

APPENDIX E

SELECTED FEDERAL LEGAL AUTHORITIES

Selected Federal Legal Authorities Pertinent to Public Health Emergencies

Prepared by the Public Health Law Program
Centers for Disease Control and Prevention

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Introduction

In the wake of the 2001 terrorist attacks, the 2003 severe acute respiratory syndrome (SARS) epidemic, Hurricane Katrina in 2005, the influenza A (H1N1) pandemic in 2009, Hurricane Sandy in 2012, and the ongoing concern about future similar events, public health officials have acted to strengthen their jurisdictions' legal preparedness for all types of public health emergencies.

Federal laws and legal authorities address a variety of concerns central to public health emergencies, such as emergency declarations, quarantine and isolation, liability and licensure of workers, and mutual aid, among others. Because these laws involve multiple federal agencies and appear in many official documents, the Centers for Disease Control and Prevention's (CDC's) Public Health Law Program (PHLP) prepared the following annotated list of selected, commonly cited federal legal authorities for reference by public health officials, legal counsel, and others.

This compilation is subject to three caveats: 1) it is not intended to be exhaustive of all relevant legal authority; 2) it was compiled in September 2009 and updated in 2014 and 2017, and reflects the laws current at the time of the latest update; and 3) only selected portions of the laws relevant to public health emergencies are presented.

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Centers for Disease Control and Prevention
Office for State, Tribal, Local and Territorial Support

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Please note that some laws listed have broad application and thus may be included under more than one topic area; only the relevant portion of the law is discussed under each topic area. These laws might have other provisions not discussed here.

General Emergency Legal Authorities

- **Homeland Security Act of 2002**

Pub. L. No. 107-296, as amended; 6 U.S.C. §§ 311–321m

The Homeland Security Act merges 22 disparate agencies and organizations into the new Department of Homeland Security (DHS), including the Federal Emergency Management Agency (FEMA). The Act charges DHS with securing the nation against terrorist attacks and carrying out the functions of all transferred entities, including acting as a focal point regarding natural and manmade crises and emergency planning. The law establishes the National Homeland Security Council, the Directorate of Border and Transportation Security, and the Office for State and Local Government Coordination, and it transfers powers from Immigration and Naturalization Service (abolished under 6 U.S.C. § 291[a]).

- **Post-Katrina Emergency Management Reform Act of 2006 (Post-Katrina Act) Pub. L. No. 109-295; 6 U.S.C. §§ 701 et. seq.**

Enacted as part of the DHS Appropriations Act, 2007, the Post-Katrina Act is intended to address various shortcomings identified in the preparation for and response to Hurricane Katrina. The Act establishes new DHS leadership positions, brings additional functions into FEMA, creates and reallocates functions to other components within DHS, and amends the Homeland Security Act in ways that both directly and indirectly affect the organization and functions of various entities within DHS. The Act enhances FEMA’s responsibilities and its autonomy within DHS.

- **Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (Stafford Act)**

Pub. L. No. 93-288, as amended; 42 U.S.C. §§ 5121–5207

The Stafford Act authorizes the President to declare a “major disaster” or “emergency” in response to an event (or threat) that overwhelms state or local governments. Declaration under the Act triggers access to federal technical, financial, logistical, and other assistance to state and local governments. The Act directs FEMA to coordinate administration of disaster relief to the states. 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. As of 2013, tribal leaders can also request a Stafford Act declaration from the President (see Sandy Recovery Improvement Act of 2013, below). The President may declare an emergency without the request of a governor or tribal leader if the emergency involves “federal primary responsibility” (such as an event occurring on federal property; for example, the bombing of the Murrah Federal Building in 1995). Title VI of the Act provides for a national system for all-hazards emergency preparedness, with authority located at both the federal and state levels.

- **Sandy Recovery Improvement Act of 2013**

Pub. L. No. 113-2 §§ 1101–1111; 42 U.S.C. §§ 5170, 5191

The Sandy Recovery Improvement Act authorizes the chief executive of a tribal government to directly request disaster or emergency declaration from the President, much as a governor can for a state. Previously, tribal groups were treated like local governments in that they could receive a federal disaster declaration only if the governor of the state in which the tribe was located requested one.

- **Sections 201 and 301 of the National Emergencies Act**
50 U.S.C. §§ 1621, 1631

The National Emergencies Act authorizes the President to declare a “national emergency.” The proclamation of a national emergency must be transmitted immediately to Congress and published in the Federal Register. The declaration of emergency (or contemporaneous or subsequent executive orders) must specify the powers or authorities made available by virtue of the declaration. A national emergency can be terminated if the President issues a proclamation or if Congress enacts a joint resolution terminating the emergency. A national emergency will terminate automatically upon the anniversary of the proclamation unless the President renews the proclamation by transmitting notice to Congress and publishing it in the Federal Register.

