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The Pandemic and All-Hazards Preparedness Act (S. 3678): Provisions and Comparison with Current Law and Related Proposals

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Summary

Authorities to direct federal preparedness for and response to public health emergencies are found principally in the Public Health Service Act (PHS Act). Two recent laws provided the core of these authorities: **P.L. 106-505**, the Public Health Threats and Emergencies Act of 2000 (Title I of the Public Health Improvement Act), and **P.L. 107-188**, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which reauthorized several existing authorities and created new ones in the aftermath of the 2001 terror attacks.

The laws above built upon existing broad authorities allowing or requiring the Secretary of Health and Human Services (HHS) to prepare for or respond to outbreaks of infectious disease and other unanticipated health threats. Other laws — such as those creating a new Department of Homeland Security (DHS) and a program (Project BioShield) to encourage the development of specific countermeasures that would not otherwise have a commercial market — have added to the federal government's slate of preparedness and response authorities as well. Further, the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act, administered by DHS), which authorizes federal assistance and other activities in response to presidentially declared emergencies and major disasters, is also, to some extent, a source of federal authority for the response to public health threats.

Authority for a number of preparedness and response programs in the PHS Act expires at the end of FY2006, and the 109th Congress is considering reauthorization. Expiring authorities include the position of the Assistant Secretary for Public Health Emergency Preparedness, grants to states to build public health and hospital capacity, and the National Disaster Medical System (NDMS), a national system of medical response teams. The response to Hurricane Katrina in 2005, and the threat of a possible influenza pandemic, each color the policy landscape as Congress assesses the adequacy of existing federal preparedness and response activities.

Several bills pending in the 109th Congress would address federal leadership for public health and medical preparedness and response, extend authority for certain expiring programs in the PHS Act, or both. These include **S. 3678** and **S. 3721**, which are both ready for floor consideration in the Senate, and **H.R. 5438**, which has been reported by the House Energy and Commerce Committee and is pending before the House Homeland Security Committee. S. 3678 would extend a number of expiring provisions in the PHS Act. S. 3721, while focused on amending provisions in the Homeland Security Act of 2002, also contains provisions regarding authority and coordination for public health and medical response, as does H.R. 5438. Each bill also addresses authority for NDMS.

A comparison of S. 3678 with current law and related bills, including S. 3721 and H.R. 5438, is provided in **Table 1**, later in this report. The report will be updated as circumstances warrant.

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Introduction

Authorities to direct federal preparedness for and response to public health emergencies are found principally in the Public Health Service Act (PHS Act). Two recent laws provided the core of these authorities: **P.L. 106-505, the Public Health Threats and Emergencies Act of 2000** (Title I of the Public Health Improvement Act), passed in response to the bombing of the Murrah federal building in Oklahoma City, the Tokyo sarin attack, and other incidents that raised concern about the threat of bioterrorism or other public health emergencies; and P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, passed following the September 11 and anthrax attacks in 2001.

The laws above built upon existing broad authorities allowing or requiring the Secretary of Health and Human Services (HHS) to prepare for or respond to bioterrorism, outbreaks of infectious diseases, and other unanticipated health threats. Other laws — such as those creating a new Department of Homeland Security (DHS) and a program (Project BioShield) to encourage the development of specific biological, chemical, and radiological defense countermeasures (e.g., vaccines and antidotes) that would not otherwise have a commercial market — have added to the federal government's slate of preparedness and response authorities as well. Further, the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act, administered by DHS), which authorizes federal assistance and other activities in response to presidentially declared emergencies and major disasters, is also, to some extent, a source of federal authority for the response to public health threats.

Authority for a number of preparedness and response programs in the PHS Act expires at the end of FY2006, and the 109th Congress is considering reauthorization. Expiring authorities include the position of the Assistant Secretary for Public Health Emergency Preparedness, grants to states to build public health and hospital capacity, and the National Disaster Medical System (NDMS), a national system of medical response teams. The response to Hurricane Katrina in 2005, and the threat of a possible influenza pandemic, each color the policy landscape as Congress assesses the adequacy of existing federal preparedness and response activities.

In August 2006, the Senate Committee on Health, Education, Labor and Pensions reported **S. 3678** (Burr), the Pandemic and All-Hazards Preparedness Act, which would extend a number of expiring programs in the PHS Act, and would

establish a leadership role for the Secretary of HHS in preparedness and response for public health threats. S. 3678 would also transfer authority for NDMS, now based in DHS, to HHS, where it was based before the creation of the Department of Homeland Security in 2002. The bill is ready for floor consideration in the Senate.

Also in August 2006, the Senate Committee on Homeland Security and Governmental Affairs reported **S. 3721** (Collins), the Post Katrina Emergency Management Reform Act of 2006, which would amend the Homeland Security Act of 2002 to retain the Federal Emergency Management Agency (FEMA) within DHS. Among other provisions affecting public health and medical preparedness and response, the bill would require clearer joint operational planning between HHS and DHS, and would retain NDMS in FEMA. The bill is ready for floor consideration in the Senate.

In May 2006, the House Energy and Commerce Committee reported **H.R. 5438** (Barton), the Public Health and Medical Emergency Coordination Act of 2006, which would establish HHS as the lead federal agency for public health and medical preparedness and response activities, and would transfer NDMS from DHS to HHS. The bill is pending before the House Homeland Security Committee.

The 109th Congress is also considering the expansion of authorities in the PHS Act to encourage the development of biodefense countermeasures, first established in **P.L. 108-276**, the Project BioShield Act of 2004.[1] Thus far, congressional action in this area has progressed independently of action to reauthorize public health and medical preparedness and response programs.

A comparison of S. 3678 with current law and related bills, including S. 3721 and H.R. 5438, is provided in **Table 1**, later in this report. The report will be updated as circumstances warrant.

Legislative History

The 109th Congress

One of the most difficult challenges faced by Congress and other policymakers following the 2001 terror attacks was that of envisioning those catastrophic threats for which the nation must be prepared, defining the capabilities needed to assure national preparedness, and determining the appropriate federal activities and effective incentives needed to achieve national preparedness among federal, state, and local governments, and the private sector. Both P.L. 106-505 and P.L. 107-188 called on the Secretary of HHS, in collaboration with other stakeholders, to define core national capacities for preparedness and response for public health and medical emergencies. The process has been a challenge, though recent efforts at DHS to develop national *Target Capabilities* have helped to define certain large-scale capabilities — such as rapid disease detection, mass prophylaxis, and medical surge

[1] For more information, see CRS Report RS21507, *Project BioShield*, by Frank Gottron.

— that would be required for an effective response to mass casualty incidents, and that would require a substantial federal coordinating effort.[2] **S. 3678**, reported in the Senate, would amend existing authority to require the Secretary of HHS to prepare a quadrennial National Health Security Strategy and implementation plan, to include preparedness goals for federal, state, and local governments in harmony with national preparedness and response efforts carried out by DHS.

In light of the response to Hurricane Katrina and efforts to prepare for a flu pandemic, Congress has debated whether federal responsibilities to address public health threats are clearly defined, particularly with regard to the respective roles of the Secretaries of HHS and DHS. Efforts are under way in the 109th Congress to review federal emergency and disaster response authorities in DHS, including the structure and organization of the Federal Emergency Management Agency (FEMA).[3] **S. 3678** and **S. 3721**, reported in the Senate, and **H.R. 5438**, reported in the House,[4] propose to establish or clarify the role of the Secretary of HHS in the federal response to public health emergencies. Other bills (e.g., **H.R. 5441**, the Department of Homeland Security Appropriations Act, 2007, passed by the Senate, and **H.R. 5351**, reported in the House[5]) would delegate certain of these authorities and responsibilities to DHS, through its Chief Medical Officer.

Since FY2002, Congress has provided approximately $7 billion in grants to states to build public health and hospital preparedness for public health threats. Presumably due to national security concerns and other sensitivities, HHS has not published comprehensive or state-specific information regarding states' performance toward meeting the objectives for these grant programs. Congress has been keenly interested in the management of these grants, on topics ranging from the relevance of broad program goals in achieving national preparedness, to the rigor of fiscal accounting mechanisms, to the balance of federal vs. state funding shares, to issues of program transparency. Several bills (e.g., **S. 3678**, reported in the Senate, and **S. 2792**, introduced in the Senate) propose modifications to these grant programs, for which authority expires at the end of FY2006. S. 3678 would extend the programs while adding certain new program elements, including federal authority to withhold funds for failure to meet program requirements, and a state matching requirement. S. 2792 would also authorize a matching requirement, and would require the Secretaries of HHS and DHS to develop a single Internet-based point of access from which states could apply for public health and hospital preparedness grants.

