

Frequently Asked Questions
about
Federal Public Health Emergency Law



**Based on the April 28, 2009, teleconference “Federal Public Health
Emergency Law: Implications for State & Local Preparedness and
Response” and prepared by the
Public Health Law Program
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Frequently Asked Questions about Federal Public Health Emergency Law

September 2009

I. Introduction

On April 26, 2009, the Acting Secretary of the federal Department of Health and Human Services (HHS) issued a nationwide public health emergency declaration in response to human infections from influenza A (H1N1) virus. In addition, the World Health Organization raised the level of influenza pandemic alert to the highest level on June 11, 2009. Subsequently, the HHS declaration was renewed by HHS Secretary Kathleen Sebelius on July 24, 2009.

Local and state health agencies are the first line of preparedness for infectious disease pandemics and other threats to the health of the public. Their success hinges on many factors, including, among others, their “legal preparedness,” that is, their understanding and use of laws and legal authorities that support effective response. Those legal authorities are complex and involve laws at the federal, state, local, and tribal levels. Further, they are found in multiple sectors, including not only the public health sector but also in emergency management, health care, law enforcement, education, and transportation.

Because a number of federal laws relevant to public health emergencies have been revised and updated in recent years, in the spring of 2009 CDC’s Public Health Law Program and CDC’s Coordinating Office for Terrorism Preparedness and Emergency Response invited four senior federal attorneys to update public health practitioners and counsel on current, pertinent federal laws in a 90-minute national facilitated teleconference on April 28, 2009. By coincidence, the teleconference “Federal Public Health Emergency Law: Implications for State and Local Preparedness and Response” took place at the beginning of the H1N1 pandemic. The faculty highlighted provisions of federal law especially relevant to that new threat. Following the presentation, members of the large audience – more than 1,300 public health and other professionals – focused many of their questions on issues related to the pandemic.

This report – *Frequently Asked Questions about Federal Public Health Emergency Law* – is derived from the April 28 program and the dialogue between the faculty and participants that followed. The questions and answers are organized in four categories: Legal Authorities, Public Health Emergency Procedures, Isolation and Quarantine Issues, and Workforce Issues.

Although the contents of this report were reviewed by the faculty, the report is a product of the CDC Public Health Law Program and the Program takes responsibility for any errors it may contain. To view the entire April 28 presentation and access the transcript, please visit http://www2a.cdc.gov/phlp/webinar_04_29_2009.asp.

The teleconference faculty included:

- Susan Sherman, JD, MHS, and Jennifer Ray, JD, MPH, Office of the General Counsel, U.S. Department of Health and Human Services
- Diane Donley, JD, Office of Chief Counsel, Federal Emergency Management Agency, U.S. Department of Homeland Security; and
- Kim Dammers, JD, Assistant U.S. Attorney, Northern District of Georgia, U.S. Department of Justice, at the time on detail to CDC.

The CDC Public Health Law Program is grateful to the faculty and to Brian Kamoie, JD, MPH, Deputy Assistant Secretary and Director, Office of Policy, Strategic Planning and Communications, Office of the Assistant Secretary for Preparedness and Response, HHS, who introduced the program.

The CDC Public Health Law Program provides many additional resources on public health emergency legal preparedness accessible in the “CDC Public Health Emergency Legal Preparedness Clearinghouse” at <http://www.cdc.gov/phlp>:

- Up-to-date information on legal issues and resources related to infectious disease outbreaks
- The training curricula *Public Health Emergency Law 3.0* and *Forensic Epidemiology 3.0*
- The *Social Distancing Law Assessment Template*
- The *Menu of Suggested Provisions for Public Health Mutual Aid Agreements* and companion *Inventory of Mutual Aid Agreements and Related Provision*”
- A three-part portfolio of resources for improved coordination across public health, law enforcement, the judiciary, and the corrections sector, and
- The *National Action Agenda for Public Health Legal Preparedness*

The Program also publishes the monthly *CDC Public Health Law News*, a digest of developments in public health law and guide to new resources for improved public health legal preparedness. Subscribe at the [CDC Public Health Law News Web site](http://www2a.cdc.gov/phlp/cphln.asp) (<http://www2a.cdc.gov/phlp/cphln.asp>).

II. Questions and Answers

Within this document, you will find frequently asked questions extrapolated from information provided by the faculty of the April 28, 2009 teleconference “[Federal Public Health Emergency Law](#)”. The questions and answers are grouped into four categories: legal authorities, public health emergency procedures, isolation and quarantine, and workforce issues.

