



TRACIE

HEALTHCARE EMERGENCY PREPAREDNESS
INFORMATION GATEWAY

Healthcare-Related Disaster Legal/ Regulatory/
Federal Policy
Topic Collection
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Topic Collection: Healthcare-Related Disaster Legal/ Regulatory/ Federal Policy

As the number of declared disasters increases, it is imperative that healthcare professionals are aware of state and federal emergency management resources and support, as well as the authorities under which response operations may be conducted. More specifically, it is critical that healthcare practitioners understand legislation and related programs that will allow them to respond during times of crisis knowing that certain liabilities have been waived, and much-needed human and material resources will be more readily available to them. The following resources highlight select laws, key issues, lessons learned, tools, and promising practices that can help healthcare professionals better understand the environment in which they will be asked to respond during large-scale emergencies.

NOTE: Many laws and regulations that have direct effects on healthcare operations during disasters are state and local (e.g., Good Samaritan, licensure/reciprocity, liability, emergency powers, health declarations, and county ordinances on EMS service provision) and are not addressed in detail in this Topic Collection. It is critical that planners and providers be aware of the issues specific to their jurisdictions.

Each resource in this Topic Collection is placed into one or more of the following categories (click on the category name to be taken directly to that set of resources). Resources marked with an asterisk (*) appear in more than one category.

[Must Reads](#)

[Disaster Legal/Regulatory Considerations for Healthcare Systems](#)

[Education and Training](#)

[Event-Specific Lessons Learned](#)

[Federal and State Authorities/Legislation](#)

[Guidance/Guidelines](#)

[Response Roles, Responsibilities, and Plans](#)

[Volunteers](#)

[Agencies and Organizations](#)

Must Reads

Association for State and Territorial Health Officials. (2013). [Emergency Authority and Immunity Toolkit](#).

This toolkit contains a review of key emergency authority and immunity concepts; a summary of federal laws and policies pertaining to emergency planning and response; and a series of fact sheets addressing fundamental issues or legal authorities, issue briefs, and state analysis guides.

Centers for Disease Control and Prevention, Public Health Law Program. (2014). [Selected Federal Legal Authorities Pertinent to Public Health Emergencies](#).

This document summarizes a selection of key federal legal authorities pertaining to public health emergencies.

Federal Emergency Management Agency. (2013). [National Response Framework](#).

The framework highlights how the agencies involved in disaster preparedness work together as a "whole community." There are links to the framework document and Emergency Support Function (ESF), Support, and Incident Annexes on this page, including ESF #8, Public Health and Medical Services.

National Emergency Management Association. (n.d.). [Emergency Management Assistance Compact \(EMAC\)](#). (Accessed 3/16/2016.)

This webpage provides information on the Emergency Management Assistance Compact (EMAC), a congressionally-mandated interstate mutual aid agreement that has been adopted by all 50 states and the District of Columbia. Under EMAC, state assets (supplies, equipment, and/or volunteers) may be deployed to a requesting state. Reimbursement, liability, compensation, and licensure issues are also addressed. The website has links to training and education resources, as well as a document library, and information on deployable resources. The "[Learn about EMAC](#)" menu provides helpful documents for those not familiar with the agreement and process.

Orenstein, D. and White, L. (2015). [Emergency Declaration Authorities Across All States and D.C.](#) Robert Wood Johnson Foundation, Network for Public Health Law.

This document provides a listing of state statutory and regulatory authorities for emergency declarations in all 50 U.S. States and the District of Columbia. Emergency declarations, public health emergency declarations, and other types of declarations that may relate to the public's health are included.

Stier, D. and Goodman, R. (2007). [Mutual Aid Agreements: Essential Legal Tools for Public Health Preparedness and Response](#). American Journal of Public Health. 97(Suppl 1): S62–S68.

The authors provide an overview of the "basic legal framework for states to accomplish interstate and international mutual aid, identify gaps in that framework, and suggest steps that could be taken to address those gaps." The need for mutual aid for smaller-scale incidents that fall outside the scope of the Emergency Management Assistance Compact is highlighted. Summaries of relevant authorities are included.

U.S. Department of Health and Human Services. (2006). [HIPAA Privacy Rule: Disclosures for Emergency Preparedness - A Decision Tool](#).

This guidance can help users determine how the HIPAA Privacy Rule applies to the information in question. Users can go to the question that relates most closely to their inquiry and follow the flow of information to locate a response.

U.S. Department of Health and Human Services. (2013). [Provider Survey and Certification Frequently Asked Questions: Declared Public Health Emergencies: All Hazards, Health Standards and Quality Issues](#).

This document provides answers to frequently asked questions about healthcare delivery after natural and human-caused disasters.

U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. (2009). [Requesting an 1135 Waiver](#).

When the U.S. Department of Health and Human Services Secretary declares a public health emergency under Section 319 of the Public Health Service Act, s/he may temporarily waive or modify certain requirements to ensure that there are enough health care resources and services available to meet the needs of the public's health. A presidential declaration of emergency under the National Emergencies Act or Stafford Act is also required for Section 1135 waivers. This document highlights examples of waivers and other related information.

U.S. Department of Health and Human Services, Health Resources and Services Administration. (2006). [Emergency System for Advance Registration of Volunteer Health Professionals \(ESAR-VHP\) — Legal and Regulatory Issues](#).

