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Public Health and Medical Emergency Management: Issues in the 112th Congress

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Summary

Key recent events—the 2001 terrorist attacks, Hurricane Katrina, and the H1N1 influenza (“flu”) pandemic, among others—sharpened congressional interest in the nation’s ability to respond to health threats. For the response to health emergencies, most authority resides with state and local governments, and most capacity resides in the private sector. The federal government plays a key role, however, providing numerous forms of assistance for planning and preparedness, as well as for response and recovery. Previous Congresses passed a number of laws intended to establish clear federal leadership roles and responsibilities and effective organizational structures, in the Departments of Health and Human Services (HHS) and Homeland Security (DHS) in particular. Nonetheless, challenges persist in coordinating federal preparedness and response efforts.

From FY2002 through FY2010, Congress provided about \$11.4 billion in grants to states and territories to strengthen public health and medical system capacity in preparedness for health threats. However, depending on the incident, dedicated funding for the actual response to these threats may or may not be available. For example, it is not clear that infectious disease incidents (such as bioterrorism or a flu pandemic) would qualify for major disaster assistance under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act). Also, although the HHS Secretary has authority for a Public Health Emergency Fund, Congress has not appropriated monies to the fund for many years. Finally, there is no federal assistance program designed purposefully to cover uncompensated or uninsured health care costs for disaster victims.

Another challenge is ensuring that the right medical products are available, and that they can be delivered to those in need in a timely manner. Previous Congresses established Project BioShield and the Biomedical Advanced Research and Development Authority (BARDA) in HHS to encourage private-sector development of medical countermeasures, such as drugs and vaccines, that lack commercial markets. Given the high cost and financial risk inherent in the development of new medical products, debate continues about how to balance these costs and risks between the federal government and product developers.

Given the current budgetary climate, spending for public programs, including emergency management programs, may be significantly constrained. Under the circumstances, the 112th Congress may be interested in approaches that improve community resilience in the face of disasters through better integration of the private sector in planning and response activities and better leveraging of routine capabilities for incident response, among others. The 112th Congress is also likely to remain interested in optimizing coordination, efficiency, and accountability in federal activities. Finally, for a number of health emergency activities authorized by previous Congresses, appropriations authority has expired or will expire at the end of FY2011. If the 112th Congress considers reauthorization, the matter of efficient use of federal resources is likely to be front and center during its deliberations.

This report, which will be updated, summarizes key issues in domestic public health and medical preparedness and response, and discusses selected federal programs, citing other CRS reports and other sources of additional information. Specifically, it discusses issues regarding government leadership, organization, and capacity; health system preparedness and response; the development, procurement, and use of countermeasures; and the defense against specific threats, including foodborne outbreaks and bioterrorism, among others.

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Background

Several events in the past decade sharpened congressional interest in the nation's ability to track and respond to health threats. Key incidents include the airline and anthrax attacks in 2001, Hurricane Katrina in 2005, and the H1N1 influenza ("flu") pandemic in 2009. In 2010, the United States rendered aid following the devastating earthquake in Haiti by, among other things, airlifting critically injured victims to the U.S. mainland. Residents of southern states experienced a massive oil spill in the Gulf of Mexico. Each of these incidents challenged existing incident response mechanisms, reminded policymakers of known gaps, and unmasked gaps that had theretofore gone unnoticed.

Three important principles color the issues in public health and medical emergency management. First, pre-incident (or *preparedness*) and post-incident (or *response*) functions are very different. At each level of government, these functions involve different legal authorities, leadership roles, organizational structures, and funding mechanisms. Generally, during an incident, certain conditions must be met before a jurisdiction can implement response activities or access funds reserved for that purpose.

Second, states and localities, rather than the federal government, are the seats of most authority and responsibility for the oversight of both health care and emergency management. For example, state laws generally authorize governors to order and enforce the evacuation of residents in emergency situations. Except under extraordinary circumstances, the federal government generally does not dictate the conduct of either health care or emergency management activities to state or local officials, or to health care providers. The federal government can, however, attach conditions to the expenditure of federal grant funds, in furtherance of national goals.

Finally, while most public health functions—broad, population-based programs, such as restaurant inspections to ensure food safety—are inherently governmental, the nation's health care system—which delivers professional health care services to individuals—is primarily private and for-profit. Providers and facilities operate in an increasingly competitive marketplace in which emergency planning is not always seen as a necessary expense. For example, hospitals may be reluctant to maintain empty beds or to stockpile costly medical products to be ready for incidents that may not occur.

In 2006, the 109th Congress established or reauthorized relevant programs and activities, principally in the Departments of Health and Human Services (HHS) and Homeland Security (DHS), responding to problems identified during prior incidents. Appropriations authority for many of these programs and activities has expired or expires at the end of FY2011, and the 112th Congress may consider reauthorization. Given the current budgetary climate, spending for public programs, including emergency management programs, may be significantly constrained. Under the circumstances, Congress may be interested in approaches to improve the efficiency of incident response mechanisms, to enhance the integration of the private sector in planning and response activities, to fully leverage routine capabilities for incident response, and to strengthen program accountability, among other things.

This report, which will be updated as needed, summarizes key issues in the preparedness for and response to domestic, civilian public health and medical incidents, citing other CRS reports and additional sources of information.

Public Health Emergency Management Laws

The 109th Congress enacted two comprehensive laws affecting public health and medical preparedness and response. The Pandemic and All-Hazards Preparedness Act (PAHPA, P.L. 109-417), passed in 2006, established or extended programs for public health emergency preparedness and response activities in HHS, and established the Biomedical Advanced Research and Development Authority (BARDA) to spur the development of medical countermeasures.¹ The Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA, Title VI of P.L. 109-295) reorganized DHS and, within it, the Federal Emergency Management Agency (FEMA). PKEMRA also codified the position of DHS Chief Medical Officer, with primary responsibility within DHS for medical issues related to natural and man-made disasters and terrorism.²

Appropriations authority for a number of activities last reauthorized in PAHPA has expired, or will expire at the end of FY2011, and the 112th Congress may consider reauthorization. Activities with expired or expiring appropriations authority include, among others,

- state grants for public health and hospital preparedness;
- the Strategic National Stockpile (SNS) of drugs and medical products;
- the National Disaster Medical System (NDMS), a cadre of rapid-response teams; and
- the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), a national database of volunteer health workers.

In addition to programs with finite appropriations authority, Congress may also examine a number of permanent authorities. These include, for example, the authority of the HHS Secretary to declare a public health emergency, and to access a special fund for response purposes;³ authorities of the HHS Secretary or the Commissioner of the Food and Drug Administration (FDA) to ensure the safety of foods and medical products;⁴ and authorities of the President to declare an emergency or a major disaster and provide specified forms of assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act).⁵

DHS has not operated under an authorization bill since it was originally established in 2003 (P.L. 107-296). Past Congresses have considered, but not enacted, homeland security authorizations bills. Representative Peter King, chairman of the House Committee on Homeland Security, has said he intends to introduce such a bill in the 112th Congress.⁶

¹ CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by (name redacted) and (name redacted).

² P.L. 109-295, 120 Stat. 1409, 6 U.S.C. §321e.

³ CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted).

⁴ CRS reports on these authorities are available on the CRS websites “Food Safety,” <http://crs.gov/pages/subissue.aspx?cliid=2621&parentid=13>, and “Medical Product Regulation,” <http://crs.gov/pages/subissue.aspx?cliid=2678&parentid=13>.

⁵ CRS Report RL33053, *Federal Stafford Act Disaster Assistance: Presidential Declarations, Eligible Activities, and Funding*, by (name redacted).

⁶ Chris Strohm, “Congress Faces Series of Homeland Security Decisions,” *National Journal*, January 7, 2011.

Issues for Congress

Government Leadership, Organization, and Capacity

Federal Leadership and Coordination

For public health and medical preparedness and response, the roles and responsibilities of principals in HHS and DHS have shifted in past years. The 109th Congress provided some clarity, but refinement of these roles and responsibilities is likely to continue for some time to come. Pursuant to PAHPA and PKEMRA, applicable activities in DHS are led by the DHS Chief Medical Officer (CMO), and in HHS by the HHS Assistant Secretary for Preparedness and Response (ASPR). PKEMRA provided that the DHS CMO “shall have the primary responsibility *within the Department* for medical issues related to natural disasters, acts of terrorism, and other man-made disasters,” while PAHPA provided that the “Secretary of [HHS] shall lead all *Federal* public health and medical response to public health emergencies and incidents”⁷ (emphasis added). Hence, the Secretary of Homeland Security coordinates all federal emergency and disaster response activities; the DHS CMO coordinates both preparedness and response activities for public health and medical care, but only within DHS; and the Secretary of HHS, through the ASPR, leads all federal public health and medical response activities, under the overall leadership of the Secretary of Homeland Security.

