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The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law

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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), and are administered by the Secretary of Health and Human Services (HHS). Three 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), established a number of new programs and authorities, including grants to states to build public health preparedness. **P.L. 107-188**, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, was passed in the aftermath of the 2001 terror attacks. It reauthorized several existing programs and established new ones, including grants to states to build hospital and health system preparedness. **P.L. 108-276**, the Project BioShield Act of 2004, established authorities to encourage the development of specific countermeasures (such as drugs and vaccines for bioterrorism agents) that would not otherwise have a commercial market.

The laws above built upon existing broad authorities allowing or requiring the Secretary of HHS to prepare for or respond to outbreaks of infectious disease and other unanticipated health threats. Other laws — such as **P.L. 107-296**, creating a new Department of Homeland Security (DHS) — have added to the slate of public health 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.

The 109th Congress passed **P.L. 109-417**, the Pandemic and All-Hazards Preparedness Act. The act reauthorized a number of expiring preparedness and response programs in the PHS Act, and established some new authorities, including the creation of a Biomedical Advanced Research and Development Authority (BARDA), a new office in HHS to support, coordinate, and provide oversight of advanced development of vaccines and biodefense countermeasures. The act's provisions reflected the concerns of Members of the 109th Congress and others regarding the flawed response to Hurricane Katrina in 2005, and the threat of a possible influenza pandemic. A comparison of provisions in P.L. 109-417 with preexisting law is provided in **Table 1** later in this report.

The 110th Congress will likely be interested in the implementation of provisions in P.L. 109-417, and in the continued evolution of relationships between HHS, DHS, the states, and others among whom coordination is essential in a time of heightened concern about national security. Members of the 110th Congress may wish to consider legislation to address additional expiring public health authorities, such as the Select Agent program to control access to pathogens that could be used for bioterrorism, which expires at the end of FY2007. Congress may also wish to examine the adequacy of certain permanent emergency response and funding authorities of the Secretary of HHS.

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The Pandemic and All-Hazards Preparedness Act (P.L. 109-417): Provisions and Changes to Preexisting Law

Introduction

On December 19, 2006, President George W. Bush signed **S. 3678**, the Pandemic and All-Hazards Preparedness Act (P.L. 109-417), which authorizes appropriations through FY2011 to improve bioterrorism and other public health emergency preparedness and response activities, and establishes the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services (HHS) for the advanced research and development of medical countermeasures.

The Pandemic and All-Hazards Preparedness Act effected the second comprehensive reauthorization of federal programs designed to improve the nation's readiness for public health threats such as bioterrorism or pandemic influenza. Many of these authorities, found principally in the Public Health Service Act and implemented by the Secretary of Health and Human Services (HHS), were first explicitly authorized in 2000 (**P.L. 106-505**), amid growing concerns about global terrorist activity and emerging infectious diseases. Congress reviewed, extended and expanded many of these authorities following the terrorist attacks of 2001 (**P.L. 107-188**). The anthrax attacks, in particular, had put a harsh spotlight on a public health system that was poorly coordinated and otherwise unfit for 21st century challenges.

As the 109th Congress began its consideration of the Pandemic and All-Hazards Preparedness Act in 2005, Hurricane Katrina slammed into the Gulf Coast, while a new strain of avian flu, on a steady march across Europe and Asia, threatened a global pandemic. In this context, Members of Congress considered the challenges of bolstering a public health system that is based largely in state authority, and a healthcare system that is largely in private hands. Congress grappled, on the federal level, with integrating the new Department of Homeland Security (DHS) into the nation's preparedness and response activities. The challenges of building effective, coordinated systems across federal agencies, with state and local governments, with private industry, with citizens, and with foreign nations, were formidable as well.

The 110th Congress will likely be interested in the implementation of provisions in P.L. 109-417, and in the continued evolution of relationships between HHS, DHS, the states, and others among whom coordination is essential in a time of heightened concern about national security. Members of the 110th Congress may wish to consider legislation to address additional expiring public health authorities, such as

the Select Agent program to control access to pathogens that could be used for bioterrorism, which expires at the end of FY2007. Congress may also wish to examine certain permanent emergency response and funding authorities of the Secretary of HHS.

This report discusses some key provisions in the Pandemic and All-Hazards Preparedness Act (P.L. 109-417), and provides a history of prior public health and medical preparedness and response legislation. A comparison of provisions in P.L. 109-417 with preexisting law is provided in **Table 1** later in this report.

Legislative History

The 109th Congress

In July 2006, Senator Burr introduced **S. 3678**, the Pandemic and All-Hazards Preparedness Act. This bill proposed a comprehensive reauthorization of health preparedness and response programs in Title I of P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In addition, several bills were introduced in the 109th Congress to enhance Project BioShield, the HHS program to develop and procure specific countermeasures (such as drugs and vaccines for victims of bioterrorism) for the Strategic National Stockpile. These included **S. 3** (Gregg), **S. 975** (Lieberman), **S. 1873** (Burr), **S. 1880** (Kennedy), **S. 2564** (Burr), and **H.R. 5533** (Rogers).[1] The two legislative initiatives proceeded along parallel tracks until December 2006, when BioShield provisions were attached to S. 3678 as a new Title IV, and the amended bill passed in both chambers. The bill was signed by the President on December 19, 2006, and became P.L. 109-417. Some key provisions of this law are discussed below. A comparison of provisions in P.L. 109-417 with preexisting law is provided in **Table 1** later in this report.