- **Pets Evacuation and Transportation Standards (PETS) Act of 2006**
Pub. L. No. 109-308; 42 U.S.C. §§ 5170(b), 5196, 5196(b)

The PETS Act amends the Stafford Act to require the FEMA Director to ensure that state and local emergency preparedness plans “take into account the needs of individuals with household pets and service animals prior to, during, and following a major disaster or emergency.”

- **Homeland Security Presidential Directive 5 (HSPD-5) (February 28, 2003)**

HSPD-5 is intended to “enhance the ability of the United States to manage domestic incidents.” The Directive describes federal policies and objectives; identifies steps for improved coordination among federal, state, and local authorities; and tasks the Secretary of Homeland Security with developing a National Incident Management System and National Response Plan.

- **Homeland Security Presidential Directive 8 (HSPD-8) (December 17, 2003)**

HSPD-8, as a companion to HSPD-5, “establishes policies to strengthen the preparedness of the United States to prevent and respond to” manmade and natural disasters and other emergencies. The Directive requires the Secretary of Homeland Security to develop a national domestic all-hazards preparedness goal, which establishes “measurable readiness priorities and targets” and “readiness metrics and elements.” The Directive also requires relevant federal agencies to make financial assistance and support available to states, support the development of first responder equipment standards, and establish a training program to meet the national preparedness goals.

- **Emergency Management Assistance Compact (EMAC) of 1996**
Pub. L. No. 104-321

EMAC facilitates resource sharing among member states during an emergency. The National Emergency Management Association (NEMA) administers EMAC, which has been enacted by every state. A governor’s declaration of emergency and request for assistance triggers EMAC for the requesting state. An assisting state then responds to the request by providing the needed

resources. Further, EMAC establishes that the requesting state is responsible for compensating the assisting state for any expenses incurred.

Legal Authorities Specific to Public Health Emergencies

- **Section 319 of the Public Health Service Act: Public Health Emergencies**

42 U.S.C. § 247d

This section of the Public Health Service Act authorizes the Secretary of the Department of Health and Human Services (HHS) to determine that a public health emergency exists if “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.” From the determination of a public health emergency flows the ability of the Secretary to “take such action as may be appropriate” and to use funds from the Public Health Emergency Fund (when appropriated). The public health emergency determination remains effective until the Secretary either declares that the emergency no longer exists, or at the expiration of 90 days, whichever occurs first. If the Secretary determines that the same or additional facts continue to warrant a public health emergency, he or she may renew the declaration for 90-day periods. As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, section 319 also allows the Secretary, upon request by a governor or tribal organization, to authorize the temporary reassignment of state and local public health department or agency personnel funded in whole or in part through programs authorized under the Public Health Service Act for the purpose of immediately addressing a federally declared public health emergency. As amended by the 21st Century Cures Act of 2016, Pub. L. No. 114255, the Secretary may waive the requirements of the Paperwork Reduction Act with respect to voluntary collections of information after 1) issuing a 319 public health emergency determination or determining that a disease or disorder is significantly likely to become a public health emergency, and 2) determining that the public health emergency or significant likelihood of a public health emergency necessitates waiver of the Paperwork Reduction Act. The Secretary may waive these requirements during the immediate investigation of, and response to, such public health emergency, or for the period of time necessary to determine whether a disease or disorder will become a public health emergency. The waiver also extends to the immediate post-response review of a public health emergency if such review does not exceed a reasonable length of time.

- **Section 311 of the Public Health Service Act: General Grant of Authority for Cooperation**
42 U.S.C. § 243

This provision of the Public Health Service Act states that the Secretary of HHS shall assist states and local authorities in the prevention and suppression of communicable diseases and to help state and local authorities enforce quarantine regulations. This section also authorizes the Secretary to accept state and local authorities’ assistance with enforcement of federal quarantine regulations. Further, this section authorizes the Secretary to develop a public health emergency management plan and, at the request of a state or local authority, extend temporary assistance regarding public health emergencies.

- **Section 319F-2 of the Public Health Service Act: Strategic National Stockpile and Security (the Stockpile)**

42 U.S.C. § 247d-6b; 42 U.S.C. § 300hh-10(c)(3)(b)

The Stockpile (including drugs, vaccines, biological products, medical devices, and other supplies) is maintained by the Secretary of HHS, in collaboration with CDC's Director, and in coordination with the Secretary of Homeland Security, to provide for the emergency health security of the United States. The Secretary may deploy the Stockpile to respond to an actual or potential public health emergency, protect the public health or safety, or as required by the Secretary of Homeland Security, respond to an actual or potential emergency. The responsibility and authority to coordinate the Strategic National Stockpile has been assigned to the Assistant Secretary for Preparedness and Response under 42 U.S.C. § 300hh-10(c)(3)(b).

