



Public Health and Medical Preparedness and Response: Issues in the 111th Congress

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Summary

Key recent events—the 2001 terrorist attacks, Hurricane Katrina, and concerns about an influenza (“flu”) pandemic, among others—sharpened congressional interest in the nation’s systems to track and respond to public health threats. The 109th Congress passed several laws that established, reorganized, or reauthorized key public health and medical preparedness and response programs in the Departments of Health and Human Services (HHS) and Homeland Security (DHS). The 110th Congress was engaged in oversight of the implementation of these laws, focused in particular on such matters as (1) the fitness of HHS and DHS—in terms of authority, funding, policies, and workforce—to respond to health emergencies; (2) the effectiveness of coordination among them and other federal agencies; and (3) the status of major initiatives such as pandemic flu preparedness and disaster planning for at-risk populations. The 111th Congress is likely to remain engaged in oversight of the nation’s readiness for health threats.

The Obama Administration may reconsider homeland security objectives and priorities established by the George W. Bush Administration. Shifts in doctrine or priority, if any, may manifest as key positions are filled, or in the budget proposal for FY2010. Also, early in its first session, the 111th Congress is considering proposals in the American Recovery and Reinvestment Act (the economic stimulus proposal) to enhance funding for the development of medical countermeasures (e.g., drugs and vaccines), and for pandemic flu preparedness.

The 111th Congress may review HHS’s disaster response capabilities, including its authority to declare a public health emergency and the means to fund its response efforts. Among other things, it is not clear that 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 no-year Public Health Emergency Fund, Congress has not appropriated monies to the fund for many years. Finally, since Hurricane Katrina, Congress has urged and HHS has adopted a more aggressive federal role in the response to health emergencies.

At this time, there is no federal assistance program designed purposefully to cover the uncompensated or uninsured health care costs for disaster victims. The 111th Congress may reconsider earlier proposals to provide such assistance under certain circumstances.

Health emergencies often involve scarcities of resources (including personnel), movement restrictions, business and school closures, and other constraints. While state and local governments have the primary authority over such measures as quarantine and isolation, a comprehensive response to a public health emergency may involve overlapping governmental authorities and attendant legal and economic issues.

The 108th Congress launched Project BioShield to encourage the development of medical countermeasures that lack commercial markets. Some concerns remain about the program’s ability to attract private-sector developers. Also, the 109th Congress provided a means for liability protection for product developers and others, if countermeasures are used during a health emergency. A corresponding program to compensate persons who may be injured by such covered countermeasures has not been funded.

This report summarizes key issues in domestic public health and medical preparedness and response, citing other CRS Reports and sources of additional information.

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Background

Three important principles color the issues in public health and medical preparedness and response. First, preparedness and response are different functions. At each level of government, they involve different leadership roles, legal authorities, 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 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 health care or emergency management activities to state or local officials, or to health care providers.¹ Finally, most public health functions—broad, population-based programs, such as restaurant inspections to assure food safety—are inherently governmental. In contrast, 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.

The 2001 terrorist attacks, the flawed response to Hurricane Katrina, and concerns about an influenza (“flu”) pandemic sharpened congressional interest in the nation’s ability to track and respond to health threats. The 109th Congress established or reauthorized relevant programs and activities in the Departments of Health and Human Services (HHS) and Homeland Security (DHS). The 110th Congress focused on oversight of these activities, in particular (1) the fitness of HHS and DHS—in terms of authority, funding, policies, and workforce—to respond to health emergencies; (2) the effectiveness of federal agency coordination; and (3) the status of major initiatives such as pandemic flu preparedness and disaster planning for at-risk populations.

The 111th Congress is likely to remain engaged in oversight of the nation’s readiness for health threats. It faces a different and dynamic landscape, however. The new Administration will likely bring with it some shifts in preparedness priorities, in direction and degree yet to be shown. The nation’s health care system is the subject of a vigorous reform debate. Although emergency management is not the focus of that debate, significant system reforms, if enacted, would likely affect emergency planning needs and system response capacity. And the nation’s unsettled economy poses a dilemma for policy makers. Future spending for public programs may be significantly constrained, unless a program were seen as a means for job creation, or some other engine of economic stimulus. It remains to be seen where federal programs to address health emergencies will fit into this complex picture.

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

¹ The federal government can, however, attach conditions to the expenditure of federal grant funds, in furtherance of national goals.