The Government Accountability Office (GAO) noted, in the context of pandemic flu planning, that “these federal leadership roles ... involve shared responsibilities, and it is not clear how these would work in practice.”⁸ GAO has recommended, among other things, that that DHS and HHS conduct training and exercises to ensure that federal leadership roles are clearly defined and understood.

Federal incident response activities are coordinated according to the *National Response Framework* (NRF), an “all-hazards” response plan published by DHS.⁹ Public health and medical response activities (under the leadership of HHS) are laid out in an annex to the plan called *Emergency Support Function #8*, or ESF-8. These activities, at the federal, state, and local levels, are commonly referred to as ESF-8 activities. (The NRF replaced the earlier National Response Plan, incorporating lessons from the flawed response to Hurricane Katrina.¹⁰) Nonetheless, some leadership gaps and conflicts remain in ESF-8. In addition to the interrelated roles of the HHS

⁷ P.L. 109-295, 120 Stat. 1409; P.L. 109-417, §101, 120 Stat. 2832.

⁸ GAO, *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed*, GAO-09-909T, July 29, 2009, <http://www.gao.gov>.

⁹ Department of Homeland Security, *National Response Framework*, Washington, DC, January 2008, <http://www.fema.gov/emergency/nrf/>. See also CRS Report RL34758, *The National Response Framework: Overview and Possible Issues for Congress*, by (name redacted).

¹⁰ Reports and investigations detailing problems associated with the National Response Plan include U.S. Congress, Senate Committee on Homeland Security and Governmental Affairs, *Hurricane Katrina: A Nation Still Unprepared*, 109th Cong., 2nd sess., S.Rept. 109-322 (Washington: GPO, 2006); U.S. Congress, House Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina, *A Failure of Initiative: Final Report of the House Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina*, 109th Cong., 2nd sess., H.Rept. 109-377 (Washington: GPO, 2006), and the White House Homeland Security Council, *The Federal Response to Hurricane Katrina: Lessons Learned* (Washington: February 23, 2006).

ASPR and the DHS CMO discussed above, there are concerns about a lack of leadership clarity for responder health and safety (see “The Health and Safety of Disaster Responders”); emergency sheltering; mass fatality management; and mental health services, among others.¹¹

National Health Security Strategy (NHSS)

PAHPA requires the HHS Secretary to publish a comprehensive, all-hazards national public health and medical response strategy and implementation plan (the “National Health Security Strategy,” or NHSS), beginning in 2009, and quadrennially thereafter. The NHSS is to include a process for achieving several specific preparedness goals enumerated in the statute.

HHS published the first NHSS in December 2009, saying that national health security is a key element in achieving broader national security objectives. The NHSS states that it is designed to achieve two overarching goals: (1) build community resilience, defined in the NHSS as the sustained ability of communities to withstand and recover—in both the short and long terms—from adversity, and (2) strengthen and sustain health and emergency response systems.¹² Also, the NHSS outlines approaches to better integrate routine and emergency capabilities, in order to improve the health system’s responsiveness despite resource constraints. The 112th Congress may be interested in reviewing the NHSS and monitoring the status of its implementation.

HHS Response Capability and Funding Authority

The 112th Congress may consider the adequacy of permanent authorities of the HHS Secretary for responding to public health threats, including authority to declare a public health emergency and the expanded authorities that flow from it.¹³ Members of Congress may also consider how HHS funds any of its disaster response activities that are not reimbursable by FEMA under the Stafford Act. Although the HHS Secretary has authority for a “no-year” Public Health Emergency Fund (i.e., funds are available until expended), Congress has not appropriated monies to the fund since FY1999, and there are no monies in the fund at this time.

Also, it is not clear that a flu pandemic or bioterrorism incident would qualify as a major disaster under the Stafford Act. The definition of major disaster in the law does not explicitly include or exclude infectious diseases, and past interpretations of the provision’s applicability to bioterrorism and naturally occurring infectious diseases have varied. President Obama did not issue a Stafford Act declaration (either for emergency or major disaster) in response to the 2009 H1N1 influenza pandemic, and response costs were borne through supplemental appropriations.¹⁴

¹¹ For more information, see “Unclear Federal Leadership for Certain Response Functions,” in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted).

¹² HHS, *National Health Security Strategy* (NHSS), December 2009, p. 4. See also *Biennial Implementation Plan*, draft, July 19, 2010. Both documents at <http://www.phe.gov/Preparedness/planning/authority/nhss/Pages/default.aspx>.

¹³ CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted). See also HHS, “Department of Health and Human Services Secretarial Declaration of a Public Health Emergency,” <http://www.hhs.gov/disasters/discussion/planners/section319declaration.html>; and, for an explanation of authorities invoked for the response to the 2009 H1N1 flu pandemic, CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by (name redacted) and (name redacted).

¹⁴ CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by (name redacted) and (name redacted).

If major disaster assistance were applicable in infectious disease incidents, substantial FEMA funds could be available to support HHS response activities.¹⁵

DHS Office of Health Affairs

Congress has been interested in the activities of the DHS Office of Health Affairs (OHA) and the responsibilities of its head, the department's Chief Medical Officer (CMO), since the CMO position was established in 2005.¹⁶ Congress assigned the following responsibilities (among others) to the CMO: (1) serving as the principal advisor to the DHS Secretary and the FEMA Administrator on medical and public health issues; (2) coordinating DHS biodefense activities; (3) ensuring coordination of all DHS medical preparedness and response activities; and (4) serving as the principal DHS liaison to other federal agencies; state, local, and tribal governments; and private sector entities, regarding medical and public health matters. Several Members of Congress have been interested in the scope of authority of the CMO, the organization of OHA, the BioWatch program administered by OHA, and other matters.

Considering the number of routine and emergency public health and medical responsibilities borne by DHS and other federal departments and agencies, the CMO has operational responsibility for very few, serving as an advisor with respect to the rest. For example, Congress has clarified that the Secretary of HHS is responsible for coordinating federal response efforts under the NRF ESF-8 annex, Public Health and Medical Services.¹⁷ Also, although the CMO is responsible for ensuring the safety of DHS personnel during the response to emergencies, DHS and OHA do not provide direct medical care or assistance. They rely on HHS or other assets to meet this responsibility.¹⁸ As noted by the current CMO, Dr. Alexander Garza, during his confirmation hearing, OHA is a young entity, and its roles and relationships with federal and non-federal preparedness and response partners are, in many ways, works in progress.¹⁹

Some Members of Congress, particularly some appropriators, have expressed concern about OHA's management of the BioWatch program, a sensor network in major cities intended to detect a large-scale aerosol release of a bioterrorism agent. Most recently, Members expressed reservations and withheld funding over concerns that sensor upgrades had not been properly evaluated before deployment.²⁰

¹⁵ CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?* by (name redacted).

¹⁶ The CMO position was established administratively in 2005 and codified in PKEMRA in 2006 (P.L. 109-295, Title VI, §611; 6 U.S.C. §321e). OHA was established administratively in 2008, to be headed by the CMO with the title of Assistant Secretary for Health Affairs and Chief Medical Officer. The Assistant Secretary designation is authorized under the Homeland Security Secretary's general authority to appoint assistant secretaries (6 U.S.C. §113(a)(9)).

¹⁷ The Pandemic and All-Hazards Preparedness Act (PAHPA), P.L. 109-417, §101; 42 U.S.C. §300hh.

¹⁸ See "Responses to pre-hearing questions," U.S. Congress, Senate Committee on Homeland Security and Governmental Affairs, Hearing on the Nomination of Alexander G. Garza To Be Assistant Secretary and Chief Medical Officer, Department of Homeland Security, 111th Cong., 1st sess., July 28, 2009, S.Hrg. 111-574, Washington, DC.