- **Public Health Security and Bioterrorism Preparedness and Response Act of 2002 Pub. L. No. 107-188**

The Act amends the Public Health Service Act to “improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.” The Act requires the Secretary of HHS to “develop and implement” a coordinated strategy in the form of a national preparedness plan. The Act also establishes the position of Assistant Secretary for Public Health Emergency Preparedness (renamed the “Assistant Secretary for Preparedness and Response,” see Pandemic and All-Hazards Preparedness Act, below), who is responsible for coordinating the operations of the National Disaster Medical System and other emergency response activities within HHS. The Act also provides the Secretary of HHS with the authority to regulate select agents and toxins and to temporarily exempt individuals or entities from the requirements of these regulations if necessary to provide for a timely response to a public health emergency. Additionally, several provisions for protection of the food and drug supply are included. Further, the Act directs the Secretary to establish and maintain the Emergency System for Advance Registration of Health Professions Volunteers (ESAR-VHP).

- **Pandemic and All-Hazards Preparedness Act of 2006
Pub. L. No. 109-417**

The Act identifies the Secretary of HHS as the lead federal official for public health emergency preparedness and response, and establishes the Assistant Secretary for Preparedness and Response (formerly named the “Assistant Secretary for Public Health Emergency Preparedness,” see Public Health Security and Bioterrorism Preparedness and Response Act of 2002, above). The Act also provides new authorities for developing countermeasures, establishes mechanisms and grants to continue strengthening state and local public health security infrastructure, and addresses surge capacity by placing the National Disaster Medical System and the ESAR-VHP under the purview of HHS.

- **Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013
Pub. L. No. 113-5; 42 U.S.C. §§ 247d, 300hh-1(b)(3)(E), 247d-3a(b)(2)(a)(iii), 247d-6d(i)(7)(iii),
21 U.S.C. § 360bbb-3, et seq.**

PAHPRA reauthorized funding for provisions of the Pandemic and All-Hazards Preparedness Act of 2006, as well as amended several provisions of the Public Health Service Act and the Food Drug and Cosmetic Act. PAHPRA requires Pandemic and All-Hazards Preparedness Act fund recipients to account for children and “at-risk individuals” in their All-Hazards Public Health Emergency Preparedness and Response Plan, as well as coordinate with local Metropolitan

Medical Response Systems, local Medical Reserve Corps, and the local Cities Readiness Initiative. Additional PAHPRA changes made to authorities described elsewhere in this document are contained in the entries addressing

- Section 319 of the Public Health Service Act: Public Health Emergencies
- The Public Readiness and Emergency Preparedness (PREP) Act of 2005
- Emergency Use Authorization

- **Section 1135 of the Social Security Act: Authority to Waive Requirements During National Emergencies**

42 U.S.C. § 1320b-5

Section 1135 of the Social Security Act authorizes the Secretary of HHS to waive or modify certain requirements of Medicare, Medicaid, and the State Children's Health Insurance Program during certain emergencies. Section 1135 waivers require both 1) a declaration of national emergency or disaster by the President under the National Emergencies Act or the Stafford Act, and 2) a public health emergency determination by the Secretary under the Public Health Service Act. Waivers may be requested by affected healthcare providers in the emergency area during the emergency period. The Secretary may make a waiver retroactive to the beginning of the emergency period or any subsequent date thereafter. The waiver generally expires at the termination of the applicable declaration of emergency or disaster under the National Emergencies Act or Stafford Act or determination of public health emergency under the Public Health Service Act. In addition, the Secretary may specify that the waivers terminate 60 days from publication, which may be extended, provided that neither the original 60-day period nor any extension extends beyond termination of the applicable declaration or determination. Waivers related to the Emergency Medical Treatment and Active Labor Act and the Health Information Portability and Accountability (HIPAA) Privacy Rule (see below) are subject to different requirements and may terminate after 72 hours.

- **Public Readiness and Emergency Preparedness (PREP) Act of 2005**

Pub. L. No. 109-148; 42 U.S.C. §§ 247d-6d, 247d-6e

The PREP Act authorizes the Secretary of HHS to issue a declaration that provides immunity from tort liability for claims of loss (except willful misconduct) caused by, arising out of, relating to, or resulting from administration or 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. The immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. As amended by PAHPRA (see above), the PREP Act immunity explicitly applies to products or technology intended to enhance medical countermeasures, in addition to the countermeasures themselves. PAHPRA also extends immunity to countermeasures authorized under sections 564A and 564B of the Federal Food, Drug, and Cosmetic Act (see below). The Secretary's declaration includes, among other things,

- The countermeasures covered by the declaration
- The category of diseases, health conditions, or health threats for which administration and use of the countermeasures recommended
- The effective time period of the declaration

- The population of individuals receiving the countermeasure
- Limitations, if any, on the geographic area for which immunity is in effect
- Limitations, if any, on the means of distribution of the countermeasure
- Any additional persons identified by the Secretary as qualified to prescribe, dispense, or administer the countermeasures

The Act also authorizes a fund in the United States Treasury to provide compensation for injuries directly caused by administration or use of the countermeasure covered by the Secretary's declaration.