One of the most difficult challenges faced by Congress and other policymakers following the 2001 terror attacks was to envision those catastrophic threats for which the nation must be prepared, define the capabilities needed to assure national preparedness, and determine the appropriate federal activities and incentives needed to achieve these goals among federal, state, and local governments, and the private sector. Both of the earlier bioterrorism laws, P.L. 106-505 and P.L. 107-188, had 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. However, recent efforts at DHS, to develop national preparedness goals and target capabilities, have helped to define certain large-scale public health and medical capabilities — such as rapid disease detection, mass prophylaxis, and medical surge — that would be required for an effective response to mass casualty incidents, and that would require a substantial federal coordinating effort.[2] The Pandemic and All-Hazards Preparedness Act would

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

[2] For more information, see CRS Report RL32803, *The National Preparedness System:* (continued...)

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 at DHS.

In October 2006, the President signed **P.L. 109-295**, the Post-Katrina Emergency Management Reform Act of 2006 (called the "Post-Katrina Act," included in DHS appropriations for FY2007). The act reauthorized and reorganized programs in the Federal Emergency Management Agency (FEMA, in DHS).[3] Among other things, the law also codified the position of Chief Medical Officer (CMO) at DHS, the individual who coordinates all departmental activities regarding medical and public health aspects of disasters. Since the Secretary of DHS serves as the federal lead for a coordinated national response to disasters, including terrorism, Members of Congress were interested in clarifying the relationship between the CMO and the Secretary of HHS in disaster preparedness and response. The Post-Katrina Act provides that the CMO "shall have the primary responsibility *within the Department* for medical issues related to natural disasters, acts of terrorism, and other man-made disasters."[4] (Emphasis added.) The Pandemic and All-Hazards Preparedness Act provides that "The Secretary of Health and Human Services shall lead all *Federal* public health and medical response to public health emergencies and incidents covered by the National Response Plan...."[5] (Emphasis added.) Members of Congress will likely be interested in how this statutory division of authority is implemented by the two departments.

The 109th Congress considered several measures to improve Project BioShield, a program to encourage the development of promising chemical, biological, radiological, or nuclear countermeasures that the private sector might not otherwise develop. The 108th Congress launched the program in the Project BioShield Act of 2004 (P.L. 108-276), providing $5.6 billion for the program over 10 years. Project BioShield allows the government to guarantee a market for specified amounts of particular countermeasures. Under this program, HHS can solicit bids for specific countermeasures and execute contracts for the delivery of countermeasures at guaranteed prices even if the countermeasure has up to eight more years of development.[6] The government only pays for the countermeasure on delivery. As time has passed with little perceived progress on some major identified countermeasure targets, criticism of this program has mounted. The cancellation of the next-generation anthrax vaccine contract, the largest BioShield contract to date, has highlighted these criticisms.

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[2] (...continued)
Issues in the 109th Congress, by Keith Bea.

[3] See CRS Report RL33729, *Federal Emergency Management Policy Changes After Hurricane Katrina: A Summary of Statutory Provisions*, by Keith Bea, Barbara L. Schwemle, L. Elaine Halchin, Francis X. McCarthy, Frederick M. Kaiser, Henry B. Hogue, Natalie Paris Love and Shawn Reese.

[4] P.L. 109-295, 120 STAT 1409.

[5] P.L. 109-417, Section 101.

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

The 109th Congress considered several measures to improve Project BioShield results, including **S. 3** (Gregg), **S. 975** (Lieberman), **S. 1873** (Burr), **S. 1880** (Kennedy), **S. 2564** (Burr), and **H.R. 5533** (Rogers). Congress incorporated some of the proposals in these bills into the Pandemic and All-Hazards Preparedness Act, Title IV. This law requires the HHS Secretary to develop and make public a strategic plan to guide HHS research and development and procurement of countermeasures. It also creates the Biodefense Advanced Research and Development Authority (BARDA) in HHS. This office is to help implement the strategic plan, directly support countermeasure advanced development, and facilitate communication between the government and countermeasure developers. This law allows HHS to make milestone-based payments for Project BioShield contracts which do not have to be repaid even if the product is never delivered. It also permits the HHS Secretary to hold meetings and execute specific agreements with multiple potential countermeasure developers that would otherwise violate antitrust laws, contingent on prior approval of the Attorney General and the Chairman of the Federal Trade Commission.

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. The Pandemic and All-Hazards Preparedness Act extended the programs, adding certain new program elements including federal 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 federal Internet website available to the public.