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Glossary of Terms

ASP–Average Sales Price

ASPR–Assistant Secretary for Preparedness and Response

CHIP–Children’s Health Insurance Program

CMS–Centers for Medicare and Medicaid Services

EMTALA–Emergency Medical Treatment and Active Labor Act

ESF–Emergency Support Function

ESAR-VHP–Emergency System for Advanced Registration of Volunteer Health Professionals

EUA–Emergency Use Authorization

FEMA–Federal Emergency Management Agency

FFDCA–Federal Food, Drug, and Cosmetic Act

HHS–United States Department of Health and Human Services

HIPAA–Health Insurance Portability and Accountability Act

NDMS–National Disaster Management System

PHSA–Public Health Service Act

PREP Act–Public Readiness and Emergency Preparedness Act

REMS–Risk Evaluation and Mitigation Strategies

SNS–Strategic National Stockpile

SSA–Social Security Act

USERRA–Uniform Services Employment and Re-Employment Rights Act

A. Legal Authorities

1. What authorities does the United States Department of Health and Human Services have in public health emergencies?

Primarily, HHS authorities flow from the Public Health Service Act (PHSA) that was enacted in 1944 and has been amended many times since then. According to the PHSA, the Secretary of HHS “shall lead all Federal public health and medical response to public health emergencies and incidents covered by the National Response [Framework].” HHS is the primary agency for Emergency Support Function (ESF) 8 under the National Response Framework, which covers public health and medical response. HHS is also a support agency for ESF 6, covering mass care, emergency assistance, housing, and human services. Section 311 of the PHSA provides the Secretary of HHS with authority to extend temporary assistance to states or localities to meet health emergencies at the request of states or local authorities, including utilizing HHS personnel, equipment, medical supplies and other resources, when state resources are overwhelmed by an emergency situation. HHS also requires funding and resources to respond to other emergency events.

While Section 311 gives HHS broad authority to assist a state or locality during an emergency, if a Stafford Act declaration is issued by the President, HHS would generally do so under a Mission Assignment from FEMA. The Secretary may authorize assistance regardless of a formal declaration of a public health emergency or a Stafford Act declaration. Additional authority comes from the Federal Food, Drug, and Cosmetic Act when relevant to emergency response as well as Social Security Act authorities.

2. What is the Stafford Act and how does it apply to public health emergencies?

In 1950, the first public law was passed creating a federal disaster relief program. The Robert T. Stafford Disaster Relief and Emergency Assistance Act (The Stafford Act), amending the Disaster Relief Act of 1974, was passed in 1988 and functions as one of the primary disaster relief legal authorities. The Stafford Act authorizes the President to issue a major disaster or an emergency declaration in response to an event (or threat) that overwhelms state or local government. The governor of an affected state must first respond to the disaster and execute the state’s emergency plan before requesting that the President declare a major disaster or emergency and the governor must certify that the magnitude of the emergency exceeds the state’s capability. Declaration under the Stafford Act triggers access to disaster relief funds as appropriated by Congress. The fund has several billion dollars to be immediately available for the emergency needs of states and local governments. The Stafford Act also authorizes the Federal Emergency Management Agency (FEMA) to coordinate administering all of the disaster relief to the states.

3. What is the purpose and function of the Pandemic and All-Hazards Preparedness Act?

The Pandemic and All-Hazards Preparedness Act passed in 2006 amends the PHSA and identifies the Secretary of HHS as the lead federal official for public health emergency preparedness and response and also establishes the HHS Assistant Secretary for Preparedness

and Response (ASPR). The ASPR serves as the Secretary of HHS's principle advisor on matters related to public health and medical emergency preparedness. The act also provides new authorities for development of countermeasures and establishes mechanisms and grants to continue strengthening of state and local public health security infrastructure and addresses surge capacity by placing the National Disaster Medical System under the purview of HHS.

4. What is the Public Readiness and Emergency Preparedness (PREP) Act? What are current examples of declarations under the PREP Act?

The PREP Act authorizes the Secretary to issue a declaration to provide immunity from tort liability (except for willful misconduct) for claims

- Of death; physical, mental, emotional injury, illness, disability, condition or fear thereof, including medical monitoring, property damage, loss, including business interruption loss
- Causally related to administration or use of "covered countermeasures" including design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use
- Against "covered persons"

The PREP Act also authorizes an emergency fund in the United States Treasury for compensation for injuries from covered countermeasures used and administered under a declaration issued by the Secretary under the PREP Act.

Covered countermeasures include security countermeasures against biological, chemical, radiological, or nuclear threats and qualified pandemic and epidemic products, including drugs, biological products (including vaccines), or devices that are licensed, approved, or cleared by the Federal Food and Drug Administration, authorized for emergency use by the FDA under section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA), or authorized for investigational use by the FDA.

To make a declaration under this act, the statute requires that the Secretary consider the desirability of encouraging design, development, clinical testing, investigation, manufacturer labeling, and any additional factors relevant to creating a countermeasure. The Secretary has to determine that a disease, health condition, or threat to health, constitutes a public health emergency or a credible risk of future public health emergency.

The PREP Act declarations are designed to encourage manufacturers to develop countermeasures during public health emergencies knowing that they will be protected from liability. Current PREP Act declarations include.

