of the *Notice of Privacy Practices*, along with other informational fact sheets when they come into a POD. The *Notice of Privacy Practices* is included in the POD Toolkit (Document 3.4). A supply of original brochures will be made available to all POD sites for distribution.

## B. Procurement of Private Property

Local planners are not likely to encounter this issue, but should be familiar with the legal authority of the NMDOH to procure the use of private property during a public health emergency.

The New Mexico public health laws (PHA) and regulations provide authority in the NMDOH, through its Secretary, to among other things: (1) investigate, control and abate the causes of disease and other conditions of public health significance;

(2) maintain and enforce rules for the control of communicable diseases and other conditions deemed to be dangerous to public health; and (3) to do all things necessary and to take such measures on the advice of the NMDOH medical officer as are deemed necessary and proper for the protection of the public health. PHA § 24-1-3.C., M. and V., NMSA (1978) and § 7.4.3.9, NMAC.

The New Mexico public health emergency response laws (PHERA) specifically provide that the Secretary of Health, in coordination with the Secretary of Public Safety and the Director of Homeland Security and Emergency Management may “utilize, secure or evacuate health care facilities for public use”... “in order to protect the health, safety and welfare of the people in the state during a [governor-declared] public health emergency.” § 12-10A-6.A.(1), NMSA (1978). “Health care facility” includes:

- (1) a facility licensed by the State under the Public Health Act;
- (2) a nonfederal facility or building, whether public or private, for-profit or nonprofit, that is used, operated or designed to provide health services, medical treatment, nursing services, rehabilitative services or preventive care;
- (3) a federal facility, with appropriate federal entity consent; or
- (4) the following properties when used for, or in connection with, health-related activities: (a) laboratories; (b) research facilities; (c) pharmacies; (d) laundry facilities; (e) health personnel training and lodging facilities; (f) patient, guest and health personnel food service facilities; and (g) office or office buildings used by persons engaged in health care professions or services. § 12-10A-3.E.(1), NMSA (1978).

PHERA further provides that the state shall pay just compensation to the owner of a health care facility or any other property that is lawfully taken or appropriated by the secretary of health for temporary or permanent use during a public health emergency. The amount of compensation due shall be calculated in the same manner as compensation due for taking of property pursuant to nonemergency eminent domain procedures, as provided by the New Mexico Eminent Domain Code and the compensation calculated shall include lost revenues and expenses incurred due to the taking or appropriating of property, including a health facility. Appeal and hearing rights of the owner of property taken and procedures therefore are provided under PHERA. § 12-10A-15., NMSA (1978).

### **C. Legal Protections for State Employees and Volunteers**

State of New Mexico employees performing their job duties and responsibilities during a public health emergency are entitled to the protections of the New Mexico Tort Claims Act (TCA) and the New Mexico Workers’ Compensation Act (WCA) while acting within the scope of their duties as “public employees.”

All NM-MRCServes registered volunteers requested by the NNMDOH to render volunteer services during a public health emergency or during emergency preparedness training, drills or exercises are afforded the liability protections of the

New Mexico TCA. However, this does not mean that they are all *immune* from liability.

Specifically, NM-MRCServes volunteers who are licensed in New Mexico or otherwise permitted by law to provide health care services are covered for professional liability (i.e., defense and indemnity) for damages caused by their negligence while acting within the scope of their duties providing health care services. §§ 41-4-3.F.(3) and 41-4-10., NMSA (1978). NM-MRCServes volunteers who are non-licensed health care professionals or lay volunteers are entitled to immunity from tort liability, unless immunity is waived under the TCA for the specific activities in which the volunteers are engaged (e.g., operation of a motor vehicle, etc.), in which case they are still covered for liability (i.e., defense and indemnity) for damages caused by negligence while acting within the scope of their duties as a volunteer. §§ 41-4-3.F.(3) and 41-4-4., NMSA (1978).

All NM-MRCServes volunteers who are unpaid licensed health care professionals and deployed by the NMDOH within the state during a declared public health emergency or outside the state in response to a request for emergency assistance under the Emergency Management Assistance Compact are covered under the New Mexico WCA as “public employees.” § 52-1-3.1.B., NMSA (1978). However, there is no coverage for injury or death that occurs to these volunteers during emergency preparedness training, drills or exercises. NM-MRCServes volunteers who are non-licensed health care professionals or lay volunteers are not covered by NM workers’ compensation benefits for volunteer services as they are not “public employees” as defined under the WCA. § 52-1-3.1.B., NMSA (1978).

All other volunteers who are not registered in NM-MRCServes (i.e., volunteers otherwise selected, approved and assigned in accordance with NMDOH protocols and procedures as set forth in the Secretary’s Protocols, including “spontaneous volunteers”) are entitled to the same legal protections for liability for negligence and workers’ compensation benefits as NM-MRCServes registered volunteers (and to the same extent based upon whether they are licensed health care professionals, non-licensed health care professionals or lay volunteers). These volunteers must be requested and deployed by the NMDOH to provide volunteer services in an official capacity during a public health emergency and must be acting within the scope of such authorized services.

The services of non-NM-MRCServes registered volunteers (including “spontaneous volunteers”) must be rendered pursuant to a written Volunteer Agreement entered into with the NMDOH prior to the time such services are assigned and performed, and services will be limited to the scope of services as approved by NMDOH and specifically identified in the agreement. See Secretary’s Protocols in POD Toolkit (Document 6.1), Section 5, and Volunteer Agreement (Document 3.2) in POD Toolkit.