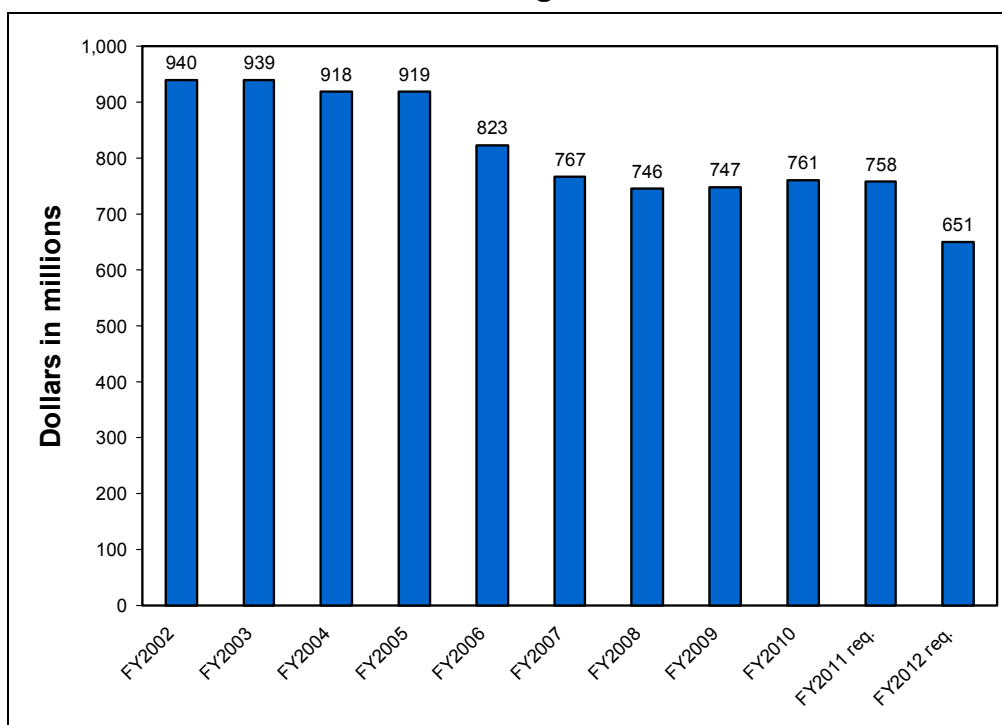
¹⁹ *Ibid.*, p. 7.

²⁰ See "Office of Health Affairs" in CRS Report R41189, *Homeland Security Department: FY2011 Appropriations*, coordinated by (name redacted).

State Grants for Public Health Preparedness and Response

From FY2002 through FY2010, Congress provided about \$7.6 billion in cooperative agreement funds to states and territories to strengthen public health preparedness for public health threats²¹ (see **Figure 1**). The Cooperative Agreement for Public Health Emergency Preparedness (PHEP) is administered by the HHS Centers for Disease Control and Prevention (CDC).²² In addition to providing preparedness funding for all grantees, it provides funding to academic Centers for Public Health Preparedness and Advanced Practice Centers to develop and disseminate evidence-based state and local public health preparedness practices. PAHPA extended authority for this program, adding authority to withhold funds for failure to meet program requirements, a state matching requirement, and a requirement that the Secretary of HHS publish certain information about program activities and performance on a public website.²³ Appropriations authority for the program expires at the end of FY2011, and the 112th Congress may consider reauthorization.

Figure 1. Appropriations: State Grants for Public Health Preparedness, FY2002 Through FY2012



Source: Compiled by CRS from HHS annual “Budget in Brief” documents, <http://dhhs.gov/asfr/ob/docbudget/>.

Notes: HHS is currently operating under a continuing resolution for FY2011 that provides temporary funding at FY2010 funding levels for most programs through early March 2011. CRS Report R41521, *Labor, Health and Human Services, and Education: FY2011 Appropriations*, coordinated by (name redacted). Amounts presented do not include supplemental funds for pandemic influenza preparedness and response (FY2006 and FY2009) and for smallpox vaccination (FY2003).

²¹ Cooperative agreements, a type of grant, are provided to 62 grantees, comprising all 50 states, 8 territories, and 4 major metropolitan areas: the District of Columbia, New York City, Los Angeles County, and Chicago.

²² See CDC, <http://emergency.cdc.gov/cotper/coopagreement/>.

²³ Public Health Service Act §319C-1; 42 U.S.C. §247d-3a.

The PHEP cooperative agreement program has been challenging for federal managers and state awardees alike. It has been helpful in expanding technical capacity, such as laboratory and information technology infrastructure; it has been less successful in ensuring a stable, competent workforce for public health emergency management.²⁴ State and local health departments have had some difficulty staffing their preparedness programs. They cite public health workforce shortages and the challenge of recruiting with annual discretionary or “soft” funding, a challenge exacerbated by the recent recession.²⁵ In addition, federal managers have had difficulty developing meaningful and measurable performance goals for the program.²⁶

The PHEP cooperative agreement program supports *preparedness* activities. PHEP funding is not intended to serve as a source of funds for *response* efforts once an incident occurs, and no dedicated federal funding mechanism exists to provide emergency response assistance to state health departments. Depending on the circumstances, federal funds may be available from a variety of sources. (See the previous section, “HHS Response Capability and Funding Authority.”) Funding is a challenge when an incident does not involve a major disaster declaration under the Stafford Act. As noted earlier, the HHS Secretary has authority for a no-year Public Health Emergency Fund, but the fund is empty at this time. The costs of HHS’s response to a non-Stafford public health incident (including the provision of assistance to states) are sometimes addressed through emergency supplemental appropriations, as happened with the 2009 H1N1 influenza pandemic and the 2010 Haiti earthquake.²⁷

Health System Preparedness and Response

Medical Surge Capacity

Policymakers have long been concerned about medical surge capacity, that is, the ability of health systems to manage mass casualty incidents. The successful response to such incidents requires the coordination of several elements, for which response capability rests variously with federal, state, or local authorities, or in the private sector. These elements are (1) patients, who may require rescue or medical evacuation; (2) a health care facility, which could range from an existing hospital, to a triage and first aid station in a shelter, to a field tent with cots; (3) a competent health care workforce; (4) medical equipment and non-perishable medical supplies; (5) drugs,

²⁴ See for example CDC, *Public Health Preparedness: Strengthening the Nation’s Emergency Response State by State*, September 21, 2010, <http://emergency.cdc.gov/publications/2010phprep/download.asp>; and Trust for America’s Health, *Ready Or Not 2010: Protecting the Public’s Health from Disease, Disasters, and Bioterrorism*, December 2010, <http://healthyamericans.org/reports/bioterror10/>.

²⁵ See National Association of County and City Health Officials (NACCHO), “Local Health Department Job Losses and Program Cuts: Findings from January/February 2010,” research brief, May 2010, <http://www.naccho.org/topics/infrastructure/lhdbudget/index.cfm>; GAO, *Public Health and Hospital Emergency Preparedness Programs: Evolution of Performance Measurement Systems to Measure Progress*, GAO-07-485R, March 23, 2007, <http://www.gao.gov>; and Trust for America’s Health, *Ready or Not 2010: Protecting the Public’s Health from Disease, Disasters, and Bioterrorism*, December 2010, <http://healthyamericans.org/reports/bioterror10/>.

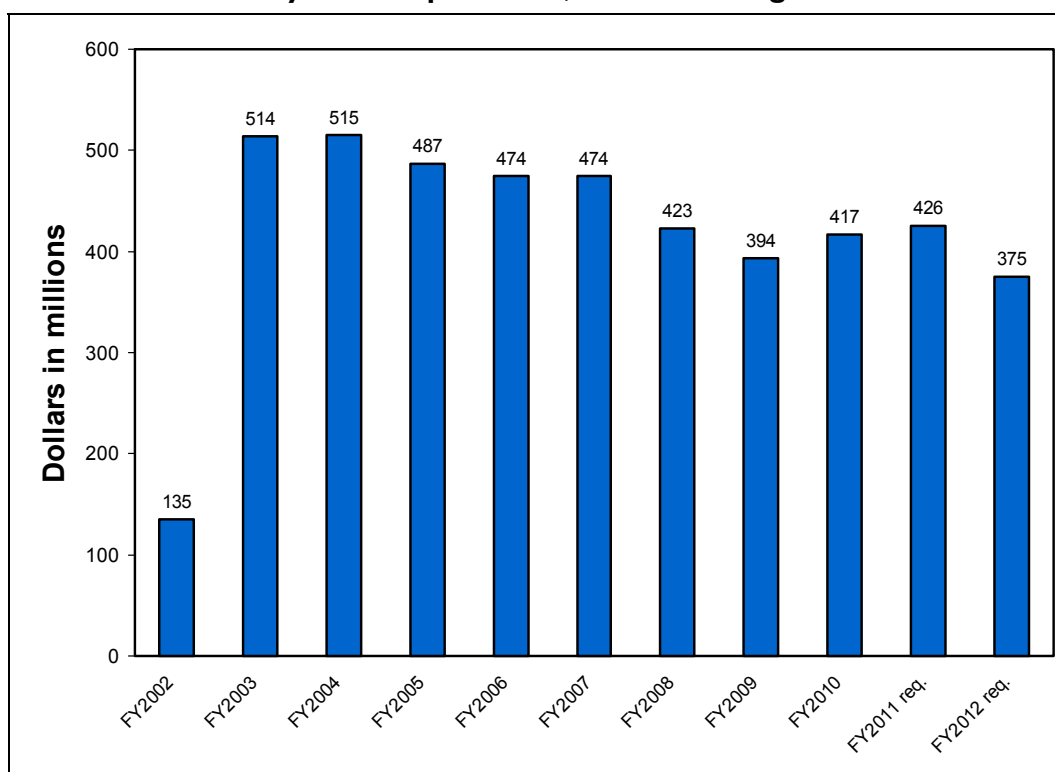
²⁶ See for example Christopher D. Nelson, Ellen Burke Beckjord, and David J. Dausey, et al., “How Can We Strengthen the Evidence Base in Public Health Preparedness?” *Disaster Medicine and Public Health Preparedness*, vol. 2, no. 4 (December 2008), pp. 247-250.