- Pandemic Influenza Vaccines, 72 Fed. Reg. 4710, 67731 73 Fed. Reg. 61871, 74 Fed. Reg. 30294
- Pandemic Influenza Antivirals, 73 Fed. Reg. 61861, 74 Fed. Reg. 29213
- Anthrax Countermeasures, 73 Fed. Reg. 58239

- Botulinum Toxin Countermeasures, 73 Fed. Reg. 61864
- Acute Radiation Countermeasures, 73 Fed. Reg. 61866
- Smallpox Countermeasures, 73 Fed. Reg. 61689
- Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices, 73 Fed. Reg. 78362

5. Who is covered by the PREP Act?

The PREP Act provides liability immunity coverage for the United States, manufacturers, distributors, program planners (state, local and tribal government as well as others who supervise or administer countermeasure programs), qualified persons (licensed health professionals and others identified by the Secretary who prescribe, administer, or dispense countermeasures), and officials, agents, employees of all of those mentioned.

6. What actions may the Secretary take under Section 319 of the PHS Act when he or she declares a public health emergency?

Under Section 319 of the PHS Act, when the Secretary has declared a public health emergency, the Secretary can take appropriate actions consistent with her other authorities to respond to the public health emergency, including making grants; entering into contracts; and investigating the cause, treatment, or prevention of the disease or disorder. In addition, the Secretary may access the Public Health Emergency Fund appropriated by Congress (although currently there are no funds appropriated to this fund).

7. What other discretionary actions may the Secretary take once he or she has declared a public health emergency?

Certain authorities have been added to the PHS Act; the Social Security Act (SSA); the Federal Food, Drug, and Cosmetic Act (FFDCA); and other laws administered by the Secretary that permit him or her to take certain discretionary actions when he or she has declared a public health emergency under Section 319 of the PHS Act.

For example, the Secretary may:

- *Waive or modify certain requirements:* Under Section 1135 of the SSA, the Secretary may waive or modify certain requirements of Medicare, Medicaid, State Children's Health Insurance Program (CHIP) and Health Insurance Portability and Accountability Act (HIPAA) as necessary to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in SSA programs and that providers of such services in good faith who are unable to comply with certain statutory requirements are reimbursed and exempted from sanctions for noncompliance, absent fraud or abuse.
- *Exempt for 30 days a person from select agent requirements:* as necessary to provide for timely participation of the entity in a response to a domestic or foreign public health emergency that involves the select agent or toxin. HHS and USDA published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law

107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins.

- *Waive certain prescription and dispensing requirements:* Under Section 505-1(f) of the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) has the authority to require Risk Evaluation and Mitigation Strategies (REMS) for a prescription drug as necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if FDA determines that the drug is effective but is associated with a serious adverse drug experience, and could not be approved (or approval would be withdrawn) without the required elements to mitigate the risk and other potential REMS elements are not sufficient to mitigate the risk.
- *Adjust Medicare reimbursement for certain Part B drug:* In the case of a public health emergency in which there is a documented inability to access drugs and biologicals and a associated increase in the price of a drug or biological that is not reflected in the manufacturer's average sales price (ASP) for one or more quarters, the Secretary may use the wholesale acquisition cost or other reasonable measure of drug or biological price instead of the manufacturer's ASP. The substituted price or measure may be used until the price of the drug or biological has stabilized and is substantially reflected in the manufacturer's ASP.
- *Waive certain Ryan White HIV/AIDS grant program requirements.* Under Section 2683 of the PHSA, up to five percent of the funds available under each of the Parts A and B base supplemental pools may be shifted to ensure access to care during the time period when the Secretary declares a public health emergency or when the President declares an emergency or major disaster under the Stafford Act or the National Emergencies Act.
- *Make temporary appointments:* The Secretary may make temporary (up to one year or the duration of the emergency) appointments of personnel to positions that directly respond to the public health emergency when the urgency of filling positions prohibits examining applicants through the competitive process.
- *Declare an emergency justifying an emergency use authorization (EUA):* Under Section 564 of the FFDCA, the Secretary can declare an emergency that justifies an EUA that allows for the use of unapproved drugs, devices, or biological products, or for the use of approved drugs, devices, or biological products for a not yet approved purpose.

8. What is an 1135 waiver?

Section 1135 waivers are authorized by the Social Security Act and are applicable only in the 'emergency area' during the 'emergency period' as outlined in the declarations. An emergency area and period is where and when there is: a) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Stafford Act, *and* b) a public health emergency declared by the Secretary. The waiver lists types of requirements that can be waived or modified to assist states in providing surge capacity such as waiver or modification of bed limits for critical access hospitals. When the Secretary issues an 1135 waiver, hospitals and other entities usually work with HHS Regional Centers for Medicare and Medicaid Services (CMS) officials to seek specific waivers or modifications on a case-by-case basis.

Certain Emergency Medical Treatment and Labor Act (EMTALA) sanctions and Health Insurance Portability and Accountability Act (HIPAA) sanctions that can be waived for just a

short time. This is not a waiver of HIPAA in its entirety. The waiver of HIPAA sanctions and non-pandemic infectious disease related waivers of sanctions under EMTALA are limited to a 72 hour period beginning upon implementation of a hospital disaster protocol.

9. When the Secretary issues an 1135 waiver, what Medicare, Medicaid, CHIP, and HIPAA requirements may be temporarily waived or modified?