This report summarizes legal issues pertaining to the use of volunteer health professionals during disasters, particularly liability and immunity issues.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2013). [Public Health Emergency Declaration Q&As](#).

This webpage includes questions and answers regarding the discretionary actions the Secretary of the U.S. Department of Health and Human Services may take in response to a public health emergency.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (n.d.) [Emergency System for Advanced Registration of Volunteer Health Professionals \(ESAR-VHP\)](#). (Accessed 10/5/2015.)

This webpage describes the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP) program, which provides standards and guidelines to assist states with setting up standardized volunteer databases to support public health and

medical response during disasters. ESAR-VHP registries allow volunteers' identities, licenses, credentials, accreditations, and hospital privileges to be verified in advance of an emergency, facilitating more rapid deployment.

U.S. Food and Drug Administration. (2013). [Emergency Preparedness and Response: Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 \(PAHPRA\)](#).

This act contains legal authorities to help bolster and maintain U.S. preparedness for public health emergencies related to chemical, biological, radiological, and nuclear agents, and emerging infectious disease threats. Links to legislative information, emergency use of medical countermeasures (MCM), and authorities related to MCM development are also provided.

U.S. Food and Drug Administration. (2015). [Emergency Use Authorizations](#).

This webpage explains the U.S. Food and Drug Commissioner's authority to issue an Emergency Use Authorization (EUA) for unapproved medical products or unapproved uses of approved medical products during emergencies caused by chemical, burn, radiological, or nuclear (CBRN) threat agents when approved products/uses do not exist. There is also a list of current EUAs, and a link to Frequently Asked Questions about EUAs.

Disaster Legal/Regulatory Considerations for Healthcare Systems

Botosaneanu, A., Wu, H., Wasserman, J. and Jacobson, P.D. (2011). [Achieving Public Health Preparedness: How Dissonant Views on Public Health Law Threaten Emergency Preparedness and Response](#). (Abstract only). *Journal of Public Health*. 33(3): 361-368.

Interviews with public health and emergency management officials noted distinctly different perceptions about public health law which could adversely affect inter-agency collaboration. Clarification for both entities on legal authorities, scope, and ethical concerns related to both federal and state laws is recommended to advance joint emergency preparedness.

Hodge, J. and Brown, E. (2011). [Assessing Liability for Health Care Entities that Insufficiently Prepare for Catastrophic Emergencies](#). (Abstract only.) *Journal of the American Medical Association*. 306(3): 308-309.

Using the *Preston v Tenet Healthsystem Memorial Medical Center* case as a backdrop, the authors discuss considerations related to the assessment of liability for healthcare entities that do not adequately prepare for large-scale emergencies.

Hodge, J.G. Jr. (2012). [The Evolution of Law in Biopreparedness](#). (Abstract only). *Biosecurity and Bioterrorism*. 10(1):38-48.

Legal advancements since 2001 are discussed in their role to improve response in public health emergencies in an effort to decrease morbidity and mortality. However issues remain to resolve coordination among agencies, promote timely legal decision making including declarations of an emergency, disaster or public health emergency and liability protection for emergency responders.

Hodge, J.G. Jr., Garcia, A.M., Anderson, E.D. and Kaufman, T. (2009). [Emergency Legal Preparedness for Hospitals and Health Care Personnel](#). (Abstract only). [Disaster Medicine and Public Health Preparedness](#). 3(Suppl): S37 - S44.

The legal requirements for hospital emergency preparedness during disaster declarations are discussed in terms of issues that may be encountered. The risk and liability associated with a failure to plan and prepare and to be capable of real-time decision-making are detailed including negligence, discrimination and criminal culpability during and after medical triage.

Hodge, J.G. Jr., Lant, T., Arias, J., and Jehn, M. (2011). [Building Evidence for Legal Decision Making in Real Time: Legal Triage in Public Health Emergencies](#). (Abstract only). [Disaster Medicine and Public Health Preparedness](#). 5(Suppl): S242 - S251.

The authors assessed real-time decision-making processes among legal and public health professionals during a fictitious public health emergency scenario and found that the perception of relevance of legal preparedness impacted decision-making. Lessons learned are shared for integration in future exercises or real public health emergencies.

Hodge, J.G., Hanfling, D. and Powell, T. (2013). [Practical, Ethical, and Legal Challenges Underlying Crisis Standards of Care](#). (First page only.) *Journal of Law, Medicine, and Ethics*. 41(Suppl 1): 50-55.

The authors discuss law and policy issues anticipated to arise during implementation of crisis standards of care.

Hodge, J.G., Measer, G. and Agrawal, A.M. (2014). [Top 10 Issues in Public Health Legal Preparedness and Ebola](#). *American Bar Association Health e-Source*. 10(3).

The article reviews the “top 10” key areas of law and policy to prepare attorneys to provide “competent” guidance on the legal aspects of public health control and mitigation during emergencies.

Hoffman, S., Goodman, R.A. and Stier, D.D. (2009). [Law, Liability, and Public Health Emergencies](#). (Abstract only), [Disaster Medicine and Public Health Preparedness](#). 3(2): 117-125.

Liability exposure issues in public health emergencies are presented that can affect the spectrum of the healthcare delivery system with insufficient qualified staff, resource

issues and an overwhelming patient surge. Immunity sources are discussed for public and private sector responders, including volunteers.