Key Legislation in Prior Congresses

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 a Biomedical Advanced Research and Development Authority (BARDA) in HHS to oversee the development and procurement of medical countermeasures (e.g., diagnostic tests, drugs, and vaccines).² The Post-Katrina Emergency Management Reform Act of 2006 (PKA, Title VI of P.L. 109-295) reorganized DHS and, within it, the Federal Emergency Management Agency (FEMA). The PKA 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.³

Issues for Congress

Government Leadership, Organization, and Capacity

The Presidential Transition

The Obama Administration may reconsider any number of homeland security objectives, and its priorities are likely to differ, at least somewhat, from those of the George W. Bush Administration. For example, the Bush Administration placed considerable emphasis on the detection of and response to a large-scale biological attack. Among other things, it established the BioWatch system of air monitors in major cities, and redirected federal funds from states to these cities to bolster planning for mass dispensing of antibiotics in response to an attack. These efforts were criticized from all sides. Some said they were excessive and drained resources from routine public health and biomedical research needs. Others said they were insufficient to protect the public in a timely manner. Still others questioned the basic effectiveness of the programs. Critiques are likely to continue, whether the Obama Administration maintains its predecessors' priorities, or redirects them.

The transition also marks the first transfer of presidential authority for the Department of Homeland Security (DHS), and for a number of homeland security positions and programs established since 2001. These positions include the Assistant Secretary for Health Affairs and Chief Medical Officer at DHS (DHS CMO),⁴ the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS), and their corresponding offices and activities.

Shifts in doctrine or priority in the new Administration, if any, may manifest when key positions are filled, or when the budget proposal for FY2010 is unveiled.

² CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by Sarah A. Lister and Frank Gottron.

³ P.L. 109-295, 120 Stat. 1409, 6 U.S.C. § 321e.

⁴ In the George W. Bush Administration, one individual served in this position with both titles.

Executive Branch Organization

Based on debates in the 110th Congress, the 111th Congress may consider removing FEMA from DHS and re-establishing it as a separate agency, as it was in the Clinton Administration. Other substantial reorganizations of federal homeland security agencies do not appear to be under debate at this time. Congress may consider relocating certain programs, however. (See, for example, the subsequent discussion of the “Select Agent Program.”) Also, President Obama may consider the administrative reorganization of certain homeland security functions, such as those of the Homeland Security Council (HSC). President George W. Bush established the HSC in the Executive Office of the President shortly after the 2001 terrorist attacks.⁵ From 2005 through 2008, the HSC served as the hub of federal preparedness activities for pandemic flu, coordinating activities across HHS, DHS, the State Department, and other federal departments and agencies.⁶ Some have called for a merger of the HSC with the larger National Security Council (NSC), citing a number of overlapping responsibilities shared by the two.⁷ It is reported that President Obama has called for a comprehensive review of the functions of the NSC.⁸

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 remain a work in progress for some time to come. Pursuant to the PAHPA and the PKA, applicable activities in DHS are led by the DHS CMO, and in HHS by the HHS ASPR. The PKA 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 the PAHPA provided that the “Secretary of [HHS] shall lead all *Federal* public health and medical response to public health emergencies and incidents....”⁹ (Emphasis added.) Hence, the Secretary of Homeland Security leads all federal emergency and disaster response activities; the DHS CMO leads 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 leadership roles involve shared responsibilities, and it is not clear how these would work in practice.”¹⁰ GAO recommended that DHS and HHS conduct training and exercises to ensure that federal leadership roles are clearly defined and understood.

⁵ CRS Report RS22840, *Organizing for Homeland Security: The Homeland Security Council Reconsidered*, by Harold C. Relyea.

⁶ See, for example, comments of Frances Fragos Townsend, Former Assistant to President George W. Bush for Homeland Security and Counterterrorism, hearing of U.S. Congress, Senate Committee on Homeland Security and Governmental Affairs, *Structuring National Security and Homeland Security at the White House*, 111th Cong., 1st sess., February 12, 2009.

⁷ See, for example, Rob Margetta, “Is HSC and its Chief Transitioning Out of the New Administration?,” *CQ Homeland Security*, December 3, 2008. For more information about the NSC, see CRS Report RL30840, *The National Security Council: An Organizational Assessment*, by Richard A. Best Jr.

⁸ Karen DeYoung, “Obama’s NSC Will Get New Power,” *Washington Post*, February 8, 2009, p. A1.

⁹ P.L. 109-295, 120 Stat. 1409; P.L. 109-417, § 101, 120 Stat. 2832.