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[2] For more information, see CRS Report RL32803, *The National Preparedness System: Issues in the 109th Congress*, by Keith Bea.

[3] See CRS Report RL33369, *Federal Emergency Management and Homeland Security Organization: Historical Developments and Legislative Options*, by Henry B. Hogue and Keith Bea.

[4] H.R. 5438 has been reported by the House Committee on Energy and Commerce and has been referred to the House Committee on Homeland Security for further action.

[5] H.R. 5351 has been reported by the House Committee on Homeland Security and has been referred to the House Committees on Transportation and Infrastructure, and Energy and Commerce, for further action.

There has been considerable discussion in the 109th Congress regarding whether a public health disaster response could function effectively when NDMS, a key federal medical response asset, is based at DHS rather than at HHS.[6] Congressional and White House investigators each found that NDMS deployments in response to Hurricane Katrina were made by FEMA without the involvement of personnel at HHS.[7] The Administration "strongly supports" the transfer of NDMS to HHS, where it was based before the creation of DHS.[8] Others might contend that DHS should retain control over NDMS as part of its comprehensive response authority. Members of Congress have debated whether the concerns regarding NDMS operation and deployment are amenable to an administrative solution or whether relocation of the asset, requiring legislative action, is needed. Various bills in the 109th Congress propose to retain NDMS in DHS, or to transfer it back to HHS. Bills proposing NDMS retention in DHS include **S. 3721** (which is ready for Senate floor consideration), **H.R. 5351**, and **S. 3595**. Bills proposing the transfer of NDMS to HHS include **S. 3678** (which is ready for Senate floor consideration), **H.R. 5438**, reported in the House, and **H.R. 5441**, the Department of Homeland Security Appropriations Act, 2007, passed in the Senate. (The House-passed H.R. 5441 does not include a comparable provision.)

Authority for health professions programs in Title VII of the Public Health Service Act expired in 2002, and may be considered for extension by the 109th Congress. These programs, administered by the Health Resources and Services Administration (HRSA), are primarily intended to alleviate shortages and maldistributions of healthcare workers. The public health workforce has, in contrast, received little federal attention over the years. Congress may consider Title VII programs in the context of preparedness in both the public health and healthcare sectors.[9] **S. 506**, introduced in the Senate, would provide scholarship and loan repayment programs for health professionals who work in government public health agencies. **S. 3678**, reported in the Senate, would authorize a loan repayment demonstration project for individuals who serve in health professional shortage areas or areas at high risk of a public health emergency.

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[6] NDMS consists of a number of medical response teams that can deploy to a scene rapidly and set up field operations that are self-sustaining for up to 72 hours, until additional federal support arrives. Additional information about NDMS is available in CRS Report RL33096, *2005 Gulf Coast Hurricanes: The Public Health and Medical Response*, by Sarah A. Lister.

[7] See the U.S. House of Representatives, *A Failure of Initiative: The Final Report of the Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina*, p. 297, Feb. 2006, at [http://katrina.house.gov/]; U.S. Senate, Committee on Homeland Security and Governmental Affairs, *Hurricane Katrina: A Nation Still Unprepared*, chapter 24, p. 29, May 2006, at [http://hsgac.senate.gov/]; and the White House, *The Federal Response to Hurricane Katrina: Lessons Learned*, p. 47, Feb. 2006, at [http://www.whitehouse.gov/reports/katrina-lessons-learned/].

[8] Office of Management and Budget, "Statement of Administration Policy: H.R. 5441 — Department of Homeland Security Appropriations Bill, FY2007," Senate version, July 12, 2006, p. 2, at [http://www.whitehouse.gov/omb/legislative/sap/109-2/hr5441sap-s.pdf].

[9] For more information, see the section "Trends Affecting the Health Workforce: Emergency Preparedness," in CRS Report RL32546, *Title VII Health Professions Education and Training: Issues in Reauthorization*, by Bernice Reyes-Akinbileje.

Major Legislation in the 107th and 108th Congresses

Following the terror attacks of 2001, the 107th Congress passed the **Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188,** signed in June 2002, often called "the Bioterrorism Act") to improve the nation's readiness for bioterrorism, emerging infectious diseases, and other public health threats and emergencies. The program of grants for state and local public health capacity, administered by the Centers for Disease Control and Prevention (CDC), was reauthorized at $1.08 billion for FY2003, and such sums as may be necessary through FY2006.[10] (The program had previously been authorized at $50 million for FY2001, prior to the terror attacks.) The law stipulated a funding formula, including a base amount plus an amount determined by population, with the intent that every state and territory receive funding for a variety of core public health preparedness activities. Under prior statutory authority (see below), the grants had been competitive.

The Bioterrorism Act also established, for the first time, a program of grants to states to prepare hospitals, clinics and other healthcare facilities for bioterrorism and other mass-casualty events, to be administered by HRSA. Congress authorized $520 million for this program in FY2003, and such sums as may be necessary through FY2006.

The Bioterrorism Act contained a number of other provisions for public health preparedness. Title I of the Act included numerous additional provisions for building federal public health capacity, including creation of the position of Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) at HHS, and expansion of security and preparedness activities at CDC. Title I also expanded the program for the national stockpile of drugs to treat potential victims of terrorism or other public health emergencies, and changed its name from the National Pharmaceutical Stockpile to the Strategic National Stockpile (SNS). Title II of the Act called on the Secretary of HHS to register facilities (e.g., laboratories) and individuals in possession of *Select Agents,* those biological agents and toxins that pose a severe threat to public health and safety, and to promulgate new safety and security requirements for such facilities and individuals. Title III contained several provisions to protect the nation's food and drug supply and enhance agricultural security. Finally, Title IV of the act included provisions aimed at protecting the nation's drinking water supply, including authorizing $160 million to provide financial assistance to community water systems to conduct vulnerability assessments and prepare response plans.[11]

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[10] The authorization for FY2002 funds was signed in June 2002, after the actual emergency supplemental appropriation for FY2002 was passed in January 2002 and distribution of awards to states was imminent. Conferees reported (in H.Rept. 107-481, accompanying P.L. 107-188) that they did not intend to delay or disrupt the ongoing awards process, and directed the Administration to continue its current approach to the awards.

[11] For a summary of P.L. 107-188, see CRS Report RL31263, *Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188): Provisions and Changes to Preexisting Law,* by C. Stephen Redhead, Donna U. Vogt, and Mary E. Tiemann.

In creating the new Department of Homeland Security, the 107th Congress considered a variety of public health preparedness programs and where they would best be located. In the end, the **Homeland Security Act (P.L. 107-296**, signed in November 2002) transferred to the new department only the Metropolitan Medical Response System (a municipal grant program), NDMS, and budget authority for the SNS, leaving most public health preparedness and response activities in HHS. P.L. 107-296 directed the Secretary of HHS to collaborate with the Secretary of DHS in setting priorities for human health-related countermeasures research and development, and for all public health-related activities to improve state, local, and hospital preparedness and response, though these programmatic activities remained at HHS.

The **Project BioShield Act of 2004 (P.L. 108-276**, signed in July 2004) created market incentives for the development of drugs, vaccines, biologics, other treatments and tests for biological and chemical agents — collectively called *countermeasures* — that would not otherwise be attractive to entrepreneurs.[12] In addition, budget authority for the SNS was transferred from DHS back to HHS in the Act, though both the Secretaries of HHS and of DHS retain authority to deploy SNS assets in an emergency. CDC continues to provide administrative management of the SNS, as it always has.

Major Legislation Prior to the 2001 Terrorist Attacks

Prior to the terrorist attacks of 2001, Congress passed the **Public Health Threats and Emergencies Act of 2000 (Title I of the Public Health Improvement Act, P.L. 106-505**, signed in November 2000) to address growing concerns about bioterrorism and emerging infectious diseases, and about the ability of the public health system to respond. Among other provisions, the law authorized $50 million for FY2001 (and such sums as may be necessary through FY2006) for competitive grants to build capacity in state and local health departments. This and other provisions would augment several public health infrastructure programs begun by CDC in the 1990s, including grants to states for epidemiology and laboratory capacity, and the creation of the Laboratory Response Network to assure nationwide capability for testing of biological agents during an actual or suspected bioterrorism incident.