Jacobson, PD., Wasserman, J., Botoseneanu, A. et al. (2011). [The Role of Law in Public Health Preparedness: Opportunities and Challenges](#). (Abstract only). *Journal of Health Politics, Policy and Law*. 37(2): 297-328.

The results of a study of 144 interviews in nine states noted gaps in how local public health and emergency management professionals perceived legal requirements. The authors note that training in legal preparedness and being able to receive timely clarification to resolve issues could improve morbidity and mortality outcomes during a public health emergency.

Education and Training

Federal Emergency Management Agency, Emergency Management Institute. (2013). [IS-800.B: National Response Framework, an Introduction](#).

This three-hour course provides an overview of the National Response Framework.

Federal Emergency Management Agency, Emergency Management Institute. (2013). [IS-808: Emergency Support Function \(ESF\) #8 – Public Health and Medical Services](#).

This 30-minute course provides an overview of Emergency Support Function (ESF) 8, Health and Medical Services.

Hodge, J.G. (2012). [Public Health Law 101: A CDC Foundational Course for Public Health Practitioners—Privacy and Confidentiality](#). Centers for Disease Control and Prevention.

The Public Health Law 101 course provides an introduction to fundamental principles of law, ethics, and the legal system as they frame public health practice in the United States. It is meant to be delivered by attorneys. Module 6 content includes a review of the basic principles of health information privacy, confidentiality, and security, as well as the scope, structure, and implementation of the HIPAA privacy rule.

Hodge, J.G. (2013). *Public Health Law in a Nutshell: Chapter 10-Public Health Legal Preparedness and Response*. (Book available for purchase.) West Academic Publishing.

This brief chapter provides an assessment of the legal environment in declared emergencies involving the public's health. It is a key starting point for anyone attempting to assess federal, state, and local legal provisions and responsibilities in major crisis events.

Hodge, J.G., Arias, J.L., Brown, E.F. (2013). [Public Health and the Law: An Emergency Preparedness Training Kit](#). National Association of County and City Health Officials.

This is a customizable training kit to help local jurisdictions prepare their public health staff and legal counsels to better understand the legal environment in which they must plan for, respond to, and recover from emergencies. The kit consists of a PowerPoint presentation; an Instruction Manual; component summaries updated in 2012; and a sample packet of modifications made by Florida State University in September 2013. There is also a 53-minute video to guide users of the training kit.

Mayer, H., Kosmos, C., and Marcozzi, D. (2012). [What PPD \(Presidential Policy Directive\) #8 Means to County and City Public Health and Medical Practitioners](#). National Association of County and City Health Officials (NACCHO).

This hour-long webinar describes Presidential Policy Directive (PPD)-8 and the capabilities associated with its implementation.

Savoia, E., Biddinger, P.D., Fox, P. et al. (2009). [Impact of Tabletop Exercises on Participants' Knowledge of and Confidence in Legal Authorities for Infectious Disease Emergencies](#). (Abstract only). *Disaster Medicine and Public Health Preparedness*. 3(2):104-110.

An infectious disease scenario that combined training with a tabletop exercise was analysed as effective in advancing knowledge about legal authorities, policies and procedures and assisted in identification of local gaps that could impact confidence in operationalizing isolation and quarantine measures, restriction in public movement and public spaces, and mass prophylaxis. Participants were more aware that legal authorities existed than policies and procedures associated with how to implement them.

Event-Specific Lessons Learned

*Clancy, T., Christensen, K., and Cortacans, H.P. (2014). [New Jersey's EMS Response to Superstorm Sandy: A Case Study of the Emergency Management Assistance Compact](#). (Abstract only.) *Prehospital Disaster Medicine*. 29(3):326-9.

The authors describe the State of New Jersey's activation of the Emergency Management Assistance Compact (EMAC) in response to Superstorm Sandy. Each EMAC phase is described, and the authors share best practices that can be used by emergency healthcare providers and planners.

Hodge, J.G., Gostin, L.O., Hanfling, D. and Hick, J.L. (2015). [Law, Medicine, and Public Health Preparedness: The Case of Ebola](#). *Public Health Reports*. 130:2-4.

The authors share guidance on topics at the intersection of law, medicine, and preparedness for managing Ebola, including the willingness among health workers and entities to handle known or suspect cases; use of novel treatments and experimental drugs; isolation, quarantine, and other social-distancing measures in medical settings; and

prospective liabilities of health workers or entities for medical errors or omissions in the handling or treatment of Ebola cases.

Federal and State Authorities/Legislation

(Note: All volunteer-related resources are located in the “[Volunteers](#)” section of this document.)

Association for State and Territorial Health Officials (ASTHO). (2013). [Emergency Authority and Immunity Toolkit](#).

This toolkit contains a review of key emergency authority and immunity concepts; a summary of federal laws and policies pertaining to emergency planning and response; and a series of fact sheets addressing fundamental issues or legal authorities, issue briefs, and state analysis guides.

Centers for Disease Control and Prevention, Public Health Law Program. (2014). [Selected Federal Legal Authorities Pertinent to Public Health Emergencies](#).

This document summarizes a selection of key federal legal authorities pertaining to public health emergencies.

*Clancy, T., Christensen, K., and Cortacans, H.P. (2014). [New Jersey's EMS Response to Superstorm Sandy: A Case Study of the Emergency Management Assistance Compact](#). (Abstract only.) *Prehospital Disaster Medicine*. 29(3):326-9.