¹⁰ U.S. Government Accountability Office, *Influenza Pandemic: Opportunities Exist to Clarify Federal Leadership Roles and Improve Pandemic Planning*, GAO-07-1257T, September 26, 2007, <http://www.gao.gov>; and CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

Federal incident response activities are coordinated according to the *National Response Framework* (NRF), and “all-hazards” blueprint published by DHS.¹¹ Public health and medical response activities (under the leadership of HHS) are laid out in an NRF annex 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. Nonetheless, some leadership gaps and conflicts remain in ESF-8. In addition to the inter-related roles of the HHS ASPR and the DHS CMO, discussed above, there are concerns about a lack of leadership clarity for responder health and safety (see the subsequent section “The Health and Safety of Disaster Responders”); emergency sheltering; mass fatality management; and mental health services, among others.¹²

On January 28, 2009, DHS Secretary Janet Napolitano announced an action directive to review the Department’s plans for the response to a large-scale medical incident.¹³ The directive required specific DHS offices and components, working with state and local partners, to review and assess current plans (including ESF-8 in the NRF), relevant homeland security grant programs, and other matters. DHS components were to report to the Secretary by February 24, 2009.

Strategic Planning

The 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.¹⁴ The NHSS is to include a process for achieving a number of preparedness goals enumerated in the statute. In 2007, the Bush Administration published a homeland security directive to establish a “national strategy for public health and medical preparedness,” including implementation steps.¹⁵ The directive stated that the principles and actions it contained were to be incorporated into the NHSS, and serve as a foundation to address the preparedness goals prescribed by the PAHPA.

On September 30, 2008, the Office of the HHS ASPR awarded a delivery order (a type of contracting mechanism) to the RAND Corporation, to provide support in developing the NHSS during FY2009.¹⁶ The 111th Congress may be interested in monitoring the NHSS development process, in particular whether the leadership of the Office of the HHS ASPR maintains steady progress toward completion during the Obama Administration, and the extent to which the strategy and its accompanying plans and goals reflect, or are consistent with, any changes in doctrine or priority that may be adopted by the new Administration.

¹¹ 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 Bruce R. Lindsay.

¹² 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 Sarah A. Lister.

¹³ Department of Homeland Security, “Secretary Napolitano Issues Action Directives on First Responder Health Surge Capacity and Hurricane Katrina,” press release, January 28, 2009, <http://www.dhs.gov/ynews/releases>.

¹⁴ CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by Sarah A. Lister and Frank Gottron.

¹⁵ President George W. Bush, *Homeland Security Presidential Directive 21, Public Health and Medical Preparedness*, Washington, DC, October 18, 2007.

¹⁶ General Services Administration, Federal Procurement Data System, contract transaction #18599705, September 30, 2008.

HHS Response Capability and Funding Authority

The 111th 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.¹⁷ Members of Congress may also consider how HHS funds any of its disaster response activities that are not reimbursable by FEMA. Although the HHS Secretary has authority for a no-year Public Health Emergency Fund, Congress has not appropriated monies to the fund for many years. Also, it is not clear that a flu pandemic would qualify as a major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (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. If major disaster assistance were applicable in a flu pandemic, substantial FEMA funds could be available to support HHS response activities.¹⁸

State Grants for Public Health and Health System Preparedness

Since 2002, Congress has provided more than \$9 billion in grants to states to strengthen public health and hospital preparedness for public health threats. The PAHPA extended the programs, 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.¹⁹ The Cooperative Agreement for Public Health Emergency Preparedness is administered by the Centers for Disease Control and Prevention (CDC).²⁰ The Hospital Preparedness Program is administered by the HHS ASPR.²¹ The programs have been challenging for federal managers and state awardees alike. Among other things, federal managers have had difficulty developing meaningful and measurable performance goals for the programs.²² Also, state awardees have had some difficulty staffing their preparedness programs. Some have cited, as explanations, public health workforce shortages, and the challenges of recruiting with annual discretionary or "soft" funding.²³

¹⁷ CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister. 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>.

¹⁸ CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.

¹⁹ CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by Sarah A. Lister and Frank Gottron.

²⁰ See <http://emergency.cdc.gov/cotper/coopagreement/>.

²¹ See <http://www.hhs.gov/aspr/opeo/hpp/index.html>.

²² 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; and Nicole Lurie, Jeffrey Wasserman, and Christopher D. Nelson, "Public Health Preparedness: Evolution Or Revolution?," *Health Affairs*, vol. 25, no. 4 (July/August 2006), pp. 935-945.