In the **Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104-132**, signed in April 1996), Congress called on the Secretary of HHS to establish a program to identify and list specific infectious agents that could be used for bioterrorism, and to require the registration of facilities (typically laboratories) shipping those agents. The resultant *Select Agent* program is overseen by CDC and the U.S. Department of Agriculture (USDA). Program authority was expended and extended through FY2007 in P.L. 107-188, in the aftermath of the anthrax attack.

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[12] For more information on Project BioShield, see CRS Report RS21507, *Project BioShield*, by Frank Gottron.

Additional Congressional Research Service (CRS) Reports

For more information regarding provisions in P.L. 107-188, see:

- CRS Report RL31263, *Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188): Provisions and Changes to Preexisting Law*, by C. Stephen Redhead, Donna U. Vogt, and Mary E. Tieman.

For more information regarding public health preparedness and response authorities and programs in general, and in the context of specific threats, see:

- CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister;
- CRS Report RL31719, *An Overview of the U.S. Public Health System in the Context of Emergency Preparedness*, by Sarah A. Lister;
- CRS Report RL33096, *2005 Gulf Coast Hurricanes: The Public Health and Medical Response*, by Sarah A. Lister; and
- CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister.

For more information regarding the Stafford Act and related preparedness and response planning activities in DHS, see:

- CRS Report RL33053, *Federal Stafford Act Disaster Assistance: Presidential Declarations, Eligible Activities, and Funding*, by Keith Bea; and
- CRS Report RL32803, *The National Preparedness System: Issues in the 109th Congress*, by Keith Bea.

For more information regarding Project BioShield, see:

- CRS Report RS21507, *Project BioShield*, by Frank Gottron.

Table 1. Comparison of Current Law with S. 3678 and Related Bills

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
National Preparedness and Response for Public Health Emergencies: Federal Authority, Leadership and Organization			
National Health Security Strategy, plan and capacities	Section 2801 of the Public Health Service (PHS) Act requires the Secretary of Health and Human Services (HHS), pursuant to PHS Act Section 319A, to develop and implement a national plan to prepare for and respond to bioterrorism and other public health emergencies. Establishes five national preparedness goals: (I) assist state and local governments in the event of bioterrorism or other public health emergencies; (ii) ensure that state and local governments have the capacity to detect and respond to such emergencies; (iii) develop and maintain countermeasures; (iv) ensure coordination and minimize duplication of federal, state, and local planning, preparedness, and response activities; and (v) enhance hospital and other healthcare facility readiness. Requires the Secretary to coordinate with state and local governments and develop outcome measures to evaluate progress in implementing the national plan and achieving its five goals. Requires the Secretary to report to Congress within 1 year, and biennially thereafter, on progress made towards meeting the national preparedness goals, including recommendations for new legislative	Repeals existing Sections 319A and 2801 of the PHS Act. Establishes a new Section 2802(a) of the PHSA, requiring the Secretary, beginning in 2009 and every 4 years thereafter, to prepare and submit to Congress a coordinated National Health Security Strategy and implementation plan for public health emergency preparedness and response. The strategy shall identify the process for achieving the preparedness goals described in subsection (b) and be consistent with the National Preparedness Goal, the National Incident Management System and the National Response Plan (NRP), developed by the Department of Homeland Security (DHS), or any successor plan. The strategy and plan shall include an evaluation of progress made by federal, state, local, and tribal entities toward preparedness, and a strategy to establish a prepared public health workforce. Establishes a new Section 2802(b) of the PHS Act requiring that the National Health Security Strategy include preparedness goals for: (1) integration of response capabilities and systems;	

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
	authority to protect public health. [42 U.S.C. § 300hh] Section 319A of the PHS Act requires the Secretary, together with state and local health officials, to establish those capacities needed for national, state, and local public health systems to be able to detect, diagnose, and contain outbreaks of infectious disease, drug-resistant pathogens, or acts of bioterrorism. Authorizes $4 million for FY2001, and such sums as may be necessary for FY2002 — FY2006. [42 U.S.C. § 247d-1]	(2) capabilities for public health preparedness and response; (3) capabilities for medical preparedness and response; (4) provisions for the needs of "at risk" individuals (defined as children, pregnant women, senior citizens and other individuals who have special needs in the event of a public health emergency, as determined by the Secretary); (5) coordination of federal, state, local, and tribal planning, preparedness, and response activities; and (6) continuity of federal, state, local, and tribal operations in the event of a public health emergency. [Section 103]	
Federal leadership for public health and medical preparedness and response	No applicable provision.	Repeals the existing Section 2801 of the PHS Act and establishes a new Section 2801 requiring the Secretary to lead all federal public health and medical response to public health emergencies and incidents covered by the NRP or any successor plan. The Secretary shall, in collaboration with the Secretaries of Veterans Affairs (VA), Defense (DOD), Transportation, Homeland Security, and the head of any other relevant federal agency, and consistent with the NRP or successor plan, establish an interagency agreement under which the Secretary shall assume operational control of emergency public health and medical response assets, as necessary, in the event of a public health emergency. [Section 101]	**S. 3721** (reported in the Senate) requires the Secretaries of DHS and HHS to establish a memorandum of understanding defining the roles and responsibilities of their respective departments in providing for public health and medical care under the NRP, or in the event that the Secretary of HHS declares a public health emergency under section 319 of the PHS Act. Requires the Secretary of DHS, in conjunction with other federal departments and agencies, to develop strategic and operational plans to respond effectively to natural or man-made disasters, in support of the NRP. Among other requirements, the DHS Secretary's planning shall address preparedness and deployment of health and

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
			medical resources, including clearly defining the responsibility for logistics, security, and other support assets, and the ability to track these resources. [Section 404] **H.R. 5438** (reported by the House Cmte. on Energy and Commerce, referred to the House Cmte. on Homeland Security) amends Section 2811 of the PHS Act to state that HHS shall be the primary agency for the coordination of federal assistance to supplement state, local, and tribal resources for preparing for or responding to a bioterrorist attack or other public health or medical emergency. [Section 3]
Assistant Secretary	Section 2811(a) of the PHS Act authorizes the appointment of an Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) in HHS to: coordinate all HHS preparedness and response activities related to bioterrorism and other public health emergencies; coordinate HHS efforts to bolster state and local emergency preparedness for a bioterrorist attack or other public health emergency, and evaluate the progress of such entities in meeting the benchmarks and other outcome measures contained in the national plan and in meeting the core public health capabilities established	Redesignates the existing PHS Act Section 2811 as Section 2812 and creates a new Section 2811 to establish within HHS the position of Assistant Secretary for Preparedness and Response (ASPR), to be appointed by the President and confirmed by the Senate. Upon enactment, transfers to the ASPR all functions, personnel, assets and liabilities of the ASPHEP. The ASPR shall: (1) advise the Secretary on matters relating to public health and medical preparedness and response; (2) manage and have the authority to deploy federal public health and medical personnel including the National Disaster Medical System (NDMS); (3)	**S. 3042** creates in HHS a new position of Assistant Secretary for Public Health, encompassing the existing authorities and responsibilities of the ASPHEP, who is responsible in general for HHS preparedness and response activities, and the Assistant Secretary for Health, who, among other duties, oversees the Surgeon General and the Commissioned Corps of the U.S. Public Health Service. [Section 105]

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
	pursuant to 319A; and interface with other federal agencies and state and local entities. This position does not require Senate confirmation. Authorizes such sums as may be necessary for FY2002 — FY2006. [42 U.S.C. § 300hh-11]	oversee the advanced research, development and procurement of countermeasures pursuant to Sections 319F-1 and 319F-3, and maintain the Strategic National Stockpile (SNS); (4) coordinate with relevant federal, state, local and tribal health officials to ensure integration of preparedness and response activities, and to promote improved emergency medical services with respect to public health emergencies; (5) provide logistical support for medical and public health aspects of federal response to public health emergencies, in coordination with the Secretaries of VA and Homeland Security, the General Services Administration and other public and private entities; and (6) provide leadership in international programs, initiatives and policies dealing with public health and medical emergency preparedness and response. The ASPR shall have authority over and responsibility for the functions, personnel, assets and liabilities of NDMS, the Hospital Preparedness Cooperative Agreement (pursuant to Section 319C-2, as designated in this Act), and the Public Health Preparedness Cooperative Agreement (pursuant to Section 319C-1); and shall coordinate the Medical Reserve Corps (pursuant to Section 2813, as designated in this Act), the Emergency System for the Advance Registration of Volunteer Health Professionals (pursuant to Section 319I); the SNS; and the Cities Readiness Initiative. [Section 102]	