There was considerable discussion in the 109th Congress regarding whether a medical disaster response could function effectively when the National Disaster Medical System (NDMS), a key federal medical response asset, was based at DHS rather than at HHS.[7] NDMS had been transferred from HHS to DHS in P.L. 107-296, the Homeland Security Act, effective when the new department was created in 2003. In studying the response to Hurricane Katrina, Congressional and White House investigators found that, among other problems, NDMS deployments were made by FEMA without the knowledge or involvement of personnel at HHS.[8] The

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[7] NDMS consists of a number of medical response teams that can deploy to a scene rapidly and set up self-sustaining field operations 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.

[8] 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 (continued...)

Pandemic and All-Hazards Preparedness Act transferred NDMS back to HHS, effective January 1, 2007.[9] (Congress also made this transfer in the Post-Katrina Act. The transfer was supported by the Administration.[10])

A key to the management of incidents of bioterrorism or emerging infectious disease threats is the ability to detect the incidents early, and to distribute countermeasures to affected populations in time to prevent or cure illness. An element of early detection are the information systems used to report and compare a variety of types of relevant information in a timely manner across jurisdictions. The Pandemic and All-Hazards Preparedness Act requires the Secretary of HHS to establish a national electronic network for sharing of public health surveillance information in near-real time, and authorizes grants to states to establish or operate systems in this network. The act also requires the Secretary to establish a nationwide system to track influenza vaccine that may be used during a pandemic, and to identify ways to expand the use of telehealth capabilities in emergency response. Achieving near-real-time national information systems for disease detection or resource tracking is complicated by the need to develop a common set of data standards to serve multiple purposes. At the same time, the systems must address concerns about the privacy and security of personal health information, as well as commercially sensitive information such as the health status of food-producing animals, or the quantities and distribution pathways of patented medicines.[11]

Authority for health professions programs in Title VII of the Public Health Service Act expired in 2002. These programs, administered by the Health Resources and Services Administration (HRSA), an agency in HHS, 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.[12] The Pandemic and All-Hazards Preparedness Act 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. **S. 506**, the Public Health

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[8] (...continued)
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/].

[9] See HHS NDMS home page at [http://www.ndms.dhhs.gov/].

[10] 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].

[11] For more information, see the HHS Health Information Technology home page at [http://www.hhs.gov/healthit/], and the biosurveillance workgroup page at [http://www.hhs.gov/healthit/ahic/bio_main.html]. See also CRS Report RL32858, *Health Information Technology: Promoting Electronic Connectivity in Healthcare*, by C. Stephen Redhead.

[12] 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.

Preparedness Workforce Development Act of 2005, introduced in the Senate, proposed broader provisions to provide scholarship and loan repayment programs for health professionals who work in government public health agencies. The bill did not advance in the 109th Congress.

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. A 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.[13] (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,[14] and expansion of security and preparedness activities at CDC. Title I also expanded the program for the Strategic National Stockpile (SNS) of countermeasures to diagnose and treat potential victims of terrorism or other public health emergencies. Title II of the act called on the Secretary of HHS to register 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

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[13] The authorization for FY2002 funds was signed in June 2002, after the 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.

[14] This position was renamed the Assistant Secretary for Preparedness and Response, and the authorities were amended, in the Pandemic and All-Hazards Preparedness Act.

assistance to community water systems to conduct vulnerability assessments and prepare response plans.[15]

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.[16] 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.

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. The act 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.

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

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[15] 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.

[16] For more information on Project BioShield, see CRS Report RS21507, *Project BioShield*, by Frank Gottron and CRS Report RL32549, *Project BioShield: Legislative History and Side-by-Side Comparison of H.R. 2122, S. 15, and S. 1504*, by Frank Gottron and Eric A. Fischer.

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.

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 Project BioShield, see

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

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.
- 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.

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

- CRS Report RL33729, *Federal Emergency Management Policy Changes After Hurricane Katrina: A Summary of Statutory Provisions*, by Keith Bea, Barbara L. Schwemle, L. Elaine Halchin, Francis X. McCarthy, Frederick M. Kaiser, Henry B. Hogue, Natalie Paris Love, and Shawn Reese.
- 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.

Table 1. Provisions of P.L. 109-417, the Pandemic and All-Hazards Preparedness Act, and Comparison with Preexisting Law

	Preexisting Law	P.L. 109-417
TITLE I: NATIONAL PREPAREDNESS AND RESPONSE, LEADERSHIP, ORGANIZATION AND PLANNING		
Federal leadership for public health and medical preparedness and response: functions of the Secretary of Health and Human Services (HHS)	No applicable provision.	Repeals the existing Section 2801 of the Public Health Service (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 National Response Plan (NRP) or any successor plan. The Secretary shall, in collaboration with the Secretaries of Veterans Affairs (VA), Defense (DOD), Transportation, the Department of Homeland Security (DHS), 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 (excepting members of the armed forces under the authority of the Secretary of Defense, and any associated assets), as necessary, in the event of a public health emergency. [Section 101]
Assistant Secretary for Preparedness and Response	Section 2811(a) of the PHS Act authorized 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	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,