²³ See Association of State and Territorial Health Officials, *States of Preparedness: Health Agency Progress, Second Edition*, Washington, DC, September 2008, <http://www.astho.org/pubs/StatesofPreparedness2008fin.pdf>; and U.S. Government Accountability Office, *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>.

Economic Stimulus

In January 2009, the House passed H.R. 1, the American Recovery and Reinvestment Act of 2009 (ARRA), a spending and tax cut proposal intended to stimulate the nation's flagging economy. It included \$900 million in proposed funding for public health and medical preparedness and response, as follows: (1) \$430 million for the advanced development and procurement of medical countermeasures through the Biomedical Advanced Research and Development Authority (BARDA);²⁴ (2) \$420 million for pandemic flu preparedness for facility construction and the development and/or purchase of vaccines, drugs, supplies, and equipment; and (3) \$50 million for improvements in cyber-security at HHS. On February 10, 2009, the Senate passed a different version of H.R. 1 without comparable provisions. (An earlier Senate version, S.Amdt. 98, would have provided \$870 million for pandemic flu preparedness, with instructions similar to those in the House-passed bill. S.Amdt. 98 did not propose funding for BARDA or for cyber-security.) Neither proposal included enhanced funding for the CDC or HHS/ASPR public health or hospital preparedness grants to states, discussed earlier. The BARDA and pandemic flu provisions in the House bill were removed in conference. The President signed ARRA into law on February 17, 2009 (P.L. 111-5), providing \$50 million for cyber-security improvements at HHS.

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 large increases in caseloads that would result from mass casualty incidents. The successful response to such incidents requires the coordination of several elements, which are variously based in federal, state or local authority, or in the private sector. These elements are (1) patients, who may require rescue or medical evacuation; (2) a treatment facility, which may be an existing hospital, or a field tent with cots; (3) a competent health care workforce; (4) appropriate medical equipment and non-perishable medical supplies; (5) appropriate drugs, 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 ways to establish this capacity in the private sector, with mixed success.²⁵ For example, the HHS Hospital Preparedness Program (described above) makes grants to state governments to work with private health care facilities and systems in assuring regional surge capacity, but the effectiveness of the program has been questioned.

²⁴ BARDA is in the Office of HHS/ASPR and is discussed in a subsequent section of this report, "Project BioShield".

²⁵ 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>; U.S. Government Accountability Office, *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 Amy H. Kaji, Kristi L. Koenig, and Roger J. Lewis, "Current Hospital Disaster Preparedness," *JAMA*, vol. 298 (November 14, 2007), pp. 2188-2190.

Traditionally, the federal government has helped guide states' disaster readiness efforts primarily by providing guidance and funding for preparedness activities, and by assisting with the costs of response activities. During Hurricane Katrina, the shortcomings of this approach with respect to medical surge capacity were evident. Since then, there has been a trend toward expanding the role of the federal government through direct procurement and deployment of medical response assets, providing a stronger backstop for state, local, and private-sector response efforts. For example, the PAHPA authorized HHS to acquire mobile medical assets, such as Field Medical Stations (FMS).²⁶

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 2008.²⁷ The Strategic National Stockpile (SNS) of medical supplies and drugs, as well as the National Disaster Medical System and other programs to provide emergency health workers, have also been expanded since 2005.²⁸ The costs to *procure* FMS and SNS assets are borne in annual discretionary appropriations and may be fairly easily tracked. In contrast, many of the costs to *deploy* these and other assets in a disaster response, in addition to the staffing costs required to support these deployments, are often reimbursed by FEMA from the Disaster Relief Fund.²⁹ The federal government has not published information about the costs associated with HHS's responses to Hurricanes Gustav and Ike. The Congress may be interested in seeking information about these costs, in order to determine whether they represent an appropriate and sustainable investment of federal effort.

Finally, the 111th 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.³⁰ The response to Hurricane Katrina in 2005 prompted a re-examination 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 its Substance Abuse and Mental Health Services Administration), FEMA (which funds the state programs), and states and their contractors (which implement them) are not always clear.

²⁶ CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by Sarah A. Lister and Frank Gottron.

²⁷ 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>.

²⁸ See HHS, "Federal Public Health and Medical Assistance," <http://www.hhs.gov/disasters/discussion/planners/medicalassistance.html>.

²⁹ CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

³⁰ CRS Report RL33738, *Gulf Coast Hurricanes: Addressing Survivors' Mental Health and Substance Abuse Treatment Needs*, by Ramya Sundararaman, Sarah A. Lister, and Erin D. Williams.