²⁷ U.S. assistance to Haiti included the airlift of many critically injured victims to hospitals on the U.S. mainland, which were later reimbursed with supplemental appropriations. CRS Report R41232, *FY2010 Supplemental for Wars, Disaster Assistance, Haiti Relief, and Other Programs*, coordinated by (name redacted).

vaccines, tests, and other perishable medical supplies; (6) a system of medical records; and (7) a health care financing mechanism.

Facing growing cost constraints for several decades, the largely private health care sector has sought to avoid having the unused, reserve capacity (such as empty beds) that would be needed in such situations. Since 2001, the federal government has sought to establish this capacity in the private sector, with mixed success. For example, the Hospital Preparedness Program, run by the HHS ASPR, has provided about \$3.8 billion in cooperative agreement funds to state and territorial governments from FY2002 through FY2010, to work with private health care facilities and systems in ensuring regional surge capacity in the event of a mass casualty incident.²⁸ Appropriations for the program are displayed in **Figure 2**.

Figure 2. Appropriations: State Grants for Hospital and Health System Preparedness, FY2002 Through FY2012



Source: Compiled by CRS from HHS annual "Budget in Brief" documents, <http://dhhs.gov/asfr/ob/docbudget/>.

Notes: HHS is currently operating under a continuing resolution for FY2011 that provides temporary funding at FY2010 funding levels for most programs through early March 2011. CRS Report R41521, *Labor, Health and Human Services, and Education: FY2011 Appropriations*, coordinated by (name redacted).

Evaluations of efforts to ensure medical surge capacity offer mixed reviews; also, as with the CDC grants for public health preparedness, developing performance metrics for the Hospital

²⁸ Cooperative agreements are provided to the same 62 grantees that receive CDC Public Health preparedness cooperative agreements (see footnote 21). HHS, ASPR, Hospital Preparedness Program, <http://www.phe.gov/preparedness/planning/hpp/pages/default.aspx>.

Preparedness Program grants has been a challenge.²⁹ As with the CDC grants for public health preparedness, PAHPA extended authority for the Hospital Preparedness Program, adding similar accountability provisions.³⁰ Appropriations authority for the program expires at the end of FY2011.

Historically, the federal government has helped states with disaster response primarily by providing guidance and funding for preparedness activities, and assisting with the costs of response activities. During Hurricane Katrina, the shortcomings of this approach with respect to medical surge capacity were evident.³¹ Since then, there has been an expansion of the federal role through direct procurement and deployment of medical response assets, providing a stronger backstop for state, local, and private-sector response efforts. For example, PAHPA authorized HHS to acquire mobile medical assets, such as Field Medical Stations (FMS).³²

HHS assets and personnel were deployed extensively for the evacuation and care of individuals with special needs before and during Hurricanes Gustav and Ike in the fall of 2008.³³ The Strategic National Stockpile (SNS) of medical supplies and drugs, the National Disaster Medical System (NDMS), and other programs to provide emergency health workers have been expanded since 2005.³⁴ The costs to *procure* FMS and SNS assets are provided through discretionary appropriations. In contrast, the costs to *deploy* these and other assets in a disaster response (including staffing costs) may be reimbursed by FEMA from the Disaster Relief Fund, if the Stafford Act is invoked, or must be obtained from other sources.

The 112th Congress may examine the performance of the federal Crisis Counseling Assistance and Training Program (CCP), which is authorized in the Stafford Act and administered jointly by HHS, FEMA, and the states to address mental health problems among disaster victims.³⁵ The response to Hurricane Katrina in 2005 prompted a reexamination of the CCP and other federal assistance programs that address disaster mental health. Concerns include the lack of a sound evidence base to identify effective services; the timeliness of services provided; the appropriate scope and duration of these services; and matters of organization, cost, and accountability. For example, the respective roles and responsibilities of HHS (which provides technical expertise for state CCP programs through SAMHSA, the Substance Abuse and Mental Health Services Administration), FEMA (which funds the state programs), and states and their contractors (which

²⁹ See, for example, Eileen Salinsky, *Strong as the Weakest Link: Medical Response to a Catastrophic Event*, National Health Policy Forum, Background Paper No. 65, Washington, DC, August 8, 2008, <http://www.nhpf.org/library/details.cfm/2640>; GAO, *Emergency Preparedness: States Are Planning for Medical Surge, but Could Benefit from Shared Guidance for Allocating Scarce Medical Resources*, GAO-08-668, June 13, 2008, <http://www.gao.gov>; and Institute of Medicine, *Medical Surge Capacity: Workshop Summary*, Washington, DC, 2010, <http://www.iom.edu/Reports/2010/Medical-Surge-Capacity-Workshop-Summary.aspx>.

³⁰ Public Health Service Act §319C-1; 42 U.S.C. §247d-3a.

³¹ Congressional and White House reports critiquing the Hurricane Katrina response are cited in footnote 10.

³² CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by (name redacted) and (name redacted).

³³ HHS: “HHS Supports Medical Evacuations in Preparation for Hurricane Gustav,” press release, August 31, 2008; and “HHS Provides State Assistance in Preparing for Hurricane Ike, Recovering from Hurricane Gustav,” press release, September 11, 2008, <http://www.hhs.gov/news>.

³⁴ See HHS, “Federal Public Health and Medical Assistance,” <http://www.hhs.gov/disasters/discussion/planners/medicalassistance.html>.

³⁵ CRS Report RL33738, *Gulf Coast Hurricanes: Addressing Survivors’ Mental Health and Substance Abuse Treatment Needs*, by (name redacted), (name redacted), and (name redacted).

implement them) are not always clear. Also, notwithstanding the CCP program's limitations, when incidents occur for which the Stafford Act is not invoked but which nonetheless have mental health effects among the affected population, there is not always a clear alternative source of funding to support CCP-like interventions.³⁶

Workforce Surge Capacity

The response to a mass casualty incident requires additional *health care workers*, those who provide direct care to the injured. The response to health incidents in general typically requires additional *public health workers* to track illnesses and injuries, monitor food and water safety, and take such other actions as needed to ensure health and safety among affected populations. The means to achieve and sustain surge capacity in the health care and public health workforces, especially in a climate of budget constraint, is one of the more persistent challenges in emergency management.³⁷

Several federal programs address ways to bolster the ranks of health care workers for emergency medical response. These include ensuring civil liability protection for volunteer health professionals (VHPs) and establishing a national system to verify licenses and credentials when VHPs volunteer across state lines. While efforts are ongoing among states and on the federal level, uniform systems for the protection and verification of VHPs do not yet exist.³⁸ NDMS,³⁹ administered by the HHS ASPR, and the Medical Reserve Corps (MRC),⁴⁰ administered by local governments with federal assistance, provide surge capacity to bolster the local emergency response workforce. These layered approaches can be effective during moderate incidents, but may themselves become overwhelmed during mass casualty incidents such as Hurricane Katrina.⁴¹ Appropriations authority for NDMS, the MRC, and the national VHP license verification system was established or reauthorized in PAHPA and expires in FY2011. The 112th Congress may consider reauthorization.

In addition, several federal programs address ways to bolster the ranks of public health workers for emergency response. PAHPA authorized a loan repayment demonstration project for individuals who serve in state or local health departments in defined areas of need, but the authority has not been implemented.⁴² In 2010, in the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148, as amended), the 111th Congress authorized a new component of the U.S. Public Health Service Commissioned Corps. Under the new Ready Reserve Corps, officers will

³⁶ Ibid. The Deepwater Horizon oil spill in the Gulf of Mexico provides a recent example of a non-Stafford incident with reported mental health effects. In December 2010, SAMHSA provided grants to affected states to establish surveillance for resulting mental health problems. SAMHSA, "SAMHSA Distributes Grants to Help Meet the Behavioral Healthcare Needs of People Affected by the Deepwater Horizon Oil Spill," press release, December 6, 2010, <http://www.samhsa.gov/newsroom/>.

³⁷ See, for example, Trust for America's Health, *Ready or Not 2010: Protecting the Public's Health from Disease, Disasters, and Bioterrorism*, December 2010, <http://healthyamericans.org/reports/bioterror10/>.

³⁸ CRS Report R40176, *Emergency Response: Civil Liability of Volunteer Health Professionals*, by (name redacted).

³⁹ HHS, *National Disaster Medical System*, <http://www.hhs.gov/aspr/oepo/ndms/index.html>.

⁴⁰ HHS, *About the Medical Reserve Corps*, <http://www.medicalreservecorps.gov/About>.