	Preexisting Law	P.L. 109-417
	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 pursuant to Sec. 319A; and interface with other federal agencies and state and local entities. The position did not require Senate confirmation. Authorized such sums as may be necessary for FY2002 - FY2006. [42 U.S.C. § 300hh-11]	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) oversee the advanced research, development and procurement of countermeasures pursuant to Sections 319F-1 and 319F-3; (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 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 Strategic National Stockpile (SNS) and the Cities Readiness Initiative; and other

	Preexisting Law	P.L. 109-417
		duties as determined appropriate by the Secretary. Repeals Section 319A. Authorizes the appropriation of such sums as may be necessary for FY2007-FY2011. [Section 102]
Strategic National Stockpile	PHS Act Section 319F-2 provided 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 health emergency. Required the Secretary to manage the SNS, in coordination with the Secretaries of DHS and VA, and ensure its physical security. Protected 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. Authorized $640 million for FY2002 and such sums as may be necessary for FY2003-FY2006, in addition to amounts in a special reserve fund, and authorized, for smallpox vaccine development, $509 million for FY2002 and such sums as may be necessary for FY2003-FY2006. [42 U.S.C. § 247d-6b]	Amends Section 319F-2(a)(1) of the PHS Act [42 U.S.C. § 247d-6b(a)(1)] to require the Secretary to collaborate with Director of the Centers for Disease Control and Prevention in maintaining the SNS. Requires the Secretary to conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review. Does not extend appropriations authority for the SNS, which expired in FY2006. [Section 102]
At-risk individuals	No comparable provision. P.L. 107-188 required, in 2002, the establishment of the National Advisory Committee on Children and Terrorism, which sunset after one year. Additional provisions in the PHS Act required the Secretary to consider the needs of children and other vulnerable populations when conducting a variety of preparedness activities.	Establishes a new Section 2814 of the PHS Act to address 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. Requires the Secretary to take the needs of at-risk individuals into account in managing several preparedness

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		programs, including the SNS and preparedness grants to states. Requires the Secretary, not later than one year after enactment, to prepare and submit to Congress a report describing the progress made on implementing the duties described in this section. Amends Section 319F(b)(2) to require the Secretary to establish an Advisory Committee on At-Risk Individuals and Public Health Emergencies. For the Advisory Committee, does not explicitly authorize funding for FY2007, but authorizes the appropriation of such sums as may be necessary for FY2008 and each subsequent fiscal year. [Sections 102 and 301]
National Health Security Strategy	Section 2801 of the PHS Act required the Secretary of 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. Established 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. Required 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. Required the Secretary	Repeals existing Sections 319A and 2801 of the PHS Act. Establishes a new Section 2802(a) of the PHS Act, requiring the Secretary, beginning in 2009 and every four 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 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.

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	to report to Congress within one year, and biennially thereafter, on progress made towards meeting the national preparedness goals, including recommendations for new legislative authority to protect public health. [42 U.S.C. § 300hh] Section 319A of the PHS Act required 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. Authorized $4 million for FY2001, and such sums as may be necessary for FY2002-FY2006. [42 U.S.C. § 247d-1]	Establishes a new Section 2802(b) requiring that the National Health Security Strategy include preparedness goals for: (1) integration of response capabilities and systems; (2) capabilities for public health preparedness and response; (3) capabilities for medical preparedness and response; (4) provisions for the needs of at-risk individuals; (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]
TITLE II: PUBLIC HEALTH SECURITY PREPAREDNESS		
Grants to states for public health preparedness: eligible entities and authority for appropriations	Section 319C-1 of the PHS Act required the Secretary to make awards to eligible entities to improve public health preparedness and response to bioterrorism and other public health emergencies. Eligible entities were 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 was to take priority over other public health emergencies, subject to	Repeals PHS Act Sections 319B and 319C. Repeals and replaces PHS Act subsections 319C-1(a) through (i) and adds or redesignates subsections (i) through (k). 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.

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	any modification in the assessment of risk by the Secretary. Authorized $1.08 billion for FY2003 for block grants to states and territories, and such sums as may be necessary for FY2004-FY2006. Note: The requirement that public health preparedness funding be awarded as block grants applied only to FY2003; greater flexibility in awarding funding was provided to the Secretary beyond FY2003. [42 U.S.C. § 247d-3a] Note: The funding formula and certain other administrative requirements were established jointly for both the public health and hospital preparedness grants, and are described in later sections.	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) 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, of which $35,000,000 shall be used for Real-Time Disease Detection Improvement grants, and such sums as may be necessary for FY2008-FY2011, and $10 million for FY2007 for a study of best practices for required drills, and for activities to assure preparedness for the needs of at-risk individuals. [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), (j) and (k), as established in this act, are described in later sections.