Under Section 1135, the following Medicare, Medicaid, CHIP and HIPAA requirements may be waived or modified:

- Conditions of participation or other certification requirements, or program participation and similar requirements for individual providers or types of providers.
- Pre-approval requirements for providers or health care items or services.
- Requirements that physicians and other health care professionals hold licenses in the state in which they provide services if they have a license from another state and are not affirmatively barred from practice in that state or any state in the emergency area (note however, that this waiver is for the purposes of Medicare, Medicaid, and CHIP reimbursement only – states determine whether a non-federal provider is authorized to provide services in the state without state licensure).
- Sanctions under EMTALA for redirection of an individual to another location to receive a medical screening examination pursuant to a state emergency preparedness plan, or in the case of a public health emergency involving a pandemic infectious disease, a state pandemic preparedness plan, or for transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the emergency. A waiver of EMTALA sanctions is effective only if actions under the waiver do not discriminate on the basis of a patient's source of payment or ability to pay. EMTALA waivers are subject to special time limits.
- Sanctions related to stark self-referral prohibitions that could apply when a physician refers a patient for services to a provider with whom the physician has a financial interest.
- Deadlines and time tables for performing required activities to allow timing of such deadlines to be modified.
- Limitations on payments to permit Medicare Advantage Choice enrollees to use out-of-network providers in an emergency situation. To the extent possible, the Secretary must reconcile payments so that enrollees do not pay additional charges and so that the plan pays for services included in the capitation payment.
- Sanctions and penalties arising from noncompliance with HIPAA privacy regulations relating to: a) obtaining a patient's agreement to speak with family members or friends or honoring a patient's request to opt out of the facility directory, b) distributing a notice of privacy practices, or c) the patient's right to request privacy restrictions or confidential communications. The waiver of HIPAA requirements is effective only if actions under the waiver do not discriminate on the basis of a patient's source of payment or ability to pay. These HIPAA waivers under are subject to special time limits.

Medicare, Medicaid, and CHIP requirements are not automatically waived or modified by the issuance of an 1135 waiver. Rather, the Centers for Medicare & Medicaid Services (CMS) receive requests from affected hospitals, health care facilities, and health care providers for

waivers or modifications of specific requirements and issues instructions or guidance as needed. CMS reviews such requests and generally approves the requested waivers or modifications on a case-by-case basis. Regardless of whether the Secretary has made a formal public health emergency declaration under Section 319 of the PHSA, and even in the absence of an 1135 waiver, other SSA provisions and CMS regulations may provide certain flexibilities that may be implemented as appropriate to address an emergency or disaster. CMS works closely with affected hospitals, health care facilities, and health care providers during such situations to address their concerns.

When the Secretary issues an 1135 waiver, HHS automatically waives such sanctions and penalties described in the 1135 waiver in the emergency area for 72 hours beginning when a hospital disaster protocol is implemented. The waiver of HIPAA requirements is effective only if actions under the waiver do not discriminate on the basis of a patient's source of payment or ability to pay. Also, the waiver only applies if the hospital has implemented its hospital disaster protocol. The HIPAA sanctions and penalties that may be waived when an 1135 waiver is issued are specified in the 1135 waiver document and do not waive HIPAA in its entirety. Even without an 1135 waiver, there are various flexibilities and exceptions that may apply to permit covered entities to share protected health information during a public health emergency. See the HHS Web page [Emergency Preparedness Planning and Response](http://www.HHS.gov/ocr/hipaa/emergencyPPR.html) (<http://www.HHS.gov/ocr/hipaa/emergencyPPR.html>) for more information about the application of HIPAA during public health emergencies (whether or not the Secretary makes a formal public health emergency declaration under section 319 of the PHSA, or issues an 1135 waiver).

Waivers or modifications under section 1135 of the SSA may be retroactive to the beginning of the emergency period (or to any subsequent date). The waiver or modification terminates either upon termination of the emergency period or 60 days after the waiver or modification is first published (subject to 60-day renewal periods until termination of the emergency). However, waivers of EMTALA (except in the case of a pandemic disease) or HIPAA requirements are effective only for 72 hours beginning on implementation of a hospital disaster protocol. A waiver of EMTALA sanctions in connection with an emergency involving a pandemic disease (such as pandemic influenza) is effective until the termination of the pandemic-related public health emergency. However, a particular waiver or modification will terminate prior to the ultimate termination date described in this paragraph (e.g., prior to the 72 hour time period after a hospital begins to implement its disaster protocol) if the Secretary determines that as of an earlier date, the waiver or modification is no longer necessary to accomplish the purposes set forth in Section 1135(a).

B. Public Health Emergency Procedures

10. What is a public health emergency and how is a declaration of public health emergency made?

Under Section 319 of the Public Health Services Act (42 U.S.C. § 247d), the Secretary may declare a public health emergency if the Secretary determines, after consultation with such public health officials as may be necessary, that “(1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists.” The broad definition gives HHS discretion to determine if a particular event constitutes a public health emergency. A public health emergency declaration lasts for 90 days and can be terminated earlier if the Secretary determines the emergency no longer exists. It can also be renewed by the Secretary for additional 90 day periods if the emergency continues to exist.