Workforce Surge Capacity

The HHS Health Resources and Services Administration (HRSA) manages several health professions programs intended to alleviate shortages and maldistributions of physicians, nurses, and others who provide health care services to individuals.³¹ These programs are not, however, geared toward assuring disaster surge capacity in the health care workforce. Efforts to bolster the ranks of health professionals for disaster response include ensuring civil liability protection for volunteer health professionals, and establishing a national system to verify their licenses and credentials. While efforts are ongoing among states and on the federal level, a uniform system for protection of volunteer health professionals does not yet exist.³²

Surge capacity in the public health workforce—those workers who assure safe food and water, conduct diseases surveillance, and carry out other public health activities in response to disasters—has received little federal attention until recently. The 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.³³

At this time, the National Disaster Medical System, administered by the HHS ASPR,³⁴ and the Medical Reserve Corps, administered by local governments with the assistance of the HHS Office of the Surgeon General,³⁵ provide surge capacity to bolster the local disaster response workforce in both health care and public health.

The Health and Safety of Disaster Responders

Responsibility for the health and safety of disaster response workers is a matter of concern in the National Response Framework (NRF). GAO found that the efforts of the Occupational Safety and Health Administration (OSHA, in the Department of Labor) during the response to Hurricane Katrina were 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.³⁶ Some Members of Congress and others 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.³⁷ Instead, the NRF contains a revised Worker Safety and Health Support Annex.³⁸

³¹ See, for example, CRS Report RL32546, *Title VII Health Professions Education and Training: Issues in Reauthorization*, by Bernice Reyes-Akinbileje; and CRS Report RL32805, *Nursing Workforce Programs in Title VIII of the Public Health Service Act*, by Bernice Reyes-Akinbileje.

³² CRS Report R40176, *Emergency Response: Civil Liability of Volunteer Health Professionals*, by Vivian S. Chu.

³³ CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by Sarah A. Lister and Frank Gottron.

³⁴ HHS, *National Disaster Medical System*, <http://www.hhs.gov/aspr/opeo/ndms/index.html>.

³⁵ HHS, *About the Medical Reserve Corps*, <http://www.medicalreservecorps.gov/About>.

³⁶ U.S. Government Accountability Office, *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>.

³⁷ 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.

³⁸ NRF, Worker Safety and Health Support Annex, <http://www.fema.gov/emergency/nrf/>.

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.³⁹ 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.

Congress or the Bush Administration provided special assistance to address this concern three times in response to recent disasters. Following the September 11, 2001 terrorist attacks, HHS provided funding to hospitals, clinics, and other health care facilities (including privately owned facilities) near the three affected sites (in NY, PA, and VA), that either provided unreimbursed health care services to victims, or suffered other economic hardship as a result of road closures or other infrastructure effects.⁴⁰ Through intermittent appropriations, Congress has funded a program to provide medical screening, monitoring, and treatment services to responders and others who were exposed to hazards at the World Trade Center site in NY following the 2001 terrorist attack, and who are now experiencing health problems that are believed to have resulted from those exposures.⁴¹ Following Hurricane Katrina, Congress provided \$2 billion to cover the state share of Medicaid costs associated with evacuees and individuals living in declared disaster areas (for states with approved federal waivers), and to restore access to care in affected areas.⁴²

Legislative proposals in the 110th Congress would have: authorized the HHS Secretary to use a special fund to provide temporary emergency health care coverage for uninsured individuals affected by public health emergencies (H.R. 6569/S. 3312); or addressed the health care needs of responders and others who are ill purportedly as a result of exposures at World Trade Center site in NY following the 2001 terrorist attack (for example, H.R. 1414/ S. 201, S. 1119, H.R. 1247, H.R. 3543, H.R. 6594, and H.R. 7174). None of these proposals was enacted.

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.⁴³ 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,

³⁹ 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 Sarah A. Lister; and CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, Sarah A. Lister and C. Stephen Redhead, Coordinators.

⁴⁰ 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 its action.

⁴¹ 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 Sarah A. Lister.

⁴² U.S. Government Accountability Office, *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>.

⁴³ 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*, Sarah A. Lister and C. Stephen Redhead, Coordinators.