- **Emergency Use Authorization** ○ **Section 564 of the Federal Food, Drug, and Cosmetic Act**

- **21 U.S.C. § 360bbb-3**

- Under section 564 of the Federal Food, Drug, and Cosmetic Act, if

- 1) The Secretary of HHS has determined that there is a public health emergency or a significant potential for a public health emergency that affects or may affect national security or the health of US citizens abroad that involves a chemical, biological, radiological, or nuclear (CBRN) agent or agents
 - 2) The Secretary of Homeland Security has determined that there is an actual or significant potential for a domestic emergency involving a heightened risk of attack with a CBRN agent or agents
 - 3) The Secretary of Defense has determined that there is an actual or significant potential for heightened risk to the military involving a heightened risk of attack with a CBRN agent or agents, *or*
 - 4) The Secretary of Homeland Security has identified a material threat pursuant to section 319F-2 of the Public Health Service Act sufficient to affect national security or the health and security of US citizens abroad that involves a CBRN agent or agents

The Secretary of HHS may, based upon one of the preceding determinations, declare that circumstances exist to justify an Emergency Use Authorization (EUA) for an unapproved drug, device, or biological product, or for an unapproved use of an approved drug, device, or biological product. Once an emergency is declared, the Food and Drug Administration (FDA) Commissioner may issue an EUA for a particular product or products, assuming other statutory criteria and conditions are met. 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. EUA authority for sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act was expanded by the 21st Century Cures Act of 2016, Pub. L. No. 114-255, to include drugs approved for use in animals.

- **Section 564A of the Federal Food, Drug, and Cosmetic Act**

- **21 U.S.C. § 360bbb-3a**

- Enacted by PAHPRA (see above), section 564A established streamlined mechanisms to facilitate certain medical countermeasure preparedness and response activities without

having to issue an EUA (which can be a time- and resource-intensive process). These new authorities, applicable to eligible FDA-approved medical products intended for use during a CBRN emergency, include

- 1) Allowing CDC, under delegated authority, to create and issue, and government stakeholders to disseminate, special emergency use instructions about the FDA-approved conditions of use for such medical countermeasures before a CBRN event occurs
- 2) Permitting the FDA to waive otherwise applicable manufacturing requirements, such as storage or handling, to accommodate emergency response needs; allowing mass dispensing of medical countermeasures during an actual CBRN emergency event without requiring an individual prescription for each recipient of the medical countermeasure, if permitted by state law or if in accordance with an order issued by the FDA Commissioner, and
- 3) Expanding the current waiver authority for risk evaluation and mitigation strategies to encompass any element for medical countermeasures to mitigate the health effects of a CBRN emergency

- **Section 564B of the Federal Food, Drug, and Cosmetic Act**

- **21 U.S.C. § 360bbb-3b**

- Enacted by PAHPRA (see above), section 564B permits federal, state, and local governments to pre-position medical countermeasures in anticipation of approval or clearance, or issuance of an EUA, enabling them to better prepare for potential rapid deployment during an actual CBRN emergency.

Public Safety and Security

- **Posse Comitatus Act of 1878**

- **18 U.S.C. § 1385**

- The Posse Comitatus Act generally prohibits the use of federal military personnel in a law enforcement capacity within the United States unless authorized by the US Constitution or an act of Congress. Certain exceptions exist, such as when the Department of Defense aids the Department of Justice in responding to an emergency situation involving a weapon of mass destruction [10 U.S.C.A. § 382].

- **Insurrection Act of 1807**

- **10 U.S.C. §§ 331-335**

- The Insurrection Act grants authority to the President to call the National Guard into federal service in the event of an insurrection in any state or if a state fails to uphold the constitutional rights of its citizens.

- **Emergency Federal Law Enforcement Assistance Act of 2006 42 U.S.C. § 10501, et seq.**

- Under the Emergency Federal Law Enforcement Assistance Act, the Attorney General may provide law enforcement assistance, including federal personnel, in response to a governor's written request, when he or she determines that such assistance is necessary to provide an

adequate response to a law enforcement emergency. To the extent federal personnel would be used to enforce state or local law, they should be deputized or otherwise authorized under state or local law to exercise the key law enforcement powers (arrest, search, seizure) involved in enforcing those laws.