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
Assessing public health needs	PHS Act Section 319B authorizes grants to states and local public health departments to evaluate the extent to which they can achieve the capacities identified pursuant to Section 319A. Requires the Secretary to develop a national framework for the evaluations. Authorizes $45 million for FY2001, and such sums as may be necessary for FY2002 - FY2003. [42 U.S.C. § 247d-2]	Repeals Section 319A of the PHS Act. Does not modify Section 319B.	**S. 3042** amends Section 319B of the PHS Act to require the Secretary, not later than 180 days after enactment, to establish and review annually, guidelines for grantees to assess their preparedness, and to evaluate performance. Such guidelines shall define the responsibilities of the public health entities involved, and describe the activities that are the responsibility of the federal government, the state and local public health authorities, healthcare providers, and other organizations, respectively, consistent with the NRP. Authorizes $75 million for FY2007 and such sums as may be necessary for subsequent fiscal years.
Public health emergency authorities and emergency fund	PHS Act Section 319 authorizes the Secretary to determine that a public health emergency exists, establishes the Public Health Emergency Fund, and authorizes such sums as may be necessary. Requires an annual report to Congress on expenditures from the Fund. Requires the Secretary to notify Congress within 48 hours of declaring a public health emergency. Provides that public health emergencies expire by announcement of the Secretary or after 90 days, whichever comes first, and permits the Secretary to renew emergency declarations, subject to the same 90-day limitation. Allows the Secretary during a public health emergency to waive deadlines for the submission of data and reports	(EMTALA provision: see below)	**S. 1769** amends PHS Act Section 319 to state that determinations of a public health emergency shall specify the geographic area to which such determinations apply. Authorizes the Secretary, upon such a determination and in the area to which it applies, to waive certain statutory requirements, and to apply such waivers retroactively, including: extensions of certain administrative, reporting and budget deadlines; requirements regarding the eligibility of adults and children for participation in vaccine access programs authorized in Section 317 of the PHS Act and Section 1928 of the Social Security Act; federal matching requirements for programs in the PHS Act; provisions related to the designation of

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
	by individuals or public or private entities pursuant to any law administered by the Secretary. Requires the Secretary to notify Congress of such an action and publish a notice in the *Federal Register*. [42 U.S.C. § 247d] Authorizes the Secretary to modify or waive certain statutory or regulatory requirements following a determination of a public health emergency pursuant to PHS Act Section 319 AND an emergency or disaster declaration by the President pursuant to the National Emergencies Act [50 U.S.C. § 1601] or the Stafford Act [42 U.S.C. § 5121 et seq.]. Requirements that may be waived or modified include: (1) conditions of participation and certain other requirements in the Medicare, Medicaid and SCHIP programs; (2) federal requirements for state licensure of health professionals; (3) certain provisions of the Emergency Medical Treatment and Active Labor Act of 1985 (EMTALA: see additional information below); (4) certain sanctions prohibiting physician self-referral (so-called "Stark" provisions); (5) modification, but not waiver, of deadlines and timetables for performance of required activities; (6) limitations on certain payments for health care items and services furnished to individuals enrolled in a Medicare + Choice plan; and (7) sanctions and		health workforce shortage areas; certain licensing requirements for physicians and other health professionals who volunteer to provide medical services; and certain provisions in the federal Food, Drug, and Cosmetic Act related to the administrative detention of foods. The Secretary shall notify Congress of any such waivers within 2 days, and shall publish in the *Federal Register* a notice of such waivers in a timely manner. [Section 101] Authorizes the Secretary, when a determination of a public health emergency has been made, to extend the maximum period of assistance to states in Section 311 of the PHS Act from six months to 18 months, with respect to assistance to geographic areas that are the subject of such a determination. [Section 201] Requires the Secretary, within 120 days of enactment, to submit to Congress a report on specific regulatory requirements and funding formulas under the PHS Act that would assist the Secretary in responding to a public health emergency, as declared under Section 319. [Section 302] **S. 3042** establishes a Bioterrorism and Public Health Response Emergency Fund to provide short-term assistance to hospitals, federally qualified health centers, rural health clinics, public health laboratories, and other healthcare providers and other members of the public health

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
	penalties that arise from noncompliance with certain patient privacy requirements of the Health Insurance Portability and Accountability Act of 1996. [42 U.S.C. § 1320b-5]		workforce, as determined appropriate by the Secretary, in the event of bioterrorism or other public health emergency. Authorizes such sums as may be necessary for FY2007 and each subsequent fiscal year. [Section 2813]
Public health emergency authorities — EMTALA[a]	EMTALA: When there is a concurrent public health emergency determination pursuant to PHS Act Section 319 [42 U.S.C. § 247d] AND an emergency or disaster declaration by the President pursuant to either the National Emergencies Act [50 U.S.C. § 1601] or the Stafford Act [42 U.S.C. § 5121 et seq.], the Secretary may waive certain EMTALA requirements [42 U.S.C. § 1395dd] as follows: if a hospital within such a declared emergency area implements its disaster protocol as a consequence of the emergency, the hospital may be exempt, for 72 hours, from the prohibitions against the transfer of a non-stabilized individual, and the direction or relocation of individuals to an alternate location for medical screening pursuant to an appropriate state emergency preparedness plan. [42 U.S.C. § 1320b-5]	Amends Section 1135(b) of the Social Security Act [42 U.S.C. § 1320b-5(b)] regarding the waiver of EMTALA requirements when there is a concurrent public health emergency determination pursuant to PHS Act Section 319 AND an emergency or disaster declaration by the President pursuant to the National Emergencies Act [50 U.S.C. § 1601] or the Stafford Act [42 U.S.C. § 5121 et seq.], as follows: If the public health emergency declared pursuant to Section 319 of the PHS Act involves a pandemic infectious disease: (1) the Secretary's waiver or modification of EMTALA requirements regarding direction of individuals to alternate locations for medical screening shall be pursuant to the appropriate state emergency preparedness or pandemic plan; and (2) if a hospital within such a declared emergency area implements its disaster protocol as a consequence of the emergency, the hospital may be exempt, for 60 days or until the termination of the Secretary's declaration, whichever is sooner, from the prohibitions against the transfer of an individual who has not been stabilized and the direction of individuals to an	

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		alternate location for medical screening. This provision is effective upon enactment. [Section 302]	
Federal assistance to states	Section 311(c)(2) of the PHS Act authorizes the Secretary of HHS, at the request of the appropriate state or local authority, to extend temporary (not in excess of six months) assistance to states or localities in meeting health emergencies of such a nature as to warrant federal assistance. The Secretary may, for such assistance provided, require reimbursement as he determines reasonable under the circumstances. Any reimbursement so paid shall be credited to the applicable appropriation for the U.S. Public Health Service for the year in which such reimbursement is received. [42 U.S.C. § 243(c)(2)]	No applicable provision.	**S. 1769** amends Section 311 of the PHS Act to provide that if the Secretary declares a public health emergency pursuant to section 319 of the PHS Act, the six-month limitation for assistance to states may be extended for a period not to exceed 18 months, with respect to assistance to geographic areas that are the subject of such declaration. [Section 201]
Federal working groups and advisory committees	PHS Act Section 319F, subsections (a) through (d) creates a single interagency working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies, to be established by the Secretary in coordination with other federal officials. Requires the working group or its subcommittees to meet periodically to consult on, assist in and make recommendations on topics related to preparedness and response for bioterrorism and other public health emergencies (including research and development for	Repeals existing PHS Act Section 319F, subsections (a) through (d).	