11. May the Secretary declare a “potential” public health emergency?

The Secretary has the discretion to determine that a disease or condition presents a public health emergency, or a public health emergency otherwise exists, based on conditions that exist prior to the actual outbreak of disease or natural catastrophe. For example, the Secretary may declare a public health emergency based on emergency needs that exist preceding the outbreak of disease or in anticipation of a storm before a hurricane makes landfall. The statutory language in section 319 of the PHS Act, however, does not explicitly use the term “potential” public health emergency.

12. How does a public health emergency declaration relate to a Presidential declaration of an emergency or major disaster under the Stafford Act?

A public health emergency declaration under Section 319 of the PHS Act and a Presidential declaration of an emergency or disaster under the Stafford Act are distinct and separate declarations.

When an incident overwhelms or is anticipated to overwhelm State resources, the Governor may request federal assistance, including assistance under the Stafford Act. The Stafford Act authorizes the President to provide financial and other assistance to State and local governments, certain private nonprofit organizations, and individuals to support response, recovery, and mitigation efforts following Presidential emergency or disaster declarations.

The Stafford Act is triggered by a Presidential declaration of a major disaster or emergency, when an event causes damages of sufficient severity and magnitude to warrant federal disaster assistance to supplement the efforts and available resources of States, local governments, and the disaster relief organizations in alleviating the damage, loss, hardship, or suffering. Most incidents are not of sufficient magnitude to warrant a Presidential declaration. However, if State and local resources are insufficient, a Governor may ask the President to make such a declaration. Ordinarily only a Governor can initiate a request for a Presidential emergency or major disaster declaration. In extraordinary circumstances, the President may unilaterally declare a major disaster or emergency.

Unlike a Presidential declaration of a major disaster or emergency under the Stafford Act which ordinarily requires a formal request by a state Governor, there is no requirement that a Governor or other entity make a formal request in order for the Secretary to declare a public health emergency under section 319 of the PHS Act. The President may declare a major disaster or emergency under the Stafford Act in the absence of a Secretarial declaration of a public health emergency under section 319 of the PHS Act. Likewise, the Secretary of HHS may declare a public health emergency under section 319 of the PHS Act in the absence of a Presidential declaration under the Stafford Act.

While a Presidential declaration under the Stafford Act and a Secretarial declaration of a public health emergency are separate declarations, sometimes a Stafford Act declaration is required in order for the Secretary to exercise certain authorities. For example, in order for the Secretary to exercise his waiver authority under section 1135 of the SSA to temporarily waive or modify certain Medicare, Medicaid, CHIP, and HIPAA requirements, there must be a public health emergency declaration in place, as well as a Presidential declaration of a major disaster or emergency pursuant to the Stafford Act (or the National Emergencies Act).

13. What is a request for declaration?

A governor may request the President declare a major disaster or emergency, following execution of the state's emergency plan. The President may make this declaration if the governor certifies in writing that the severity and magnitude of the emergency is beyond the capability of the state justifying the need for federal assistance.

14. What is a declaration of federal primary responsibility?

The President may declare an emergency without the request of a governor if the emergency involves "federal primary responsibility" (such as if the event occurs on federal property, for example the bombing of the Murrah Federal Building in 1995). Alternatively, the President may issue a declaration of federal primary responsibility for public health issues that are a joint state and federal responsibility and not primarily federal responsibility.

15. What types of disaster assistance are available?

Disaster assistance programs are grouped into three categories: public assistance, individual assistance and hazard mitigation. Public assistance includes emergency work and permanent work to assist states, local governments, and certain private non-profits. Funding for public assistance is divided into either a 75% federal share/25% state share or as dictated by the President. Disaster assistance program activities are frequently executed by FEMA in the form of Mission Assignments or are contracted to a support agency and managed by FEMA. Individual assistance may occur immediately following an emergency event and is limited to \$30,000 per person for direct financial assistance for housing and other disaster-related needs. Hazard mitigation assists state and local governments to decrease the loss of life and property due to natural disasters and enables measures to be implemented quickly when beginning recovery activity.

16. What is the role of the Federal Emergency Management Agency (FEMA) in public health emergencies?

The Homeland Security Act was passed in 2002 and moved FEMA, a previously independent agency, to the Department of Homeland Security where it is today. In response to Hurricane Katrina, the Post Katrina Emergency Management Reform Act was passed on October 4, 2006 changing FEMA's authority and mission. The updated mission of FEMA is "to reduce the loss of life and property and protect the Nation from all hazards, including natural disasters, acts of terrorism, and other man-made disasters, by leading and supporting the Nation in a risk-based, comprehensive emergency management system of preparedness, protection, response, recovery, and mitigation." FEMA works with state, local, and tribal governments, emergency response providers, other federal agencies, and the private sector.