Control of Communicable Diseases

- **Section 311 of the Public Health Service Act: General Grant of Authority for Cooperation
42 U.S.C. § 243**

This provision of the Public Health Service Act states that the Secretary of HHS shall assist states and local authorities in the prevention and suppression of communicable diseases and to help state and local authorities enforce quarantine regulations. This section also authorizes the Secretary to accept state and local authorities' voluntary assistance with enforcement of federal quarantine regulations. Further, this section authorizes the Secretary to develop a public health emergency management plan and, at the request of a state or local authority, extend temporary assistance regarding public health emergencies.

- **Section 361 of the Public Health Service Act: Regulations to Control Communicable Diseases
42 U.S.C. § 264**

This section of the Public Health Service Act authorizes the Secretary of HHS to make and enforce regulations "to prevent the introduction, transmission, or spread of communicable diseases" into the states and possessions of the United States from foreign countries or possessions or from one state into another. This section also authorizes the apprehension, detention, examination, and conditional release of individuals with certain communicable diseases that are specified in an executive order of the President (see Executive Order 13296 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and Executive Order 13674 [July 31, 2014]). The process prescribed for isolating or quarantining such individuals is provided for in 42 C.F.R. Parts 70 and 71 (see below).

- **Section 362 of the Public Health Service Act: Suspension of Entries and Imports from Designated Places to Prevent Spread of Communicable Diseases
42 U.S.C. § 265**

This section of the Public Health Service Act authorizes the Secretary of HHS, if he or she determines that a communicable disease exists in a foreign country and that introduction of persons from this foreign country poses a serious danger of introducing the disease into the United States, to suspend in the interests of public health the "introduction of persons" from those foreign countries or places for the time necessary to avert the danger, in accordance with approved regulations. This provision may also be applied to the introduction of property (see below).

- **Interstate Quarantine 42 C.F.R. Part 70**

These federal regulations allow the CDC Director to take measures to prevent the spread of communicable diseases from one state or possession into another, including in the event that the Director determines that the measures taken by the health authorities of a state (including

political subdivisions) or possession are insufficient to prevent such communicable disease spread. These regulations also authorize the detention, isolation, quarantine, or conditional release of persons for purposes of preventing the interstate spread of communicable diseases listed in an executive order of the President. See Executive Order 13296, as amended by Executive Order 13375 and Executive Order 13674.

- **Foreign Quarantine 42 C.F.R. Part 71**

These federal regulations allow the CDC Director to take measures to prevent the introduction, transmission, and spread of communicable diseases into the United States from foreign countries. Among other things, the regulations require the commander of an aircraft or master of a ship destined for a US port to report the occurrence of any deaths or ill persons onboard to CDC. These regulations also authorize the Director to inspect and detain ships and planes arriving into the United States as may be necessary to prevent the spread of communicable diseases, as well as regulate the importation of infectious biological agents, infectious substances, and vectors. The Director may also isolate, quarantine, or place arriving persons under public health surveillance whenever the Director reasonably believes that the person is infected with or has been exposed to any of the communicable diseases listed in an executive order of the President. See Executive Order 13296, as amended by Executive Order 13375 and Executive Order 13674.

- **Executive Order 13295: Revised List of Quarantinable Communicable Diseases (April 4, 2003)**

This Executive Order identifies the eight communicable diseases (cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, and SARS), for which an individual can be apprehended, detained, examined, or conditionally released by federal public health authorities under 42 C.F.R. §§ 70 and 71.

- **Executive Order 13375: Amendment to Executive Order 13295 Relating to Certain Influenza Viruses and Quarantinable Communicable Diseases (April 1, 2005)**

This Executive Order amends Executive Order 13295 by adding “influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic” to the list of communicable diseases for which an individual can be apprehended, detained, examined, or conditionally released by federal public health authorities under 42 C.F.R. §§ 70 and 71.

- **Executive Order 13674: Amendment to Executive Order 13295 Revised List of Quarantinable Communicable Diseases (July 31, 2014)**

This Executive Order amends Executive Orders 13295 and 13375 by updating the reference to SARS on the list of communicable diseases for which an individual can be apprehended, detained, examined, or conditionally released by federal public health authorities under 42 C.F.R. §§ 70 and 71 to read as follows: “Severe acute respiratory syndromes, which are diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled.”

- **Penalties for Violation of Quarantine Law**

- **42 U.S.C. § 271**

- This statutory provision states that violation of federal quarantine regulations is a crime punishable by a fine of not more \$1,000 or by imprisonment for not more than one year, or both. Implementing regulations are found at 42 C.F.R. Part 71.2. These penalties are strengthened under the sentencing classification provisions of 18 U.S.C. §§ 3559 and 3571, which provide for more strict penalties for criminal violations that would otherwise be classified as Class A misdemeanors. Under these strengthened penalties, individuals may be punished by a fine of up to \$100,000 per violation not resulting in the death of an individual, or up to \$250,000 per violation resulting in the death of an individual [18 U.S.C. 3559, 3571(b)]. Organizations may be fined up to \$200,000 per violation not resulting in the death of an individual and \$500,000 per violation resulting in the death of an individual [18 U.S.C. 3559, 3571(c)].