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Grants for Real-Time Disease Detection Improvement	No comparable provision.	Established a new PHS Act Section 319C-1(h) authorizing the Secretary to award grants to hospitals, clinical laboratories, universities or poison control center that participate in the interoperable network of data systems established in Section 319D by this act, for pilot demonstration projects to use advanced diagnostic medical equipment to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance, and to report any results from such project to state, local, and tribal public health entities. Authorizes the appropriations of $35 million for FY2007, and such sums as may be necessary for FY2008-FY2011. [Section 201]
Grants for public health and hospital preparedness — funding formula, risk-based funding, and pass-through requirement	Note: Provisions described here applied to both the public health and hospital preparedness grants established in PHS Act Section 319C-1. PHS Act Section 319C-1(j) required the Secretary, for FY2003, to award block grants to states and territories for public health and hospital preparedness, with each grantee guaranteed a minimum level of funding plus an additional amount based on population. Established different minimum amounts for states and territories based upon the available appropriation. The District of Columbia and the Commonwealth of Puerto Rico were considered states for the purposes of this section. Authorized 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	Note: Provisions described here apply to both the public health preparedness grants established in Section 201 of this act, and the hospital preparedness partnership grants established in Section 305 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 applied in preexisting law to FY2003, through FY2011. Authorizes the Secretary, for FY2007, to make awards for certain political subdivisions, as such authority applied in preexisting law to FY2003. Authorizes the Secretary, for FY2007, to make awards for

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	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. Authorized 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. Required the Secretary, for FY2003, to ensure that appropriate portions of such awards were 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]	additional unmet need, as such authority applied in preexisting 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]
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 PHS Act Section 319C-1. Section 319A of the PHS Act required the Secretary to establish, by June 2003, and to revise every five years, capacities for	Note: Provisions described here apply to both the public health preparedness grants established in Section 201 of this act, and the hospital preparedness partnership grants established in Section 305 of this act. Establishes a new PHS Act Section 319C-1(g) requiring the

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	national, state and local public health systems to combat public health threats. Section 319B required 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]	Secretary, within 180 days of enactment, to: (1) develop and apply measurable evidence-based benchmarks and objective standards to measure grantees' preparedness, including annual test and exercise requirements; 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]
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 201 of this act, and the hospital preparedness partnership grants established in Section 305 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

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		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]
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 PHS 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 public funds provided for activities under this section. [42 U.S.C. § 247d-3a(j)]	Note: Provisions described here apply to both the public health preparedness grants established in Section 201 of this act, and the hospital preparedness partnership grants established in Section 305 of this act. For awards for public health and hospital preparedness made pursuant to PHS Act Sections 319C-1(i) and 319C-2(h), 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 201 of this act, and the hospital preparedness grants established in Section 305 of this act. Establishes new PHS Act Section 319C-1(j), requiring grantees to submit to the Secretary annual reports describing funded

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		activities, performance with respect to program goals and objectives, appropriate budget information, and other reporting requirements, which are to be determined by the Secretary within 180 days of enactment . 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 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. Establishes new PHS Act Section 319C-1(k), requiring the Secretary to compile the data submitted by grantees and make such data available in a timely manner on a public Internet website in a useful format to provide information on those activities that are best contributing to the achievement of outcome goals. [Sections 201 and 305]

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Public health surveillance and information technology networks	PHS Act Section 319D(a) recognized CDC's essential role in defending against and combating bioterrorism and other public health emergencies. Section 319D(b) provided for the establishment of public health alert communications and surveillance networks and required 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) authorized 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 or consortia of states to enhance surveillance 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). Requires the Secretary, in consultation with the Federal Communications Commission and other relevant federal agencies, to evaluate and report to Congress on the status of national telehealth capabilities, and means to integrate and expand these capabilities to address public health threats. Authorizes the appropriation of such sums as may be necessary for FY2008-FY2011. [Section 202]
Public health workforce enhancements	Section 319H of the PHS Act authorized 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. Authorized such	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

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	sums as may be necessary for FY2002-FY2006. [42 U.S.C. § 247d-7a] Section 338L of the PHS Act authorized 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]	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. 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-FY2010. [Section 203]

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Influenza 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 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.

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		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]
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]
Revitalization of the PHS Commissioned Corps	No generally applicable provision. The Commissioned Corps of the PHS is authorized in PHS Act Sections 203-221 [42 U.S.C. §§ 204 et seq.], which establish grades, ranks and titles, appointments, pay and allowances, promotion, separation and retirement, and other provisions.	Establishes a new PHS Act Section 203A regarding deployment readiness for an *urgent or emergency public health care need* of national, state or local significance, defined as: (1) a national emergency declared by the President under the National Emergencies Act [50 U.S.C. §§ 1601 et seq.]; (2) an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. §§ 5121 et seq]; a public health emergency declared by the Secretary under PHS Act section 319; or (4) any emergency that, in the judgment of the Secretary, is appropriate for the deployment of members of the Corps. Requires the Secretary to establish readiness requirements (including training and medical exams) for the active-duty Regular Corps and Active Reserves, and means of assessment and accountability, and to establish

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		appropriate procedures for deployment. Amends PHS Act Section 214 to grant the Secretary the sole authority to deploy any Commissioned Corps officer assigned under this section to an entity outside of the HHS (except with respect to the United States Coast Guard and the Department of Defense, and except as provided in agreements negotiated with officials at agencies where officers of the Commissioned Corps may be assigned) for service under the Secretary's direction in response to an urgent or emergency public health care need. Amends PHS Act Section 331(f) to authorize the emergency deployment of Commissioned Corps personnel serving in the National Health Service Corps during their period of obligated service, providing that the Secretary determines that deployment would not cause unreasonable disruption to health care services provided in the community in which such officer is providing health care services. [Section 206]
TITLE III: ALL-HAZARDS MEDICAL SURGE CAPACITY		
National Disaster Medical System (NDMS)	Section 2811(b) of the PHS Act authorized 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. Required the Secretary of HHS 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. Appointed activated NDMS volunteers as temporary federal employees. Established liability protections, compensation for	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]