17. Is a public health emergency declaration required for HHS to provide assistance to states or localities?

Even without a public health emergency declaration, the Secretary has broad legal authority to provide assistance to states and to conduct research studies. For example, under Section 301 of the PHSA, the Secretary has broad authority to render assistance and promote research, investigations, demonstrations, and studies into the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man. Similarly, under Section 311 of the PHSA, the Secretary is authorized to assist states and their political subdivisions in the prevention and suppression of communicable diseases and to develop and take necessary actions to implement a plan under which personnel, equipment, medical supplies, and other resources of the Public Health Service and other agencies under the jurisdiction of the Secretary may be effectively used to control the epidemics of any disease or condition and to meet other health emergencies or problems. The Secretary may also activate the National Disaster Medical System and deploy the Strategic National Stockpile without a public health emergency declaration.

18. Is a declaration of public health emergency required for the Secretary to provide liability immunity under the PREP Act?

Under the PREP Act, Pub. L. No. 109-148, the Secretary may issue a declaration that provides tort liability immunity (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration and use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is independent of a public health emergency declaration, and the Secretary does not have to declare a public health emergency to issue a PREP Act declaration or for liability immunity under the PREP Act to take effect. For more information about the PREP Act, please visit the PREP Act site at: <http://www.HHS.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-ga.html>.

19. Does a public health emergency declaration waive or preempt state licensing requirements for healthcare providers?

A public health emergency declaration does not waive or preempt state licensing requirements. States determine whether and under what circumstances a non-federal healthcare provider is authorized to provide services in the state without state licensure.

As discussed above, when the Secretary issues an 1135 waiver, the Secretary may waive Medicare, Medicaid or CHIP requirements that physicians and other health care professionals hold licenses in the State in which they provide services. This would be for Medicare, Medicaid or CHIP reimbursement purposes only, and would apply only if the physicians or other health care providers have an equivalent license from another State (and are not affirmatively barred from practice in any State in the emergency area).

20. Does a governor or other official have to make a formal request for a federal declaration of public health emergency or for an 1135 waiver?

There is no requirement under Section 319 of the PHSA, or under Section 1135 of the SSA that a state or other entity make a formal request for a public health emergency declaration or an 1135 waiver. When state or local officials believe that a public health emergency declaration and 1135 waivers are needed to assist the response to a particular event, HHS encourages them to work with the HHS Regional Emergency Coordinator at the HHS regional office in their area who can help facilitate the request. Hospitals, healthcare entities, and health care providers who have concerns about Medicare, Medicaid, and CHIP requirements should contact the Centers for Medicaid & Medicare Services (CMS) regional office in their area who can help address such concerns.

21. What is the Strategic National Stockpile (SNS)? How is it governed and how can it be deployed?

Under 42 U.S.C. § 247d-6b, the HHS Secretary, in coordination with the Secretary of Homeland Security, and in consultation with the CDC Director, maintains a stockpile of drugs, vaccines, and other biological products, as well as medical devices and other supplies in such numbers, types, and amounts as determined by the Secretary of HHS to be appropriate and practicable to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations. ASPR exercises the responsibilities and authorities of the Secretary with respect to coordination of the Strategic National Stockpile.

Items in the SNS can be deployed by the Secretary of Homeland Security to respond to an actual or potential emergency or by the HHS Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect public health and safety. The declaration of a public health emergency is not required to deploy the stockpile and contents can be deployed in advance of a public health emergency.

22. Under what circumstances may investigational medications or products be used?

Under the Project Bioshield Act, if the HHS Secretary has declared a public health emergency, the Secretary of Homeland Security has declared an actual or significant potential for a domestic emergency, *or* the Secretary of Defense has declared actual or significant potential for heightened risk to the military, the FDA may issue an Emergency Use Authorization (EUA) to allow for use of unapproved new drugs, off label use of drugs approved for other purposes, unlicensed biological products, or medical devices not yet approved when responding to the emergency. The EUA expires when the declaration of emergency terminates or when authorization is revoked. The FDA Commissioner may impose conditions on the use of the drug or device. All declarations and EUA documents are published in the federal register.

C. Isolation and Quarantine Issues

23. What are isolation and quarantine and when are such measures used?

Isolation is used to separate and restrict movement of ill persons found to be infected with a quarantinable disease from those who are healthy to prevent the spread of the quarantinable disease. For examples, hospitals use isolation for patients with infectious tuberculosis.

Quarantine is used to separate and restrict the movement of a well person who does not show signs of illness, but is reasonably believed to have been exposed to the infectious agent that causes a quarantinable disease. These people may have been exposed to a communicable disease and not know it, or they may have the communicable disease but do not show symptoms. Both quarantine and isolation are used to help limit the spread of communicable diseases.

24. What is social distancing and what are some examples?

Social distancing measures decrease the transmission or spread of an outbreak in a population by limiting social interaction. Social distancing measures can include, for example, school and daycare center closures, cancelation of large public gatherings (e.g., concerts, theaters), limitations for other public contacts (e.g., markets, public transit), and quarantine, among others. These measures can increase the efficacy of other public health interventions, such as vaccination.