- **Emergency Medical Treatment and Active Labor Act (EMTALA)**

- **42 U.S.C. § 1395dd**

- EMTALA requires that hospitals accepting Medicare payments provide patients coming to the emergency department appropriate medical screening for emergency medical conditions without regard to citizenship, legal status, or ability to pay. If the patient is found to have an emergency medical condition, the hospital must either provide further examination and treatment until the patient is stabilized, or, if the hospital is unable to stabilize the patient, the hospital must arrange for transfer of the individual to a capable facility. Patients cannot be denied stabilizing treatment or discharged prematurely based on prior unpaid debts to the hospital. While patients cannot be held criminally liable, hospitals may seek judgments against non-paying patients in civil court for the amounts owed.

- **State Health Laws Observed by United States Officers**

- **42 U.S.C. § 97**

- This provision states that US Coast Guard and customs officers, as well as “military officers commanding in any fort or station upon the seacoast,” shall observe quarantines and health laws imposed by states regarding the arrival of vessels, and according to their respective powers, aid in the execution of such state health laws and quarantines as directed from time to time by the Secretary of HHS.

- **Quarantine Duties of Consular and Other Officers**

- **42 U.S.C. § 268(b)**

- These statutes state the duty of Customs and Border Protection and the US Coast Guard to aid in the execution of federal quarantine and the enforcement of federal quarantine rules and regulations.

- **Immigration Authority**

- **8 U.S.C. §§ 1182 and 1222, 42 U.S.C. § 252**

- Under these provisions, DHS and HHS are charged with conducting physical and mental examinations of arriving aliens. Under 8 U.S.C. § 1182, aliens are inadmissible in to the United States on health-related grounds if determined to have a communicable disease of public health significance, certain mental or physical defects, to be a drug abuser or addict, or to have failed

to present documentation of vaccination against vaccine-preventable diseases as set forth in the statute. The process that HHS prescribes for conducting the medical examinations is provided for in 42 C.F.R. Part 34 (see below).

- **Medical Examination of Aliens**

- **42 C.F.R. Part 34**

- CDC administers this regulation, which describes and specifies the medical examination criteria that aliens must undergo before they may be admitted to the United States. The medical examination applies to aliens outside the US applying for an immigrant visa; aliens arriving in the US; aliens required by DHS to have a medical examination; and applicants in the US applying for adjustment of their immigration status to that of permanent legal resident. Aliens determined to have a communicable disease of public health significance are generally inadmissible unless granted a waiver by DHS.

Managing Transportation

- **Transportation Security Administration Authority to Cancel or Ground Flights**

- **49 U.S.C. §§ 114 and 44905(b)**

- The Transportation Security Administration has the authority to cancel a flight or prevent planes from landing if “a decision is made that a particular threat cannot be addressed in a way adequate to ensure, to the extent feasible, the safety of passengers and crew of a particular flight or series of flights.”

- **Federal Aviation Administration Authority to Restrict Airport Access or Airspace**

- **49 U.S.C. §§ 40101(d), 40103(b), 44701, and 46105(c)**

- The Federal Aviation Administration (FAA) has authority to stop, redirect, or exclude flights in US airspace for public safety and has the authority to restrict airport access due to emergency conditions on the ground. If the FAA Administrator believes it necessary, he or she may “prescribe regulations and issue orders immediately to meet the emergency.”

Managing Animals, Food, and Other Property

- **Control of Communicable Diseases**

- **21 C.F.R. Part 1240**

- Similar to the regulations governing interstate quarantine, these regulations allow the FDA Commissioner to take measures to prevent the spread of communicable diseases from one state or possession into another in the event that the Commissioner determines that the measures taken by the health authorities of a state (including political subdivisions) or possession are insufficient to prevent such communicable disease spread. These regulations also govern the interstate transport of mollusks, milk, turtles, certain birds, garbage, and drinking water.

- **Foreign Quarantine**

- **42 C.F.R. Part 71**

In addition to allowing the CDC Director to take measures to prevent the introduction, transmission, and spread of communicable diseases into the United States from foreign countries, including through the isolation and quarantine of arriving individuals, these regulations also govern the importation of certain animals, including dogs, cats, turtles, and nonhuman primates, as well as regulate the importation of infectious biological agents, infectious substances, and vectors.

- **Section 361 of the Public Health Service Act: Regulations to Control Communicable Diseases 42 U.S.C. § 264**

For purposes of carrying out and enforcing regulations enacted under section 361 of the Public Health Service Act, this section states that the Secretary of HHS “may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings . . .”