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	work injuries, and employment and re-employment rights for NDMS volunteers. Authorized such sums as may be necessary for FY2002 — FY2006 for NDMS operations and for the HHS ASPHEP. [42 U.S.C. § 300hh-11] The Homeland Security Act of 2002 (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]. Required 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]	Note: P.L. 109-295, Department of Homeland Security Appropriations Act, 2007, also transferred NDMS to HHS, effective January 1, 2007. The transfer has been carried out. See [http://www.ndms.dhhs.gov/index.html].
Enhancing medical surge capacity	No applicable provision.	Establishes a new PHS Act Section 2803, 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]

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Emergency Medical Treatment and Active Labor Act (EMTALA)[a]	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 or the Stafford Act, 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 alternate location for medical screening. This provision is effective upon enactment. [Section 302]
Encouraging health professional volunteers	Section 319I to the PHS Act required 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. Authorized the Secretary to encourage states to permit out-of-state health professionals to provide health services during public health emergencies. Authorized $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 (the "verification network"), 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 Medical Reserve Corps (MRC); assure state access

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		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 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 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 supersede 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]
Core education and training	PHS Act Section 319F(g) required the Secretary, in collaboration with the interagency working group and professional organizations, to award grants: (1) to develop education materials to teach health officials and other emergency	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

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	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; (2) to develop education materials for community-wide planning to respond to bioterrorism or other public health emergencies; (3) 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 (4) to provide for the dissemination and teaching of these materials. Authorized 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)]	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]
Partnerships for state and regional hospital preparedness to improve surge capacity	Section 319C-1 of the PHS Act required 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 were states, political subdivisions of states, or consortia of subdivisions. Authorized $520 million for FY2003 and such sums as may be necessary for FY2004 — FY2006. [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. These provisions are described in earlier sections of this table, along with other provisions in Title II of P.L. 109-417.	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 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 provide assurance that they will adhere to any

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	Section 319C-2 of the PHS Act authorized grants to improve community and hospital preparedness for bioterrorism and other public health emergencies. Eligible entities were 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 took priority over other public health emergencies, subject to any modification in the assessment of risk by the Secretary. Authorized such sums as may be necessary for FY2004-FY2006. [42 U.S.C. § 247d-3b]	applicable guidelines established by the Secretary. 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 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

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		fiscal requirements are established jointly for both the hospital preparedness grants described here, and the public health preparedness grants in Section 201. These administrative and fiscal requirements, in PHS Act Sections 319C-1(g), (j) and (k), as established in this act, are described in earlier sections of this table, along with other provisions in Title II of P.L. 109-417.
Department of Veterans Affairs	Directed 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. Required 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. Required 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. Required 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. Authorized $133 million for FY2002, and such sums as may be necessary for FY2003-FY2006. [38 U.S.C. § 8117]	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 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]
TITLE IV: PANDEMIC AND BIODEFENSE VACCINE AND DRUG DEVELOPMENT		
Biomedical Advanced Research and Development Authority	No applicable provision.	Creates a new section 319K of the PHS Act requiring the Secretary to develop and publish a strategic plan to integrate biodefense and emerging infectious disease requirements with advanced research and development, strategic innovation

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		initiatives, and the procurement of countermeasures. This plan is due by June 2007. The plan will guide HHS's R&D, innovation support, and procurement of countermeasures to chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases. Establishes the Biomedical Advanced Research and Development Authority (BARDA) in HHS. The director of this office, guided by the strategic plan, will: facilitate collaboration between HHS, other federal agencies, industry, and academia; promote and financially support countermeasure advanced R&D; facilitate FDA advice to countermeasure producers to promote product approval; and financially support innovation to reduce countermeasure development time and price. Grants the Secretary "other transaction" authority for BARDA activities, similar to that of the DOD Secretary found in 10 U.S.C. § 2371. Provides the Secretary several authorities when awarding BARDA-related grants, contracts, cooperative agreements, or other transactions. These include the use of: increased simplified acquisition and micropurchase thresholds; expedited peer review; personal services contracts, and competition limits. The Secretary may request that any data generated through this support be provided to the HHS on demand. Allows BARDA to: make advanced payments and milestone-based payments; make awards to foreign nationals; and establish research centers.