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.⁴⁴ The authority has not yet been implemented. According to GAO, as of May 2008, HHS had not articulated a plan for doing so.⁴⁵ Federal agency responsibilities and funding mechanisms are not clear without such a plan. For example, within HHS, at least three components—the ASPR, as well as the Agency for Toxic Substances and Disease Registry and the National Institute for Occupational Safety and Health, both in CDC—have relevant authorities and responsibilities that overlap. Also, a major disaster typically triggers federal coordinating mechanisms laid out in the NRF, which places OSHA in the lead in assuring responder health and safety.⁴⁶ In 2008, GAO recommended, for future disasters, that HHS develop plans to register all responders during a disaster, as part of a comprehensive departmental plan to assure responder health during and after disasters.⁴⁷ GAO said that such a plan should also include a means to implement medical monitoring programs, or to assist states and localities in doing so. To meet the intent of the SAFE Port Act, such a plan must also address affected individuals who are not responders.

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.⁴⁸ The PAHPA requires the 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. The PKA required the head of FEMA to appoint a Disability Coordinator, charged, among other things, with coordinating emergency management policies and practices for individuals with disabilities.⁴⁹ 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.⁵⁰

⁴⁴ The Security and Accountability For Every (SAFE) Port Act, P.L. 109-347, § 709, 120 Stat. 1947, Oct. 13, 2006.

⁴⁵ U.S. Government Accountability Office, *HHS Needs to Develop a Plan That Incorporates Lessons from the Responder Health Programs*, GAO-08-610, May 30, 2008, <http://www.gao.gov>.

⁴⁶ 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 Sarah A. Lister.

⁴⁷ U.S. Government Accountability Office, *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>.

⁴⁸ Shortly before the 2005 hurricanes, the National Council on Disability issued a major report on emergency 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.

⁴⁹ CRS Report RS22254, *The Americans with Disabilities Act and Emergency Preparedness and Response*, by Nancy Lee Jones.

⁵⁰ P.L. 110-161, the FY2008 Consolidated Appropriations Act, Division G, Title V, 121 Stat. 2213-2217; and HHS Administration for Children and Families, “Notification of the Establishment of the National Commission on Children and Disasters,” 73 *Federal Register* 51489-51490, September 3, 2008. See also, the section “Children and Disasters” in (continued...)

The 111th Congress is likely to be interested in the continued evolution of these efforts, in particular, how well these federal efforts address the diversity of special needs that exist in the population, and how well they are coordinated with each other in planning, and during disaster response. GAO has commented, for example, that the Office of the FEMA Disability Coordinator has generally not coordinated its work with a key federal agency—the National Council on Disability—as it is required to do by the PKA.⁵¹

Defense Against Specific Threats

Pandemic Influenza Preparedness

To prepare for the threat of a human flu pandemic, the 109th Congress provided \$6.1 billion in emergency supplemental funding for FY2006.⁵² Most of it has supported an HHS initiative to expand domestic vaccine production capacity.⁵³ The Congressional Budget Office (CBO) has analyzed the uncertainties and financial risks associated with this robust investment in applied research and infrastructure development, noting that the success of the HHS initiative may be affected, among other things, by the outcomes of research efforts to improve vaccine technology, and the extent to which the demand for seasonal flu vaccine can sustain the costs of expanded production capacity and more sophisticated vaccine production technology over the long term.⁵⁴

Given the considerable federal investment in preparing for this threat, the 111th Congress is likely to remain interested in the status of national preparedness efforts. Additional issues of potential interest may include (1) the priority given by the Obama Administration to continued planning efforts, including its budget request for FY2010; (2) future federal leadership for planning efforts (see the earlier discussion of the HSC in the section “Executive Branch Organization”); and (3) the status of state preparedness efforts.⁵⁵ Finally, as mentioned earlier, it is not clear that a flu pandemic would qualify as a major disaster under the Stafford Act.⁵⁶ If so, substantial FEMA funds could be made available for HHS response activities. If not, alternative funding options available to the Secretary of HHS are limited. (See the earlier section of this report, “HHS Response Capability and Funding Authority.”)

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CRS Report RL34758, *The National Response Framework: Overview and Possible Issues for Congress*, by Bruce R. Lindsay.

⁵¹ U.S. Government Accountability Office, *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>.

⁵² CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister; and CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister.

⁵³ For more information, see HHS Pandemic Planning Updates I through VI, March 2006 through January 2009, <http://www.pandemicflu.gov/plan/federal/index.html>.

⁵⁴ Congressional Budget Office, *U.S. Policy Regarding Pandemic-Influenza Vaccines*, Washington, DC, September 2008, <http://www.cbo.gov/doc.cfm?index=9573>.