- **Section 362 of the Public Health Service Act: Suspension of Entries and Imports from Designated Places to Prevent Spread of Communicable Diseases 42 U.S.C. § 265**

This section of the Public Health Service Act authorizes the Secretary of HHS, if he or she determines that a communicable disease exists in a foreign country and that introduction of property from this foreign country poses a serious danger of introducing the disease into the United States, to suspend in the interests of public health the “introduction of property” from those foreign countries or places for the time necessary to avert the danger, in accordance with approved regulations.

- **Pets Evacuation and Transportation Standards (PETS) Act of 2006
Pub. L. No. 109-308; 42 U.S.C. §§ 5170(b), 5196, 5196(b)**

The PETS Act amends the Stafford Act to require the FEMA Director to ensure that state and local emergency preparedness plans “take into account the needs of individuals with household pets and service animals prior to, during, and following a major disaster or emergency.”

Liability, Workers’ Compensation, and Licensure

- **Federal Tort Claims Act
28 U.S.C. §§ 1346(b), 2671–2680**

The Act waives the doctrine of sovereign immunity so that the United States can be held liable for the negligent acts or omissions of federal employees committed within the scope of their federal employment. Claims based on discretionary functions or intentional torts are explicitly precluded. Further, suits by military personnel for injuries sustained during service (also known as the *Feres* doctrine) have been deemed by the courts as outside of the Act. To proceed against the United States, the Attorney General must certify that the federal employee was acting within the scope of his office or employment, or, if the Attorney General refuses, the employee may petition the court to make this finding and certify. Once certified, the United States replaces the employee as the party defendant in the suit.

- **Federal Employee Compensation Act of 1993**

Pub. L. No. 103-3; 5 U.S.C. § 81

The Federal Employee Compensation Act provides workers' compensation to civilian federal employees injured or killed while performing their duties. An injured employee or the family of an employee killed while performing his duties is entitled to related medical services and benefits unless the employee intended to bring about the injury or death, caused the injury or death through the employee's own willful misconduct, or the injury or death was proximately caused by the employee's intoxication.

- **Public Readiness and Emergency Preparedness (PREP) Act of 2005 Pub. L. No. 109-148; 42 U.S.C. §§ 247d-6d, 247d-6e**

The PREP Act authorizes the Secretary of HHS to issue a declaration that provides immunity from tort liability for claims of loss (except willful misconduct) caused by, arising out of, relating to, or resulting from administration or 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. The immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. As amended by PAHPRA (see above), PREP Act immunity also explicitly applies to products or technology intended to enhance medical countermeasures, in addition to the countermeasures themselves. PAHPRA also extends immunity to countermeasures authorized under sections 564A and 564B of the Federal Food, Drug, and Cosmetic Act (see above). The Secretary's declaration includes, among other things, the countermeasures covered by the declaration; the category of diseases, health conditions, or health threats for which administration and use of the countermeasures recommended; the effective time period of the declaration; the population of individuals receiving the countermeasure; limitations, if any, on the geographic area for which immunity is in effect; limitations, if any, on the means of distribution of the countermeasure; and any additional persons identified by the Secretary as qualified to prescribe, dispense, or administer the countermeasures. The Act also authorizes a fund in the United States Treasury to provide compensation for injuries directly caused by administration or use of the countermeasure covered by the Secretary's declaration.

- **Volunteer Protection Act of 1997**

Pub. L. No 105-295; 42 U.S.C. §§ 14501–14505

The Volunteer Protection Act supports and promotes the activities of organizations that rely on volunteers by providing the volunteers some protections from liability for economic damages for activities relating to the work of the organizations. Under the Act, to be found not liable for the injury caused by a negligent act or omission of the volunteer, the volunteer must have been acting within the scope of his or her responsibilities in the nonprofit or government agency. The volunteer must have appropriate licensure or certification if required for the volunteer's duties; he or she must not have acted with gross negligence, reckless disregard, willful or criminal misconduct, or flagrant indifference; and the injury cannot have occurred while the volunteer was intoxicated. Further, the injury cannot have occurred while the volunteer was operating an automobile or other vehicle for which the state requires an operator's license and insurance. This Act does not limit the liability of the nonprofit or government agency. The Act does not limit an injured party's ability to sue for non-economic damages, provide immunity to the nonprofit organization or government entity supervising the volunteer, nor limit a nonprofit or

government entity's ability to bring a civil action against the volunteer. States may opt out of the Volunteer Protection Act.

- **Emergency Management Assistance Compact (EMAC) of 1996**

- **Pub. L. No. 104-321**

- EMAC facilitates resource sharing among member states during an emergency. The National Emergency Management Association (NEMA) administers EMAC, which has been enacted by every state. A governor's declaration of emergency and request for assistance triggers EMAC for the requesting state. An assisting state then responds to the request by providing the needed resources, including personnel. EMAC stipulates that a provider who is licensed or certified in one state will be considered licensed or certified in the receiving state subject to limitations described in the requesting state's governor's order. EMAC provides for protection of officers or employees of the assisting state from tort liability for negligent acts or omissions unless the officer or employee acted with gross negligence, recklessness, or willful misconduct. EMAC also requires that each state provide for worker's compensation in instances of injury or death for their own employees.