The authors describe the State of New Jersey’s activation of the Emergency Management Assistance Compact (EMAC) in response to Superstorm Sandy. Each EMAC phase is described, and the authors share best practices that can be used by emergency healthcare providers and planners.

Courtney, B., Sherman, S., and Penn, M. (2013). [Federal Legal Preparedness Tools for Facilitating Medical Countermeasure Use During Emergencies](#). (Abstract only.) *Journal of Law, Medicine & Ethics*. 41(Suppl 1):22-7.

The authors discuss federal legal tools that are critical to enhancing medical countermeasure legal preparedness for public health emergencies. They focus on the Public Readiness and Emergency Preparedness (PREP) Act and Emergency Use Authorization (EUA) authority to facilitate the emergency use of countermeasures.

Figley, P. (2009). [Understanding the Federal Tort Claims Act: A Different Metaphor](#). American University Washington College of Law.

This article explains the Federal Tort Claims Act (FTCA), which allows the government to be sued and assume the liability of its employees and volunteers for negligence occurring as part of their normal duties.

Hodge, J. and White, L. (2012). [Model State Emergency Health Powers Act: Summary Matrix](#). Robert Wood Johnson Foundation, Network for Public Health Law.

This matrix provides state-specific links to statutory or regulatory provisions related to the major sections of the Model State Emergency Health Powers Act.

Hodge, J., Orenstein, D., O'Keefe, S. et al. (2012). [Public Readiness and Emergency Preparedness \(PREP\) Act: Scope of Liability Protections](#). Robert Wood Johnson Foundation, Network for Public Health Law.

The authors explain that non-governmental entities or persons are covered under liability protections of the federal PREP Act, and that non-federally owned stockpiles of covered countermeasures are also covered by the Act.

Hoffman, S. (2006). [Responders' Responsibility: Liability and Immunity in Public Health Emergencies](#). Case Western Reserve University School of Law, Scholarly Commons.

The author reviews laws related to liability and immunity and provides a proposal to address gaps in the legislation. Specifically, she advocates for paid health care professionals who must care for patients during disasters as part of their jobs to be afforded the same protections extended to volunteers.

Kels, C.G. (2015). [Dispensing Medical Countermeasures: Emergency Use Authorities and Liability Protections](#). (Abstract only) Health Security. 13(2): 139-151.

The evolution of authorities and public health liability protection for emergency use of medical countermeasures, associated with the Pandemic and All-Hazards Preparedness Reauthorization Act, is analyzed to advance emergency preparedness and response activities and protection of personnel.

National Conference of State Legislatures. (2014). [State Quarantine and Isolation Statutes](#).

This webpage includes a table that summarizes state law authority for quarantine and isolation within state borders, including authority to initiate quarantine and isolation, limitations on state quarantine powers, and penalties for violations.

National Emergency Management Association. (n.d.). [Emergency Management Assistance Compact \(EMAC\)](#). (Accessed 3/16/2016.)

This webpage provides information on the Emergency Management Assistance Compact (EMAC), a congressionally-mandated interstate mutual aid agreement that has been adopted by all 50 states and the District of Columbia. Under EMAC, state assets (supplies, equipment, and/or volunteers) may be deployed to a requesting state. Reimbursement, liability, compensation, and licensure issues are also addressed. The website has links to training and education resources, as well as a document library, and

information on deployable resources. The “[Learn about EMAC](#)” menu provides helpful documents for those not familiar with the agreement and process.

Orenstein, D. (2011). [Pandemic and All-Hazards Preparedness Reauthorization Act \(PAHPRA\) of 2013: State-Based Isolation or Quarantine Procedures](#). Robert Wood Johnson Foundation, Network for Public Health Law.

This factsheet provides links to a sample of language from state statutes, regulations, and model law regarding confidentiality measures relevant to state-based isolation or quarantine procedures.

Orenstein, D. and White, L. (2015). [Emergency Declaration Authorities Across All States and D.C.](#) Robert Wood Johnson Foundation, Network for Public Health Law.

This document provides a listing of state statutory and regulatory authorities for emergency declarations in all 50 U.S. States and the District of Columbia. Emergency declarations, public health emergency declarations, and other types of declarations that may relate to the public’s health are included.

Ray, J. (2009). [Federal Declaration of a Public Health Emergency](#). (Abstract only.) *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*. 7(3): 251-258.

This article outlines the Health and Human Services Secretary's public health emergency (PHE) authority, discusses possible discretionary actions that the secretary may take after declaring a PHE, and provides examples of PHE declarations that have been issued.

Sherman, S. (2011). [Legal Considerations in a Nuclear Detonation](#). (Abstract only.) *Disaster Medicine and Public Health Preparedness*. 5(Suppl 1):65.

Although the focus of the article is nuclear events, it provides a general overview of legal authorities relevant to emergencies.

Sherman, S., Foster, J., and Vaid, S. (2009). [Emergency Use Authority and 2009 H1N1 Influenza](#). (Abstract only.) *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*. 7(3):245-50.

This article discusses the steps that the Department of Health and Human Services follows to authorize emergency use of products under section 564 of the Federal Food, Drug and Cosmetic Act through Emergency Use Authorizations.