⁵⁵ See HHS, *Assessment of States' Operating Plans to Combat Pandemic Influenza*, HHS Report to the Homeland Security Council, Washington, DC, January 2009, <http://www.pandemicflu.gov/plan/states/index.html>; and CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale.

⁵⁶ CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.

Communicable Disease Control

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.⁵⁷

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.⁵⁸

Recent incidents have expanded Congress's longstanding interest in the security of U.S. borders to include concerns about communicable diseases in 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.⁵⁹ Policy makers 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 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.

Finally, health emergencies often involve scarcities of resources, including personnel, equipment, drugs, and vaccines. Prioritizing the use of these resources to maximize benefit requires careful study of scientific and medical evidence, and raises complex legal and ethical questions that are best considered before emergencies arise.⁶⁰

Select Agent Program

Legislation in the 110th Congress (S. 3127/H.R. 6671) proposed to reauthorize 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.⁶¹ Program authority expired at the end of FY2007.

⁵⁷ CRS Report RL33201, *Federal and State Quarantine and Isolation Authority*, by Kathleen S. Swendiman and Jennifer K. Elsea; CRS Report RS22219, *The Americans with Disabilities Act (ADA) Coverage of Contagious Diseases*, by Nancy Lee Jones; and CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Kathleen S. Swendiman.

⁵⁸ CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by Nancy Lee Jones and Jon O. Shimabukuro.

⁵⁹ CRS Report RL34144, *Extensively Drug-Resistant Tuberculosis (XDR-TB): Emerging Public Health Threats and Quarantine and Isolation*, by Kathleen S. Swendiman and Nancy Lee Jones.

⁶⁰ CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by Nancy Lee Jones.

⁶¹ 42 U.S.C. § 262a and 7 U.S.C. § 8401. See CDC Select Agent Program, <http://www.cdc.gov/od/sap/>, and APHIS (continued...)

The bills, which were not enacted, proposed some program enhancements, such as expanded training requirements and an incident reporting system, but would have left the program under CDC and APHIS.

In August 2008, the Federal Bureau of Investigation (FBI) announced that it believed a Department of Defense scientist had been responsible for the 2001 anthrax attacks.⁶² The individual took his own life before charges could be filed, so the case will not reach a legal conclusion. Nonetheless, the incident has 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 the pathogens. Subsequently, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism—which was mandated by Congress before the matter involving the anthrax scientist was publicly known—recommended, among other things, the expansion of government oversight of laboratories that house the most dangerous biological pathogens and toxins.⁶³ The Commission did not recommend that leadership for the Select Agent Program be changed. However, at a hearing on the Commission’s report, Senators Joseph Lieberman and Susan Collins (the Chairman and Ranking Member, respectively, of the Senate Committee on Homeland Security and Governmental Affairs) signaled that they were considering introducing legislation in the 111th Congress that would put DHS in charge of regulating biological pathogens in the future.⁶⁴ CDC and APHIS have the appropriate scientific and technical expertise to support the program, but the Senators were concerned that they may lack the homeland security and national security expertise that is also required. However, some members of the biomedical research community were concerned about proposals to move the program into DHS when legislation to establish the new department was under consideration in 2002.⁶⁵ They argued, successfully at the time, that the program should remain with CDC and APHIS.

Development, Procurement, and Use of Countermeasures

Project BioShield

The 108th Congress launched Project BioShield to encourage the development of countermeasures 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,

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Agricultural Select Agent Program, http://www.aphis.usda.gov/programs/ag_selectagent/.

⁶² Federal Bureau of Investigation, “Anthrax Investigation: Closing a Chapter,” August 6, 2008, <http://www.fbi.gov/page2/august08/amerithrax080608a.html>.

⁶³ 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.gov/home/>.

⁶⁴ U.S. Congress, Senate Committee on Homeland Security and Governmental Affairs, *Prevention of Weapons of Mass Destruction Proliferation and Terrorism*, 110th Cong., 2nd sess., December 11, 2008. See also Matthew M. Johnson, “Lieberman to Seek Tougher Regulations for Biological Research Labs,” *CQ Homeland Security*, December 11, 2008.