⁴¹ See, for example, the chapter "Medical Care" in U.S. Congress, House Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina, *A Failure of Initiative: Final Report of the House Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina*, 109th Cong., 2nd sess., H.Rept. 109-377 (Washington: GPO, 2006), p. 267ff., <http://www.gpoaccess.gov/katrinareport/mainreport.pdf>.

⁴² P.L. 109-417, §203, 120 Stat. 2848, 42 U.S.C. §254u, December 19, 2006.

be subject to involuntary call to active duty by the U.S. Surgeon General in order to bolster public health workforce capacity.⁴³ This program has also not been implemented at this time. The CDC PHEP cooperative agreements, discussed earlier, provide funds that state and territorial grantees can use to pay for recruitment, training, and salaries. However, grantees have had difficulty recruiting and retaining qualified personnel with these “soft” funds, and may face other impediments, such as hiring freezes, that are not ameliorated by the federal funds. In addition, the amount of funding limits the extent to which it can effectively bolster the public health workforce at the local level. (The extent to which funds “pass through” from states to localities for this or any other purpose is unclear.) It is reported that the recent recession has led to significant staff contraction in local health departments.⁴⁴

Disaster Victims and Health Care Costs

There is no federal assistance program designed purposefully to cover the uncompensated or uninsured costs of individual health care that may be needed as a result of a disaster.⁴⁵ There is not consensus that this should be a federal responsibility. Nonetheless, if faced with a mass casualty incident, hospitals, physicians, and other providers could face considerable pressure to deliver care without a clear source of reimbursement.

Several federal programs provide limited assistance for this purpose. Assistance may be available pursuant to a declaration under the Stafford Act, including cash assistance to individuals; costs associated with the deployment of federal medical teams, equipment, and supplies; assistance to government and non-profit entities for the costs of health care services of an emergency nature rendered as a direct result of a declared incident;⁴⁶ and mental health crisis counseling assistance to communities affected by a declared major disaster.⁴⁷ Assistance is more limited when the Stafford Act is not invoked. Recent examples of this include the 2009 H1N1 influenza (“flu”) pandemic,⁴⁸ the 2010 Haiti earthquake (in which many victims were airlifted to hospitals on the U.S. mainland),⁴⁹ and the 2010 Gulf oil spill.⁵⁰ Even when assistance is available under the

⁴³ P.L. 111-148, §5210, 124 Stat. 614, March 23, 2010. See “USPHS Commissioned Corps Ready Reserve Corps,” fact sheet, undated, http://www.usphs.gov/pdf/USPHS_COMMISSIONED_CORPS_READY_RESERVE_CORPS_Fact_Sheet.pdf.

⁴⁴ The National Association of County and City Health Officials (NACCHO) reports that, based on survey results, local health departments (LHDs) lost 23,000 jobs to layoffs and attrition between January 2008 and December 2009, roughly 15% of the entire LHD workforce. NACCHO, “Local Health Department Job Losses and Program Cuts: Findings from January/February 2010 Survey,” research brief, May 2010, <http://www.naccho.org/topics/infrastructure/lhdbudget/index.cfm>.

⁴⁵ For more information, see “Federal Assistance for Disaster-Related Health Care Costs,” in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted), and CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, coordinated by (name redacted) and (name redacted).

⁴⁶ FEMA, Disaster Assistance Policy (DAP) 9525.4, “Emergency Medical Care and Medical Evacuations,” July 16, 2008, <http://www.fema.gov/pdf/government/grant/pa/policy.pdf>, authorized under §§403 and 502 of the Stafford Act.

⁴⁷ See CRS Report RL33738, *Gulf Coast Hurricanes: Addressing Survivors’ Mental Health and Substance Abuse Treatment Needs*, by (name redacted), (name redacted), and (name redacted).

⁴⁸ CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by (name redacted) and (name redacted).

⁴⁹ See “Medical Evacuation” in CRS Report R41023, *Haiti Earthquake: Crisis and Response*, by (name redacted) and (name redacted).

⁵⁰ CRS Report R41234, *Potential Stafford Act Declarations for the Gulf Coast Oil Spill: Issues for Congress*, by (name redacted).

Stafford Act, it is generally limited in scope, amount, and duration, and may fall short of actual uncompensated medical care costs.⁵¹

Congress and/or the George W. Bush Administration provided special assistance to address the problem of uncompensated medical care costs in response to several recent incidents, as follows:

- Following the September 11, 2001, terrorist attacks, HHS provided funding to hospitals and other health care facilities (including privately owned facilities) near the three affected sites (in New York, Pennsylvania, and Virginia) that either provided unreimbursed health care services to victims or suffered other economic hardship as a result of road closures or other infrastructure effects.⁵²
- Since 2002, Congress has funded a program to provide health services to responders and others who were exposed to hazards at the World Trade Center (WTC) site in New York following the 2001 terrorist attacks, and who are now experiencing health problems believed to have resulted from those exposures.⁵³ (As discussed later, this program was recently explicitly authorized in modified form. See “Care of Long-Term Needs of 9/11 Victims.”)
- Following Hurricane Katrina in 2005, Congress provided \$2 billion to cover the state share of Medicaid costs for evacuees from, and individuals living in, declared disaster areas, and to restore access to care in affected areas.⁵⁴
- In response to the 2009 H1N1 flu pandemic, Congress provided supplemental appropriations to, among other things, finance the cost of vaccines, drugs, and medical supplies.⁵⁵
- Finally, in response to the Haiti earthquake of January 2010, Congress provided supplemental appropriations to reimburse U.S. hospitals for a portion of the costs of care for Haitian evacuees, and to assist states in providing Medicaid services to eligible evacuees.⁵⁶

Each action above was implemented after the incident occurred, and in some cases considerable time elapsed before funds were available. To address this, legislative proposals in the 111th Congress would have authorized the HHS Secretary to use a special fund to provide temporary

⁵¹ For example, assistance provided pursuant the Stafford Act for health care services is generally limited to services of an emergency nature, and is generally provided only to governmental or not-for-profit entities. Assistance provided to individual disaster victims pursuant to the Stafford Act may be used to pay health care costs, but total assistance is capped at \$30,200 (for FY2011) for an individual or household. CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted).

⁵² See HHS, “Emergency Awards for Healthcare Under Section 319 of the PHS Act Grants for Immediate Response,” *67 Federal Register* 15206-15208, March 29, 2002, the second of two notices of availability of funds. HHS invoked the public health emergency authority in Section 319 of the Public Health Service Act to support this action.

⁵³ CRS Report R41292, *Comparison of the World Trade Center Medical Monitoring and Treatment Program and the World Trade Center Health Program Created by Title I of P.L. 111-347, the James Zadroga 9/11 Health and Compensation Act of 2010*, by Scott Szymendera and (name redacted).

⁵⁴ GAO, *Hurricane Katrina: Allocation and Use of \$2 Billion for Medicaid and Other Health Care Needs*, GAO-07-67, February 28, 2007, <http://www.gao.gov>.

⁵⁵ CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by (name redacted) and (name redacted).

⁵⁶ CRS Report R41232, *FY2010 Supplemental for Wars, Disaster Assistance, Haiti Relief, and Other Programs*, coordinated by (name redacted).

emergency health care coverage for uninsured individuals affected by public health emergencies (H.R. 2231/S. 957). These bills did not advance, however.

Depending on its implementation, the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), the recently enacted health care law, may mitigate concerns about disaster-related uncompensated care to some extent by decreasing the ranks of the uninsured.⁵⁷ However, PPACA does not alter the existing legal landscape under which the care of work-related injuries is meant to be financed through workers' compensation systems rather than health insurance. Further, PPACA does not address the ongoing debate about the role of workers' compensation in covering the costs of chronic health conditions that arise long after a work-related exposure (such as during the response to a disaster), and that may or may not have been caused by that exposure.⁵⁸

Medical Monitoring Following a Disaster

After the 2001 terrorist attack on the World Trade Center, some responders developed chronic health problems believed to have resulted from hazardous exposures during the rescue, recovery, and clean-up operations.⁵⁹ Efforts to track and address these problems were hampered because, at the outset, no central registry was established to identify all responders and other on-site workers, and no program was established to monitor their health going forward, in order to quickly detect common or unusual illness patterns in the cohort.

Following Hurricane Katrina, the 109th Congress enacted the SAFE Port Act (P.L. 109-347). One of its provisions authorizes the President, acting through the Secretary of HHS and pursuant to a major disaster declaration under the Stafford Act, to establish medical monitoring programs, if needed, to track the health status of individuals (not limited to responders) who may experience hazardous exposures as a result of the disaster.⁶⁰ The authority has not yet been implemented.⁶¹ Implementation could involve at least three HHS components—the ASPR, as well as the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute for Occupational Safety and Health (NIOSH), both in CDC—each of which has relevant authorities and responsibilities that overlap somewhat.