Stier, D. and Goodman, R. (2007). [Mutual Aid Agreements: Essential Legal Tools for Public Health Preparedness and Response](#). *American Journal of Public Health*. 97(Suppl 1): S62–S68.

The authors provide an overview of the "basic legal framework for states to accomplish interstate and international mutual aid, identify gaps in that framework, and suggest steps

that could be taken to address those gaps." The need for mutual aid for smaller-scale incidents that fall outside the scope of the Emergency Management Assistance Compact (EMAC) is highlighted. Summaries of relevant authorities are included.

The White House. (2003). [Homeland Security Presidential Directive \(HSPD\) 5: Management of Domestic Incidents](#). U.S. Department of Homeland Security.

This directive establishes the National Incident Management System (NIMS) to ensure a comprehensive and unified approach to crisis and consequence management across all levels of government in the U.S.

The White House. (2007). [Homeland Security Presidential Directive \(HSPD\) 21: Public Health and Medical Preparedness](#). Federation of American Scientists.

This directive establishes a National Strategy for Public Health and Medical Preparedness. It requires planning for a rapid and coordinated public health and medical response during large-scale disasters.

U.S. Congress. (n.d.). [Social Security Act Section 1135](#). U.S. Social Security Administration. (Accessed 3/10/2016.)

This is the text of Section 1135 of the Social Security Act, which allows the Secretary of Health and Human Services (HHS) to temporarily waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) requirements affecting healthcare facilities and providers during declared national public health emergencies.

U.S. Congress. (2006). [Pandemic and All-Hazards Preparedness Act](#). Library of Congress.

This Act amended the Public Health Service Act to establish the Assistant Secretary for Preparedness and Response (ASPR); amend and enhance authorities to prepare for and respond to public health emergencies, provided new authorities for a number of programs, including the advanced development and acquisitions of medical countermeasures; and called for the establishment of a quadrennial National Health Security Strategy.

U.S. Congress. (2013). [National Emergencies Act \(NEA\)](#). U.S. Government Publishing Office.

The National Emergencies Act (NEA) allows the president to declare a national emergency and provides a framework for exercising.

U.S. Congress. (2013). [Pandemic and All-Hazards Preparedness Reauthorization Act of 2013](#). U.S. Government Publishing Office.

This Act reauthorizes funding for public health and medical preparedness programs (e.g., the Hospital Preparedness Program), amends the Public Health Service Act to provide

state health departments flexibility in assigning human resources to meeting critical needs in a disaster, authorizes funding through 2018 for the purchase of medical countermeasures, and provides Bio Shield more flexibility in supporting research and development of potential medical countermeasures.

U.S. Congress. (2013). [Public Health Service Act, as Amended, Sections 301-3351](#). U.S. Government Publishing Office.

This document contains the text for relevant sections of the Public Health Service (PHS) Act. The PHS Act forms the foundation of HHS' legal authority for responding to public health emergencies. Among other things, it authorizes the HHS Secretary to lead all Federal public health and medical response to public health emergencies and incidents covered by the National Response Framework (section 2801); to direct the U.S. PHS and other components of the Department to respond to a public health emergency (sections 203A, 311); to declare a public health emergency (PHE) and take such actions as may be appropriate to respond to the PHE consistent with existing authorities (section 319); to assist states in meeting health emergencies (section 311); to control communicable diseases (sections 361-369); to maintain the Strategic National Stockpile (319F-2); to provide for the operation of the National Disaster Medical System (section 2812); to establish and maintain a Medical Reserve Corps (section 2813); and to potentially provide targeted immunity for covered countermeasures to manufacturers, distributors, certain classes of people involved in the administration of a program to deliver covered treatments to patients, and their employees (319F-3).

U.S. Congress. (2013). [Public Readiness and Emergency Preparedness Act \(PREP Act\)](#). Health Resources and Services Administration.

This is the original text of the Public Readiness and Emergency Preparedness (PREP) Act, which allows the Secretary of Health and Human Services (HHS) to issue a declaration providing immunity from state and federal liability to persons and entities involved in the manufacture, testing, distribution, administration, and use of covered countermeasures, and provides a compensation program to certain individuals who receive covered countermeasures. A PREP Act declaration may be declared even if a public health emergency is not. The PREP Act, as codified as sections 319F-3 and 319F-4 of the PHS Act, 42 U.S.C. 247d-6d and 247d-6e, was amended in 2013 by the Pandemic and All-Hazards Preparedness Reauthorization Act.

U.S. Congress. (2013). [Stafford Act: Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, April 2013](#). Federal Emergency Management Agency.

The Stafford Act establishes the statutory authority for most federal disaster response activities and assistance to state, local, and tribal governments. In particular, the Stafford Act creates the system for federal financial and physical assistance during a presidential emergency or major disaster declaration.

U.S. Congress. (2015). [Federal Regulations: Title 44, Chapter 1, Subchapter D, Part 206- Emergency Management and Assistance](#). U.S. Government Publishing Office.

This link to the electronic code of federal regulations includes those for federal emergency management and assistance by the Federal Emergency Management Agency (FEMA) after disasters.

U.S. Department of Health and Human Services. (1996). [Health Information Portability and Accountability Act of 1996: Privacy Rule](#). U.S. Government Publishing Office.