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		Allows the Secretary to give priority to countermeasures that are likely to be safe and effective for children, pregnant women, the elderly, and other at-risk individuals. Allows the Secretary to appoint highly qualified individuals to scientific or professional positions or as special consultants for BARDA at the highest level of senior level pay for terms not to exceed five years. The Secretary can hire no more than 100 such individuals or 50% of the total number of BARDA employees, whichever is less. The Secretary will report use of these hiring authorities to Congress biennially. Establishes the "Biodefense Medical Countermeasure Development Fund" to fund BARDA activities and authorizes the appropriation of $1.07 billion for FY2006 — FY2008 to remain available until expended. Exempts technical and scientific data generated through BARDA activities from disclosure under the Freedom of Information Act (FOIA) if the data reveal significant and not otherwise publicly known vulnerabilities to CBRN threats. Information exempted will be reviewed every five years to determine the need for continued nondisclosure. This exemption sunsets seven years after enactment. Allows working groups under BARDA or the National Biodefense Science Board (see below) to expire after five years. [Section 401]

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National Biodefense Science Board	No applicable provision.	Creates a new Section 319L of the PHS Act establishing the National Biodefense Science Board, to provide the Secretary with expert advice and guidance on scientific, technical matters related to current and future CBRN agents, including those that occur naturally. Board membership will include preeminent scientific, public health, and medical experts. This will include such federal officials as necessary to support the functions of the board; four individuals from industry; four individuals from academia; five other members, one of which must be a practicing healthcare provider and another which must be from an organization representing healthcare consumers. Board members may serve no more than two consecutive three-year terms or a total of three nonconsecutive terms. The initial board meeting will occur within one year of enactment and at least twice annually thereafter. Vacancies will be filled in the same manner as the initial appointments and will have no affect on the powers of the board. The Secretary will appoint one of the members as the chairperson. The board may hold hearings and take testimony as it deems advisable. The members of the board who are federal government employees may not receive additional pay. Other members will receive pay not to exceed the daily rate equivalent of Executive Schedule level IV for each day engaged in board work. Each member will receive travel expenses and per diem when appropriate. Federal government employees can be detailed to the board without loss of civil service status or privilege. The Secretary may create working groups to identify innovative

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		countermeasure research, to identify accepted animal models for countermeasure research or other research tools that may accelerate countermeasure development, and to obtain advice regarding development of countermeasures likely to be safe and effective for children, pregnant women, and other vulnerable populations. Authorizes appropriation of $1 million for FY2007 and each subsequent fiscal year. [Section 402]
Clarification of countermeasures covered by Project BioShield	Section 319F-1(a) of the PHS Act [42 U.S.C. § 247d-6a(a)] defined a "qualified countermeasure" as a drug, biological product, or device that the Secretary determines is a priority to treat, identify, or prevent harm from any CBRN agent that may cause a public health emergency affecting national security or adverse health consequences caused by use of such products.	Amends Section 319F-1(a) of the PHS Act [42 U.S.C. § 247d-6a(a)] to define a "qualified countermeasure" as a drug, biological product, or device that the Secretary determines is a priority to diagnose, mitigate, to treat harm from any CBRN agent (including those that cause infectious disease) that may cause a public health emergency affecting national security or adverse health consequences caused by use of such products. Defines infectious disease as a disease acquired by a person and that reproduces in that person.
	Section 319F-2(c)(1)(B) of the PHS Act [42 U.S.C. § 247d-6b(c)(1)(B)] Defines "security countermeasure" to mean a drug, biological product or device that the Secretary determines to be a priority to treat, identify, or prevent harm from any CBRN agent identified as a material threat, or to treat, identify, or prevent adverse health consequences caused by use of such products; the Secretary determines it is a necessary countermeasure; and is approved for the market or is a countermeasure that the Secretary has determined will likely qualify for such approval within eight years or has been authorized for an emergency use	Amends Section 319F-2(c)(1)(B) of the PHS Act [42 U.S.C. § 247d-6b(c)(1)(B)], striking "treat, identify, or prevent" each place it appears and inserting "diagnose, mitigate, prevent, or treat."

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	by the Secretary. Section 510(a) of the Homeland Security Act of 2002 is the authorization for appropriations for Project BioShield countermeasure acquisitions.	Amends Section 510(a) of the Homeland Security Act of 2002 [6 U.S.C.§ 320(a)] by adding at the end "None of the Funds made available under this subsection shall be used to procure countermeasures to diagnose, mitigate, prevent, or treat harm resulting from any naturally occurring infectious disease or other public health threat that are not security countermeasures under Section 319F-2(c)(1)(B)." [Section 403]
Technical assistance	No applicable provision.	Amends the Federal Food, Drug, and Cosmetic Act chapter V subchapter E [21 U.S.C. § 360bbb et seq.] by adding section 565 "Technical Assistance." This establishes a team of experts in the Food and Drug Administration to provide countermeasure manufacturers with off-site and on-site assistance. [Section 404]
Collaboration and coordination	No applicable provision.	Allows the Secretary to conduct meetings and consultations with multiple countermeasure developers regarding the development, manufacture, distribution, purchase, or storage of countermeasures that would otherwise violate antitrust laws. The Secretary must notify (including topics to be discussed) the Attorney General, the Chairman of the Federal Trade Commission (FTC), and the DHS Secretary before such meetings. The Secretary will lead the meetings. The meetings must be open to the Attorney General; the FTC Chairman; the DHS Secretary; and individuals involved in the development, manufacture, purchase, storage, or distribution of countermeasures. Discussions will be limited to "covered activities" (defined below), and held in a manner to ensure that no national security, confidential commercial, or proprietary information is disclosed outside the meeting.