Personal Health Information and Privacy

- **Privacy Act of 1974**

- **5 U.S.C. § 552a**

- The Privacy Act describes the fair collection, maintenance, use and dissemination by a government agency of records containing personal identifiers (e.g., name, social security number, date of birth). Generally, the Act requires that information compiled in a federal record for a specific individual may not be used for another purpose without consent of the individual. The Act prevents disclosure of information contained in the record without an individual's written consent, unless the disclosure is one of the 12 exceptions expressly stated within the Act. Under most circumstances, individuals are allowed to request access to their own records and to challenge inaccurate information. The Act also outlines the civil remedies available if a government agency makes an unauthorized disclosure of an individual's personal information.

- **Health Insurance Portability and Accountability Act (HIPAA) of 1996: Privacy Rule Pub. L. No. 104-191**

- The HIPAA Privacy Rule protects certain patient information (including health insurance and billing information, medical records, and conversations with providers) from being disclosed by covered entities (including most health insurance companies, healthcare providers, and health information clearinghouses) for reasons other than providing treatment and care, billing and payment, protecting the public's health (such as through surveillance of specific diseases), or reporting required information to police (such as gunshot wounds). Information cannot be disclosed outside the HIPAA provisions without the patient's express written permission. Covered entities must have safeguards in place to protect patient health information to ensure that it is not mishandled. If a Section 319 Emergency has been declared, the Secretary of HHS may waive certain sanctions for non-compliance with HIPAA. Note that CDC is not a covered entity under HIPAA, nor are state or local public health departments, unless they also treat patients. Regulations are found at 34 C.F.R. Part 160 and Subparts A and E of 164.

- **Family Educational Rights and Privacy Act (FERPA) of 1973**
Pub. L. No. 93- 380, as amended; 20 U.S.C. § 1232g

FERPA applies to all educational agencies and institutions receiving funds under any program from the United States Department of Education, which encompasses virtually all public schools and universities, as well as some private schools. The school or agency may not disclose student records without a parent's or eligible student's written consent (an eligible student is either 18 years or older, or is attending a post-secondary institution at any age). FERPA also gives parents and eligible students the right to access and review records. Parents and eligible students may request explanation of items in the record, seek amendment to records for information that is "inaccurate, misleading, or in violation of the student's privacy" and may request a hearing to challenge the content of the record if the school or agency does not agree to the amendment. Disclosure to teachers and other relevant employees of the school or agency without consent of the parent or eligible child is allowed for legitimate educational purposes; disclosure without consent is also allowed in several express purposes, including "in connection with an emergency if knowledge of the information is necessary to protect the health or safety of the student or other individuals." For this exception, the school or agency must make a determination that there is an "articulable and significant threat" to the health and safety of the student or other individuals, taking into consideration a totality of the circumstances. Regulations are found at 34 C.F.R. Part 99.

Related Federal Guidance

- **National Response Framework (January 2008; updated May 2013)**

The National Response Framework is a guide to how the United States conducts all-hazards response, and is intended to capture specific authorities and best practices for managing incidents that range from the serious but purely local, to large-scale terrorist attacks or catastrophic natural disasters. In addition to the core document, the framework contains Emergency Support Function (ESF) Annexes, which group federal resources and capabilities into functional areas to serve as the primary mechanisms for providing assistance at the operational level. Common roles of federal agencies during emergencies are grouped together into 15 ESFs with different responsibilities based on these roles. Within each ESF, there is at least one primary agency, support agencies, and an ESF coordinator that is selected to oversee the ESF.

- ESF #8 is designated for Public Health and Medical Services. HHS is the Primary Agency and Coordinator for ESF #8. ESF #8 outlines the roles of the Primary Agency and each Supporting Agency when providing assistance to state, tribal, and local governments during public health emergencies or threats.
- ESF#13 is designated for Public Safety and Security. The US Department of Justice is the Primary Agency and Coordinator for ESF #13. This ESF is activated in situations requiring extensive public safety and security and where state, tribal, and local government resources are overwhelmed or are inadequate or for federal-to-federal support.

The Framework also contains Incident Annexes that describe the concept of operations to address specific contingency or hazard situations or an element of an incident requiring

specialized application of the Framework. The Biological Incident Annex outlines the actions, roles, and responsibilities associated with a human disease outbreak of known or unknown origin requiring federal assistance. HHS is the coordinating agency for this annex. The Food and Agriculture Incident Annex describes the roles and responsibilities associated with incidents involving agriculture and food systems that require a coordinated federal response. Both HHS and the Department of Agriculture are the coordinating agencies for this annex.

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