The HIPAA Privacy Rule, comprised of 45 CFR Part 160 and Subparts A and E of Part 164, was adopted under section 264 of HIPAA, P.L. 104-191. The Rule was modified by HHS pursuant to the HITECH provisions of the American Recovery and Reinvestment Act of 2009, P.L. 111-5, and the Genetic Information Nondiscrimination Act of 2008, P.L. 110-233. The Rule establishes minimum Federal standards for safeguarding the privacy of certain individually identifiable health information (known as “protected health information” or PHI). When the HHS Secretary has declared a public health emergency and the President has declared an emergency under the Stafford Act or National Emergencies Act, under section 1135 of the Social Security Act, the Secretary may temporarily waive the sanctions or penalties for noncompliance with certain provisions of the Privacy Rule.

*U.S. Department of Health and Human Services. (2006). [HIPAA Privacy Rule: Disclosures for Emergency Preparedness - A Decision Tool](#).

This guidance can help users determine how the HIPAA Privacy Rule applies to the information in question. Users can go to the question that relates most closely to their inquiry and follow the flow of information to locate a response.

U.S. Department of Health and Human Services. (2013). [Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers](#). Federal Register. Vol. 78, No. 249.

This **proposed regulation** rule lists national emergency preparedness requirements for health care providers and suppliers participating in Medicare and Medicaid, including home health agencies. (Note: ASPR TRACIE will update when final rule is published.)

*U.S. Department of Health and Human Services. (2014). [2014 Public Health Emergency Medical Countermeasures Enterprise \(PHEMCE\) Strategy and Implementation Plan](#).

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is an interagency coordinating body led by the HHS Assistant Secretary for Preparedness and Response (ASPR), comprising the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and interagency partners at the Departments of Veterans Affairs (VA), Defense (DoD), Homeland Security (DHS), and Agriculture (USDA). It coordinates the development,

acquisition, stockpiling, and use of medical products that are needed to effectively respond to a variety of potential high consequence public health emergencies, whether naturally occurring or intentional. This plan describes PHEMCE's priorities for the next five years.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2013). [Public Health Emergency Declaration Q&As](#).

This webpage includes questions and answers regarding the discretionary actions the Secretary of Health and Human Services may take in response to a public health emergency.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2014). [ASPR Strategic Plan](#).

This document provides information on ASPR's mission, vision, and values and their plans for achieving six public health emergency-specific goals.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2014). [Legal Authority of the Secretary of Health and Human Services](#).

The U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response summarizes legal authorities of the Secretary to respond to public health emergencies under the Public Health Service Act, as amended by the Pandemic and All-Hazards Preparedness Act (PAHPA) and the Pandemic and All-Hazards Preparedness Reauthorization (PAHPRA) Act and provides links to related legal authorities and frequently asked questions.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2014). [National Disaster Medical System](#).

This webpage describes the National Disaster Medical System (NDMS) and its role within the National Response Framework. NDMS is a federally coordinated asset that can support disaster medical response at the state and local level, such as through Disaster Medical Assistance Teams (DMATs).

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2014). [PREP Act Q&As](#).

This webpage includes questions and answers intended for the manufacturing industry, the healthcare community, and state and local government officials about the Public Readiness and Emergency Preparedness (PREP) Act. It does not represent an exhaustive review of the PREP Act's provisions in all contexts or a protocol for the implementation of the PREP Act.

*U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2015). [National Health Security Strategy and Implementation Plan: 2015-2018.](#)

The goal of the National Health Security Strategy is "to strengthen and sustain communities' abilities to prevent, protect against, mitigate the effects of, respond to, and recover from incidents with negative health consequences." The plan outlines five strategic objectives for achieving this goal.

U.S. Department of Homeland Security. (2010). [Healthcare and Public Health Sector-Specific Plan: An Annex to the National Infrastructure Protection Plan.](#)

This annex to the National Infrastructure Protection Plan applies to the healthcare and public health sector which is a significant contributor to the U.S. economy and supports caring for a surge of disaster casualties.

U.S. Department of Homeland Security. (2011). [National Infrastructure Protection Plan: Healthcare and Public Health Sector.](#)

This factsheet provides an overview of how the National Infrastructure Protection Plan applies to the healthcare and public health sector.

U.S. Department of Homeland Security. (2011). [Presidential Policy Directive \(PPD\) 8: National Preparedness.](#)

In 2011, President Obama directed the development of a national preparedness goal that stressed security and resilience through preparation for natural and human-caused events.

U.S. Food and Drug Administration. (2013). [Emergency Preparedness and Response: Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 \(PAHPRA\).](#)

This act contains legal authorities to help bolster and maintain U.S. preparedness for public health emergencies related to chemical, biological, radiological, and nuclear (CBRN) agents, and emerging infectious disease threats. Links to legislative information, emergency use of medical countermeasures (MCM), and authorities related to MCM development are also provided.

U.S. Food and Drug Administration. (2015). [Emergency Use Authorizations.](#)

This webpage explains the U.S. Food and Drug Commissioner's authority to issue an Emergency Use Authorization (EUA) for unapproved medical products or unapproved uses of approved medical products during emergencies caused by chemical, burn, radiological, or nuclear (CBRN) threat agents when approved products/uses do not exist. There is also a list of current EUAs, and a link to Frequently Asked Questions about EUAs.

Guidance/Guidelines

Federal Emergency Management Agency. (2015). [National Incident Management System](#).