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	countermeasures to treat, prevent, and identify exposure to biological agents). Establishes the National Advisory Committee on Children and Terrorism and the Emergency Public Information and Communications (EPIC) Advisory Committee, both of which sunset after one year. Requires the Secretary to develop a strategy to communicate information on bioterrorism and other public health emergencies, and recommends establishing a federal website on bioterrorism. [42 U.S.C. § 247d-6]		
Grants for Public Health and Hospital Preparedness			
Grants to states for public health preparedness	Section 319C-1 of the PHS Act requires the Secretary to make awards to eligible entities to improve public health preparedness and response to bioterrorism and other public health emergencies. Eligible entities are states, political subdivisions of states, or consortia of subdivisions. Eligible entities must have completed a Section 319B evaluation of core public health capacity needs and must, within 60 days of receiving an award, submit an emergency preparedness and response plan describing the activities to be carried out. Use of funds for preparedness and response to bioterrorism and outbreaks of infectious disease takes priority over other public health emergencies, subject to any modification in the assessment of risk by the Secretary. Authorizes $1.08 billion for FY2003 for block grants to states and territories, and such sums as may be necessary for FY2004 —	Repeals and replaces PHS Act Sections 319C-1(a) through (I) and amends remaining subsections. Defines eligible entities as states, consortia of states, or certain political subdivisions of states. Grantees shall prepare and submit to the Secretary, as required, an All-Hazards Public Health Emergency Preparedness and Response Plan, to contain information including pandemic influenza planning and certain additional criteria. Grantees shall submit to the Secretary, as required, reports regarding the annual conduct of drills, grantees' performance according to standards defined by the Secretary, and other information. Eligible entities shall, by FY2009, participate in the Emergency System for Advance Registration of Volunteer Health Professionals. Awards shall be used to achieve the preparedness goals described under the following subsections of Section 2802(b) (as established in this Act)	**S. 2792** amends PHS Act Section 319C-1 to, among other provisions, require the Secretary to develop and apply measurable critical benchmarks and performance standards to grantees. Extends program authority through FY2010. [Section 2] **S. 3042** amends PHS Act Section 319C-1, to require: the concurrence of the governor or chief elected official of the eligible entity, and of local jurisdictions, with the annual application; and additional planning requirements, including the conduct of drills. Requires the Secretary to establish performance standards for grantees, to conduct biennial evaluations of grantee performance, and to report on such evaluations publicly, to the extent that the Secretary determines such availability does not threaten

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	FY2006. Note: The requirement that public health preparedness funding be awarded as block grants applies only to FY2003; greater flexibility in awarding funding is provided to the Secretary beyond FY2003. [42 U.S.C. § 247d-3a] Note: The funding formula and certain other administrative requirements are established jointly for both the public health and hospital preparedness grants, and are described in later sections.	regarding: (1) integration; (2) public health capability; (4) the needs of at-risk individuals; (5) coordination; and (6) continuity of operations. (Note: Goal #3, medical capability, is not a required activity for these grants.) The Secretary shall consult with the Secretary of DHS to assure the coordination of relevant activities. Authorizes $824 million for awards for FY2007 and such sums as may be necessary for FY2008 — FY2011, and $10 million for FY2007 for a study of best practices for required drills. [Section 201] Note: The funding formula and certain other administrative and fiscal requirements are established jointly for both the public health preparedness grants described here and the hospital preparedness grants described below. These administrative and fiscal requirements, in Sections 319C-1(g) and (I), as established in this Act, are described in later sections.	national security. Establishes criteria for withholding of funds and designates a maximum carryover amount. Extends program authority through FY2010. [Section 103]
Grants for hospital and health system preparedness	Section 319C-1 of the PHS Act requires the Secretary to make awards to eligible entities to enhance the preparedness of hospitals (including children's hospitals), clinics, health centers, and primary care facilities, for bioterrorism and other public health emergencies, and for related planning and administrative activities. Eligible entities are states, political subdivisions of states, or consortia of subdivisions. Authorizes $520 million for FY2003 and such sums as may be necessary for FY2004 — FY2006. [42 U.S.C. § 247d-3a]	Repeals the existing PHS Act Section 319C-2 and substitutes a new Section 319C-2, which requires the Secretary to award competitive grants to eligible entities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. Eligible entities shall be: (1) "partnerships" of: (I) one or more hospitals, at least one of which shall be a designated trauma center; AND (ii) one or more other local health care facilities, including clinics, health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes; AND (iii) one or more states, one or more political subdivisions of states, or consortia of the	

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	Note: The funding formula and certain other administrative requirements are established jointly for both the public health and hospital preparedness grants, and are described in later sections. Section 319C-2 of the PHS Act authorizes grants to improve community and hospital preparedness for bioterrorism and other public health emergencies. Eligible entities are partnerships between one or more hospitals (or other healthcare facilities) and one or more states and/or local governments. Grant proposals must be coordinated and consistent with the state's emergency preparedness and response plan. Use of funds for preparedness and response to bioterrorism and outbreaks of infectious disease takes priority over other public health emergencies, subject to any modification in the assessment of risk by the Secretary. Authorizes such sums as may be necessary for FY2004 — FY2006. [42 U.S.C. § 247d-3b]	two; or (2) states, political subdivisions of states, or consortia of the two, that are eligible for public health preparedness grants pursuant to Section 319C-1(b)(1) (as designated in this Act), provided that such entities assure the Secretary that they will retain not more than 25% of the award for administrative and other support functions. Eligible entities shall submit applications for awards to include such information as the Secretary may require, and consistent with the states' All-Hazards Public Health Emergency Preparedness and Response Plan and other relevant state and local activities. Awards shall be used to achieve the preparedness goals described under the following subsections of Section 2802(b), as established in this Act: (1) integration; (3) medical capability; (4) the needs of at-risk individuals; (5) coordination; and (6) continuity of operations. (Note: Goal #2, public health capability, is not a required activity for these grants.) In making awards the Secretary shall consider whether proposals: would enhance coordination among the variety of health system partners in the area; would include one or more NDMS-participating hospitals; and are for areas that, as determined by the Secretary in consultation with the Secretary of DHS, face a high degree of risk or have a significant need for funds to achieve the required preparedness goals. Authorizes $474 million for FY2007 and such sums as may be necessary for FY2008 — FY2011. The Secretary may reserve a portion of	

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		this amount to make awards for "partnership" entities as described in subsection (b)(1)(A), as established in this Act. Remaining amounts for award to states and political subdivisions shall be allocated according to the formula and other requirements in Section 319C-1(h), as established in this Act. [Section 305] Note: The funding formula and certain other administrative and fiscal requirements are established jointly for both the hospital preparedness grants described here, and the public health preparedness grants. These administrative and fiscal requirements, in Sections 319C-1(g) and (I), as established in this Act, are described below.	
Grants for public health and hospital preparedness — funding formula, risk-based funding, and pass-through requirement	Note: Provisions described here apply to both the public health and hospital preparedness grants established in PHA Act Section 319C-1. PHS Act Section 319C-1(j) requires the Secretary, for FY2003, to award block grants to states and territories for public health and hospital preparedness, with each state/territory guaranteed a minimum level of funding, plus an additional amount based on population. Establishes different minimum amounts for states and for territories, based upon the available appropriation. The District of Columbia and the Commonwealth of Puerto Rico are considered states for the purposes of this section.	Note: Provisions described here apply to both the public health preparedness grants established in Section 319C-1 of this Act, and the hospital preparedness partnership grants established in Section 319C-2 of this Act. Amends PHS Act Section 319C-1, redesignating subsection (j) as subsection (h), and requiring that the Secretary maintain the funding formula, as it applies in current law to FY2003, through FY2011. Authorizes the Secretary, for FY2007, to make awards for certain political subdivisions, as such authority applies in current law to FY2003.	