The Health and Safety of Disaster Responders

The National Response Framework (NRF) designates the Occupational Safety and Health Administration (OSHA, in the Department of Labor) as the lead agency in ensuring responder

⁵⁷ The act, its individual insurance requirement, and certain other provisions, are the subject of litigation. For more information, see CRS Report R40725, *Requiring Individuals to Obtain Health Insurance: A Constitutional Analysis*, by Jennifer Staman et al., and CRS Report R41331, *Individual Mandate and Related Information Requirements under PPACA*, by (name redacted).

⁵⁸ For more information about workers' compensation and chronic illness, see CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, coordinated by (name redacted) and (name redacted).

⁵⁹ For more information, see "World Trade Center Medical Monitoring and Treatment Program," in CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, coordinated by (name redacted) and (name redacted).

⁶⁰ The Security and Accountability For Every (SAFE) Port Act, P.L. 109-347, §709, 120 Stat. 1947, October 13, 2006.

⁶¹ GAO discusses the possible implementation of this provision in a 2008 report, GAO, *HHS Needs to Develop a Plan That Incorporates Lessons from the Responder Health Programs*, GAO-08-610, May 30, 2008, <http://www.gao.gov>.

health and safety.⁶² GAO found that the response to Hurricane Katrina was hampered by confusion about OSHA's role. GAO noted in particular that disagreements between FEMA and OSHA regarding OSHA's role delayed FEMA's authorization of mission assignments to fund OSHA's response activities.⁶³ Some Members of Congress and others had sought to have worker health and safety elevated from a Support Annex to an Emergency Support Function in the NRF, which would have given OSHA more autonomy in commencing its response activities.⁶⁴ Instead, the NRF contains a revised Worker Safety and Health Support Annex.⁶⁵

In 2007, OSHA issued two documents clarifying its role in emergency response operations. In a request for information in the *Federal Register*, OSHA noted that several of its existing health and safety standards applied to emergency response personnel. However, the standards were not designed, individually or collectively, to serve as a comprehensive emergency response standard, and they did not address the full range of hazards or concerns currently facing emergency responders.⁶⁶ Nonetheless, in a revised directive, OSHA said that its Hazardous Waste Operations and Emergency Response (HAZWOPER) standard, which covers emergency response operations for releases of hazardous substances, would also apply to terrorist incident responses involving chemical, biological, radiological, or nuclear materials.⁶⁷ OSHA also stated that it would exercise discretion regarding whether to use its regulatory authorities during incident response, versus limiting its role to the provision of technical and other assistance.⁶⁸

In 2008 GAO recommended that HHS develop plans to register all responders during a disaster, as part of a comprehensive departmental plan to ensure responder health during and after disasters.⁶⁹ In February 2011, CDC's National Institute for Occupational Safety and Health (NIOSH) published a draft guidance for public comment, "Emergency Responder Health Monitoring and Surveillance."⁷⁰ The draft document proposes a framework for monitoring and conducting surveillance of the health and safety of responders during the entire cycle of emergency response, including pre-deployment, deployment, and post-deployment phases. (It should be noted that to meet the intent of the SAFE Port Act, discussed above, a plan such as this must also address affected individuals who are not responders.)

⁶² For more information, see "Unclear Federal Leadership for Certain Response Functions," in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by (name redacted).

⁶³ GAO, *Disaster Preparedness: Better Planning Would Improve OSHA's Efforts to Protect Workers' Safety and Health in Disasters*, GAO-07-193, March 28, 2007, <http://www.gao.gov>.

⁶⁴ Katherine Torres, "DHS Denies OSHA Power to Invoke Emergency Response Plan, Official Says," *Occupational Hazards*, vol. 70 (March 1, 2008); and "Despite Lawmakers' Concerns, OSHA's Role in NRF Remains Unchanged," *Inside OSHA*, February 4, 2008.

⁶⁵ NRF, Worker Safety and Health Support Annex, <http://www.fema.gov/emergency/nrf/>.

⁶⁶ OSHA, "Emergency Response and Preparedness: Request for Information," 72 *Federal Register* 51735-51743, September 11, 2007.

⁶⁷ OSHA, "Inspection Procedures for 29 CFR 1910.120 and 1926.65, Paragraph (q): Emergency Response to Hazardous Substance Releases," Instruction CPL 02-02-073, effective August 27, 2007, <http://www.osha.gov/index.html>.

⁶⁸ *Ibid.*

⁶⁹ GAO, September 11: HHS Needs to Develop a Plan That Incorporates Lessons from the Responder Health Programs, GAO-08-610, May 30, 2008, <http://www.gao.gov>.

⁷⁰ CDC, "Emergency Responder Health Monitoring and Surveillance: Notice of draft publication available for public comment," 76 *Federal Register* 6475, February 4, 2011.

Care of Long-Term Needs of 9/11 Victims

On January 2, 2011, President Obama signed the James Zadroga 9/11 Health and Compensation Act of 2010 (P.L. 111-347). The law establishes the World Trade Center Health Program (WTCHP) within HHS to provide medical monitoring and treatment benefits to eligible World Trade Center (WTC) responders as well as residents of lower Manhattan and parts of Brooklyn (referred to as survivors). The WTCHP will begin providing benefits on July 1, 2011, and is funded by the act through FY2015 (or FY2016, if funds have not been exhausted by then).⁷¹

The WTCHP will replace the WTC Medical Monitoring and Treatment Program (MMTP) currently administered by CDC using routine appropriations. The WTCHP may face challenges similar to those seen in the current program, including difficulties in ensuring access to services for individuals who do not reside in the New York City area. Also, the WTCHP does not currently authorize treatment services for otherwise eligible individuals based on their having any form of cancer. Although the law authorizes the Secretary to carry out a process to determine if certain cancers should be eligible for treatment under the program, it may be difficult for the Secretary to determine whether or not to cover common cancers that may have occurred regardless of an individual's exposures at the WTC site. It is generally not possible to determine the cause of cancer in a specific individual. Withholding services for treatment of cancers would pose a burden for at least some victims, who may not have an alternate source of payment for their care. However, making common cancers eligible for treatment could burden the program, which is limited in terms of funds, years of operation, and numbers of participants.

The law would, beginning in July 2014, prohibit the WTCHP from paying for monitoring and treatment services for any participant who does not carry health insurance coverage that is slated to be required under PPACA at that time.⁷² Depending on its implementation, PPACA could benefit individuals affected by WTC-related health problems if it ensures that they can get health insurance despite having existing health conditions. But PPACA does not alter legal precedent that establishes that work-related illness and injury are addressed through workers' compensation systems rather than through health insurance; insurers could deny coverage for conditions claimed to be work-related.⁷³ Also, workers' compensation plans may not cover the costs of chronic health conditions that arise after a work-related exposure, if it is not clear that the condition was caused by that exposure.⁷⁴ As a consequence, the WTCHP provides a source of payment for chronic conditions in eligible responders that may not be otherwise available, even if PPACA's expansions of access to insurance are fully implemented.

Planning for the Needs of Special Populations

The terrorist attacks of 2001 and the hurricanes of 2005 showed that some people may be at greater risk, or more in need of special services, during and after a disaster.⁷⁵ PAHPA requires the

⁷¹ CRS Report R41292, *Comparison of the World Trade Center Medical Monitoring and Treatment Program and the World Trade Center Health Program Created by Title I of P.L. 111-347, the James Zadroga 9/11 Health and Compensation Act of 2010*, by Scott Szymendera and (name redacted).

⁷² See the earlier section, "Disaster Victims and Health Care Costs."

⁷³ See "Workers' Compensation Systems" in CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, coordinated by (name redacted) and (name redacted).

⁷⁴ *Ibid.*, "Introduction."

⁷⁵ Shortly before the 2005 hurricanes, the National Council on Disability issued a major report on emergency (continued...)

Secretary of HHS to consider, in emergency planning, the needs of at-risk individuals, defined as children, pregnant women, senior citizens, and others as determined by the Secretary. PKEMRA required the head of FEMA to appoint a Disability Coordinator to, among other things, coordinate emergency management policies and practices for individuals with disabilities.⁷⁶ The 110th Congress authorized and appropriated funds for a National Commission on Children and Disasters, which has been established in the HHS Administration for Children and Families.⁷⁷

In response to its mandate in PAHPA, in 2008 HHS published a report on the status of implementation of provisions regarding at-risk individuals.⁷⁸ In addition to expanding and clarifying the definition of at-risk individual, HHS discussed its efforts regarding coordination of existing departmental activities; education and outreach to responders, providers, and the community of at-risk individuals; and related efforts.