25. What communicable diseases merit isolation or quarantine?

States have laws that authorize quarantine and isolation to control the spread of communicable diseases based on the state's police power authority to protect the health, safety, and welfare of its citizens. These laws can vary from state to state and can be broad or specific. In some states, local health authorities are empowered to implement quarantine and isolation based on state law.

Federal quarantine and isolation authority is limited, to those communicable diseases specified in an executive order of the President, i.e., "quarantinable diseases". The most current list is found in Executive Order 13295, as amended by Executive Order 13375. These quarantinable diseases include cholera; diphtheria; infectious tuberculosis; plague; smallpox; yellow fever; viral hemorrhagic fevers; severe acute respiratory syndrome (SARS), and influenza caused by novel or reemerging influenza viruses that are causing, or have the potential to cause, a pandemic.

27. What laws govern federal isolation and quarantine?

Under section 361 of the Public Health Service Act, CDC may apprehend, examine, detain, or conditionally release persons with certain communicable diseases that are listed in an Executive Order of the President, i.e., "quarantinable diseases." This includes the authority to quarantine and isolate persons to prevent the spread of these diseases. (42 U.S.C. § 264),

Also under 42 U.S.C. § 264, CDC may apprehend and examine individuals traveling from one state into another if the CDC Director reasonably believes that such individuals may be infected

with a quarantinable disease in its qualifying stage. A qualifying stage means that the disease is in a communicable stage, or a pre-communicable stage, but only if the disease would be likely to cause a public health emergency if transmitted to other individuals. Additionally, the Director must reasonably believe that the individual is moving or about to move from one state into another or constitutes a probable source of infection to other individuals, who while infected with such disease in its qualifying stage, will be moving from one state into another. If such individuals are found to be infected, they may be detained as reasonably necessary.

Federal regulations governing quarantine and isolation are found in the Code of Federal Regulations at 42 CFR parts 70 and 71. Part 70 governs interstate quarantine and isolation, while part 71 deals with foreign quarantine and isolation. In November, 2005, CDC proposed revisions to its federal regulations governing quarantine and isolation. At the time of publication of this report, the final quarantine regulations were expected to be published in the near future.

28. What duties and obligations exist with respect to individuals under quarantine or isolation?

It is well recognized that freedom from physical restraint is a liberty interest protected by the due process clauses of the Fifth and Fourteenth amendments to the United States Constitution. In general, due process includes the following elements: reasonable and adequate notice of the action that the government is taking, typically through a written order; an opportunity to be heard on a timely basis, typically through some form of hearing or other proceeding; access to legal counsel; and review of the government's actions by an impartial decision-maker.

29. What is CDC's role with respect to quarantine and isolation?

States have primary responsibility for controlling the spread of communicable diseases within their borders. CDC serves a primary role for controlling the introduction, transmission, and spread of communicable diseases at United States ports of entry. For example, when alerted about an ill passenger or crewmember by a pilot of a plane or captain of a ship, CDC may briefly detain the conveyance for purposes of investigating the cause of the illness onboard and to determine whether it may be communicable. In recent history, only a few public health events have prompted federal isolation or quarantine orders.

30. How is quarantine and isolation enforced?

Public health authorities at the federal, state, or local level may sometimes seek help from police or other law enforcement officers to enforce a public health order. Under the Public Health Service Act, United States Customs and Border Protection (CBP) and the United States Coast Guard (USCG) are required to assist CDC in enforcing its quarantine regulations. In most jurisdictions, violating a quarantine or isolation order is punishable by fines and/or imprisonment.

D. Workforce Issues

31. Who are essential service providers and what access are they allowed during an emergency situation?

According to Section 427 of the Stafford Act (42 U.S.C. 5189e), the head of a federal agency “may not deny or impede access to the disaster site to an essential service provider whose is necessary to restore and repair an essential service.” Essential service providers include municipal, nonprofit, or private for-profit entities that provide telecommunications service, electrical power, natural gas, water and sewer services or any other essential service as determined by the President.

32. For what purpose are personnel deployed by the Department of Health and Human Services in an emergency?

Personnel are deployed to provide medical surge for activities such as sheltering, patient collection, patient evacuation, case management, epidemiologic investigations, and operating federal medical stations.

33. What legal issues are involved with deployment of personnel in the event of an emergency?

When healthcare personnel are deployed across state lines, licensing, workers compensation, and liability concerns may arise. At the state and federal levels, liability and licensure are covered by a patchwork of different sources, some of which are addressed here.