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	Authorizes the Secretary, for FY2003, to make awards for certain political subdivisions, as follows: the Secretary may reserve a portion of appropriations to make awards to not more than 3 political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. Authorizes the Secretary, for FY2003, to reserve a portion of appropriations for awards to eligible entities that have an additional unmet need to build capacity to identify, detect, monitor, and respond to public health threats, and that face a particularly high degree of risk of such threats. The Secretary shall consider the District of Columbia to have a significant unmet need, and to face a particularly high degree of risk for such purposes, on the basis of the concentration of entities of national significance located within the District. Requires the Secretary, for FY2003, to ensure that appropriate portions of such awards are made available to political subdivisions, local health departments, hospitals (including children's hospitals), clinics, health centers, or primary care facilities, or consortia of such entities. [42 U.S.C. § 247d-3a]	Authorizes the Secretary, for FY2007, to make awards for additional unmet need, as such authority applies in current law to FY2003. Requires the Secretary to ensure that awardees make available appropriate portions of awards to political subdivisions and local departments of public health through a process involving the consensus, approval or concurrence with such local entities. [Section 201]	

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Grants for public health and hospital preparedness — performance measurement and withholding of funds	Note: Provisions described here apply to both the public health and hospital preparedness grants established in PHA Act Section 319C-1. Section 319A of the PHS Act requires the Secretary to establish, by June 2003, and revise every five years, capacities for national, state and local public health systems to combat public health threats. Section 319B requires the Secretary to award grants to states to conduct assessments of their status with respect to these capacities. [42 U.S.C. §§ 247d-1, d-2]	Note: Provisions described here apply to both the public health preparedness grants established in Section 319C-1 of this Act, and the hospital preparedness partnership grants established in Section 319C-2 of this Act. Establishes a new PHS Act Section 319C-1(g) requiring the Secretary, within 180 days of enactment, to: (1) develop and apply measurable evidence-based benchmarks and objective standards to measure grantees' preparedness; and, (2) develop criteria for state pandemic influenza plans. The Secretary shall provide appropriate technical assistance to grantees, and develop and implement a process to notify grantees of their failure to meet requirements established in (1) and (2). Establishes formulas by which the Secretary shall withhold portions of awards from grantees that fail to meet requirements. Requires the Secretary to reallocate any such amounts to hospital and health system "partnership" entities described in Section 319C-2(b)(1) (as established in this Act), giving preference to entities in states from which amounts are withheld. Amounts withheld are increased for consecutive failures. Authorizes the Secretary to waive or reduce withholding for one or more grantees if there are mitigating factors. [Section 201]	**S. 2792** amends PHS Act Section 319C-1 (applying to both public health and hospital preparedness grants) to require the Secretary to develop and apply measurable critical benchmarks and performance standards to the grant programs, including requirements for annual drills and submission of annual expenditure reports. Requires the Secretary to give preference in making awards to entities that demonstrate in their applications approaches that would enhance coordination among the variety of healthcare facilities in the area. [Section 2]

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Grants for public health and hospital preparedness — matching requirement	No applicable provision.	Note: Provisions described here apply to both the public health preparedness grants established in Section 319C-1 of this Act, and the hospital preparedness partnership grants established in Section 319C-2 of this Act. Amends PHS Act Section 319C-1, adding a new requirement, beginning in FY2009, that awardees make available non-federal funds to support the cooperative agreements, in the amount of 5% of the total amount for the first fiscal year, and 10% of the total amount for the second and subsequent fiscal years. Non-federal amounts may be provided directly or through public or private donations, and may be in cash or in kind. [Section 201]	**S. 1769** authorizes the Secretary to waive federal matching requirements under any provision of the PHS Act, when the Secretary has declared a public health emergency pursuant to Section 319 of the Act and determines that an entity in an affected area is unable to provide funds. The Secretary may grant such a waiver for the fiscal years covered by such emergency declaration. [Section 101] **S. 2792** prohibits the Secretary from making a grant to a state under Section 319C-1 unless the state agrees to make available, directly or through public or private donations, non-federal contributions toward such costs in an amount equal to: with respect to a state with a population of more than 2 million, not less than $1 for each $1 of federal funds; and, with respect to a state with a population of 2 million or less, not less than $1 for each $4 of federal funds provided in the grant. [Section 2]
Grants for public health and hospital preparedness — maintenance of state funding	Note: Provisions described here apply to both the public health and hospital preparedness grants established in PHA Act Section 319C-1. PHS Act Section 319C-1, subsection (j), requires that amounts appropriated to states for public health and hospital preparedness be used to supplement and not supplant other state and local	Note: Provisions described here apply to both the public health preparedness grants established in Section 319C-1 of this Act, and the hospital preparedness partnership grants established in Section 319C-2 of this Act. For awards for public health and hospital preparedness made pursuant to PHS Act Sections	

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	public funds provided for activities under this section. [42 U.S.C. § 247d-3a(j)]	319C-1 and 319C-2, as established in this Act, grantees shall maintain expenditures for public health or health care preparedness, respectively, at a level not less than the average level of such expenditures maintained by the grantee for the preceding two-year period. Clarifies that awards may be used to pay salary and related expenses of public health and other professionals employed by state, local, or tribal agencies, who are carrying out activities supported by such awards, regardless of whether the primary assignment of such personnel is to carry out such activities. [Sections 201 and 305]	
Grants for public health and hospital preparedness — additional fiscal and administrative provisions	No applicable provisions.	Note: Provisions described here apply to both the public health preparedness grants established in Section 319C-1 of this Act, and the hospital preparedness grants established in Section 319C-2 of this Act. Establishes a new PHS Act Section 319C-1(I), requiring grantees to submit to the Secretary annual reports describing funded activities, performance with respect to program goals and objectives, appropriate budget information, and other requirements. Grantees shall, not less than every two years, conduct an independent audit of program expenditures. For activities not in accordance with program requirements, and after notice and opportunity for a hearing, grantees shall repay to the United States such amounts as	

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		determined by the Secretary; and the Secretary may withhold payment of funds for such activities. Requires the Secretary, in consultation with states and political subdivisions, to determine maximum annual percentages of awards that may be carried over into the next fiscal year. Amounts exceeding this percentage shall be returned to the Secretary for reallocation to hospital and health system "partnership" entities described in Section 319C-2(b)(1) (as established in this Act), giving preference to entities in states from which amounts are withheld. Provides for grantees to appeal such withholdings, and for the Secretary to grant waivers.	
Other Public Health Capacities			
Public health surveillance and information technology networks	PHS Act Section 319D(a) recognizes CDC's essential role in defending against and combating bioterrorism and other public health emergencies. Section 319D(b) provides for the establishment of public health alert communications and surveillance networks and requires the Secretary, within one year and in cooperation with health care providers and state and local public health officials, to establish technical and reporting standards for such networks. Section 319D(c) authorizes such sums as may be necessary for FY2002 — FY2006 to national communications and surveillance networks. [42 U.S.C. § 247d-4(b)]	Amends PHS Act Section 319D(a) to recognize CDC's role in defending against and combating public health threats both domestically and abroad. Creates a new PHS Act Section 319D(d) to require that the Secretary: within two years of enactment, establish a nationwide interoperable near real-time electronic public health "situational awareness" (surveillance) network; within 180 days of enactment, submit to Congress a strategic plan outlining steps to develop, implement, and evaluate the network; and develop program elements and required activities. Creates a new Section 319D(e) authorizing the Secretary to award grants to states to enhance surveillance	**S. 2792** would create a new Section 311A of the PHS Act authorizing the Secretary to develop a national real-time surveillance program for notifiable diseases and conditions. Within 180 days of enactment, the Secretary, in consultation with state and local health authorities and others, shall certify a list of infectious diseases, environmental exposures or poisons, and other conditions for which real-time surveillance and control constitute a critical public health need. Requires the CDC Director to establish and maintain a national electronic surveillance program in compliance with certain regulations promulgated under the Health Insurance

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		capability, for activities consistent with interoperability and other technological standards, and other requirements determined by the Secretary. Requires, within four years of enactment, that the Government Accountability Office conduct an independent evaluation, and submit to the Secretary and the Congress a report concerning the activities conducted under subsections (d) and (e). Creates a new Section 319D(f) authorizing the Secretary to make awards to hospitals, clinical laboratories, universities, poison control centers or professional organizations in the field of poison control, and to other situational awareness network participants to enhance medical detection and reporting capability. Authorizes $102 million for FY2007 for subsections (d), (e), and (f), of which $35 million is to carry out subsection (f); and such sums as may be necessary to carry out subsections (d), (e), and (f) for FY2008 — FY2011. [Section 202]	Portability and Accountability Act of 1996, and certain other requirements. The CDC Director shall analyze and report on information obtained through this program. The Secretary shall provide technical assistance (which may include financial assistance) to government and private program participants. Requires healthcare providers receiving reimbursements through the Medicare and Medicaid programs to register with the Secretary to receive health alerts in the case of a public health emergency or other circumstance requiring active surveillance. Requires the Secretary to make awards to states to conduct notifiable disease surveillance, and to withhold, from states determined not to be reporting in a timely manner, funding through the Preventive Health and Health Services Block Grant (Part A of Title XIX of the PHS Act). In addition, healthcare providers or facilities shall not be eligible to receive Medicare or Medicaid reimbursement if the Secretary determines, based on a state notification, that such provider or facility has consistently failed to report to the state, in a timely manner, instances of notifiable diseases. Authorizes such sums as may be necessary to carry out this section. [Section 3]
Strategic National Stockpile	PHS Act Section 319F-2 provides statutory authority for a Strategic National Stockpile (SNS) of drugs, vaccines, medical devices, and other supplies to meet the nation's health security needs in the event of a bioterrorist attack or other public	No applicable provision.	