This website includes a description of the National Incident Management System (NIMS), and links to NIMS resources for various purposes and audiences.

Hanfling, D., Altevogt, B.M., Viswanathan, K., and Gostin, L.O. (eds.) (2012). [Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response](#). Institute of Medicine of the National Academies Press.

This report was designed to help authorities operationalize the concepts first developed in the 2009 Institute of Medicine (now known as the National Academy of Medicine) document titled, “Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report.” Volume 1, Section 3 provides an overview of legal and liability issues in catastrophic disasters. Legal and regulatory issues are a frequently discussed point in other areas of the document as well.

Stier, D. and Thombley, M. (2007). [Public Health Mutual Aid Agreements: A Menu of Suggested Provisions](#). Centers for Disease Control and Prevention, Public Health Law Program.

This document provides a menu of provisions for inclusion in a mutual aid agreement in support of public health emergency response. Although targeted to government planners and their legal counsels, the guidance in the document may be helpful to health care facilities as a reference for developing mutual aid agreements with other facilities to share information, data, supplies, resources, equipment, or personnel during emergencies and disasters.

U.S. Department of Health and Human Services. (2013). [Provider Survey and Certification Frequently Asked Questions: Declared Public Health Emergencies: All Hazards, Health Standards and Quality Issues](#).

This document provides answers to frequently asked questions about healthcare delivery after natural and human-caused disasters.

U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. (2009). [Requesting an 1135 Waiver](#).

When the Health and Human Services Secretary declares a public health emergency under Section 319 of the Public Health Service Act, s/he may temporarily waive or modify certain requirements to ensure that there are enough health care resources and services available to meet the needs of the public’s health. A presidential declaration of emergency under the National Emergencies Act or Stafford Act is also required for Section 1135 waivers. This document highlights examples of waivers and other related information.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2012). [Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness: January 2012.](#)

This document outlines eight capabilities for preparedness that should be used to develop and strengthen health care system emergency response capabilities. These are goals, not regulations, related to grant participation in the Healthcare Preparedness program and are listed here for reference as a condition/aim of federal grant participation.

Response Roles, Responsibilities, and Plans

Centers for Disease Control and Prevention, Public Health Law Program. (2010). [Inventory of Mutual Aid Agreements & Related Resources.](#)

This webpage summarizes international, interstate, intrastate, and tribal mutual aid agreements for emergency management as of 2010.

Chairman of the Joint Chiefs of Staff. (2013). [Defense Support of Civil Authorities.](#) Defense Technical Information Center.

This publication describes the roles of the Armed Forces of the United States in defense support of civil authorities during disasters including key differences between National Guard and active duty elements as well as the roles that they can fulfill. Chapter II focuses on "supporting a comprehensive all hazards response."

Federal Emergency Management Agency. (2013). [National Response Framework.](#)

The framework highlights how the agencies involved in disaster preparedness work together as a "whole community." There are links to the framework document and Emergency Support Function (ESF), Support, and Incident Annexes on this page, including ESF #8, Public Health and Medical Services.

Federal Emergency Management Agency. (2015). [Federal Interagency Operational Plans.](#)

Federal Interagency Operational Plans (FIOPs) describe the concept of operations for integrating and synchronizing existing national-level Federal capabilities to support local, state, tribal, territorial, insular area, and Federal plan. There is one FIOP for each mission area: prevention; protection; mitigation; response; and recovery.

Hodge, J.G., Anderson, E., Teret, S.P. et al. (2009). [Model Memorandum of Understanding Between Hospitals During Declared Emergencies.](#) Centers for Disease Control and Prevention.

This document provides the background and text for a model Memorandum of Understanding (MOU) between hospitals during declared emergencies. The model MOU

was developed by the National Center for the Study of Preparedness and Catastrophic Event Response (PACER) at Johns Hopkins University.

*U.S. Department of Health and Human Services. (2014). [2014 Public Health Emergency Medical Countermeasures Enterprise \(PHEMCE\) Strategy and Implementation Plan.](#)

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is an interagency coordinating body led by the HHS Assistant Secretary for Preparedness and Response (ASPR), comprising the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and interagency partners at the Departments of Veterans Affairs (VA), Defense (DoD), Homeland Security (DHS), and Agriculture (USDA). It coordinates the development, acquisition, stockpiling, and use of medical products that are needed to effectively respond to a variety of potential high consequence public health emergencies, whether naturally occurring or intentional. This plan describes PHEMCE's priorities for the next five years.

U.S. Department of Homeland Security. (2007). [National Strategy for Homeland Security.](#)

The National Strategy for Homeland Security provides a common framework for all preparedness efforts based on four goals: prevent and disrupt terrorist attacks; protect the American people, our critical infrastructure, and key resources; respond to and recover from incidents that do occur; and continue to strengthen the foundation to ensure our long-term success. The strategy also acknowledges the importance of preparing for natural and man-made disasters not caused by terrorism due to their potential impacts on homeland security.

Volunteers

Anderson, E.D. and Hodge, J.G. (2009). [Emergency Legal Preparedness Among Select U.S. Local Governments.](#) (Abstract only.) Disaster Medicine and Public Health Preparedness. 3(Suppl 2): S176-S184.