The Federal Tort Claims Act (FTCA), (28 USC 2672 and 1346(b)), provides that the United States shall be liable for the negligence of its officers and employees while acting within the scope of their employment, in the same manner as a private person would be liable to a claimant under the laws of the state where the injury occurred. In other words, the FTCA covers claims for property damage or personal injury or death caused by the negligence, wrongful act, or omission of a federal employee acting within the scope of his/her employment. The FTCA coverage applies as long as the act is considered part of the employee's official duties and the action in question is within the scope of employment. Obviously, therefore, the FTCA would not apply to any activities undertaken outside of the employee's official duties as a federal employee. The FTCA, however, does not provide relief to all claims arising out of the actions of government employees acting in the scope of employment. Exceptions to the FTCA, provided in 28 U.S.C. § 2680, include, for example, any claim arising in a foreign country. (28 U.S.C. §2860(k))

The Federal Employees' Compensation Act (FECA, 5 USC 8101 et seq.), provides compensation benefits to civilian employees of the United States for disability due to personal injury sustained by the employee while in the performance of work-related duties. In other words, for example, if a federal employee sustains an injury to himself/herself while operating his/her own personal vehicle in the course of business/scope of employment, FECA would apply. Benefits will not be

paid, however, if the injury is caused by the willful misconduct of the employee or by the employee's intention to bring about his or her injury, or if intoxication (by alcohol or drugs) is the proximate cause of the injury.

Many states have provisions for some sort of liability protection for healthcare providers. State Good Samaritan statutes may offer liability protection to healthcare workers but differ by states in terms of breath of coverage. The Federal Volunteer Protection Act and certain state volunteer protection acts may provide liability protection for healthcare providers. The Emergency Management Assistance Compact (EMAC), of which all states are members, provides immunity to state officers and employees that other states share with an affected state pursuant to the compact. The Uniform Emergency Volunteer Health Practitioners Acts is a model law that addresses liability and licensing and has been adopted by ten states thus far.

34. Which HHS personnel groups are eligible to be deployed in an emergency?

The Department of Health and Human Services maintains the U.S Public Health Service Commissioned Corps, the Inactive Reserve Commission Corps, and the Medical Reserve Corps for deployment during an emergency. General Schedule (GS) employees are also eligible to be deployed in an emergency.

35. What is the Commissioned Corps and how does it function?

The United States Public Health Service Commissioned Corps is one of the seven American uniformed services and is tasked with delivering public health promotion and disease prevention programs. Commissioned Corps officers hold positions of leadership in the Department of Health and Human Services as well as other government offices and agencies. According to its website, the Commissioned Corps may be deployed to “provide urgently needed public health and clinical expertise in response to large-scale local, regional and national public health emergencies and disasters.” The Office of the Surgeon General oversees the Commissioned Corps. The Inactive Reserve Corps (IRC) is comprised of public health professionals who may be called to short or long tours of active duty with the Commissioned Corps as needed, most often to provide critical coverage during staffing shortages such as in times of disaster or emergency.

36. What is the Medical Reserve Corps and how does it function?

The Medical Reserve Corps (MRC) is comprised of volunteer civilian practicing and retired physicians, nurses and other public health workers formed mainly at the community level. The purpose of the MRC is to address the community’s ongoing health needs as well as to assist the community during a large scale emergency. Willing MRC volunteers can be activated and deployed by the Secretary to assist with federal response and recovery efforts. HHS maintains sensitivity to not deploy those needed in their own communities. If MRC members are activated as intermittent employees of the public health service, they will be provided coverage for liability and workers compensation, and will have license reciprocity as if they were a federal employee. MRC members activated as intermittent employees are also covered under the Uniform Services Employment and Re-Employment Rights Act (USERRA) which protects the

reserve components of our uniformed services so individuals who are deployed do not lose their pre-deployment jobs.

37. What is the National Disaster Medical System (NDMS) and how does it function?

The National Disaster Medical System (NDMS) is a coordinated effort of the Department of Homeland Security, the Department of Defense, the Veteran's Administration, and the Department of Health and Human Services in collaboration with states, localities, and private entities. NDMS Response Teams can be deployed to provide health services; health related social services, and other appropriate human services (such as veterinary or mortuary services) to respond to the needs of victims of a public health emergency and to be present where and when the Secretary determines location is at risk of a public health emergency.

Activation and deployment of NDMS teams does not require a formal public health emergency declaration. NDMS members are intermittent employees of the public health service. When they are activated they are federal employees and have FTCA tort liability coverage and FECA workers' compensation coverage.

NDMS also covered under the Uniform Services Employment and Re-Employment Rights Act (USERRA) which protects the reserve components of our uniformed services so individuals who are deployed do not lose their pre-deployment jobs.

38. How are healthcare providers who provide assistance during an emergency licensed and registered?

The Office of Personnel Management (OPM) regulations and federal job descriptions generally require an employee to be licensed in any state. The federal government determines what qualifications are necessary and is responsible for verification of those qualifications. States have a variety of statutes and regulations to extend license reciprocity. EMAC also contains a licensing reciprocity provision. Profession specific compacts exist in some states such as the Nurse Licensure Compact. In addition, the American Red Cross has negotiated reciprocal licensing agreements with each state.

In 2002, HHS developed the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP), a system for advanced registration of healthcare providers to verify licensure, assign standardized credential levels, track hospital privileges, and mobilize volunteers, Registration with ESAR-VHP does not in and of itself constitute federal employment, although those registered in ESAR-VHP could potentially be hired on a temporary basis if HHS were to exercise hiring authority. Registration with ESAR-VHP does not qualify a public health professional for FTCA coverage or FECA coverage and does require an additional mechanism for license reciprocity.