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	health emergency. Requires the Secretary to manage the SNS, in coordination with the Secretaries of DHS and VA, and ensure its physical security. Protects information on stockpile locations from disclosure under the Freedom of Information Act. Both the Secretary of HHS [42 U.S.C. § 247d-6b(a)(2)(G)] and the Secretary of DHS [6 U.S.C. § 312] have authority to deploy the SNS. Authorizes $640 million for FY2002 and such sums as may be necessary for FY2003 — FY2006, in addition to amounts in a special reserve fund, and authorizes, for smallpox vaccine development, $509 million for FY2002 and such sums as may be necessary for FY2003 — FY2006. [42 U.S.C. § 247d-6b]		

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Programs to address national shortages of health professionals	Section 319H of the PHS Act authorizes a grant program to provide financial assistance for the education and training of individuals in any category of the health professions where there is a shortage that the Secretary determines should be alleviated to improve public health emergency readiness. Authorizes such sums as may be necessary for FY2002 — FY2006. [42 U.S.C. § 247d-7a] Section 338L of the PHS Act authorizes demonstration projects for loan repayment programs for chiropractic doctors and pharmacists, subject to the eligibility criteria, service obligations and breach of contract provisions of the National Health Service Corps (NHSC) program. [42 U.S.C. § 254t]	Amends Section 338L of the PHS Act to require the Secretary, depending upon an appropriation, to establish a demonstration project for the participation of individuals who are eligible for the NHSC loan repayment program described in PHS Act Section 338B et seq. [42 U.S.C. § 254l-1 et seq.] and who agree to serve in a state health department that serves a significant number of health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary, or in a local health department that serves a health professional shortage area or an area at risk of a public health emergency. Eligible individuals must have a degree, or be enrolled in an approved course of study, in medicine, osteopathic medicine, dentistry, an appropriate program of behavioral and mental health, or another health profession, or be certified as a nurse midwife, nurse practitioner, or physician assistant. Health professionals receiving such assistance shall comply with the service obligations, breach of contract, and other relevant provisions of the NHSC program, and shall agree to serve for a period of not less than two years. Individuals placed pursuant to this demonstration project shall not be considered by the Secretary in making shortage designations during FY2007 — FY2010. The Secretary shall report to Congress not later than three years after enactment regarding participation in the project and the impact of such participation on state, local and tribal health departments. Authorizes such sums as may be necessary for FY2007 — FY2010.	**S. 506** and **S. 3042** amend Title VII, Part E of the PHS Act, requiring the Secretary to establish a Public Health Workforce Scholarship Program to assure an adequate supply of public health professionals, and to eliminate public health preparedness workforce shortages in federal, state, local, and tribal public health agencies, by offering four-year scholarships in return for employment at such agencies. Authorizes $35 million for FY2006 and such sums as may be necessary for FY2007 — FY2011. Requires the Secretary to establish a Public Health Workforce Loan Repayment Program to provide for the repayment of loans incurred by individuals in the pursuit of relevant public health preparedness workforce educational degrees or certificates, in exchange for work at such agencies for at least three years. Requires the Secretary to award grants to public health agencies that receive public health preparedness cooperative agreements from HHS to operate state, local, and tribal public health workforce loan repayment programs. Authorizes, for the loan repayment and state grants programs, $195 million for FY2006, and such sums as may be necessary for FY2007 — FY2011.

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		Authorizes the Secretary to make awards to states to assist them in operating loan repayment programs for individuals who agree to serve in state, local, or tribal health departments that serve health professional shortage areas or other areas at risk of a public health emergency, as designated by the Secretary. Establishes loan eligibility criteria. Authorizes such sums as may be necessary for FY2007 — 2010. [Section 203]	Requires the Director of the Office of Personnel Management (OPM), in cooperation with the Secretary, to ensure that there is an online catalogue, within the OPM website, of public health workforce employment opportunities within the federal government. [S. 506, Section 3, and S. 3042, Section 201]
Vaccine tracking and distribution	No applicable provision.	Repeals existing Section 319A of the PHS Act and creates a new Section 319A, which authorizes the Secretary of HHS, with the voluntary cooperation of manufacturers, wholesalers, and distributors, to track the initial distribution of federally purchased influenza vaccine during an influenza pandemic. Requires the Secretary to promote communication between state, local, and tribal public health officials and such manufacturers, wholesalers, and distributors as agree to participate in the tracking program, regarding the effective distribution of seasonal influenza vaccine. Vaccine distribution information submitted to the Secretary or his contractors, if any, under this Act, shall remain confidential in accordance with the exception to the Freedom of Information Act (FOIA) governing trade secrets and commercial or financial information obtained from a person and privileged or confidential [5 U.S.C. § 552(b)(4)]. Any public disclosure by the agency of vaccine distribution information is subject to	**S. 1828** amends Section 319B of the PHS Act to require that the Director of the CDC establish an electronic tracking system for influenza vaccine. Such system shall collect estimates of the size of high-priority populations in each county in the United States. The Secretary of HHS shall develop guidelines for the creation of an appropriate database and protections for the confidentiality of information collected. [Section 401]

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		the criminal penalties for theft of trade secrets under 18 U.S.C. § 1832 and the exception to the prohibition on economic espionage and theft of trade secrets under 18 U.S.C. § 1833 (any otherwise lawful activity conducted by a federal or state governmental entity, or the reporting of a suspected violation of law to any federal or state governmental entity).[b] Information submitted shall also be subject to privacy protections consistent with the regulations promulgated under Section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191). Requires the Secretary to develop guidelines to ensure the confidentiality of information obtained for tracking purposes. Requires the Secretary to provide updates on implementation of this section in its quadrennial reports to the Congress, according to provisions for the National Health Security Strategy established in Section 103 of this Act. Authorizes such sums as may be necessary for FY2007 — FY2011. [Section 204]	

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
National Science Advisory Board for Biosecurity	No applicable provision. (The National Science Advisory Board for Biosecurity, which does not have an explicit authority in statute, is administered by the Office of Biotechnology Activities in the National Institutes of Health. The Board advises all federal departments and agencies on ways to minimize the possibility that knowledge and technologies stemming from vitally important biological research will be misused to threaten public health or national security. See [http://www.biosecurityboard.gov/] for more information.)	The National Science Advisory Board for Biosecurity shall, when requested by the Secretary of HHS, provide to relevant federal departments and agencies, advice, guidance, or recommendations concerning: a core curriculum and training requirements for workers in maximum containment biological laboratories; and, periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future need for increased laboratory capacity. [Section 205]	
Medical Surge Capacity			
National Disaster Medical System (NDMS)	Section 2811(b) of the PHS Act authorizes NDMS, to be coordinated by HHS, DOD, VA and the Federal Emergency Management Agency (FEMA) in collaboration with states and other appropriate public or private entities. Requires the Secretary of HHS within one year, and periodically thereafter, to conduct exercises to test the capability and timeliness of the NDMS to mobilize and respond effectively to a bioterrorist attack or other public health emergency. Appoints activated NDMS volunteers as temporary federal employees. Establishes liability protections, compensation for work injuries, and employment and reemployment rights for NDMS volunteers. Authorizes such sums as may be necessary for FY2002 — FY2006 for NDMS operations and for the HHS ASPHEP. [42 U.S.C. § 300hh-11]	Transfers the functions, personnel, assets, and liabilities of NDMS to HHS, under the responsibility of the ASPR, effective Jan. 1, 2007. Requires the Secretary of HHS, within 180 days of enactment, to conduct a joint review of NDMS, in coordination with DHS, VA, and DOD, and submit a report to Congress describing the roles, missions, appropriate size and structure of NDMS in the future. Authorizes such sums as may be necessary for FY2007 — FY2011. [Section 301]	**H.R. 5438** (reported by the House Cmte. on Energy and Commerce, referred to the House Cmte. on Homeland Security) amends Section 2811 of the PHS Act to transfer the functions, personnel, assets, and liabilities of NDMS to HHS, not later than nine months after enactment. [Section 2] **H.R. 5441**, the Department of Homeland Security Appropriations Act, 2007 (passed in Senate), transfers the functions, personnel, assets, and liabilities of NDMS to HHS, and requires that the Chief Medical Officer of DHS have primary responsibility for establishing doctrine and priorities for NDMS, supervising its medical components and exercising predeployment operational control. House-passed H.R. 5441 does not include provisions relating to NDMS.