⁶⁵ See, for example, testimony of the American Society for Microbiology, U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, hearing on *Creating the Department of Homeland Security: Consideration of the Administration’s Proposal*, 107th Cong., 2nd sess., June 25, 2002.

although the process by which procurement decisions are made has changed several times.⁶⁶ At this time, DHS manages a 10-year advance appropriation (through FY2013) to purchase countermeasures, and is responsible for conducting *Material Threat Determinations* (MTDs) to assess whether a particular hazard—such as an anthrax or sarin gas attack—poses a threat to national security. In response to an MTD, HHS evaluates the threat, and the potential need for countermeasures, in a public health context. Funds for development and procurement are drawn from the 10-year appropriation, with the approval of the President, following joint recommendations from the Secretaries of HHS and DHS. The 109th Congress established, in the PAHPA, the Biomedical Advanced Research and Development Authority (BARDA) in HHS to support countermeasure development and facilitate communication between the government and developers. The PAHPA also required the HHS Secretary to develop and publish a strategic plan to guide HHS countermeasures research, development, and procurement.⁶⁷

The BioShield program has experienced numerous problems over the years, and many have been resolved.⁶⁸ Key issues that remain are (1) the clarity of the shared roles of DHS and HHS; and (2) whether HHS can define contract terms that are perceived by product developers as sufficiently clear and lucrative to be worth their investment. The first concern appears to have improved over time, partly as a result of successive directives from Congress and the Bush Administration. Given the program's limited history of successful procurements, the second concern may persist and continue to be of interest to the 111th Congress.

Finally, intellectual property protections may affect the availability of countermeasures by making them more commercially attractive to developers, or more costly to purchasers, including governments.⁶⁹

Liability and Compensation

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.⁷⁰

In October 2008, HHS Secretary Leavitt made several such emergency declarations with respect to countermeasures for smallpox, anthrax, botulism, and acute radiation sickness, and amended a

⁶⁶ CRS Report RL33907, *Project BioShield: Appropriations, Acquisitions, and Policy Implementation Issues for Congress*, by Frank Gottron.

⁶⁷ In July, 2007, HHS published a draft plan. It has not been finalized. See HHS, Biomedical Advanced Research and Development Authority (BARDA), *Draft BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement*, Washington, DC, July 5, 2007, <http://www.hhs.gov/aspr/barda/documents/draftbardaplan.pdf>.

⁶⁸ See, for example, U.S. Government Accountability Office, *Project Bioshield: Actions Needed to Avoid Repeating Past Mistakes*, GAO-08-208T, October 23, 2007, <http://www.gao.gov>.

⁶⁹ CRS Report RL32917, *Bioterrorism Countermeasure Development: Issues in Patents and Homeland Security*, by Wendy H. Schacht and John R. Thomas; and CRS Report RL33159, *Influenza Antiviral Drugs and Patent Law Issues*, by Brian T. Yeh.

⁷⁰ CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows.

prior declaration for pandemic flu countermeasures.⁷¹ Each declaration is in effect through 2016, unless amended.

The law also establishes, in the U.S. Treasury, a “Covered Countermeasure Process Fund” to compensate those who may be harmed by a covered countermeasure. As of FY2009, the fund has not received an appropriation. No funding was requested in the annual budget submissions of the Bush Administration.

Expired Program Authorities

The 111th Congress may consider reauthorization of expired preparedness and response programs.⁷² These include authority for HHS health professions programs, which expired in 2002. These programs, in Title VII of the Public Health Service Act, aim to address underserved areas and populations, and have not focused on emergency preparedness and response in the past. However, the last reauthorization in 1998 preceded heightened concerns regarding this matter since 2001.⁷³ Also, although authority for the Strategic National Stockpile of countermeasures was amended since the terror attacks of 2001, general program authority expired at the end of FY2006 and has not been extended.⁷⁴ In addition, as discussed earlier, authority for the Select Agent program to regulate biological pathogens expired at the end of FY2007.

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⁷¹ Office of the Secretary, Department of Health and Human Services, *73 Federal Register* 58239, October 6, 2008; and *73 Federal Register* 61861-61873, October 17, 2008.

⁷² An inventory of expired and expiring authorities, organized by congressional committees of jurisdiction, is provided in Congressional Budget Office, *Unauthorized Appropriations and Expiring Authorizations*, Washington, DC, January 2009, <http://www.cbo.gov/doc.cfm?index=9960>.

⁷³ CRS Report RL32546, *Title VII Health Professions Education and Training: Issues in Reauthorization*, by Bernice Reyes-Akinbileje.

⁷⁴ Public Health Service Act § 319F-2; 42 U.S.C. § 247d-6b. See CRS Report RL33589, *The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law*, by Sarah A. Lister and Frank Gottron, for amendment to the program by the PAHPA.