GAO has commented that the Office of the FEMA Disability Coordinator has generally not coordinated its work with a key federal agency—the National Council on Disability (NCOD)—as required by PKEMRA.⁷⁹ During congressional testimony in 2010, the Disability Coordinator noted that the Office of Disability Integration and Coordination was established in FEMA in February 2010, and detailed some of the recent activities of the office. These included regular meetings with the National Council on Disability, the National Council on Independent Living, and the DHS Office for Civil Rights and Civil Liberties; technical assistance; and training.⁸⁰

In 2010, the National Commission on Children and Disasters published its first report to the President and Congress on the status of disaster preparedness in addressing the needs of pediatric populations.⁸¹ In it, the commission cited persistent readiness gaps involving specialized medical capability, emergency planning in schools, mental health care, and others. The commission called for a comprehensive national strategy to address these concerns, and offered a number of additional, more specific, recommendations.

(...continued)

preparedness and individuals with disabilities. National Council on Disability, *Saving Lives: Including People with Disabilities in Emergency Planning*, Washington, DC, April 15, 2005, http://www.ncd.gov/newsroom/publications/2005/pdf/saving_lives.pdf.

⁷⁶ P.L. 109-295, §513; 6 USC §321b. For more information, see CRS Report RS22254, *The Americans with Disabilities Act and Emergency Preparedness and Response*, by (name redacted).

⁷⁷ The National Commission on Children and Disasters, <http://www.childrenanddisasters.acf.hhs.gov/>. For more information, see CRS Report R41080, *The National Commission on Children and Disasters: Overview and Issues*, by (name redacted).

⁷⁸ HHS, Assistant Secretary for Preparedness and Response (ASPR), “Pandemic and All-Hazards Preparedness Act: Progress Report on the Implementation of Provisions Addressing At-Risk Individuals,” August 2008, <http://www.phe.gov/preparedness/legal/pahpa/pages/default.aspx>.

⁷⁹ GAO, National Disaster Response: FEMA Should Take Action to Improve Capacity and Coordination between Government and Voluntary Sectors, GAO-08-369, February 27, 2008, <http://www.gao.gov>.

⁸⁰ Testimony of Marcie Roth, Director, Office of Disability Integration and Coordination, FEMA, “Caring for Special Needs during Disasters: What’s Being Done for Vulnerable Populations?” before the House Committee on Homeland Security, Subcommittee on Emergency Communications, Preparedness, and Response, June 15, 2010. The coordination with the NCOD appears to address the concerns expressed by GAO, which found that FEMA “has generally not coordinated with [NCOD] as required by the Act, which could result in disability-related concerns not being fully addressed.” GAO, *National Disaster Response; FEMA Should Take Action to Improve Capacity and Coordination between Government and Voluntary Sectors*, GAO-08-369, February 2008, p. 26.

⁸¹ National Commission on Children and Disasters, “2010 Report to the President and Congress,” October 2010, <http://www.childrenanddisasters.acf.hhs.gov/>.

Development, Procurement, and Use of Countermeasures

Project BioShield⁸²

The 108th Congress launched Project BioShield to encourage the development of medical countermeasures (such as drugs, vaccines, and diagnostic tests) that lack commercial markets. (The program is not limited to procurement of biodefense countermeasures. Products to address radiological, chemical, and other threats are also considered.) DHS and HHS have shared responsibility for the program since its inception, although the process by which procurement decisions are made has changed several times. Among other things, HHS manages a 10-year advance appropriation (through FY2013) to purchase countermeasures based on joint recommendations from the Secretaries of HHS and DHS. Portions of that funding have been diverted to other purposes in recent years.

The 109th Congress established, in PAHPA, the Biomedical Advanced Research and Development Authority (BARDA) in HHS to oversee the department's responsibilities for countermeasures development and procurement. PAHPA also required the HHS Secretary to develop and publish a strategic plan to guide HHS countermeasures research, development, and procurement.⁸³

The BioShield program has experienced numerous problems over the years, although many have been resolved.⁸⁴ Key issues that remain are (1) the clarity of the shared roles of agencies in DHS, HHS, and other departments in determining the need for countermeasures and implementing a sound development and acquisition process; (2) the challenges in defining contract terms that are perceived by product developers as sufficiently clear and lucrative to be worth their investment; and (3) the diversion of BioShield funds to unanticipated purposes (such as acquisitions for pandemic flu preparedness), its effects on the solvency of the BioShield account, and the effects that may have on decisions made by product developers.

The Strategic National Stockpile (SNS)

The Strategic National Stockpile (SNS) program is administered by CDC to stockpile and deliver to states a variety of medical products in the event of an incident that depletes local supplies. The SNS also stockpiles certain medical countermeasures, such as anthrax vaccine, that are not available commercially.⁸⁵ The program's authority for appropriations expired at the end of FY2006.

SNS managers face three persistent challenges. First, many stockpiled items have short shelf lives and must be replaced periodically. Second, the SNS limits the amount of most procured items and

⁸² Unless otherwise noted, information in this section is drawn from CRS Report R41033, *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, by (name redacted).

⁸³ HHS, Public Health Emergency Medical Countermeasure Enterprise, "Strategy for Chemical, Biological, Radiological and Nuclear Threats," 72 *Federal Register* 13109, March 20, 2007; and HHS, Public Health Emergency Medical Countermeasure Enterprise, "Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats," 72 *Federal Register* 20122, April 23, 2007.

⁸⁴ See, for example, GAO, *Project Bioshield: Actions Needed to Avoid Repeating Past Mistakes*, GAO-08-208T, October 23, 2007, <http://www.gao.gov>.

⁸⁵ CDC, Strategic National Stockpile (SNS), <http://www.bt.cdc.gov/stockpile/>. The SNS is authorized in § 319F-2(a) of the Public Health Service Act (42 U.S.C. § 247d-6b(a)).

urges states and private health care facilities to contribute to the national effort by maintaining stockpiles of their own. Finally, after federal SNS managers deliver SNS assets to state officials, it is the responsibility of state and local officials to distribute SNS materiel to those in need. Each of these matters poses its own set of management challenges in ensuring that the right medical products are available and can be delivered to the right recipients in a timely manner. However, CDC conducts annual reviews of state capability to accept and distribute SNS assets, and has documented steady improvement in this metric in recent years.⁸⁶

Liability and Compensation: The PREP Act⁸⁷

In December 2005, Congress passed Department of Defense Emergency Supplemental Appropriations, 2006 (P.L. 109-148), including Division C, titled the Public Readiness and Emergency Preparedness Act (PREP Act). Upon a declaration of emergency, the PREP Act eliminates liability, except in the case of willful misconduct, of manufacturers and others involved in the production, distribution, and use of covered countermeasures. In October 2008, HHS Secretary Michael Leavitt made several such emergency declarations with respect to countermeasures for smallpox, anthrax, botulism, and acute radiation sickness, and amended a prior declaration for pandemic flu countermeasures. In June 2009, HHS Secretary Kathleen Sebelius issued a declaration under the PREP Act for the use of H1N1 pandemic influenza vaccines and the antiviral drugs Tamiflu and Relenza for treatment of illnesses caused by H1N1 pandemic flu.

The PREP Act's limitation on liability is a more extensive restriction on victims' ability to recover than exists in most federal tort reform statutes. However, the PREP Act also establishes, in the U.S. Treasury, a "Covered Countermeasure Process Fund" (CCPF) to compensate those who may be harmed by a covered countermeasure. The fund depends on discretionary appropriations, and saw its first appropriation in response to the H1N1 influenza pandemic. In providing emergency supplemental funding for pandemic preparedness (P.L. 111-32), Congress authorized the use of an unspecified amount of the appropriation for the CCPF. The resultant Countermeasures Injury Compensation Program, implemented by the HHS Health Resources and Services Administration (HRSA), has received \$2 million in funding, and is accepting claims.⁸⁸

Defense Against Specific Threats

Food Safety

Intentional contamination of food can result from terrorism or from economic motivation.⁸⁹ Prior to the terrorist attacks in 2001, food safety efforts focused on preventing hazards that were

⁸⁶ CDC, *Public Health Preparedness: Strengthening the Nation's Emergency Response State by State*, September 21, 2010, p. 29, http://emergency.cdc.gov/publications/2010phprep/pdf/complete_PHPREP_report.pdf. CDC also found ongoing improvement in a related program, the Cities Readiness Initiative, in which major cities are expected to receive and rapidly distribute SNS assets. *Ibid.*, pp. 29-30.

⁸⁷ Unless otherwise noted, information in this section is drawn from CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by (name redacted).

⁸⁸ HRSA, Countermeasures Injury Compensation Program, <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/>.