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
	The Homeland Security Act (P.L. 107-296), transferred the functions, personnel, assets, and liabilities of NDMS to the Secretary of Homeland Security effective in March 2003, without other amendments to program authority. [6 U.S.C. § 313] Requires the VA Secretary, in consultation with the Secretaries of HHS and DOD and the FEMA Director, to establish a training program to facilitate the participation of VA medical center staff in NDMS. [38 U.S.C. § 8117]		**H.R. 5351** creates a new Directorate of Emergency Management in DHS and requires the DHS Under Secretary for Emergency Management to have the primary federal responsibility for preparing for, mitigating against, responding to, and recovering from acts of terrorism, natural disasters, and other emergencies. Such responsibilities shall include performing the functions of and coordinating NDMS. Requires a report to Congress on various aspects of NDMS, including whether it should remain in DHS. Authorizes $85 million for each of the fiscal years 2007 through 2010. [Sections 101, 103] **S. 3721** (reported in the Senate) retains FEMA in DHS and requires the FEMA Administrator to direct NDMS with respect to the federal response to natural and man-made disasters. [Section 513] Establishes within FEMA a Chief Medical Officer, who shall establish doctrine and priorities for NDMS (consistent with the NRP), supervise its medical components, and exercise pre-deployment operational control. [Section 521] Requires the Secretary of DHS, with respect to NDMS, to plan for: the provision of resources to equip, staff, and train NDMS teams; transportation, logistics, and communications capabilities; training and outreach programs; and patient triage and tracking capabilities. [Section 404]

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
			S. 2792 extends authority for NDMS under the Secretary of DHS. Requires federal agency partners to conduct a joint review of NDMS operations, and requires the Secretary of DHS to implement resulting recommendations and monitor ongoing system performance. Authorizes such sums as may be necessary for FY2006 — FY2010. [Section 7]
Education and training of health care personnel	PHS Act Section 319F(g) requires the Secretary, in collaboration with the interagency working group and professional organizations, to award grants: (I) to develop education materials to teach health officials and other emergency personnel to identify potential bioweapons and other dangerous agents and to care for victims of public health emergencies, recognizing the special needs of children and other vulnerable populations; (ii) to develop education materials for community-wide planning to respond to bioterrorism or other public health emergencies; (iii) to develop materials for proficiency testing of lab and other public health personnel for the recognition and identification of potential bioweapons and other dangerous agents; and (iv) to provide for the dissemination and teaching of these materials. Authorizes the Secretary, in consultation with the Attorney General and the FEMA Director, to provide technical assistance for emergency response personnel training carried out by the Justice Department and FEMA. [42 U.S.C. § 247d-6(g)]	Repeals the existing PHS Act Section 319F(g) and creates new Sections 319F(a)-(e), requiring the Secretary, in collaboration with DOD, to develop core health and medical response curricula and trainings, by adapting applicable existing programs, to improve responses to public health emergencies, and authorizes $12 million for FY2007 and such sums as may be necessary for FY2008 and each subsequent fiscal year. Authorizes the Secretary to expand the Epidemic Intelligence Service by placing officers in health shortage areas, and authorizes $3 million for FY2007 and such sums as may be necessary for FY2008 and each subsequent fiscal year. Authorizes the Secretary to establish Centers for Public Health Preparedness at accredited schools of public health, and authorizes $31 million for FY2007 and such sums as may be necessary for FY2008 and each subsequent fiscal year. [Section 304]	

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
Federal activities to enhance medical surge capacity	No applicable provision.	Creates a new Section 2804 of the PHS Act, requiring the Secretary to conduct an analysis of: (1) the benefits and feasibility of improving the capacity of HHS to provide additional medical surge capacity to local communities in the event of a public health emergency, through the acquisition and operation of mobile medical assets, and other strategies; and (2) whether there are federal facilities which, in the event of a public health emergency, could be used as healthcare facilities. Authorizes the Secretary to acquire mobile medical assets. Requires the Secretary to develop appropriate memoranda of understanding with respect to any federal facilities identified by the Secretary's analysis. [Section 302]	
Health professional volunteers	Section 319I to the PHS Act requires the Secretary to establish an electronic database for the advance registration of health professionals to verify their credentials, licenses, accreditations, and hospital privileges when they volunteer to respond during public health emergencies. Authorizes the Secretary to encourage states to permit out-of-state health professionals to provide health services during public health emergencies. Authorizes $2 million for FY2002, and such sums as may be necessary for FY2003 — FY2006. [42 U.S.C. § 247d-7b]	Amends PHS Act Section 319I to require the HHS Secretary to link existing state verification systems to maintain a single national interoperable network of systems, each system being maintained by a state or group of states, for the purpose of verifying the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency. The Secretary shall: establish system requirements; incorporate the memberships of NDMS and MRC; assure state access to and confidentiality of data; assess the feasibility of integrating with comparable systems in the VA and DHS; and encourage states to establish and implement mechanisms to waive the application of licensing requirements for volunteer health professionals. Clarifies that	**S. 1769** requires the Secretary to implement a program to disseminate publicly information on health professional liability coverage and licensure requirements for intermittent disaster response personnel, as described in Section 2811(d)(1) of the PHS Act, in areas in which a public health emergency has been declared under section 319, providing information sufficient to enable health professionals to make an informed decision about providing volunteer health services. [Section 205]

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
		inclusion of an individual in the database does not constitute an appointment as a federal employee. Authorizes such sums as may be necessary through FY2011. Creates a new Section 2813 of the PHS Act requiring the HHS Secretary, within 180 days and in consultation with state, local, and tribal officials, to establish and maintain a Medical Reserve Corps (MRC) of health professions volunteers, and to develop an identification card for each member of the MRC that describes relevant licensure and certification information. Requires the Secretary to appoint a Director who shall develop drills and certification requirements, not to supercede state requirements. Authorizes the Secretary to appoint selected individuals to serve as intermittent personnel of the MRC in accordance with applicable civil service laws and regulations, and to deploy willing members of the MRC with the concurrence of the state, local, or tribal officials from the area where the members reside and cover appropriate expenses that result pursuant to an assignment by the Secretary. Authorizes $22 million for FY2007 and such sums as may be necessary for FY2008 — FY2011. [Section 303]	
Department of Veterans Affairs	Directs the VA Secretary to enhance the readiness of VA medical centers and research facilities to protect staff and respond to a chemical or biological attack, based on the results of an evaluation of the security needs at these facilities.	Amends [38 U.S.C. § 8117] to change references to VA readiness for chemical and biological attack to readiness for a public health emergency. Requires the VA Secretary to enhance the readiness of VA medical centers and research	

	Current Law	S. 3678 (as reported)	Selected Provisions in Related Bills
	Requires the VA Secretary to develop a centralized tracking system for pharmaceuticals and medical supplies and equipment throughout the VA health care system, and train VA health care personnel in emergency medical response. Requires the VA Secretary, in collaboration with the Secretaries of Defense and HHS, and the Director of FEMA, to establish a training program to facilitate VA participation in NDMS. Requires the VA Secretary, in consultation with the HHS Secretary, the American Red Cross, and the interagency working group, to provide mental health counseling to individuals seeking care at a VA medical center following a bioterrorist attack or other public health emergency. Authorizes $133 million for FY2002, and such sums as may be necessary for FY2003 — FY2006. [38 U.S.C. § 8117]	facilities by: organizing, equipping and training staff for the appropriate support of the HHS Secretary in the event of public health emergencies and incidents covered by the NRP; and, providing medical logistical support to NDMS and the Secretary of HHS, as necessary, on a reimbursable basis and in coordination with other designated federal agencies. Requires the VA Secretary, through existing procurement contracts and on a reimbursable basis, to make available, as needed, medical supplies, equipment, and pharmaceuticals in response to a public health emergency in support of the Secretary of HHS. Authorizes such sums as may be necessary for FY2007 — FY2011. [Section 306]	

Note: Unless otherwise stated, "the Secretary" refers to the Secretary of HHS, and sections in law refer to sections in the Public Health Service Act.

a. Information provided by Kathleen S. Swendiman, Legislative Attorney, American Law Division.
b. Information provided by Brian T. Yeh, Legislative Attorney, American Law Division.