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		The Secretary cannot require participants to reveal confidential, commercial, or proprietary information. The Secretary will keep a verbatim transcript of the meeting. If a determination is made that disclosing the transcript may harm national security, the transcript will not be subject to FOIA requests. Participation in these meetings will not violate antitrust laws. Conduct or agreements resulting from these meetings may also be exempt from antitrust laws subject to the approval of the Attorney General in consultation with the FTC Chairman. Written agreements between individuals or companies resulting from these meetings can be submitted by the Secretary for approval by the Attorney General in consultation with the FTC Chairman. Conduct in accordance with such approved agreements will not be violation of antitrust laws. In addition to the proposed agreement, the Secretary will provide to the Attorney General an explanation of the intended purpose of the agreement, a specific statement of the substance of the agreement, a description of the methods use to achieve the agreement's objectives, an explanation of why such an agreement is necessary, and any other relevant information. The Attorney General has 15 days to deny, grant in whole or in part, or propose modifications to submitted agreements. An exemption to the antitrust laws will be granted only to the extent that the Attorney General determines that covered conduct will not have a substantial anticompetitive effect that is not reasonably necessary for ensuring the availability of the countermeasure involved. Exemptions will be automatically renewed after three years unless the Attorney General and the FTC Chairman determine it should not be renewed.

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		Consideration by the Attorney General for granting or renewing an exemption will be considered an antitrust investigation under the Antitrust Civil Process Act [15 U.S.C. § 1311 et seq.]. The use of any information acquired under such agreement for purposes other than in the agreement are subject to antitrust laws. The Attorney General and the FTC Chair shall report the use of these exemptions biennially, starting one year after enactment. Defines "antitrust laws" as the same as that given by the Clayton Act [12 U.S.C. § 12(a)], the Federal Trade Commission Act [15 U.S.C. § 45], and any similar state laws. Defines "covered activities" as any activity relating to the development, manufacture, distribution, purchase, or storage of a countermeasure expressly exempted in the Attorney General-approved agreements. This excludes allocating market share, setting prices or exchanging information between competitors that is not reasonably necessary to execute the exempted agreements. Authority for this section shall expire six years after enactment (December 19, 2012). [Section 405]
Changes to SNS and Project BioShield procurement	42 U.S.C. § 247d-6b Strategic National Stockpile (c) Additional authority regarding procurement of certain biomedical countermeasures; availability of special reserve fund	Amends PHS Act section 319F-2 [42 U.S.C. § 247d-6b] so that the heading is "Sec. 247d-6b. Strategic National Stockpile and Security Countermeasures." Amends subsection (c) heading to remove the word "biomedical."

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	(c)(3) Assessment of availability and appropriateness of countermeasures The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).	Amends subsection (c) paragraph (3) by adding a new paragraph (B). The Secretary will institute a process to make information regarding these assessments publicly available as long as it does not reveal information that the Secretary judges would tend to harm national security or be exempt from FOIA requests.
	(c)(4)(A) Proposal to the President If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to - (i) issue a call for the development of such countermeasure; and (ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.	Inserts "not developed or" before "currently."
	(c)(5)(B) Requirements In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following: (i) The quantities of the product that will be needed to meet the needs of the stockpile.	Replaces "to meet the needs of the stockpile" with "to meet the stockpile needs."
	(c)(7)(B) Interagency agreement; costs (i) Interagency agreement The Homeland Security Secretary shall enter into an agreement	Strikes clause (ii). Under the previous law, other Project BioShield acquisitions costs to HHS were paid from the funds appropriated for the Strategic National Stockpile. Authorization

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	with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund under paragraph (10) shall be available for payments made by the Secretary to a vendor for such procurement. (ii) Other costs The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1) of this section.	for those funds expired in FY2006.
	(c)(7)(C)(ii) Contract terms A contract for procurements under this subsection shall (or, as specified below, may) include the following terms: (I) Payment conditioned on delivery The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government.	Amends the contract terms in paragraph (I) to allow HHS to pay vendors milestone payments before product delivery. These payments shall not exceed 50% of the total contract cost and do not have to be repaid if the vendor fails to deliver finished product.

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	No applicable provision.	Adds new subsections to the contract terms paragraph allowing HHS to include new requirements in Project BioShield acquisitions. HHS may specify in the acquisition contract that the vendor is the exclusive government supplier of the product for the duration of the contract, as long as the vendor can meet the government's needs. The company cannot assign this exclusivity to another entity without the Secretary's approval. HHS may require that a Project BioShield product manufacturer establish a domestic manufacturing capability to be able to quickly respond to an emergency request for a surge of product. HHS may specify countermeasure characteristics the government requires for acceptance, including dosing and administration properties. HHS may specify the amount of funding that HHS will spend to develop the product.
	(8) Interagency cooperation (A) In general In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.	Amends subparagraph (8) to allow other executive agencies to obtain countermeasures under procurement contracts established by HHS.

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.

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