⁸⁹ An example of the latter is the melamine contamination of pet food ingredients from China in 2007. Melamine—added to boost the ingredients' protein readings—sickened or killed hundreds of dogs and cats in North America. See (continued...)

common in food production and processing, such as infectious pathogens in fresh poultry, and pesticide residues in crops. After the attacks, the focus shifted to include the prevention of intentional contamination of food. Whether intentional or not, large foodborne outbreaks can affect hundreds of people and can have serious economic consequences for affected commodities, as well as for commodities that are not directly linked to the outbreak. Although there has not recently been a large human foodborne outbreak in the United States resulting from intentional contamination, the public response to the 2001 anthrax attacks and to highly publicized unintentional foodborne outbreaks suggests that an intentional incident of food contamination, especially if it were an act of terrorism, could have consequences far beyond any resulting illnesses.⁹⁰

The 111th Congress passed the FDA Food Safety Modernization Act (P.L. 111-353), a comprehensive expansion of FDA's authority to ensure the safety of the nation's food supply.⁹¹ The law addresses intentional and unintentional contamination of food in a number of provisions. For example, it requires FDA to develop food safety standards, and requires food producers and processors to develop comprehensive food safety plans. In addition, the law requires the Secretaries of HHS and Agriculture to develop a National Agriculture and Food Defense Strategy, implementation plan, and research agenda, to be consistent with the National Incident Management System, the National Response Framework, the National Infrastructure Protection Plan, the National Preparedness Goals, and other federal emergency management documents.

The law provides for limited amounts of fees and other sources of revenue. Although FDA's enhanced regulatory authorities were effective upon enactment, much of the implementation of the law, including substantial increases in FDA's inspection activities, could depend on discretionary appropriations.⁹²

Pandemic Influenza

Beginning in 2005, in response to growing concern about an emerging H5N1 avian influenza ("bird flu") strain in Asia and Europe, Congress provided \$6.1 billion in emergency supplemental funding for FY2006 to prepare for the threat.⁹³ In March 2009, a new and different flu strain—the H1N1 "swine flu"—emerged and caused the first flu pandemic in more than 40 years. The

(...continued)

CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*, by (name redacted) and (name redacted).

⁹⁰ In 1984, public health officials in Oregon closed all salad bars in the city of The Dalles after linking a widespread *Salmonella* outbreak to consumption at salad bars in multiple restaurants. Through a subsequent criminal investigation, law enforcement officials determined that the salad bars had been intentionally contaminated by members of a local religious commune in an effort to sicken residents on the day of a local election, thereby influencing the results. Thomas J. Török, Robert V. Tauxe, Robert P. Wise, et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars," *JAMA*, vol. 278, no. 5, 1997, pp. 389-395.

⁹¹ For more information, see CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*, coordinated by (name redacted). Food safety regulatory authorities and responsibilities of the FDA, the U.S. Department of Agriculture, and other departments and agencies are described in CRS Report RS22600, *The Federal Food Safety System: A Primer*, by (name redacted).

⁹² Alaina Busch, "FDA Weighs Resource Options As Funding Issues Loom For Food Safety Law," *InsideHealthPolicy.com*, January 6, 2011.

⁹³ CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by (name redacted), and CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by (name redacted).

President did not issue a declaration under the Stafford Act in response to the incident. Lacking an alternate funding source, Congress provided up to \$7.7 billion in emergency supplemental appropriations for FY2009 for the pandemic response.⁹⁴

The H1N1 pandemic was not as deadly as some earlier pandemics, but it posed a substantial public health challenge nonetheless. The Administration is reported to be preparing a comprehensive after-action report to plumb the lessons from the incident, but such a report, if completed, has not been made publicly available. Among the issues that may be of interest to the 112th Congress are options for financing the response to an infectious disease incident, as discussed earlier,⁹⁵ and progress toward the development of a more timely influenza vaccine in the future.⁹⁶

Communicable Disease Control⁹⁷

The response to communicable disease threats may involve movement restrictions, business and school closures, compulsory treatments, and other constraints. While state and local governments have the primary authority over these domestic containment measures, a comprehensive response to a public health emergency may involve overlapping governmental authorities and attendant legal and economic issues.

Managing employers' and workers' concerns during outbreaks of communicable disease—in particular, a flu pandemic—may be especially difficult. For example, if workers fear losing their employment or their wages, compliance with public health measures such as isolation or quarantine may suffer. Although public health officials typically recommend, whenever possible, that isolation or quarantine measures be voluntary rather than compulsory, voluntary measures may not provide the same level of job protection for workers who miss work in order to comply with them.⁹⁸

Recent incidents have expanded Congress's long-standing interest in the security of U.S. borders to include concerns about communicable diseases among travelers, which is a matter of federal jurisdiction. These incidents have brought into question the divisions of authority and effectiveness of coordination among federal agencies that are responsible for disease control, and for the security of the borders and the transportation infrastructure.⁹⁹ Policymakers have noted that if these systems are unable to respond to common and expected infectious disease threats such as tuberculosis, they may also be unable to respond to more serious threats such as pandemic

⁹⁴ CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by (name redacted) and (name redacted).

⁹⁵ See "HHS Response Capability and Funding Authority."

⁹⁶ See White House, President's Council on Science and Technology, "Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza," August 19, 2010, <http://www.whitehouse.gov/administration/eop/ostp/pcast/docsreports>.

⁹⁷ Unless otherwise noted, information in this section is drawn from CRS Report RS22219, *The Americans with Disabilities Act (ADA) Coverage of Contagious Diseases*, by (name redacted); CRS Report RL33201, *Federal and State Quarantine and Isolation Authority*, by (name redacted) and (name redacted); CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by (name redacted); and CRS Report R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by (name redacted).

⁹⁸ CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by (name redacted) and (name redacted).

⁹⁹ CRS Report RL34144, *Extensively Drug-Resistant Tuberculosis (XDR-TB): Emerging Public Health Threats and Quarantine and Isolation*, by (name redacted) and (name redacted).

flu or bioterrorism. Effective solutions are elusive, but would ideally address scientific, technical, and economic constraints; the balance of individual and collective rights; and the roles of federal, state, and local authorities, and foreign governments.

Bioterrorism: Select Agent Program

In August 2008, the Federal Bureau of Investigation (FBI) announced that it believed a Defense Department scientist (who had taken his own life) had been responsible for the 2001 anthrax attacks.¹⁰⁰ The incident heightened concerns about the effectiveness of security risk assessments (“background checks”) that FBI conducts on individuals who are registered in the Select Agent program and granted access to pathogens. Subsequently, the congressionally mandated Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism recommended a comprehensive review of the Select Agent program.¹⁰¹

Legislation introduced in the 111th Congress (S. 485/H.R. 1225)¹⁰² would have reauthorized the Select Agent program, which is jointly managed by the CDC and the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) to regulate certain biological pathogens and toxins that could be used for bioterrorism.¹⁰³ Program authority expired at the end of FY2007. The bills would have reauthorized the program and would have required, among other things, a program review, planning for surges in testing capacity, and improvements in inventory practices. They would also have authorized HHS and USDA to release certain sensitive information about the program to designated state officials if a state’s laws are adequate to protect against the further release of such information. The bills did not advance in the 111th Congress.

Bioterrorism: Biodefense Laboratory Capacity and Oversight

Since 2001, HHS, DHS, USDA, the Department of Defense (DOD), state governments, and some academic institutions have expanded or are expanding their laboratory capacity to study or test for dangerous biological pathogens and toxins. These laboratories play a key role in the biodefense effort, offering the hope of better responses to a biological attack and a better understanding of the bioterrorism threat. However, they could also increase the risk of a biological attack by being a source of materials or training. In 2008, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism recommended, among other things, the expansion of government oversight of these laboratories.¹⁰⁴

The 112th Congress may consider issues associated with domestic biodefense laboratories, such as the effectiveness of current oversight efforts, the appropriate balance between security and the

¹⁰⁰ Federal Bureau of Investigation, “Anthrax Investigation: Closing a Chapter,” August 6, 2008, <http://www.fbi.gov/page2/august08/amerithrax080608a.html>.

¹⁰¹ Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, *World At Risk: The Report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism*, New York, NY, December 2008, pp. 27-32, <http://www.preventwmd.org>.

¹⁰² Provisions to reauthorize the Select Agent program are found in Title I of these bills.

¹⁰³ 42 U.S.C. § 262a and 7 U.S.C. § 8401. CDC/APHIS Select Agent program website, <http://www.selectagents.gov/>.

¹⁰⁴ Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, *World At Risk: The Report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism*, New York, NY, December 2008, pp. 27-32, <http://www.preventwmd.org>.

transparency that fosters scientific discovery, and possible effects of domestic regulatory approaches on international collaboration.¹⁰⁵ Legislation introduced in the 111th Congress (S. 485/H.R. 1225)¹⁰⁶ would have required the HHS Secretary to review and report to Congress regarding, among other things, the adequacy of laboratory capacity, and information sharing between the biodefense and infectious disease communities. The Secretary would also have been required to develop minimal training standards for personnel, and to establish a voluntary reporting system through which laboratory personnel could report accidents and other incidents. As noted above, the bills did not advance in the 111th Congress.

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¹⁰⁵ CRS Report R40418, *Oversight of High-Containment Biological Laboratories: Issues for Congress*, by (name redacted) and (name redacted).

¹⁰⁶ Laboratory oversight provisions are found in Title II of these bills.

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