The authors discuss key issues of emergency laws among select U.S. localities in the context of the 2009 H1N1 outbreak and their application to volunteer health professionals. They maintain that differences in local laws add additional complexity to legal preparedness and necessitate more pre-disaster planning, exercises, and coordination.

Baker-White, A. (2013). [Quick Reference: Reviewing Emergency Volunteer Liability and Protections.](#) Robert Wood Johnson Foundation, Network for Public Health Law.

This one-page quick reference guide summarizes concepts and issues pertinent to emergency volunteers. It also includes an overview of state and federal laws that provide liability coverage and/or immunity to volunteers, and notes when such protections would apply.

Chu, V. (2011). [Emergency Response: Civil Liability of Volunteer Health Professionals](#). Library of Congress, Congressional Research Service.

The author provides an overview of the federal and state liability protections available to voluntary health providers who respond to disasters.

Federal Emergency Management Agency. (2012). [Citizen Corps Volunteer Liability Guide](#).

This document provides guidance on legal considerations (particularly liability) for emergency volunteer programs.

Hodge, J. and Arias, J. (2010). [Liability Risks and Protections for Volunteer Health Practitioners in Emergencies](#). Robert Wood Johnson Foundation, Network for Public Health Law.

This presentation describes different types of emergency declarations, provides examples of liability issues during disasters, and discusses the federal- and state-level availability of liability and workers' compensation coverage for volunteers.

Hodge, J.G., Pepe, R.P., and Henning, W.H. (2007). [Voluntarism in the Wake of Hurricane Katrina: The Uniform Emergency Volunteer Health Practitioners Act](#). (First page only.) *Disaster Medicine and Public Health Preparedness*. 1(1):44-50.

This article describes the development of The Uniform Emergency Volunteer Health Practitioners Act, which allows state governments during a declared emergency to give reciprocity to other states' licensees on emergency services providers so that covered individuals may provide services without meeting the disaster state's licensing requirements.

Rothstein, M. (2010). [Malpractice Immunity for Volunteer Physicians in Public Health Emergencies](#). *The Journal of Law, Medicine, and Ethics*. 38(1):149-53.

The author contends that granting immunity to volunteer health professionals during public health emergencies is unnecessary and that such laws "discriminate against poor people" and could "undermine" response efforts. Several alternative approaches are presented, such as creating compensation pools for victims of gross negligence and having the federal government indemnify emergency response volunteers instead of granting them immunity.

U.S. Congress. (1997). [Volunteer Protection Act](#). U.S. Government Publishing Office.

This is the text of the Volunteer Protection Act, which provides volunteers of nonprofit organizations or governmental entities some liability protections for economic damages resulting from activities relating to the work of the organizations. It does not cover gross negligence, willful misconduct, recklessness, or acts committed by the volunteer while

intoxicated or operating a motor vehicle. Volunteers must be licensed or certified, as required to fulfill their assigned duties.

U.S. Department of Health and Human Services, Health Resources and Services Administration. (2006). [Emergency System for Advance Registration of Volunteer Health Professionals \(ESAR-VHP\) — Legal and Regulatory Issues.](#)

This report summarizes legal issues pertaining to the use of volunteer health professionals during disasters, particularly liability and immunity issues.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (n.d.) [Emergency System for Advance Registration of Volunteer Health Professionals \(ESAR-VHP\).](#) (Accessed 3/10/2016.)

This webpage describes the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) program, which provides standards and guidelines to assist states with setting up standardized volunteer databases to support public health and medical response during disasters. ESAR-VHP registries allow volunteers' identities, licenses, credentials, accreditations, and hospital privileges to be verified in advance of an emergency, facilitating more rapid deployment.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2015). [Medical Reserve Corps.](#)

This webpage describes the Medical Reserve Corps (MRC) program, and provides links to the local units across the U.S. and its territories. The MRC is a national network of local volunteer units created to strengthen their community's health, improve its emergency response capabilities, and build its resiliency.

Uniform Law Commission-the National Conference of Commissioners on Uniform State Laws. (2007). [Uniform Emergency Volunteer Health Practitioners Act \(UEVHPA\).](#)

This is a uniform model law developed to support the rapid deployment of volunteer health professionals during disasters and provide license reciprocity to responders. Health professionals in states that have adopted this Act may register before or during an emergency to provide volunteer services "through a governmentally established registration system (e.g., ESAR-VHP or Medical Reserve Corps), with registration systems established by disaster relief organizations or licensing boards, or national or multi-state systems established by associations of licensing boards or health professionals."

Agencies and Organizations

Note: The agencies and organizations listed in this section have a page, program, or specific research dedicated to this topic area.

Centers for Disease Control and Prevention. [Office of Public Health Preparedness and Response.](#)

Centers for Medicare and Medicaid Services. [Survey and Certification, Emergency Preparedness.](#)

[Federal Emergency Management Agency.](#)

Federal Emergency Management Agency. [Emergency Management Agencies.](#)

Federal Emergency Management Agency. [Emergency Management Institute.](#)

Federal Emergency Management Agency. [Homeland Security Exercise and Evaluation Program \(HSEEP\) Policy and Guidance.](#)

[National Emergency Management Association.](#)

U.S. Food and Drug Administration. [Emergency Preparedness and Response.](#)

U.S. Department of Health and Human Services. [Office of the Assistant Secretary for Preparedness and Response.](#)

[U.S. Department of Homeland Security.](#)

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